Florida Board of Pharmacy
Controlled Substances Standards Committee Meeting

B Resort and Spa
1905 Hotel Plaza Blvd, Lake Buena Vista, FL 32830
(407) 828-2828
June 9, 2015, 2 PM

Board Members:	Gavin Meshad, Committee Chair Michele Weizer, PharmD, Board Chair Jeffery Mesaros, PharmD, J.D. Jeenu Philip, BPharm Winfield "Win" Adams, CSA
Special Committee Members:	Michael Jackson, BPharm, Florida Pharmacy Association Gary Cacciatore, Cardinal Health, Fla. Drug Wholesale Distrib. Council Mark Rubenstein, M.D., Florida Medical Association Harold Dalton, D.O., Fla. Society for Interventional Pain Physicians Natasha Polster, Walgreens Betsy Ferguson, CVS Andre Ourso, J.D, Executive Director, Fla. Board of Medicine

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AGENDA

1. Introductions
2. Discussion
    - Patient Perspective
        - Emails
        - Public Testimony
    - Pharmacist / Pharmacy Perspective
        - Testimony
    - Physician Perspective
        - Testimony
    - Wholesale Distributer Perspective
        - Testimony
3. Issues Identified
4. Solutions /Recommendations

- Potential Rules Changes
- Potential Legislative Changes
- Collaboration
- Education
- Other

Grant, Matt J

From: Mark Nolder <Bobaloo595@Hotmail.com>
Sent: Thursday, January 29, 2015 11:09 PM
To: Grant, Matt J
Subject: Prescription denial!

Mr. Grant:

I also was denied my morphine refill at a Walgreens, the pharmacist said it was at her discretion. I have been using this medicine for chronic back pain from a major back fusion that went wrong for more than a year. The Walgreen's that I normally buy my script from was out and sent me to that store because they had it in stock. As the people in your report, when I questioned why I was being denied the medication that allows me to have at least a bit of a normal life, I felt as if I was being judged by the pharmacists as a low life drug abuser, everyone around me at the pharmacy looked at me with the same judgmental eyes.
The pharmacist seemed to be using my prescription as a means to contribute to her personal vendetta against illegal usages of the medication that I use to live a slightly less miserable existence. She knows nothing of me or why my doctor prescribed the medication for me but decided to put me in the same category as the abusers whether it is true or not. The judge the jury and the executer with her pen.
The pharmacy assistant that was helping me told me under her breath (so the pharmacist couldn't hear her) "she won't fill a morphine script for anyone" which couldn't be heard by the customers around me that might have alleviate the embarrassment that I was feeling during the entire transaction.
I drove to several other pharmacies to try and fill the script without any luck that day.
Please Mr. Grant do not stop investigating this problem as it truly isn't fare to those of us that are not abusing the medications. I have also found that the pharmacists are not the only people causing a problem with people getting the meds. The pharmacists at the my neighborhood CVS told me that the pharmaceutical companies that they order their drugs from will only send a small amount to each county of the state and all of the pharmacies must divide the medications amongst all of the pharmacies within that county. If they order an amount that the pharmacy knows that they normally fill in that given month, they will only get there allotted amount even if their customers will have to go without. This is there way of regulating the drug. Just another hurdle we must jump.
Mark Nolder.
Bobaloo595@Hotmail.com

Grant, Matt J

From: Jamie MacNaughton <jamieshepard@gmail.com>
Sent: Sunday, February 01, 2015 5:57 PM
To: Grant, Matt J
Subject: CVS refused my valid prescriptions
Attachments: image1.PNG; ATT00006.txt; image2.PNG; ATT00007.txt; image3.PNG; ATT00008.txt; image4.PNG; ATT00009.txt; image5.PNG; ATT00010.txt

Hi Matt,

I was just denied my pain prescriptions, at my local CVS, in Bristol, CT (store #288).

I have chronic interstitial cystitis, which means I don't have a normal bladder lining, like everyone else. My bladder has holes in the lining, and its excruciatingly painful. I have to be very careful about everything I put into my body, as it can cause a "flare," or worsening of my symptoms. It literally feels like someone is pouring acid in my bladder, if I eat the wrong foods. I have a very severe case, and have been to over 10 specialists, just for IC. The past 6 and 1/2 years have truly been a living hell. Anyone who says they don't think about suicide, is a liar. This disease ruined my life. Not only do I have 24/7 awful pain, that feels like I'm being crushed with golf spikes, while having bowling ball pressure on top of me, but I live in my bathroom. I get horrible urinary frequency and urgency, and I'm lucky if I get two hours of sleep, straight, per night. I'm totally exhausted, and through all of my treatments (Botox, monthly trigger point injections, weekly to daily bladder instillations, physical therapy, many doctor appointments, ER visits, and recently, an implant called an Interstim, by Medtronic, which is a neurostimulator that connects to my sacral nerves, and sends signals to my brain, telling it I can pee, without having to catheterize myself 30x per day. I worked for 5 years after my diagnosis, in pure agony, but I needed the insurance, and my paycheck a all went to medical bills, gas, and my car payment. My bosses were very understanding fur about 2 years, and complete monsters for the remaining 3. I was eventually fired and humiliated at the same time, as my boss was a hot head, and I simply told her that she was harassing a disabled person. I was fired, after I made that statement. But, if I wasn't fired that day, I truly believe I would have died in a car accident. The stress from the job was causing flares and intense frequency, and urgency. There were nights, I would just sleep on the toilet, in order to get a half hour of rest, as I had horrible urinary retention, and it was taking me longer and longer to go, even with my trigger point injections (spinal needles inserted up my vagina, all the way to the bottom of my pelvic floor, to inject a steroid, to allow me to loosen my pelvic floor muscles to pee - sorry for the description). I've gotten use to being violated, pretty much weekly.

In addition to this, I have severe pelvic floor dysfunction, which means my pelvic floor muscles are like elastic bands. I could no longer use tampons, and sex became too painful, causing me severe depression. I thought YALE knew what they were doing, when I was approved for pelvic floor therapy. Finally! I thought. Unfortunately, they used the same therapy for patients with incontinence, and even though I voiced my concerns that I was having trouble voiding, the PA told me I needed to do it more, since mine was so severe... This lead to me being unable to empty, an emergency appointment, me begging her to allow me to catheterize myself, and her telling me that my condition was too severe for her, and she could no longer see me.. So I was left with horrible pain, and the complete inability to void.

I found my current doctor, who squeezed me in, because I was hysterical on the phone, and they showed me how to cath myself and give myself treatments on the same day. Thus doctor has literally saved my life, without question, in terms of knowing what she is doing. Though, this disease is not curable, so she can't do anything for my pain, but send me to a pain clinic.

So, I've been going to the same pain clinic for about 4 years, and I've been on the same medication for about a year. My doctor has to change it, if my body gets used to it, which is why I need to try different medications, to "shock the system."

These are two of my diseases ONLY. Do you think the pharmacist has any clue about what my diagnosis entails?

I'm an IC advocate, and I run my own support group, since I don't work. I spend hours helping other women to NOT make the same choices I did. I research when I can, but it has been difficult since I was diagnosed with fibromyalgia. I'm constantly tired, and my entire body hurts.

I have several autoimmune diseases. This started, several months before I graduated college, in 2008. I gained 30 pounds out of nowhere, lost clumps of hair, became extremely tired. I was diagnosed with Hashimoto's Disease. Since that diagnosis, I've had nothing but medical problems. Researchers are fairly certain Interstitial Cystitis (IC), is also an autoimmune disorder, then came Raynaud's Disease, and Fibromyalgia. I'm also currently being ruled out if having Lupus...

My sister in law had cancer, in 2010, and was cured in 6 months. She raised more money, in one day, than I have in over a year, if not working. She's cured, has a baby, a giant house, a new car, etc.. And she is still given support every year she dies her cancer walk. My family doesn't even ask how I'm doing.. It's been almost 7 years, they don't care, and see it as wining.., though she never had pain the way I do.

I also suffer from severe depression and anxiety.. I wonder why....

Anyway, I just saw your article and really connected with it. I'm at a loss as to what to do now, and do not feel that woman should get away with how badly she treated me. If you only saw her smile when she said I'm not filling these, it was like the devil himself, was in her. I'm sorry, thus happened two days ago, I'm still angry beyond measure. I can't copy and paste my reply to your article, so I will send you 4-4 screenshots- I can't remember (fibro fog, at it's finest).

Please contact me. I'd love to help turn this into something more. I really want the news stations in CT to talk about this. I also want that CVS's name on the news to show I'm not someone you can do this to. I'm literally sick over this. I can talk on the phone or over Skype. Please email me back. It would be nice to hear from someone... Anyone. I'm appalled.

Screen shots will hopefully attach.

Grant, Matt J

From: Andrea Lambert <aklambert67@gmail.com>
Sent: Friday, February 06, 2015 9:20 PM
To: Grant, Matt J
Subject: Prescriptions

Matt,
Yes I had several that I tried to get filled for 3 weeks and no pharmacy would fill them.. I had to bring them back to my doctor. I have a new prescription for a new pain medication that I now can't get filled.

If something doesn't change soon there are going to be alot more chronic pain patient suicides! I for one can not live with my pain much longer. Without these medications I have no quality of life.

How is it legal for the pharmacies, DEA and the government to deny a US citizen, (who has a legitimate and well documented condition), a legitimate prescription for a FDA approved and LEGAL drug from a legitimate medical doctor??

So many constitutional rights are being violated, as are our 4th amendment rights. Denying a person medically necessary treatment is a crime against humanity!

The US, especially Florida, needs to adopt the policies of the World Health Organization (WHO), which defines opioids as "essential medicines" for the treatment of severe pain" and states, they are absolutely essential to relieve human suffering".

Thank you,
Andrea Lambert

Grant, Matt J

From: Melanie Jackson <mjaxxson@yahoo.com>
Sent: Saturday, February 07, 2015 5:26 AM
To: Grant, Matt J
Subject: Walgreen's War Against Pain Patients

I was diagnosed with a neuroloigical disease 16 years ago and have recently moved to Florida. For all of these years I have always followed the law and instructions by my doctor, and therefore having met every single condition that Walgreens say they have set to allow me remain a customer. I have been with only one doctor for 16 years, I have been on the same dosage for several years, and I nor my doctor, have ever been contacted or questioned with concerns about my dosages. I have been told by Walgreens that there was absolutely nothing I could do, including changing my medication, that would make them reverse their decision, and that they would not speak with my doctor about it. For the kicker, the day I was denied, I was told in the morning by the Pharmacy manager that my Rx had been filled and ready for pick-up. However, when I got to the store that SAME AFTERNOON, another pharmacist was on duty, and she told me, abruptly, without cause or explanation, that even though I had been told earlier I could have them, I could not have my meds, and she would note in my file that no other branch could service me. I had now, with evidence to the contrary, been suddenly labelled an "abuser." I later called another branch that's located in the State I had recently moved from, and asked if they would look into my file to see what the problem could be. I was told by that branch that there was only the notation that I could no longer be served, and no explanation as to why. Even though the Florida pharmacist knew I was at the end of the quantity I had, she could have at least filled my new Rx that time which would allow me 30 days to find another pharmacy But she left me without any meds, knowing her doing so meant I could go into un-controlled withdrawal, which could lead to death. But Walgreens didn't care about a loyal customer who purchased from them, EXCLUSIVELY, for 16 years. As it is well known, Walgreens is only taking these extreme measures because they were hit with an $80M fine for negligently dispensing Rx, and are now making patients pay for their sins. To add insult to injury, they further burden my already stressed life by reporting the names of all of their newly rejected customers to the DEA to prove that they are now behaving. All of this leaves me in horrible pain, frustrated, humiliated, embarrassed, betrayed and MAD AS HELL!!!

GivePainAVoice

Grant, Matt J

From: Nancy Thompson <nremtnance@hotmail.com>
Sent: Saturday, February 07, 2015 6:17 PM
To: Grant, Matt J
Subject: Matt Grant

Dear Matt,

I'm so glad that this issue is being addressed, thank you for taking the time to look into it. I have had Rheumatoid Arthritis since I was a little girl. It goes in and out of remission. In 2009 it came back with a vengeance, and brought Pulmonary Hypertension secondary to left diastolic dysfunction. Those are a just a few of my diagnoses, but they are alike in that they are tied together by inflammation as a result of my RA. I take strong medications to control my RA, Plaquenil daily, and Humira injections weekly. Unfortunately I am still in a lot of pain.

Before becoming disabled, I was a Medic, someone on the other side of the stretcher. I treated ,many people who were addicted to prescription meds. I was afraid to take them, but really had no quality of life, so I finally gave in and I have been seeing Dr. Juliet Burry since 2009 for my pain. I've chosen to take low dose pain meds starting with Tylenol #3. Now I take Tylenol #4, four times a day and I have a prescription for Percocet 5-325 at night as needed.

The first prejudice from a pharmacist was at a CVS in October of last year. They had been filling all of my prescriptions including my pain meds but suddenly they were screaming at me like I was a pill seeker. "These two prescriptions should NEVER be filled together, no pharmacist should EVER fill these". "Well, You have filled them for YEARS". Rumor had it they had been sued, but bottom line CVS was not going to be filling any pain medications.

The second time was this year at Walgreens. The pharmacist said "I will not fill these prescriptions EVER, don't bother coming back". I asked if they could call my Doctor, she insisted that my Doctor wasn't relevant, her LICENSE was on the line if she filled them. After calling Walgreen's I found that they stood behind her and said they could not force them to fill anything. The same was told to me from my Doctors office. It took me almost the month of January to fill my prescriptions, Walgreen "A different one, filled my Percocet 60 tabs, and my Tylenol #4 was filled at Publix but they only had 9 pills for 2 weeks. I have at the moment a torn rotator cuff which I have been going to therapy for trying to avoid surgery. Because of that injury I have been off of my Humira *it's a biological and slows healing*. I am going to include my medical history so you can see that not only was I dealing with my RA during these times, I had major surgeries and new diagnosis as well.

It's hard enough dealing with chronic pain and not being able to "fix" it, without a Pharmacy making you feel like a common criminal. People stared at me, got up out of their chairs to watch.. I sat in my car and cried. Not for the pain medicine which was a concern, but for my dignity which was just lost in a damn Walgreens.

Thank you again,
Nancy Thompson

Nancy Thompson D.O.B 11-25-68 UPDATED 2/7/15

Major illnesses

Adrenal Insufficiency - Stress dose steroids required

Pulmonary Hypertension secondary to, Left diastolic dysfunction/ HTN / Immunosuppressed
Asthma / Chronic Pneumonia/Sleep Apnea
(Hypopnea) Uses C-Pap
Rheumatoid Arthritis / (Lupus suspected, not sero confirmed) / Ankylosing Spondylitis
Papilledema - Increased Cerebrospinal fluid Dx - Pseudotumor Cerebri LP Pressure was 33, taped down to 20.
Headache / BP back in 12 hrs.
Hashimoto's Hypothyroidtitis, Autoimmune Hives,Vitamin D Insufficiency
PCOS: Polycystic Ovarian Syndrome, IBS - just severe diarrhea / dumping now. All the time.
Fibrocystic Breast Disease (Mammo's every year since I was 25)
Chronic Pyelonephritis / horseshoe shaped kidney *2 renal arteries, 2 ureters*
AVN- Avascular Necrosis (Bilateral Hips)

Hospitalizations :

5 yrs old 1973 - Reflux into kidney , horseshoe kidney, recurrent Pyelonephritis
6 yrs old 1974 - Reflux again, Glomerulonephritis, Kidney biopsy, cysto to remove polyps
7 yrs old 1975 - Severe hives, juvenile rheumatoid arthritis and diabetes, Nephritis
11 yrs old1980 - Pneumonia
12 yrs old 1981- Dislocation L Ankle / Surgery left ankle exploratory
13 yrs old 1982- 83 - Surgery left ankle removal of osteiod osteoma / Bone island
16 yrs old 1985 - ICU - swollen spleen, severe Costachondritis caused increased hear rate
18 yrs old 1987 - Birth of son, D&C postpartum Blood transfusion x 2
24 yrs old 1992 - Closed compound fracture- Internal fixation / reduction R Ankle
35 yrs old 2003- Bronchitis / Pneumonia Severe Pleurisy
37 yrs old 2005 - Bronchitis / Pneumonia SV Tach - Thyroid Storm, Dislocation L knee, Severe Pleurisy
37 Yrs Old 2005- Admitted again SVT, Severe Pleurisy
38 yrs old 2006 - Bronchitis / Pneumonia , Severe Pleurisy
39 yrs old 2008 - SVT, severe angina, arm, jaw, Nuclear Stress Test
Dx: Normal stress test / Stable Angina
40 yrs old 2009 -Feb- L and R Heart Catheterization L cath showed no CAD, or blockages, Left Diastolic dysfunction. R c/ exercise showed Mild Pulmonary Hypertension pressure of 34. Severe angina during exercise.
2009 Mild Infection Heart Cath site, IV antibiotics, DC'd
41 yrs old 2009- Nov-Uterine Ablation with Essures / Dc'd BCP's
41 Yrs old 2009- Dec 31st -Core Decompression R hip
41 Yrs Old 2010- Feb ACTH Stim Test admitted with Chest pains / Bradycardia / Hypotensive AM Cortisol before test was 4.9
42 yrs old 2011 - Core Decompression L Hip
42 yrs old 2011- Hysterectomy - Uterus and tubes / hemorrhaged due to essures perforating the L Fallopian tube and Uterus
43 yrs old 2012 - Neuro Critical Care - Severe headache, lower back ache and blind in R eye. Severe Papilledema. Lumbar Puncture Dx Increased cerebrospinal fluid pressures @33 taped down to a pressure of 20 started Diamox as treatment. MRI of brain was clear
44 yrs old Fx of Left wrist (closed colles fracture) internal fixation/reduction. Left Ankle Avulsion Fx of the Talus.

Nancy Thompson
D.O.B. 11-25-68

Allergies:
Aspirin: Severe stomach pain with vomiting
Morphine: No Blood pressure,anaphylaxis
Reglan: Severe anxiety
IV Dye: ie: CT scan contrast, anaphylaxis.
Albuterol: a sensitivity, severe tachycardia
Only use Xoponex now.
NSAIDS : Hives, vomiting

Medications List as of 2/7/15
Hydrocortisone (Cortef) 20mgs AM 10mgs @noon
Nitro quick spray / PRN
Advair 500/50
Xoponex MDI / PRN.
Armour Thyroid 120mgs / Daily
Diamox 750mgs BID
Cardizem 120mgs / AM Coreg 12.5mgs BID
Atarax 50 mgs / BID
Plaquenil 200 mgs / BID
Protonix 40mgs / BID
Tylenol #4 / QID PRN for pain
Percocet @night PRN for pain
Xanax 0.05 mgs @ Night / RLS
Humira 40mgs every week (injection)
Vitamin D 4000 IU daily

Surgeries:
1973 - Dilation of Urethra *recurrent Pyelonephritis, urethra was the size of a 9 mo old baby*
1974 - Removal of polyps from urethra
Kidney Biopsy, Cystoscope
1980 - Cystoscope for recurrent Pyelonephritis
1981 - 82 -Left ankle exploratory for pain
Dx. Severe Calcification of joint.

1982,83 - Removal of Osteiod osteoma / bone island from lower left tibia
1987 - D&C postpartum / 2 blood transfusions.- Tonsils
1988 - Wisdom Teeth, Cystoscope
1992 - internal fixation / reduction R Ankle
1993 - Removal of hardware R Ankle
Deep Core Biopsy L breast - Dx Fibrocystic Breast disease Mammo's since 25 yrs old
1999 - Uterine Biopsy Dx. Short LH phase
2006 - Colonoscopy / Endoscopy
2008 - Nuclear Stress Test
2009 - L and R heart Catheterization
2009Uterine Ablation with Essures
2009- Core Decompression R Hip 2010- Core Decompression L Hip 2011- Hysterectomy- uterus, tubes
2014- Internal Fixation/reduction L Wrist

Grant, Matt J

From: Jennifer Kassan <jkassan820@yahoo.com>
Sent: Monday, February 09, 2015 3:38 PM
To: Grant, Matt J
Subject: Pharmacy refusing to fill my husbands narcotics

My husband has congenital back problems. He was born with a hemivertebra, scoliosis, and spina bifida occulta. He has been seen by several specialists in the past 20 years. Every physician has determined the only thing that can be done for him is to treat the pain. There is no cure for his condition and it is degenerative. His only chance (albiet very little) for any quality of life is with his pain medication. He is very diligent with going to his appointments and doing everything the physicians and pharmacy asks of him, including monthly drug tests.

The pharmacy chains (CVS, Walgreens, Walmart) refused to fill his Oxycontin or Morphine scripts 2 years ago. We were forced to find a local pharmacy that was willing to fill them. He has been getting his narcotic scripts filled at this same pharmacy for the past 2 years. His other "maintenance" medication for elevated cholesterol, etc is filled through our mail order pharmacy per our insurance plans recommendations as it is more cost effective.

Last month, this local pharmacy informed him that they will no longer be able to fill his narcotic scripts unless he has four additional medications filled there as well. They cited a DEA policy of a 4:1 ratio. We have researched this and have not been able to find any such policy. He has 2 narcotics filled each month (extended release Oxycontin and Oxycodone for break through pain). This means he has to have 8 additional medications in order to receive his two narcotic scripts each month. He does not have 8 additional medications. This seems to be more of a money making scheme then a way to control the abuse of prescription medication. In our minds this basically equates to extortion. They know our hands are tied and he needs his medication in order to function. Seems the pharmacies are getting crafty. Instead of flat out refusing to fill his scripts, they are basically making it impossible to for him to get them filled.

We would welcome the opportunity to talk to you further regarding this issue.

Andy & Jenn Kassan
386-206-4222

Grant, Matt J

From: Robinh241@gmail.com
Sent: Monday, February 09, 2015 7:52 PM
To: Grant, Matt J
Subject: Come do the crawl with ME!!

Hey there again,
I was so happy to hear that someone like you wanted to see this first hand! I only wish I could have a camera and a reporter with me just for a day so everyone could see me not be able to walk or get out of bed,or better yet to watch my children not have their mom! I know I live kind of far away from you but I have proof that its for some reason much worse down here by me. I live in North Port (Sarasota County)
You can reach me at.

Robin Haas.
941-961-7811

Sent from my Virgin Mobile phone.

Grant, Matt J

From: Snyder <msnyder5@cfl.rr.com>
Sent: Monday, February 09, 2015 7:49 PM
To: Grant, Matt J
Subject: RE: Denied prescription refills

My cell is 321-480-8228
My work number is 321-951-8695 ext 291

From: Grant, Matt J [mailto:mjgrant@hearst.com]
Sent: Monday, February 09, 2015 2:23 PM
To: Snyder
Subject: RE: Denied prescription refills

Is there a number I can reach you at to get more info?

From: Snyder [mailto:msnyder5@cfl.rr.com]
Sent: Saturday, February 07, 2015 4:45 PM
To: Grant, Matt J
Subject: Denied prescription refills

My daughter saw that you were looking for people to contact you about being denied prescription refills for pain medicine.

I have been taking the same pain medicine prescription for over ten years and have never had the problems getting them filled as I have had in the last year. It first started out that most pharmacies did not have the quantity you needed. I was getting them filled at CVS and when they reduced the quantity of what they were allowed to order every week I was forced to get my prescriptions filled at Walgreens. At first I did not have any problems but then they turned me away indicating they had asked my doctor for information and my pain management doctor refused to give them anything. I asked my doctor at one of my visits what it was that they were requesting and he told me they wanted medical records. He told me it is not the pharmacies business if you have a valid prescription as he is the doctor and knows what his patients need.

After I spoke with my doctor I asked that they give me some of my records and I would be responsible for giving them to the pharmacy. I didn't like it either, but they were holding me hostage by not filling my prescription until I gave them the records. Each time I went to get my prescription it was something new that that they came up with. After I handed over medical records I tried to have them fill the same prescription that they denied until I gave them medical records. Again they denied because they said my account was flagged and I had to wait until the following month to get it filled. At that point I had just about had it with their games. I got the name and phone number of the pharmacy supervisor and called the next day. We spoke and she told me that I also needed to answer personal medical questions in order to get my prescriptions. She asked me if I had ever tried long acting medication or pain patches..... Again I was compliant even though I felt they were over stepping their boundaries.

The icing on the cake was when I went to a different Walgreens to fill my prescription because I forgot to carry it with me to work and fill at the Walgreens down the street from my job. I was turned away because they said that I fill me prescriptions at a different Walgreens. I was floored! I just looked at the guy in the drive thru window and said "aren't all Walgreens on line"? He said yes, but that it was a new policy that went into effect with them. I drove down the road to CVS that night and they gave me no problems and happily filled my prescription.

I have been in chronic pain for almost 20 years. I have had five neck surgeries. I take the medication not because I really want to, but because I want to continue to be able to work a job. I can't even begin to express the stress that I have had to go through just to get my prescriptions filled. It has been like prescription roulette. You never know if you are going to be able to find a pharmacy to fill it. I hope this helps in your investigation. I would love to see some kind of resolution to this chronic problem. Not everyone is a drug seeking addict. There are genuine people who need the medications in order to function on a day to day basis.

Regards,

Mary Snyder

Grant, Matt J

From: dgillis580 <dgillis580@aol.com>
Sent: Friday, January 30, 2015 3:39 PM
To: Grant, Matt J
Subject: Pharmacy vs drugs.

I am 71 year old retired exectitive with a very bad back.10 years or more ago my Dr perscribed Hydrocodone 5/500 to ease back pain when I play golf. The perscription has been filled approx. every 60 to 90 days for that length of time in one CVS pharmacy in Longwood(Hunt Club). Never a question. (45 pills).
In July 2014 I went in to get a refill with script in hand and was told by head pharmacist "sorry we dont have any". Ha! When will you get some in. Dont know. Would the CVS down the street have some I dont know you will have to ask them. Would you call and ask. No!
In Sept had torn miscus and Jewitt gave me script for Hydrocodone. I had forgotten about July incident and presented the script. I am sorry Mr Gillis we don't have any. Am I on a list I asked. No answer.
A month later I was going in for oral surgery. They perscribed 4 medications. Tylenol3, "1" pill to relax me one hour prior to surgery , an antibiotic and nausea pills. I sent my sweetheart in as she has known pharmacy folks for 30 years. Same result. They would only fill amoxillin. I laughed as she now new how I felt.
Called CVS store mgr and he told me I was not on a list and he had received several complaints. Gave me no. of CVS corporate headquarters which I called and basically told them the same thing I am telling you.
We now fill all of our perscriptions at Costco in Alt Springs or Publix. Nice people, ask appropriate questions and fill order with out makng us feel like drug attacks.
Thank you for taking an interest in this. Dont stop pushing. Responses that you have listed are Bogus form CVS etc. Tx

Sent via the Samsung Galaxy Note® 3, an AT&T 4G LTE smartphone

Grant, Matt J

From: Pete Giarrusso <pete@chopperdesign.com>
Sent: Friday, January 30, 2015 1:22 PM
To: Mike and Jackie C
Subject: Re: Pain meds

Jackie,

The guy who did the story was Matt Grant.... He said there would be follow up. He did a great job... I am going to copy him on this email. You may wish to drop him a note as well. Email is below.... Sorry for your troubles...

mjgrant@hearst.com

On 1/30/2015 12:42 PM, Mike and Jackie C wrote:

> Hi Pete,
>
> I understand that you spoke to Mike about my incident with the pain meds. He told me to send you an email.
>
> I had foot surgery on Wed Jan 14th. The surgery was suppose to be an hour and a half and turned into a 4 hour procedure because he had to do more than anticipated.
>
> I was given a script for (20) Hydrocodone 7.5/325 pills instructing me to take 1 every 6 hours. I was in so much pain that I was taking 2 every 4 hours PLUS ibuprofen. I was taking them around the clock, so I was out of them by Friday.
>
> When I went to the Doctor on Friday, (because I was still in a lot of pain), he gave me a another script for the same thing. Mike took it to Publix which is where I always go and they would not fill it because the original script was suppose to last 5 days. I had to wait 2 days before they would fill it even after the Doctor's office called them and explained my situation and how I needed to take more than what was initially prescribed.
>
> So needless to say, I literally had to suffer for two days!!!!
>
> Ridiculous!!!
>
> Hope more people like you come forward.
>
> Thanks,
>
> Jackie

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Pete Giarrusso

Grant, Matt J

From: Penny Brown <ptb3990@aol.com>
Sent: Friday, January 30, 2015 11:04 AM
To: Grant, Matt J
Subject: Fwd: Need help, is there a customer/patient advocacy resource for getting chronic pain patients their medication?

My son got a call yesterday afternoon from Walgreens. They told him they will no longer fill his prescriptions. They even told him they called his Dr, because they think it is "overkill" for him to take Hydrocodone and Tramadol. The Dr told ***them*** he is managing his patient, and believes the dosage is appropriate.Travis pain is not completely managed, but it is tolerable. He was able to finally today, get it filled at Publix pharmacy, but has been without for 4 days. It's almost debilitating for him. He would not be able to function or go to work without his meds. He would be on disability. WTH is wrong with these lawmakers?

I put this E:mail together and sent it to My Fox Tampa Bay, Bay News 9, Tampa Tribune, Suncoast News, trying to light a fire. This is a very serious problem for lots of people, but when Travis is affected, I play the Mom card, LOL!!

January 15, 2015:
Walgreens refused to fill anymore prescriptions for me. I have been a customer for 20 years. NEVER have I had any illegal drug related problems. I do have a chronic painful illness (Psoriatic Rheumatoid Arthritis, it is in every single joint in my body), diagnosed at the age of 11. The problem getting the meds has only snowballed since Oct, 2014, to the point I simply can't get prescribed medications. There is no way these new laws are deterring illegal drug activity, only making it nearly impossible for those of us that truly need these medications that are being prescribed by doctors monitoring us. I have to wait until I am almost completely out of medication before I can go to the DR's office to pick up the written prescription, then when I try to get it filled, I am refused by Walgreens. I went to 10 different pharmacies just this evening to try to get my hydrocodone filled, all were out of stock.

January 16, 2015:
Called prescribing Dr. (Rheumatologist) to get assistance in filling the prescriptions for Hydrocodone 10/325 and Tramadol. They called Walgreens to no avail and suggested I try Target or Publix pharmacies. We have called numerous pharmacies this morning and am being told "out of stock". They are only allowed to carry "X" inventory, and it is on back order. What the heck am I to do?

At a loss, and would appreciate knowing where in the Tampa Bay area to get this medication ASAP, please help with an immediate reply.

In checking the internet, this problem is rampant with Walgreens (refusing to fill prescriptions) and others seem to be following their lead.

reference: http://walgreens.pissedconsumer.com/walgreens-refuses-to-fill-pain-medication-join-a-class-action-lawsuit-to-stop-the-abuse-20130514408700.html?company_id=8029

Grant, Matt J

From: Vicki Alexander <kidsdepot@msn.com>
Sent: Friday, January 30, 2015 1:04 PM
To: Grant, Matt J
Subject: Legit prescripts

My husband was in a bad car accident last July. He suffered four ruptured discs in his neck and two in his back. His doctor said they are inoperable and prescribed pain meds. But nobody will fill them. Not Walmart, not Walgreen, not Pierson pharmacy. He is in constant pain and no amount of ibuorofen or aleve will help. Thanks.

Grant, Matt J

From: Suzy Carpenter <scc218@earthlink.net>
Sent: Friday, January 30, 2015 8:33 AM
To: Grant, Matt J
Subject: Pain medication story

Hi Matt --
I watched the WESH 2 news segment last night about pain medication and just went on the website to read more about it. It was a very interesting segment, but I wish there had been some answers about how those of us with legitimate prescriptions can get our pain medication. The story hit home for me. I have stage IV metastatic breast cancer – with metastases to the bone (hip and spine), and I am in constant pain if I don't take pain meds. The only thing that works for me is oxycodone/acetaminophen, which my oncologist prescribes. He is an excellent doctor and not an "over-prescriber." One of the pharmacies even asked me who my doctor was. I told him, and he said "He's a good doctor." I said "He's a great doctor. Why won't you fill his prescription??" I took my last prescription to 13 pharmacies over a period of 3 weeks before I finally found someone who would fill it! I was literally in tears at several of the pharmacies because they either just refused to fill it or they said they were out of stock and had no idea when they would get any more in. Most of them had no sympathy whatsoever. They just said, "Sorry. I don't know what to tell you." They refused to hold onto my prescription to fill it when they got the medication in. One pharmacy said they had 16 pills (my prescription was for 240), and if I took the 16 pills, I would forfeit the rest of the prescription! I didn't do it because 16 pills would only last about 5 days. This is the most frustrating thing in the world to deal with. I have no idea where I'm going to get my next prescription filled – yes, they are making us feel like drug addicts – but I am in a lot of pain without this medication.
One pharmacy told me I could call every Monday and Friday when their orders came in to see if they got any in, but they wouldn't guarantee me anything, and the prescriptions would be filled on a first-come, first-served basis. So if somebody else beat me to the pharmacy with the same prescription, theirs would be filled first.
I don't know what to do. I don't know who to turn to. I appreciate you guys airing this segment. It makes me feel better to know I'm not in this boat alone. But what do we do??!
Thank you for listening.
Best regards,
Suzy Carpenter

Grant, Matt J

From: Amber Vann <amberv1330@gmail.com>
Sent: Monday, February 02, 2015 9:17 AM
To: Grant, Matt J

I suffer from chronic pain and have used hydrocodone for 20+ years to control my pain. When it was reclassified as a narcotic I found one pharmacy who would fill my prescription, however, the price went from$80.00 to $200.00!!!I only have a part time job and live alone and have no insurance. I am devastated. I have given up groceries so that I can have my medicine. I only eat one meal a day now. It's not fair.

Grant, Matt J

From: Eric Battles <ebattles2112@gmail.com>
Sent: Saturday, January 31, 2015 7:39 PM
To: Grant, Matt J
Subject: Pain Pills issue

Dear Mr Grant,

How are you?I can tell you that someone isn't telling the truth between the Pharmacist & DEA and/or Walgreen's or big companies like them.
I've fount to combat chronic pain a long time.
Just an example in the past. I would see a doctor every month.Then drive down to CVS being the closest one to his office.They filled the Oxy & Morphine twice.Then it was excuses.It was we are out of currently & the next delivery truck might come Friday, we don't know. How would they not know what they ordered?
Then its the Pharmacist doesn't know me personally.
So I went to Holly Hill Pharmacy a mom & pop pharmacy. They filled it twice. Then one day it was a different pharmacist when I walked in that I'd not seen the first two times. He said there is only enough pain meds for his long time customers that the DEA controls the amount they receive monthly. Then the next day when I called there i got a lady at that same pharmacy, whom said it was because I didn't fill my other type medications there is why they won't fill the pain meds,how the DEA is cracking down on them.So,it depended on what day & what person was working all with different reasons or excuses why they can't fill the narcotic pain meds.
I then went to 9 pharmacies that day always with the same 2 pain medication prescription's by same the doctor on the same day of my monthly follow up visits.
My urologist Dr Cangiano in Altamonte Springs got a letter from my insurance carrier Aetna.They implied & made it appear to all of my doctors, how i was up to something because I'd changed or went to different pharmacies to fill the narcotic pain meds.I did what anyone would have done when one pharmacy couldn't fill. I went to another one,common sense.
That urologist wasn't even prescribing me any controlled substances. But,because Aetna in their letters had said I'd been to different pharmacies over a period of months.He decided to discharge me from his practice. He never called or asked me to explain the reasoning behind things.That was really very unfair.I think he wanted to distance himself from me as if I'd done something wrong.He could have checked the state data base and he'd have seen that only one doctor was prescribing me pain meds. I was going to the various pharmacies the very same day of my monthly visits.
I'd go to example CVS. The pharmacy tech would say we are out of the oxy & we don't generally even carry the morphine.Then Walgreen's last year said that if the combination isn't to there policy they won't fill it.They claimed a given prescription must include together a time released type pain medication such as 12 hour Morphine. Then that must include an immediate release breakthrough type pain medication like Oxycodone or they won't fill it. I did meet that apparent policy, so they filled both for a while. Then it was we ran out etc.
When a Pharmacy can't say when they will again have a pain medication in stock, one can't wait a week or however long in pain & go without. So the logical thing to do is go to another pharmacy. The Medicine Shoppe Pharmacist in New Smyrna Beach has said he only has enough for his long time customers.
What is the definition of a "long time customer".That location if you searched at Utube there is a surveillance video.A robber came into that Pharmacy to rob them years back of pain medications. He pointed a gun at the Pharmacist. They had hired a armed security guard whom came around the corner from behind the counter & killed the robber shooting him dead.
I've had Pharmacist claim its the DEA fault.That they restrict & control how many bottles a given Pharmacy can receive monthly.Then I've read where the DEA claims that isn't true.So whom is telling the truth?
I've heard if one is too friendly to a given Pharmacist. That is a red flag that one is a drug seeker. So,what

should I do go inside a Pharmacy & be a jerk?
Its a major issue & its never been addressed properly. It's the Pharmacies blaming the DEA & vice versus.The drug companies claim they don't restrict the flow of pain meds, so they seem to act like its not them causing a problem.
Then some Pharmacies have signs on the doors alerting customers that they don't carry Oxycodone etc.
There is the fear of being robbed also.
The Pharmacies won't tell one over the phone if they have pain meds in stock which that is understandable.
The Pharmacists also size people up when they walk in the door.If you have long hair & are a man your a drug seeker.
If your too friendly your a drug seeker.
If you don't kiss the Pharmacists butts then people that do get the reserved pain meds filled.
It's so unfair that people like myself have to live in pain because of all the politics involved.
The drug "Oxycodone" is very effective at controlling chronic pain.It makes a persons quality of life much better.It allows one to function much better.
Why would I take a lesser drug all to suffer all so the critics around me can be happy that aren't suffering?
I appreciate you taking the time to address this very real issue.

I've found a smaller independently owned Pharmacy company that does fill both of my pain meds & hope that continues. But,I've been there where I had to spend an entire day driving from Pharmacy to Pharmacy to only end up frustrated & had to try the following day until I was able to fill them.

Thank You,

Eric Battles

Grant, Matt J

From: Tracy Daigle <tdaigle2141972@gmail.com>
Sent: Saturday, January 31, 2015 12:57 AM
To: Grant, Matt J
Subject: Walgreens and cvs

Dear Mr. Grant,

I am writing on behalf of myself and boyfriend because we have both been denied our legitimate prescriptions at walgreens and CVS. I have had multiple failed surgeries on my right shoulder and now suffer from daily chronic pain due to a complete tear in my rotator cuff. My boyfriend suffers from degenerative disk disease and anklosing spondilitis. He is prescribed the legal amount of hydrocodone....however Walgreen's refuses to fill this script because they claim it is for short term use..and the pharmacist said if he gets oxycontin they will gladly fill it. Since when has the pharmacists become able to prescribe medicine and decide what is best for the patient? We would really like to speak with you in regards to our situation. I can be reached at 386-333-4715.

Thank you.
Tracy Daigle and Robert schaier

Grant, Matt J

From: Jeff Carver <j_carver001@yahoo.com>
Sent: Saturday, January 31, 2015 6:24 AM
To: Grant, Matt J
Subject: Prescription filling problem

I suffer from scoliosis, and degenerative disk disease. I avoided pain management for years because of the pill problems the state of Florida had. In July of 2014, I could not take the pain anymore, I could not function, nor play with my children, nor work, I was forced to close my construction company, because I was not able to get relief. Once I finally found a doctor to prescribe me medicine, (low dose pain killer and soma muscle relaxer) I spent 2 weeks trying to get it filled. I am a father of two children, a former business owner, and someone who lives in a upper middle class area of Seminole county, with no criminal record. I find it absurd that the people who actually need their medicine, cannot obtain it without going through hell. It's miserable, and it's going to drive some people to suicide.

Thank you

Grant, Matt J

From: jlk_kfmn@msn.com
Sent: Saturday, January 31, 2015 9:49 AM
To: Grant, Matt J
Subject: Prescriptions of opiates

After watching your story about the inability to get prescriptions filled. I am one of those people. I was in a horrific auto accident in Jan of '08, after 21 days in the hospital and spending the next 2 1-/2 years having a total of 8 back surgeries, along with battling physical therapy just to walk again, I have to take Oxycontin. Over the years the only pharmacy I've ever used was walgreens. Due to all the other issues Ive had my pharmacist and all the techs new me by name.

Then in August of '13 I moved to Florida, which has been a nightmare ever since. From having ti change Dr and have to find a pain doctor who didnt want ti put me on high doses of other very strong opiates to dealing with Walgreens everytine I walked in they made me feel like I was a drug addict seeking pain meds. The new pharmacy was able to see every med that I had been getting while I lived in Arizona, yet they treat you like a criminal. Finally in September I went to get my refill and was told that they will no longer fill my meds. I asked to speak to the pharmacist and she said the same thing. When I asked why?, she pointed to a sign they posted that said we can refuse to fill any prescription for anyone. After calling Walgreens corporate, cingressman Daniel Webster the state medical board and an attorney, I was blown off by all of them.

I spent the next 8 hours visiting every pharmacy from Leesburg to Clermont continually be told no. I finally stopped at a small family owned one, explained my situation and had them contact my doctor, they filled it for me and have continued to work with me ever since. This past month they too are running into problems because the are only allotted a certain amount every month. This month they ran out, so I only had enough for 25 days and had to get another prescription for the last 5 days, because of the class of the medication by the DEA I have to forfit the rest of the meds Im owed. Its all insane, I lived in Az. before moving here and to fill a narcotic the pharmacist had to sent your prescription with your picture ID to a central computer bank up in Phoenix, which checked and kept records of those prescriptions. The whole process took about an hour to two hours depending on how busy a day it was.

I have so much more to the nightmare Im having to live with everyday and I know that if something isn't done soon, I will not be able to function on a daily basis, because even with my medication my pain level is between a 6-8 on a scale of 1-10 on a daily basis. Some days even worse, but if I take an extra pill I end up suffering at the end of the month because the medscan only be filled once every 30 days. Not a day or two befpre you run out but once. Help spread the word further than yoy did. Thanks,

Jeffrey Kaufman
352-223-0434
Jlk_kfmn@msn.com

Grant, Matt J

From: Pam Crooks <pcrooks3@gmail.com>
Sent: Friday, January 30, 2015 11:21 PM
To: Grant, Matt J
Subject: Prescription Problems

Hi Matt, well I was reading the article on Facebook about getting prescribed prescription fill in several area's that is not fear to people suffering themselves, I hope you or someone in your on family never has to go through what I been going through. I suffer from several things and on is an Rheumatoid Arthritis and Fibromyalgia and several other things, I sure don't wish this on my worst enemy. Without my medication I would not be able to move all day long, it does not take the pain away completely but does take the edge off,to where I can move somewhat around. If I was to live like this without my medication I would rather not live at all. I had taken my meds for 12 years and in December I was told I can NO longer fill your scripts. I left CVS so upset because the pharmacists tell me that this is the new laws in effect and was not happy. I had. I'll say it again I just hope that no one in your family has to go through what people like us, because you would never wro see your wife/ girlfriend go through this our yourself for matter. Maybe you can get a my better picture of what we go through. I hope you have the POWER off changing this for the people that need this program. Some kind of quality of life is better than nothing at all.
Thanks Grant, I sure hope this helps us out. If you have any power staet pulling those strings.

Grant, Matt J

From: Christine Brancaccio <xstine1976@gmail.com>
Sent: Friday, January 30, 2015 6:45 PM
To: Grant, Matt J
Subject: Pharmacy issue

My name is Christine. I am a 38 yo single mother of 3 (16, 4, and 4 months on Sunday). I receive SSD because i have severe rheumatoid arthritis, osteoarthritis, and fibromyalgia. I was diagnosed at 24, have had multiple surgeries to include bone fusions and joint replacements in my hands as well as ruptured tendons. My hands are clearly disfigured from these diseases, although it has also affected many other parts of my body.
I have lived in Altamonte for almost 4 years and have consistently used the CVS on Palm Springs and 436 and have always had a great relationship with them. Still do. However, this past year while i was pregnant with my youngest sonething happened and the CVS's in Seminole county are not allowed to dispense certain pain medications. Additionally, they had a policy change which prohibits them from filling narcotic prescriptions with benzodiazepines (for me, that would be my klonopin). So, i had to find a new pharmacy that would fill my prescriptions. 20 pharmacies and no luck...either because they were not accepting new patients with pain pill prescriptions or because they simply had reached their cap and couldn't accommodate anyone else. (The difficult things i need filled are 2 types of morphine and hydrocodone). Finally i found a small, independent pharmacy that when i explained my situation agreed to tske me as a customer IF I GAVE HIM ALL OF MY BUSiNESS, which i agreed to do and had CVS transfer it all over. In early Jan he contacted me to let me know he had everything but one of the morphines and as his normal supplier was put, he had to use an alternate which was $20 more and that i would have to pay him that money if i wanted my medication. I also had an out of pocket prescription for a weight loss/appetite suppressant which was $35. I am on medicare and medicaid so my prescriptions are typically 1.20.
This month when i brought him my prescriptions the amount of diet medications doubled and the price went up to $70 plus the upcharge for the morphine. I checked with CVS about their pricing and it was $29.99. I called my pharmacist to ask that he forward that one script to CVS as it was less than half and i am on an extremely limited income. He then told me he wouldnt fill my pain medications if i didnt allow him to make that money off of him and that i should have CVS fill it knowing full well they cannot. I dont have another pharmacy to go to and am afraid he will either keep my scripts as he keeps them until filling them (no one else does this) or would input something into the system negative about me (ie i "pharmacy hop"). I believe that he is not only victimizing me but likely many of his customers, as we are all made to feel like criminals when we are trying to obtain legitimate medications that we dearly need.
I have no choice but to use him this month and then hopefully can find another pharmacy to take care of me. Perhaps you have some suggestions! What he is doing may not be legal but it is morally and ethically wrong and i hope you can shed some light on the situation.
Thank you for reading my story,
Christine Adorno Rivera
3523484270

Grant, Matt J

From: Clendening, William M. <ClenWM@jea.com>
Sent: Friday, January 30, 2015 4:43 PM
To: Grant, Matt J
Subject: Special Report on pharmacies denying legitimate prescriptions

I read your article on News4Jax in Jacksonville. Thank you for exposing this statewide problem that treats real patients like criminals. Every month we have to search for a pharmacy that has the medication and will fill the prescription for my wife. Most will not tell you over the phone if they have the medication available so that requires us driving to each one until we can find it. For a patient prone to anxiety attacks these are highly anxious events that can't cause an attack. Our concern is that if doctor shopping is illegal how long before pharmacy shopping is illegal which will cut off all legitimate patients from their prescriptions. Mail order prescriptions are also being denied or cancelled which in some cases is the only way a patient's health insurance will cover the cost of those prescriptions.

Thank you again and please don't stop investigating this and reporting on it so real patients voices can be heard

Bill Clendening

Grant, Matt J

From: RENEE MCMILLEN <jreneet14@hotmail.com>
Sent: Friday, January 30, 2015 5:36 PM
To: Grant, Matt J
Subject: pain killers and narcotics are being withheld from legitimate users

I have been dealing with issue for about 2 years. First my son is ADHD confirmed by a Medical Doctor and a Psychiatrist. He is 10 years old and has been on concerta for 5 years. Walgreen's was fairly good about filling the prescription. However I learned that my employer has a special discount with CVS for prescriptions cutting them almost in half. I switched my prescriptions (for a family of four) to CVS only to be told they could not fill my son's medicine because they were out for 6 months and did not know when a new shipment would be in and would not fill it. CVS made me feel like I was abusing the drug they asked what the medicine was for, how old was my son, why had he been on this medicine for so long. My husband suggested we take him off the medicine and let him rip through the store. Then they may realize why it was needed. After several tries I finally went back to Walgreen's for this medicine and had to pay more for it.

CVS - As health care providers on the front lines of health care delivery, our pharmacists use their professional judgment and consider a variety of factors when determining whether a prescription for a controlled substance was issued for a legitimate purpose, which is part of their professional responsibility under state and federal law." Really does the pharmacist have a patients medical history? Does the pharmacist call the doctor to discuss the patient use of the prescribed medicine and alternatives available? Does the prescription say on it anywhere why the medicine is being prescribed ?From my experience no. Instead the pharmacist makes a judgement call without the facts. The system needs fixed.

Recently I had a bad car accident in September I had fractured ribs and broke my wrist and foot. I am on the mend but have been taking a low dose of hydrocodone for pain. There is not much that can be done for rib pain except rest and medicine to control pain. Last month I went to Walgreen's to be told that they had a limited supply and would not be able to fill the prescription. When I asked when the next shipment would be they stated they did not know could be weeks. So I went to another Walgreen's farther from my home and they said it was too early but come back the next day and they would fill it. Finally my husband took it back to the Walgreen's closer to us (the one that stated they did not have any) in the evening and they filled it without a problem.

However yesterday to be exact I had another experience. I took my prescription to the Walgreen near me and the Pharmacist came to the window stated he could fill it this time but next month it might be a problem. When I asked why he said they were getting a limited supply and could not guarantee the medicine would be available. Then he tried to BLACKMAIL me. He asked me if I had any other prescriptions I said yes we usually use CVS he said If I moved all of my prescriptions over to Wallgreens he would be more likely to fill my pain meds. Really !!!! I was appalled. First I would have to pay more and second I cannot get the medicine that prescribed for me! I am tired of people who need these drugs being accused of abusing them. I realize this is a problem, but there are LEGITIMATE reasons people take them. Not only that but I was victimized twice by the pharmacist trying to drum up business. If they wonder why people pharmacy hop maybe it is because the pharmacy refuses to fill the medication not because they are abusing the drug. This has really gotten out of hand.

Walgreens - "With the sharp rise in abuse of painkillers in recent years, health care professionals in all practices are continuously striving to find better ways of ensuring those medications are used only for legitimate medical purposes. What practices are they employing? How do they know if the patient has a legitimate purpose?

The doctor must have thought so or would not have prescribed the medicine. Who determines what the legitimate purposes are?

*State of Florida - While pharmacists are encouraged to use their professional judgment when filling a prescription, the Florida Board of Pharmacy has urged them to always fill what they consider a valid prescription representing a legitimate patient-physician relationship. Patients who do find it difficult to access their medications may find it beneficial to contact their physician and request that he/she reach out to their local pharmacist on their behalf to assist with getting prescriptions filled."*Well from a patient point of view this is not happening on the front lines of either Walgreens or CVS pharmacy departments and should be looked at by the State of Florida. Also why is it the patient or the one being victimized responsibility to ensure the "judgement of the pharmacist is correct" Should it not fall on the professional's duty to make a sound judgement with having all the facts and calling the doctor? These are questions that need to be asked.

Thank you for reading my email.

Renee McMillen
1229 Jeffery Dr
Port Orange FL, 32129
386-256-7373
jreneet14@hotmail.com

Grant, Matt J

From: Mike Ciavarella <cia6337@yahoo.com>
Sent: Friday, January 30, 2015 7:24 PM
To: Grant, Matt J
Subject: Drug issue

Thank you so much for going public with this drug issue. We have been using the same Walgreen drug store for the past 10 years, and we seem or I thought we knew the pharmacist only to be told she would only fill so many pills. My wife did come down from very heavy drugs that Mayo Clinic had put her on to a level that will handle her pain. My wife has had 3 leg surgeries , spleen removed , migraines, bad discs in her back and neck, fibromyalgia and now a new pain in her good leg, 2 cancer surgeries , hernia mesh in her stomach . Does this sound like someone that would abuse drugs. Pain meds are the only thing that she can take just to function to get though the day. We had been having trouble these past months trying to get the med scrips filled. The Dr has cut her down on the amount he writes, he claims no drug store will give her more. Needless to say it's affected her daily life. We run all over town trying to get them filled , to drug stores that don't know her only to make it worse because they don't know her med history. This probably only raised the price of illegal street drugs. Peg

Sent from my iPad

Grant, Matt J

From: patty mccomb <patipghgirl@gmail.com>
Sent: Friday, January 30, 2015 12:05 AM
To: Grant, Matt J
Subject: Pain in Florida

Hello, my names Patti McComb. I am a pain patient. I have had two back surgeries and need another. I hesitate to get the surgery as I do not know if the pharmacy will have and fill my Rx. I presently have spinal stenosis, 3 slipped discs, 1 herinated disc, an implanted Medtronic neurostim for nerve pain. I'm on high doses of nerve pain med, muscle rexalers, and pain meds. I also have fibro, a very painful muscular condition. It very much is stressful not to know if you can get your meds to function. We are not addicts, we are depending on our meds just as a diabetic needs insulin. I've had the injections and pt, surgery. I get drug tested, at any time I could be called for one, pill counts. My Dr
Knows I don't Dr shop because he checks the web to see where and how often I fill my meds, and where. I don't understand why this is happening but its not right. I am glad its being brought out to the public, a and this is hurting legit patients in severe God awful pain. Thank you for this report.

Grant, Matt J

From: Andrea Hawker <andrea_hawker@hotmail.com>
Sent: Thursday, January 29, 2015 8:36 PM
To: Grant, Matt J
Subject: Pain Medications

Thank you to those responsible for bringing this extremely important issue out in the open! I have not had this happen with pharmacies because:

I suffer from chronic pain from fibromyalgia and arthritis. My doctor up north gave me hydrocodone so I could take 1/2 or 1 pill at night so I could wind down and sleep. I never, ever abused it. I have never been addicted to anything in my life and won't ever be, but now that I live in Florida, the doctors will not give me anything! So, I suffer, and the quality of my life has gone straight down hill in five years and I have additional issues and a huge weight loss. I was told to take Celebrex or Aleve, etc. which I cannot take due to heart palpitations and stomach issues. So, I take Tylenol and that could damage my liver, and basically does nothing much to ease my pain. I have been snapped at and treated like a drug addict, when all I asked for was 1/2 pill to take the edge off of a long day of pain. I resent it, and I hope all the gutless so-called professionals that deny pain meds to those who truly need it will see what it is like one day to suffer constant pain. There will be a lot of suicides out there, but maybe that is what they want. It is inhumane to let this suffering go on....

Sincerely,
Andrea L. Hawker

Sent from Windows Mail

Grant, Matt J

From: Judy Dunn <djudphil@me.com>
Sent: Thursday, January 29, 2015 8:19 PM
To: Grant, Matt J
Subject: Denied pain prescription

My name is Judy Dunn,
Last November I had the same problem with CVS, I was told week after week my hydrocodone was on back order. Than I called, told it was in, I went to pick it up, told once again, still on back order. I was a customer with CVS for 10 years. I called my Doctors office & advised them of the problem, I was afraid of going through withdrawal since I have been on this drug for over 20 yrs. I had tried Walgreens & Walmart, but because I was not a customer they could not help me. I finally got my prescription filled at Publix. I informed CVS Management & removed all of my prescriptions, they lost a very good customer.
Sent from my iPad

Grant, Matt J

From: Judy Kerner <magnoliact@aol.com>
Sent: Thursday, January 29, 2015 6:39 PM
To: Grant, Matt J
Subject: THANK YOU!!!!!! FROM A PAIN PATIENT

Thank you for airing your piece tonight on the issue with getting pain prescriptions filled. It is SO frustrating to get stonewalled at every turn when you ask for answers to your questions at the pharmacies, DEA and the doctors. I stood in line at Walgreens with a prescription for tramadol two months ago (which I have had for years from my primary care doctor for fibromyalgia) and was told that they no longer filled the prescription. Tramadol is a non-narcotic pain killer and still they wouldn't fill it with no more explanation than we are not filling it anymore. I took it to CVS and they filled it for me.

I have a friend who has been on a prescription for oxycodone (5mg) for 10 years and has had it filled at the same Wal Mart Pharmacy for years where the people know her. Last month she took her prescription to be filled and because the typed quantity was a little unclear they refused to fill it but the kicker is her doctor had also hand written in the quantity. She had to go back and get a new prescription from her doctor. She then went back to Wal Mart and they said they didn't have any oxycodone in stock. She went to several pharmacies to get the prescription filled and came away with the same result. Finally, she went to Health Central Hospital's pharmacy and was able to get it filled.

I had to go to a pain management doctor for my meds (instead of my primary care doc of 25 years) due to the new DEA regulations. He was telling me that he spends most of his day fighting with pharmacies over the quantity of pain pills he prescribes to some of his pain patients. When does the pharmacist get to trump the doctor's written prescription? I could go on and on with the impositions the new DEA regulations have placed on legitimate pain patients. Everyone I talk to who is a long term pain patient feels as though they are looked upon as a drug addict (to add insult to what they are already going through). I am not a cruel person, quite the opposite, but I wish the people responsible for this mess we are faced with would have to feel someone's pain for just 1 hour and I bet their attitude would change. Oh, and one other thing, the DEA wanted to control the same of illegal drugs on the streets...what do you think the decent, law abiding pain patients are going to do when they are pushed too far...find another way to get the drugs they need to survive!

What people don't understand is that any pain patient would gladly take another medication (if they were available) to handle their pain if something other than narcotics were available. We do not have a choice.

PLEASE, PLEASE, DON'T GIVE UP ON THIS INVESTIGATION!! WE, THE PEOPLE, WANT ANSWERS!!!

Judy Kerner
1610 Red Ruffle Court
Gotha, FL 34734-5066
Cell: 321-231-6513

Grant, Matt J

From: Darlene K <bydarlenek@yahoo.com>
Sent: Wednesday, January 28, 2015 8:50 PM
To: Grant, Matt J
Subject: Upcoming Report on denying medicines

I am a 56 yr old woman - my knees were crashed in the mid 1990s and I also suffer frm degenative discs. I cannot take pain meds any longer due to kidney and liver damage they did. I hav been on the Lidocaine Patches 5% since my injury. Patches stick to the pain area. They r NOT a narcotic. Just a week in a half ago after my left knee was drained due to it swelling 3 times the size. I went to get my 3 month supply - was told it is no longer covered by my medicare plan - Florida Blue due to the fact that the government feels they know more then my doctors when it comes to my care. Since 2015 the govt changed patch category because junkie and kids r stealing them and chewing on them to get high. People like me are being punish and made to suffer because of this govt. My doctor appealed twice and my claim was denied. It would cost me almost $300 for a 3 month supply out of pocket. I am on social security disability and cannot afford that. So i hav been wheeling around my home in an office chair suffering in severe pain. I beg you to call me to get all the documents i received frm Florida Blue my medicare provider. As of today - i hav NO QUALITY OF LIFE because of this government feeling they know more about my condition then my doctors.

I look forward to speaking with you.

Sincerely,

Darlene Kravos
Ph# 321-231-8888
12727 WhiteRapids Dr
Orlando, Fl 32828

Sent from Yahoo Mail on Android

Grant, Matt J

From: Lesley Hilton <lesley.hilton@live.com>
Sent: Monday, February 09, 2015 7:19 PM
To: Grant, Matt J
Subject: Denial of Pain Meds by Pharmacies

Dear Matt,

I am in deepest appreciation for what you are doing trying to get the word out on the blatant discrimination happening with legitimate pain patients and pharmacies.

My husband and I moved here from Knoxville, TN in November of last year. He is a T-12 incomplete paraplegic. He was injured in 2005 when a car fell on him while he was standing underneath it. He owned a salvage yard in Maui Hawaii. Long story short, he was not carrying WC insurance on himself, as the owner, he didn't have to. Fast forward to today, he is not eligible for Disability because of the lack of tax credit hours and is stuck on SSI and Medicaid for the rest of his days.
We moved here to Jacksonville because of Brooks Rehab and the higher quality of healthcare in general here. We had all our "ducks in a row" before we got here. Referrals, appointments, research done, etc... Never imagined the biggest hurdle we would face would be with the pharmacies. Even though we were with CVS religiously and loyally for years, they would not fill his medications here. "We are out; there is shortage on that medication; we have a limited quantity available to us, and it is reserved for our long term patients" and that was just CVS excuses. Walgreens, much the same. Mom and Pops, they would look at the rx and say just plain old NO. We do not fill narcotic rx for new patients. We don't carry these meds, etc.
Finally, we found a small pharmacy out in Orange Park who accommodated us.. Of course, they expected us to transfer all our medications to them, which we would gladly do. Two months, no hassles, no problems. Now, my husband has had to choose a managed care plan within Medicaid. He chose UHC Community Plan, mainly because most of his specialists accept it and he was also on that plan in TN, so we knew we could get case workers to communicate and all his records for the last 4 years would be easier to access regarding prior authorizations and other hoops and hurdles we may be able to avoid. Problem is this: Our little pharmacy does not take his new insurance. Neither does CVS.

And so begins the pharmacy crawl... again.

My husband's doctor writes a 28 day supply. No leeway, no few days grace, nothing. Withdrawls are eminent. Again. This is inhumane and cruel. And dangerous. My husband has been admitted 4 times already to Memorial Hospital here. He has had a stoma (colostomy) placed. The ER, last time (which is when he wound up admitted for surgery) told us he needed to stop coming for pain control, they will stop dispensing medications to him. Only once have we accepted a prescription from them for narcotics, and it was an 8 day supply. We were HONEST with them and informed them that yes, he was scheduled to be out of medications for 6 days until we could get into the previously scheduled appointment. This was when we first moved here. If and when my husband's pain level requires a visit to the ER because his normal medications don't control it, we go strictly with the intentions to receive IV pain medication and an anti-anxiety injection, and an anti-inflammatory med.

His conditions are as follows:
Spinal cord injury resulting in incomplete paraplegia (dural tear spiraling around the cord at T-12, L-1)

Cauda Equina Syndrome
Nerve entrapment
CRPS
Proctalgia Fugax
Hardware impingment (the screws in his fusion are impinging on the cord)
Foraminial stenosis
Excessive scar tissue buildup
Failed Back syndrome

Injections and nerve blocks do not work for him because there is an interrupted pathway at the level of injury on his spinal cord. He has a Dorsal Cord Stimulator, which also does not work, and actually makes his pain worse. He was approved in Tennessee for a pain pump trail with Prialt, but would have had to travel 2 hours for maintenance, and we knew that we were moving here and getting someone to take over managing a pump not installed by them would be next to impossible.
His pain management group here has referred him for a pump here too. His stim is going to be removed by a neurosurgeon here, and after review of an upcoming myelogram, he may try to do something with the hardware issue. The neuro isn't a fan of the pump, but he will put one in. Brooks is taking him on for rehab, but doesn't want him to start therapy until his pain issues are more under control. The placement of the Stoma has helped to relieve some of the lower GI issues he suffers (chronic rectal ulcers and hemorrhoids, and the rectal area being one of the trigger zones of his CRPS flares), but he still has a long way to go.

\If you are interested in talking to us more about our story, please feel free to contact us.

Sincerely,

Lesley Hilton Young

Grant, Matt J

From: Alana Nicole <anh8475@aol.com>
Sent: Sunday, February 08, 2015 12:55 AM
To: Grant, Matt J
Subject: Medication refusal at CVS

I am responding to your Facebook post. CVS refused to fill any controlled medication and it was about year ago, right after a car accident. The pharmacist told me I on the DEA watch list and he called the prescribing physician, plus my primary physician to "let them know." I have been taking ADD medication, and my children too for years. Suddenly, I was treated like a drug addict when I presented a pain medication prescription from an orthopedic surgeon. I was mortified and never returned to CVS. I only had my prescriptions filled there, including before I moved to Florida four years ago. They lost a customer of at least 15 years.
Sincerely,
Alana Frustaci

Sent from my iPad

Grant, Matt J

From: John Morse <morse@cfl.rr.com>
Sent: Saturday, January 31, 2015 12:30 AM
To: Grant, Matt J
Subject: Prescription Medicine Problems

First, thanks for investigating this situation that affects many people.

My wife has two prescriptions for DEA type medicines that she must get filled each month on the exact day she runs out of her medicine. The local Walgreens does a great job, but sometimes they do not have the medicines in stock. This forces her to drive to store after store searching for the medicines. Walgreens pharmacy personnel are not allowed to call other stores to check inventory, because of DEA rules. Sometimes she has spent several hours searching without success and she goes without the medicine. Her pain medicine is used for the chronic pain of spinal fusion surgeries that fused 16 vertebrae and left her with very little range of motion.

The pharmacies are not the only one to blame. I have just recently experienced a prescription my doctor sent to a pharmacy on 9/21 for an antibiotic called Uribel being denied by my insurance company. AARP United Healthcare denied the prescription even in a generic form. The doctor has submitted the appeal process, but I am still without the needed medicine. Why would an insurance company deny an antibiotic, except for money?

Thanks for your efforts!

Regards,

John Morse

Grant, Matt J

From: Cynthia <ccynthiap@gmail.com>
Sent: Friday, January 30, 2015 7:04 PM
To: Grant, Matt J
Subject: Rx problem

I have suffered from a neurological disease for 15 years and require monthly pain meds to function. I have gone to the same CVS pharmacy for my meds and there have been numerous occasions where a different pharmacist will not fill my prescription. I have to deal with the same pharmacist in order to not encounter any problems. The times that there was someone new, I was told that they don't have my meds in stock even before they look. It's as soon as they see the rx. One time I verified with the usual pharmacist that the meds were in and then had a counter person hand my script back to me saying that they did not have them. When I told her that I knew they did, she became belligerent and told me that I should never have been told that information.
If I did not have this one pharmacist available to me I, too, would be unable to fill my much needed meds. I just find it amazing that such discrepancies can occur in the same pharmacy and that each pharmacist tells a different reason. What's the truth?
Something has to be done and I thank you for bringing the attention to this extremely important matter. Our quality of life depends on these medications. When did we become the punishable for the actions of drug abusers of our state? Thank you again.

Cynthia

Grant, Matt J

From: Jim Pecorilli <jpecorilli@yahoo.com>
Sent: Thursday, January 29, 2015 10:03 PM
To: Grant, Matt J
Subject: Pain Meds

Dear Matt

I seen your story about prescription drugs. On 12/16/2015 I was operated on at Orlando Regional Hospital (Rotator Cup). I received a prescription and filled it at Wallgreens with no problem. On 1/14/2015 I seen my operating doctor. He gave me another prescription , it was for Norco. I have gone to no less than 10 stores and not been able to fill it. And no explanation has been given to me. I then had both my operating doctor and my pain management doctor call Wallgreens to tell them I needed the meds. After the Pharmacy received both calls they still didn't fill it. I asked who I had to call to get this fixed. They did not give me a answer. Now I am in Rehab and could really use it and I can't get it . I am a 59 year old man who did feel like a drug addict when I tried to fill it. When I saw your story I was really upset.

Regards Jim Pecorilli
3340 Callerton Rd.
Clermont Fl. 34714
734-536-0936

Grant, Matt J

From: boscops <boscops@aol.com>
Sent: Friday, February 06, 2015 8:29 PM
To: Grant, Matt J
Subject: Medicine on WESH

I am 63, have a degree in Nsg, but due to an accident 28 yrs ago and back surgery I no longer work. My kids were 1 and 3 at that time, and except for 1 demeral, I never took any narcotics before or after surgery. I learned to keep moving since I was responsible for my kids. Then , 7 yrs my knees would no longer function. I merely wore them out. I took no narcotics prior to surgery, but after, the tendonitis was and can be excruciating that I do use a minimal perscription..I have gone to the same pharmacy for 6 yrs and mail order for medical care. In Oct, I went to have a prescription filled. It had been 4 months and I was harassed and accused of getting medicine elsewhere. I told the tech or pharmacy manager, that I was taking less, breaking them in half, and she still refused to fill it even though she had seen me for any refills in 6 yrs. And she said she was marking it on my record so that no Walgreens would honor it. This is the same tech, whom last yr I queationed, because when I picked up my perscriptions from drive thru, I refused to accept because I could tell it was short. In disbelief, she took them and put it thru the counter. It was 1/2 short, only 90 pills instead of 180, even though it was cosigner by a pharmacist. She mumbled out an apology. I should have posted a complaint because it was not unusual to be 10 or 20 short in the past, but this time I didn't move my car. After the refuse episode, I did have them filled by another store. I went back to a manager at that Walgreens and voiced my complaint to be blown off. I have since not gone back there for medicine. In Feb I did need my narcotic filled. It took three times. I was told they were out of it and waiting for a supply. I had enough to last 7 days and it finally came in. People are made to feel like crooks every time we try and get legitimate mwdic8ne. To be told, that I wasn't taking enough was ridiculous. It's called weaning off medicine and trying PT to stretch and keep from the tendon it is occurring. Oh, I know of many who abuse the system, which is more frustrating for me. I think a solution would be for every narcotic being filled, have it tied to a social security base and they can follow people legal usage. But using as little medicine as possible, I break them in half, and being treated like a criminal, is outrageous. Please feel free to contact me, and I will be happy to fill you in. Patricia Smith

Sent from my Verizon Wireless 4G LTE smartphone

Grant, Matt J

From: Lee Dog <leedog273@yahoo.com>
Sent: Thursday, January 29, 2015 9:00 PM
To: Grant, Matt J
Subject: DEA and pharmacy takeover

Mr Grant, I would like to thank you for your report on pain medications and whats happening to good honest folks in chronic pain, however, I believe you have only seen the tip of the ice berg. A few additions you may not be aware of:
* your primary care doctors have to attend a special class in order to write prescriptions for controlled substances, yet still are unable to provide refills after a period of time, so if you have chronic pain, they must refer you to a pain management doctor
* CVS and Walgreens refuse to fill prescriptions written by pain management doctors at their own discretion.These doctors are licensed by the government yet the pharmacy can refuse? I'm not talking about pill mill doctors, I speak of skilled professionals that spend time with their patients, require MRIs, urine tests, write diagnosis on the script, real doctors!
* some pharmacies refuse to accept insurance for medications written by pain management doctors, even if the insurance companies agree to pay for the medication
* some pharmacies, such as winn dixie and holly hill pharmacy will not accept any customer with narcotics because they are at their limit for how many customers they can have on controlled substance, a limit imposed by the DEA
* Some pharmacists will limit the amount of a controlled substance they will give you, such as The Medicine Shoppe on Orange Ave will only fill for 120 Percoset, even if your doctor writes the prescription for 150 Percoset
*If your regular pharmacy is out of your controlled substance, you must not attempt to go to another pharmacy, as they call this "Narcotics shopping". The pharmacies all promise that they will have your meds every month IF you transfer all of your maintenance medications to them, but then alas, they can't provide your pain medication after the first month

check out a few of these..this has been getting progressively worse for several years
www.medschat.com/topics/where-to-**fill-oxycodone**-prescription
http://www.medschat.com/topics/where-to-fill-oxycodone-prescription
http://www.medschat.com/topics/pharmacies-that-will-fill-oxycodone/
17 diff pharmacies checked and no 15mg oxycodone as they said manufactors are not filling orders .?
Oxycodone shortage: Will federal actions against pharmacy chains, drug distributors cause oxycodone shortage?
Anybody know of CVS new Policy on not more than #90 Oxycodone
Trouble at the Pharmacy filling new oxycodone script? - Yahoo Answers

Grant, Matt J

From: Diane Gracely <dianegracely@comcast.net>
Sent: Monday, February 09, 2015 8:26 AM
To: Grant, Matt J
Subject: Pill problem story

Hi Matt Grant,

I have a story for you. I live in Ocala, FL and had neck surgery on 12/3/14
I've been having problems getting my scripts filled, before and after surgery.
I also cope with a disease with NO CURE. Charcot Marie Tooth disease.
A neuromuscular disease that deformed my feet and caused me to have both feet totally reconstructed and learn to walk again. I have scoliosis, arthritis, chronic pain, and muscle spasms due to my disease PLUS many herniated discs in my back from falling so many times over the years from the poor balance cause by the disease. I have been taking morphine and hydrocodone for years. I have no problems filling my morphine YET, but have problems every month filling my hydrocodone. Right after neck surgery I could NOT get my meds filled for days at a time...
This problem has become insane for REAL patients. It is INHUMANE, period!

Thank you
Diane Gracely of Florida
(352) 470-7352

Greene, Amber K

From: Dudley, Allison M
Sent: Thursday, May 07, 2015 11:43 AM
To: Greene, Amber K
Subject: FW: Pain Medications

Please include email in materials

Allison M. Dudley, J.D.
Executive Director | Board of Pharmacy
Department of Health | Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C-00| Tallahassee, Florida 32399
Phone: (850) 245-4197

From: Dennis Sedor [mailto:dsedor@cfl.rr.com]
Sent: Wednesday, May 06, 2015 5:21 PM
To: Dudley, Allison M
Subject: Re: Pain Medications

Yes, you may share my email…
Did the people that created/pushed this ridiculous bill NOT consider how it would affect the 'legitimate' prescription holders?
What kind of law punishes people in pain by not allowing them to get the medication that would make their life a bit more bearable?
I'm sure that if one of these lawmakers suddenly came down with a serious/painful disease and was unable to get the medication
that would help them - they would 'sing a different tune'… and hopeful realize the damage they have done.
But until then, my wife, and thousands like her - suffer needlessly on a daily basis - and wondering why.

From: Dudley, Allison M
Sent: Wednesday, May 06, 2015 4:11 PM
To: 'dsedor@cfl.rr.com'
Cc: Ranne, Elizabeth
Subject: Pain Medications

Mr. Sedor:

I am sorry to hear of the pain your wife experiences and her difficulty in obtaining her medications. On June 9th, a committee of the Board of Pharmacy will be discussing the difficulties patients are experiencing. I would be happy to include your email in the materials we submit to the Board. Please let me know if we may share your concerns.

Sincerely,

Allison M. Dudley, J.D.
Executive Director | Board of Pharmacy
Department of Health | Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C-00| Tallahassee, Florida 32399
Phone: (850) 245-4197

Attention Health Care Practitioners: There have been changes to the license renewal process. To learn more visit www.flhealthsource.com. For questions, contact the Florida Department of Health toll-free at (855) 410-3344 or email us at MQAReportCE@flhealth.gov

Mission: To protect, promote and improve the health of all people in Florida through integrated state, county, and community efforts.
Vision: To be the Healthiest State in the Nation.
Purpose: To protect the public through health care licensure, enforcement and information.
Focus: To be the nation's leader in quality health care regulation.
Values: I.C.A.R.E. (Innovation, Collaboration, Accountability, Responsiveness, Excellence)
PLEASE NOTE: Florida has a very broad public records law. Most written communications to or from State officials regarding State business are public records available to the public and media upon request. Your email communications may therefore be subject to public disclosure.

Greene, Amber K

From: Dudley, Allison M
Sent: Thursday, May 14, 2015 3:18 PM
To: Greene, Amber K
Subject: FW: Correspondence to Matt Grant

Allison M. Dudley, J.D.
Executive Director | Board of Pharmacy
Department of Health | Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C-00| Tallahassee, Florida 32399
Phone: (850) 245-4197

From: Ann-Marie Mitchell [mailto:amcgahan830@gmail.com]
Sent: Thursday, May 14, 2015 11:27 AM
To: Dudley, Allison M
Subject: Re: Correspondence to Matt Grant

Hi Allison,

You can of course share my email with the Board. Thank you for bringing light on the situation. I feel a little better knowing I am not the only one with this issue. Hopefully we can get some type if reasonable response & initiate some change. It would be nice to go to the pharmacy and be treated as a normal person as opposed to being treated as a drug dealer. :)

Thank you again.

Ann-Marie McGahan

Sent from my iPhone

On Apr 27, 2015, at 12:21 PM, Dudley, Allison M <Allison.Dudley@flhealth.gov> wrote:

Thank you for sharing your story with reporter, Matt Grant, of WESH, Channel 2, Orlando. We received a copy of your email account of the challenges you have faced in having your pain prescriptions filled at local pharmacies. The Department of Health is aware of the challenges patients like you are facing in Florida and we are committed to gathering thoughts and ideas from the health care community to identify real solutions to solve this health care problem. My purpose in writing you is two-fold. First, to express my sincere sympathy for the difficulties you have faced. The second, to ask if we have your permission to share your email with the Board of Pharmacy committee members.

On June 8th, 2015, the Florida Board of Pharmacy will be convening a special committee to discuss the problem and identify solutions. Industry experts and members of the health care community will be invited to participate in a frank and open discussion. This will be a meeting open to the public and the media. We believe the most compelling evidence of the need for solutions is the personal story you and others like you have shared.

Please respond to this email with your desires. If you wish that we not share your email or that we hide your identify, we will most certainly comply with your wishes. Thank you again for sharing your experiences. We are confident that solutions will be identified and Florida patients will receive their needed medications, in the right dose, at the right time.

Sincerely,

Allison M. Dudley, J.D.
Executive Director | Board of Pharmacy
Department of Health | Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C-00| Tallahassee, Florida 32399
Phone: (850) 245-4292

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20 May 2015

Allison Dudley, J.D., Executive Director
Florida Board of Pharmacy, Florida Department of Health
Division of Medical Quality Assurance
4052 Bald Cypress Way, Bin C-04 Phone: 850.245.4095
Tallahassee, FL 32399-3251 e-mail: Allison.Dudley@flhealth.gov.

Dear Ms. Dudley

Thank you for your recent reply to my March 27th letter to the Department of Elder Affairs regarding new and stricter regulations for certain pain medications. You may share my letter with the committee to be convened on June 9th.

It gives me some hope, that I may not be the only person, who has raised concerns on this matter. In an aging population, which is living longer and who may wish to remain a more active and vital participant in their society, it is logical that the need for stronger pain medications may play a constructive role in that.

I briefly alluded to the principle of "unintended consequences" in my earlier letter, by mentioning this country's Prohibition Era. By changing certain classifications of schedule drugs, adding additional paperwork controls, and tightening dispensing guidelines it was hoped to crack down on drug abuse. Sadly this is having some negative consequences for people who have a legitimate condition and a need to take such strong medicines.

One concern of mine, is that it tends to further stigmatize a drug, which can be quite useful in caring for people with a level of pain, that exceeds the effectiveness of NSAIDs or Acetaminophen. Taking too much of those latter drugs can have fatal consequences. Recently the mother of a very dear friend of mine nearly died from gastric bleeding by taking too much Naproxen.

Tighter regulations on a pain management drug such as hydrocodone can make physicians more reluctant to suggest or prescribe it for people who might otherwise greatly benefit from it. The effect on pharmacists can be an unwarranted, heightened suspicion of anyone presenting an otherwise, very legitimate Rx.

Law abiding individuals who want or need to do some extended travel away from their immediate locale, now find themselves penalized and in a situation not unlike low-level offenders placed under "house arrest". Prescriptions written

locally in Florida aren't honored in a different state. Sadly, the ability to get a 90 day supply of a pain medication filled locally, for a person hoping to travel, has been eliminated.

With this effective "stigma" placed on a stronger pain medication, attempting to get a prescription written by an "out of state" physician unfamiliar with a patient's medical history or condition, would most likely be rather problematic, if not impossible.

Sometimes I hear the phrase and/or justification, "Due to the bad behavior of a few, the group at large must incur suffering or punishment." For incidents of public violence this could be plausible, but most certainly it should not be the basis or guiding principle for writing laws and regulations. To punish a larger group of innocent people for the actions of a few, not only is unfair; it runs the risk of generating disrespect and even contempt for those creating such rules.

I am very well aware of the problems our society faces with recreational drug abuse and drug addiction, and in some communities, the emotional pain caused by a scourge of deadly overdoses of drugs such as heroin. But reasons for drug abuse and addiction are often more tied to larger societal problems and an individual's psychological problems. Indeed, lack of opportunities for economic advancement and social mobility for a population, will only further stoke these societal ills.

Policies to try to stop criminals, or drug abusers should not be at the expense of alleviating human suffering, nor unfairly stigmatizing or compromising the free mobility of law-abiding citizens.

Pharmacists and health professional as a group, are devoted to improving quality of life. Adequately treating chronic pain is part of that. Compassion should always be their guiding principle.

Sincerely,

Herbert P. Pleiman Jr., D.D.S.
4053 Brandeis Ave.
Orlando, FL 32839-1469

Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances

American Academy of Family Physicians

American College of Emergency Physicians

American Medical Association

American Osteopathic Association

American Pharmacists Association

American Society of Anesthesiologists

American Society of Health-System Pharmacists

Cardinal Health

CVS Health

Healthcare Distribution Management Association

National Association of Boards of Pharmacy

National Association of Chain Drug Stores

National Community Pharmacists Association

Pharmaceutical Care Management Association

Purdue Pharma L.P.

Rite Aid

Walgreen Co

Executive Summary:

In recent years, the misuse and abuse of prescription medications has emerged as a growing public health problem. In addition to the tragic toll on families and communities, prescription drug abuse results in increased costs to the health care and the criminal justice systems. When used appropriately and under the direction and care of licensed health care professionals, prescription medications can improve and save lives. However, prescription medications – most notably controlled substances – can cause negative health consequences if they are abused, diverted, or used inappropriately and not as intended. In an effort to address the nation's prescription drug abuse epidemic and provide guidance to health care practitioners working to minimize diversion, misuse, and abuse of controlled substance medications while ensuring legitimate patient access, stakeholder organizations representing the spectrum of medical and pharmacist care, as well as the supply chain – manufacturers and wholesale distributors, united on October 2, 2013, and numerous times thereafter over the course of 2013 and 2014. The meetings facilitated the communications among stakeholders and resulted in the development of a consensus document detailing the challenges faced by all involved, highlighting red flag warning signs for health care practitioners to detect diversion, misuse, and abuse of controlled substance medications, and identifying aberrant behavior indicators.

The understanding of health care practitioners' roles and the collaboration and communication necessary for a dialogue and resulting consensus document shed light on unappreciated challenges, such as the demands placed on physicians to provide direct patient care and a pharmacist's corresponding responsibility doctrine outlined by Drug Enforcement Administration (DEA) regulations. Determining whether a prescription for an opioid analgesic is issued for a legitimate medical purpose is complicated by the fact that pain is a conscious experience involving interpretation of sensory input that signals a negative event and is influenced by emotion, cognition, memory, interpersonal and social context, and other factors. Appropriate pain management typically is tailored to the individual needs of the patient in collaboration with the prescriber, pharmacist and patient. Red flag warning signs are screening tools for practitioners signaling further review is necessary. Ultimately, red flag warning signs for both physicians and pharmacists were identified and placed into two categories within the consensus document – 1) those factors more indicative of substance abuse or diversion and 2) other aberrant medication-related behaviors and factors potentially indicative of substance abuse or diversion.

In sum, the goal of the stakeholder consensus document is to provide health care practitioners with an understanding of their shared responsibility to ensure that all controlled substances are prescribed and dispensed for a legitimate medical purpose as well as providing guidance on which red flag warning signs warrant further scrutiny. Overall, the challenges faced by health care practitioners can be overcome through collaboration and communication and broader efforts to prevent the diversion of controlled substances while ensuring access to the medications for patients who need them for legitimate reasons. The consensus document however, is not to be

construed as establishing any standards of care, but considered as general guidelines and as a reminder that health care practitioners must comply with federal laws and regulations and use their professional judgment when confronted with red flag warnings and aberrant patient behaviors in regard to controlled substance prescriptions.

Stakeholders' Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances[1]

Section 1 – Introduction

In recent years, the misuse and abuse of prescription medications has emerged as a growing public health problem. In addition to the tragic toll on families and communities, prescription drug abuse results in increased costs to the health care and the criminal justice systems. When used appropriately and under the direction and care of licensed health care professionals, prescription medications can improve and save lives. However, prescription medications – most notably controlled substances – can cause negative health consequences if they are abused, diverted, or used inappropriately and not as intended. The stakeholder organizations noted below represent the spectrum of the medical, pharmacist care, and supply chain – manufacturers, wholesale distributors, physicians, and pharmacists – and are committed to working together to support appropriate prescribing, dispensing, access to, and use of controlled substance prescription medications. The stakeholders recognize that any proposed policy in this area must strike a careful balance to ensure that efforts aimed to minimize the potential for diversion, misuse, and abuse of controlled substance prescription medications do not restrict access for patients with legitimate medical need.

Each of the stakeholder organizations plays an important role in addressing prescription drug abuse, although, at times, conflicting roles and responsibilities may occur among care and supply chain partners. This conflict is oftentimes caused by various reactions to legal requirements enacted to address prescription drug abuse. In fact, the impetus for assembling the stakeholder organizations revolves around the shared responsibility of physicians and other prescribers and pharmacists that ensure all controlled substances are prescribed and dispensed for a legitimate medical purpose.[2] Fulfilling this responsibility requires increased engagement and communication

[1] This document was compiled by the National Association of Boards of Pharmacy (NABP) addresses challenges and interactions of stakeholders with respect to their roles as it relates to curbing prescription drug abuse. NABP seeks to facilitate discussion and collaboration among the stakeholders; and as such, this document should not be construed as modifying current industry standards.

[2] United States Drug Enforcement Administration. 21 CFR §1306.04 Purpose of issue of prescription. (*www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol9/pdf/CFR-2014-title21-vol9-sec1306-04.pdf*). Accessed August 1, 2014.
(a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and

between pharmacists and physicians and other prescribers, which has resulted in confusion and the subsequent adopting of policies that can disrupt the collaborative interactions of these health care practitioners and ultimately affect patient care.

This document addresses the challenges each stakeholder faces, as well as the warning signs they must be aware of related to the prescribing and dispensing of controlled substances in regard to this serious public health problem and how to best collaborate to provide patient care.

Section 2 – Challenges

A. Manufacturers

Manufacturers are actively engaged in a broad range of efforts with health care practitioners, law enforcement, patient groups, family advocates, and other stakeholders to support appropriate use of medicines, but also face significant challenges related to abuse of their analgesic drug products.

Those manufacturing extended-release or long-acting opioid analgesics are subject to a stringent Risk Evaluation and Mitigation Strategy (REMS) imposed by Food and Drug Administration (FDA) which, in part, requires funding of third parties to provide continuing medical education (CME) about the safe use of these medications. If the number of prescribers completing this REMS-compliant CME doesn't reach FDA-mandated milestones, there could be substantial restrictions on access to these products. These manufacturers are also required to conduct five complicated and expensive post-marketing studies to determine if and how frequently opioid-induced hyperalgesia occurs, to quantify known risks of opioids, eg, abuse and misuse, and to study doctor-shopping, etc.

Manufacturers, like distributors discussed below, struggle to discern what constitutes a "suspicious order" to comply with Drug Enforcement Administration (DEA)-mandated monitoring of orders for products.

One approach that is unique to manufacturers for reducing abuse is the development of novel, innovative preparations of opioid analgesics that are designed to deter certain methods of abuse, ("abuse-deterrent" formulations or ADF). While FDA has issued a draft Guidance on what types of evidence yield particular label claims, a final Guidance has yet to be issued. Likewise, FDA has not issued a draft Guidance on how generic drug products referencing an innovator product with labeled abuse-deterrent properties should be developed and labeled.

Additionally, FDA has repeatedly stated that it seeks to encourage development of ADF opioid analgesics, but has yet to specify which tier(s) of labeling language outlined in the draft Guidance a specific product has earned, which limits manufacturers' ability to communicate ADF messages.

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authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Although FDA believes that ADF study summaries in the label will be informative to prescribers, it is not clear that study descriptions alone will be meaningful to most prescribers, pharmacists, or payers for interpreting the expected impact on abuse or the relative differences between drug products.

It is critical that any policies adopted to address misuse, abuse, and addiction must be balanced with and not impede the ability for patients to access needed medicines prescribed for legitimate medical purposes. Lastly, the societal benefit of these novel ADF opioids could remain unrealized if public and private payer policy disadvantages their use through formulary coverage decisions.

B. Distributors

Distributors of prescription medications – specifically controlled substances – provide a vital service to pharmacies, prescribers, and patients. The logistics of ensuring that the prescription medication supply chain operates effectively and safely are overwhelming. Amidst the processing of orders to ensure daily deliveries of needed medications and supplies is a matrix of legal requirements and business challenges.

Legal Requirements

- Record keeping – Distributors are required to create and maintain a variety of records, such as records of receipt and distribution of controlled substances and inventories.
- Verification of Registration – Distributors are required to know that the entities to which they distribute controlled substances are properly registered with DEA and applicable state agencies or make a good faith inquiry in accordance with 21 CFR §1301.74(a).[3]
- Reporting – Distributors are required to file a variety of reports with DEA. Most germane to the issue of prescription drug abuse is the requirement that distributors detect and report to DEA suspicious orders for controlled substances in accordance with 21 CFR §1301.74(b).[4] Suspicious orders are "orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

Prescribers and pharmacists are required by DEA regulations to ensure that prescriptions for controlled substances are issued for a legitimate medical purpose by a practitioner acting in the

[3, 4] United States Drug Enforcement Administration. 21 CFR §1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs. (www.gpo.gov/fdsys/pkg/CFR-2014-title21-vol9/pdf/CFR-2014-title21-vol9-sec1301-74.pdf). Accessed August 1, 2014.
(a) Before distributing a controlled substance to any person who the registrant does not know to be registered to possess the controlled substance, the registrant shall make a good faith inquiry either with the Administration or with the appropriate State controlled substances registration agency, if any, to determine that the person is registered to possess the controlled substance.
(b) The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

usual course of professional practice.[5] Distributors, unlike prescribers and pharmacists, do not interact with patients and do not have access to the information necessary to determine whether a prescription that is being dispensed by a pharmacy is legitimate. However, in addition to determining and reporting suspicious orders under 21 CFR § 1301.74(b), distributors are also expected to block, ie, prevent the distribution of suspicious orders, per DEA guidance letters.[6]

A significant challenge for distributors is applying in practice what defines a suspicious order. For distributors, the appropriate metrics to identify a suspicious order are, for the most part, the responsibility of the distributor and not delineated specifically in federal or state laws and requirements. Because of this, the metrics that are actually used vary considerably among distributors. Questions persist as to which factors should be used or how much weight certain factors should be given for determining what constitutes a suspicious order. Such factors include: the overall size of the pharmacy; how many prescriptions are filled per day; both non-controlled and controlled substances in relation to controlled substances purchased; any specialty practice within a pharmacy; affiliation(s) with health care institutions such as hospitals or clinics; the type(s) of patient population a pharmacy serves; variations in geographical or regional prescribing patterns that may affect which products are dispensed and purchased; and other factors that influence the quantity of controlled substances ordered and the ordering pattern of a pharmacy. Although an indicator of certain activities, some factors, such as national averages, may not necessarily identify abuse or diversion, nor determine whether an order or group of orders is suspicious. Absent more specific requirements, distributors must make decisions about whether to distribute an order for controlled substances based upon factors that may cause an order to be suspicious. This has led several distributors to place limits on the quantity of controlled substances they will distribute to customers and, depending on the distributor that the customer chooses, the limits may vary based upon what criteria that distributor uses and how much weight the distributor gives factors within that criteria. As a result, distributors have faced lawsuits and threats of lawsuits from DEA-registered pharmacies for either ceasing distribution of controlled substances to the pharmacies or limiting the quantity of controlled substances they will sell, which ultimately have, in some cases, negatively impacted patient access to care.

C. Prescribers/Physicians

According to the Controlled Substances Act, physicians and other prescribers have a responsibility to ensure that a prescription for a controlled substance is "issued for a legitimate medical purpose

[5] United States Drug Enforcement Administration; *Practitioner's Manual;* 2006:30
"Federal courts have long recognized that it is not possible to expand on the phrase 'legitimate medical purpose in the usual course of professional practice' in a way that will provide definitive guidelines to address all the varied situations physicians may encounter."

[6] These guidance letters are from DEA's Deputy Assistant Administrator, Office of Diversion Control, sent to registered manufacturers and distributors on September 27, 2006, February 7, 2007 and December 27, 2007.

by an individual practitioner acting in the usual course of his professional practice." The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription (see below).

Determining whether a prescription for an opioid analgesic is issued for a legitimate medical purpose is complicated by the fact that pain is a conscious experience involving interpretation of sensory input that signals a noxious event and is influenced by emotion, cognition, memory, interpersonal and social context, and other factors. Patient-reported intensity of pain may not correlate with the magnitude or identifiable source of injury. Because objective tests for pain intensity (or even the presence or absence of pain) are still at a rudimentary stage of development, the best clinical approach in most circumstances is to assume that the patient is reporting a true experience. Accepting a patient's complaint of pain as valid does not require clinical identification of a physical cause, or demand the initiation of a specific treatment. It does, however, provide a foundation for assessment and the basis for developing an effective patient-physician dialogue.

During the past two decades, growing numbers of patients with persistent non-cancer pain have been offered long-term opioid therapy. This change in prescribing behavior has been influenced by several competing interests. Undertreatment of cancer pain was described, and the aggressive use of opioid analgesics was endorsed as the most effective approach to address patient suffering. With the advent of a new array of products, this approach was extended to patients with chronic non-cancer pain, even in the absence of evidence obtained from long term, randomized controlled trials, which are not feasible. In both hospital and outpatient settings, the recognition of pain as the fifth vital sign, and the evolution of patient satisfaction surveys that include a focus on the extent to which a patient's pain is relieved, created a practice environment that, although intended to promote pain assessment and effective treatment, in general ultimately led to an increase in opioid prescriptions. Despite the substantial burden of persistent pain in the United States, access to multidisciplinary care and reimbursement for non-pharmacologic approaches is woefully inadequate. All of these factors may have contributed to the routine use of opioid analgesics.

In parallel with this increase in medical use has been a deeply concerning rise in various measures of prescription drug misuse and abuse, including nonmedical use, as well as unintentional overdoses and deaths. Non-adherence during treatment, drug abuse, addiction, unintentional overdose and diversion into the illicit marketplace are known risks of opioids and other controlled drugs. Whenever opioid analgesic drugs are considered for use, pain assessment and patient selection, risk assessment and risk stratification, drug choice, and structuring of therapy (including monitoring, maintenance, and exit strategies) are key elements comprising appropriate care.[7,8] Currently available instruments for implementing these approaches are imperfect and difficult to

[7] Katz NP, Adams EH, Benneyan JC, et al. Foundations of opioid risk management. *Clin J Pain.* 2007;23(2):103-118.
[8] Gourlay DL, Heit H, Almahrezi A. Universal precautions in pain medicine: A rational approach to the treatment of chronic pain. *Pain Med.* 2005;6:107-112.

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integrate into primary care practice, placing additional emphasis and responsibility on a physician's judgment and clinical experience, which cannot be replicated outside of the patient-physician relationship.

Just as pharmacists are operating in a multitasking environment that places high demands on time management, the ability of physicians and other prescribers to be responsive to requests for additional information is constrained by an array of existing demands that already erode their ability to provide direct patient care. These include a high frequency of requests related to refills and prescription re-authorization, prior authorization, and errors related to electronic prescribing interfaces; adapting to meaningful use, physician quality reporting systems, value-based modifiers; and, HIPAA concerns. Accordingly, responding to calls from pharmacists to clarify the legitimacy of an opioid prescription may be viewed as intrusive, depending on the nature of that call, especially if the prescriber is unaware of the pharmacist's corresponding responsibility.

D. Pharmacists

Pharmacists' associated professional services and activities vary from practice to practice and site to site. The variance is in response to the diversity of patient care needs and patients' medication use through self-care, acute care, and long-term or chronic care. These varying needs manifest in virtually all practice settings and add complexity to the patient care provided by pharmacists. Regardless of practice setting, the basis and essence of pharmacist care is communication, education, and information exchange with patients and their caregivers, prescribers, and other health care professionals. The central point of this care is the pharmacist management of medication use that strives to provide patient-centered medication therapy with the goal of positive patient outcomes.[9] In the effort to provide this patient-centered medication therapy management, collaboration between patients, prescribers, and pharmacists is imperative.

Pharmacists serve a critical role in the continuum of patient care and often serve as one of the most accessible members of the health care team. The pharmacist, through standards of care and federal and state legal requirements, assumes diverse and sometimes conflicting roles. When a patient or caregiver presents a prescription to the pharmacist, what transpires next is a complex coordination of care and oversight. The presenting of a prescription is one of a myriad of items the pharmacist is reviewing and trying to resolve in a multitasking environment involving the receipt and evaluation of prescriptions for multiple patients at once, interactions or pending interactions with prescribers, and resolution of insurance coverage and formulary issues. All of these activities occur within a limited time frame being conducive to patient convenience, while not compromising patient safety, and taking into consideration a prescription's legitimacy.

[9] J Am Pharm Assoc (2003) 2010;50:e35-e69. Dol:10.1331/JAPHA.2010.10510.

If the prescription is issued for a controlled substance, there is also the specific legal, "corresponding responsibility" requirement with which pharmacists must comply.[10] Unfortunately, the fact that pharmacists have a corresponding responsibility to ensure the legitimacy of a controlled substance prescription appears to be relatively unknown to many prescribers and has contributed to the potential for confusion and conflict between prescribers and pharmacists. This corresponding responsibility requirement overlies the existing responsibility of the pharmacist to evaluate a prescription in the context of the patient's broader medication need and history. In this regard, it is appropriate and at times necessary for pharmacists to contact prescribers to obtain additional information or clarification regarding a prescription issued for a controlled substance. In doing so, pharmacists do not intend to engage in activities outside of their scope of authority, nor intrude into the scope of practice of other professions; however, pharmacists must comply with corresponding responsibility requirements or risk being subject to the penalties for violations of controlled substance law.

Summarily, in the compressed amount of time during which a prescription is presented to the pharmacist and the patient receives his/her medication, the pharmacist's responsibilities to review, evaluate, and dispense the prescription include:

- Completing a drug utilization review that includes, but is not limited to, the evaluation of the prescription and patient record for known allergies; rational therapy contraindications; reasonable dose, duration of use, and route of administration; considering age, gender, and other patient factors; reasonable directions for use; potential or actual adverse drug reactions; drug-drug interactions; drug-food interactions; drug-disease contraindications; therapeutic duplication; proper utilization (including over- or under-utilization) and optimum therapeutic outcomes; and abuse/misuse;
- Interacting with patients or caregivers who may be unaware of what the prescription was issued for, or who are unable to provide additional information beyond the symptoms that are being experienced and discussed with the prescriber; and
- Having to decipher illegible prescriptions and/or contact prescribers due to the limited use of electronic prescribing.

The presentation of a controlled substance prescription adds the following complicating factors:

- Recognizing "red flag" warnings[11, 12] that call the prescription into question. Such warnings require the pharmacist to ensure that the prescription is being issued for a legitimate medical purpose by the prescriber acting in the usual course of his/her professional practice. This may include communicating with the prescriber to clarify the

[10] 21 CFR §1306.04

[11] Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; Decision and Order; 77 FR 108, 62,315 (Dept of Justice Oct. 12, 2012). *www.deadiversion.usdoj.gov/fed_regs/actions/2012/fr1012.htm.*

[12] East Main Street Pharmacy; Affirmance of Suspension Order 75 FR 207, 66149 (Dept of Justice Oct. 27, 2010) Available at *www.deadiversion.usdoj.gov/fed_regs/actions/2010/fr1027_3.htm.*

prescription and/or evaluate the legitimacy of a prescription, which may at times be difficult depending on the prescriber's availability, especially when prescriptions are presented outside normal business hours or on weekends.

- Satisfactorily determining legitimacy of the prescription. Communicating with prescribers can be essential in ascertaining the legitimacy of a controlled substance prescription, although simply phoning a prescriber and inquiring if the prescription is legitimate may not be satisfactory. In the case of prescribers who may be involved in abuse or diversion, it is highly unlikely that the response to an inquiry from the pharmacist concerning the legitimacy of the prescription would be to affirm that the prescription is not legitimate. Thus, the pharmacist may need to initiate additional means to evaluate the prescription. In addition, it can also be difficult to validate a prescriber's authority. For example, a prescriber may issue an otherwise legitimate prescription, but may not be authorized to write for that class of controlled substance.
- Accessing PMP data. This step is valuable and necessary in many situations. Unfortunately, the data from, operation of, and access to individual PMPs lack uniformity, may be incomplete, or are not conducive to real-time patient care demands of the compressed time frame noted above.
- Distribution restrictions implemented by wholesale distributors. Such restrictions implemented in response to enforcement actions or company policies impact the availability of medications to the pharmacist, creating another factor to resolve before dispensing can be completed.

Section 3 – Factors More Indicative of Substance Abuse or Diversion (Red Flags)

A. Patient Population and Behaviors

The patient population with persistent pain is extremely diverse and the strategies used to administer and monitor opioid therapy should be individualized based on the pain assessment, the risk of adverse effects, and the perceived likelihood of problematic drug–related behaviors.[5,6] A one-size-fits-all approach to guide treatment or to prevent substance abuse ultimately would do a great disservice to patients and the health care professionals who work hard to effectively treat their pain.

While several groups have been working to address issues surrounding the current prescription drug epidemic, the coalition of stakeholders representing the spectrum of medical, pharmacist care, and supply chain — physicians, pharmacists, manufacturers, distributors, pharmacy benefit managers, and federal and state regulatory and law enforcement agencies have come together to collate warning signs that can help assist physicians and other prescribers and pharmacists identify situations that indicate whether a patient may be more likely to be abusing or diverting prescription drugs. These warning signs have been developed to help educate and raise awareness among health care professionals about warning signs, and foster communication and collaboration

in order to minimize these activities.

Some of these warning signs are indicators of a substance use disorder, including addiction, or illicit/illegal behavior, or that a patient's health or safety is threatened. They have been identified through enforcement actions of the Drug Enforcement Administration and various clinical studies.[13,14,15,16,17,18,19,20,21,22,23,24] A subset of these actions or behaviors have been termed "red flags," and are part of a broader array of warning signs reflecting illicit/illegal activities and/or aberrant drug-related behaviors that patients who are receiving opioid analgesics may exhibit in response to therapy. Such behaviors exist along a continuum. As a term of art, red flags typically have been interpreted to be more likely to reflect drug abuse, addiction, or diversion, although a wide range of other aberrant behaviors exist that are indicative of various patterns of non-adherence (see below). When warning signs are present, health care practitioners should immediately assess the situation and/or the patient's medical and psychological condition, and determine the appropriate action, eg, continuation of treatment, intensify monitoring, refer for substance use/addiction treatment, refuse to issue/dispense a prescription. Activities on the part of the patient that violate state or federal law may require more direct action. While health care practitioners must ethically take steps to help prevent the continued misuse, abuse or diversion of opioids, some patients may need ongoing treatment. In these situations, extra care should be taken, and may include referrals to specialists and other clinically appropriate decisions.[25] The following categories of factors more indicative of substance abuse or diversion have been identified.

B. Prescribers

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[13] Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; 77 Fed. Reg. 62,315 (Dep't of Justice Oct. 12, 2012) (decision and order). Available at: *www.deadiversion.usdoj.gov/fed_regs/actions/2012/fr1012.htm.*

[14] East Main Street Pharmacy; 75 Fed. Reg. 66,149 (Dep't of Justice Oct. 27, 2010) (affirmance of suspension order). Available at: *www.deadiversion.usdoj.gov/fed_regs/actions/2010/fr1027_3.htm.*

[15] Holiday CVS, L.L.C. v. Holder, 839 F.Supp.2d 145 (D.D.C. 2012). Available at: *www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_12-cv-00191/pdf/USCOURTS-dcd-1_12-cv-00191-0.pdf.*

[16] Townwood Pharmacy; 63 Fed. Reg. 8,477 (Dep't of Justice Feb. 19, 1998) (revocation of registration). Available at *www.gpo.gov/fdsys/pkg/FR-1998-02-19/pdf/98-4201.pdf.*

[17] Grider Drug 1 & Grider Drug 2; 77 Fed. Reg. 44,069 (Dep't of Justice July 26, 2012) (decision and order). Available at: *www.deadiversion.usdoj.gov/fed_regs/actions/2012/fr0726.htm.*

[18] The Medicine Dropper; 76 Fed. Reg. 20,039 (Dep't of Justice April 11, 2011) (revocation of registration). Available at: *www.deadiversion.usdoj.gov/fed_regs/actions/2011/fr0411_10.htm.*

[19] Medicine Shoppe-Jonesborough; 73 Fed. Reg. 363 (Dep't of Justice Jan. 2, 2008) (revocation of registration). Available at: *www.deadiversion.usdoj.gov/fed_regs/actions/2008/fr0102.htm.*

[20] Medicine Shoppe-Jonesborough v. DEA, 300 Fed. Appx. 409, 2008 WL 4899525 (C.A.6).

[21] Moore TM, Jones T, Browder JH, Daffron S, Passik SD. A comparison of common screening methods for predicting aberrant drug-related behavior among patients receiving opioids for chronic pain management. *Pain Med.* 2009 Nov;10(8):1426-33.

[22] Cheatle MD, O'Brien CP, Mathai K, Hansen M, Grasso M, Yi P. Aberrant behaviors in a primary care-based cohort of patients with chronic pain identified as misusing prescription opioids. *J Opioid Manag.* 2013 Sep-Oct;9(5):315-24.

[23] Passik SD, Kirsh KL, Donaghy KB, Portenoy RK. Pain and aberrant drug-related behaviors in medically ill patients with and without histories of substance abuse. *Clin J Pain.* 2006 Feb;22(2):173-81.

[24] Passik SD, Kirsh KL. Assessing aberrant drug-taking behaviors in the patient with chronic pain. *Curr Pain Headache Rep.* 2004 Aug;8(4):289-94.

[25] Wiedemer NL, Harden PS, Arndt IO, Gallagher RM. The opioid renewal clinic: a primary care, managed approach to opioid therapy in chronic pain patients at risk for substance abuse. *Pain Med.* 2007 Oct-Nov;8(7):573-84.

In the vast majority of situations, prescribers play a key role in preventing and identifying prescription drug abuse. Proper education and training, and vigilance with respect to appropriate patient selection and prescribing practices can help minimize diversion and abuse as well as ensure patients do not suffer unnecessary delays or denials in care, including access to opioid analgesics when appropriate. Practice guidelines, best practices and model policies have evolved from a variety of sources to promote responsible opioid prescribing and establish standards of care.

Initial Visit/Presentation

- Patients who travel to the prescriber's practice as a group and all request controlled substance prescriptions on the same day.
- Patient declines physical examination, or permission to obtain past records, or to undergo diagnostic tests.
- Patient statements and conduct suggest abuse of controlled substances, eg, appears sedated, confused, intoxicated, or exhibits withdrawal symptoms, or has physical signs of drug abuse.

Medication Taking/Supply

- Patient exhibits multiple unexplained dose escalations or other non-adherence to the treatment plan.
- Patient uses a route of drug administration other than the method prescribed, eg, injecting or inhaling oral formulations; ingesting transdermal formulations.
- Patient repeatedly seeks medications from non-coordinated sites of care; possible examples could include the emergency department, urgent care facilities, or walk-in clinics.
- Patient suffers an unintentional (or intentional) overdose.

Patient Behavior/Communication

- Patient behavior or PDMP report provides evidence that the patient is obtaining controlled substance prescriptions from multiple health care practitioners without the prescribers' knowledge of the other prescriptions.
- Patient was discharged from another physician practice for egregious behavior.
- Patient pressures physician to prescribe by implying or making direct threats to the prescriber or staff.[26]

Treatment Plan Related

- Patient repeatedly resists changes in the treatment plan, despite clear evidence of adverse physical or psychological effects from the drug.
- Patient refuses to sign, or fails to comply with, an opioid pain care agreement governing their use of opioid analgesics.

[26] If the prescriber feels physically threatened, issue the prescription to avoid confrontation; then contact authorities.

Illicit/Illegal

- Prescriber is made aware that patient alters, forges, or rewrites prescriptions.
- Prescriber receives reliable information that patient is diverting or selling medication, or "borrowing" drugs from others.
- Patient indicates that drugs will be shared with others or sold.
- Patient requests controlled substance prescriptions written in the names of other people for whom the patient is not the designated caregiver.

C. Pharmacists

Patient-centered medication therapy management provided by pharmacists becomes increasingly more complex when a patient is prescribed a controlled substance and the medication therapy involves the management of various types of acute and chronic pain. In these situations, the ethical and legal corresponding responsibilities that help define the dispensing of controlled substances must be considered and followed.

When presented with a prescription for a controlled substance, pharmacists must exercise their professional judgment and must adhere to their corresponding responsibility to determine whether a prescription for a controlled substance has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice. That evaluation determines the next steps taken by the pharmacist and includes options such as a discussion with the prescriber in order to ensure the validity of the prescription and address red flag warning signs prior to dispensing.

These red flags may indicate that a controlled substance prescription is not being obtained for a legitimate medical purpose, but for diversion or abuse, thereby possibly necessitating additional steps by the pharmacist. Any time a red flag occurs, it should be evaluated in an attempt to appropriately interpret its nature, and patient management should be pursued based on this interpretation and the seriousness of the warning signs. Of course, the warning signs are not intended to prevent the dispensing of a legitimate controlled substance prescription.

Presentation of the Prescription

- Patients travel in groups and/or have unexplainable common factors in their relationships with each other, for example, groups of patients present prescriptions for the same controlled substances from the same prescriber, or multiple family members or patients living at the same address present similar controlled substance prescriptions to the pharmacy on the same day.[8,9]
- Patient presents prescriptions for controlled substances written in the names of other people (does not apply to designated caregivers presenting prescriptions for patient).[27]

[27] Drug Enforcement Administration: *Pharmacist's Manual*; 2010:66-68.

- Patient presents a prescription for controlled substance that the pharmacist knows, or reasonably believes, that another pharmacy refused to fill.
- Handwritten prescription is presented at the pharmacy looking altered (quantity changed) or flawlessly thorough (contains patient address, quantity spelled out, patient date of birth, multiple provider identifiers, lacks common abbreviations, etc.).[26]
- Pharmacist becomes aware that prescriber's DEA registration has been previously suspended or revoked, or is pending suspension or revocation.[8]

Patient Behavior

- Patient pressures the pharmacist to dispense controlled substance by making implied or direct threats.[28]
- Patient shows physical signs associated with controlled substance abuse, such as needle tracks or scars on neck, arms, feet, or ankles.
- Patient's statements and conduct suggest abuse of controlled substances, such as appearing sedated, confused, intoxicated, or exhibiting withdrawal symptoms.
- Patient obtains same or similar controlled substance prescription from multiple health care practitioners without disclosing those existing controlled substance prescriptions.[12,13,14]
- Patient obtains controlled substance medications from one pharmacy while having received the same or similar controlled substance(s) from other pharmacy(ies) without disclosing those existing controlled substance prescriptions.
- Patient presents prescriptions for highly abused controlled substance medications.[29]
- Patient presents several prescriptions written for controlled and non-controlled substances, but only wants the controlled substance medication(s) dispensed.
- Patient has a history of untruthfulness when filling controlled substance prescriptions.

Medication Taking/Supply

- Patient presents prescriptions for large quantities or large number of prescriptions for controlled substances.[9]
- Therapeutic duplication of two or more long-acting and/or two or more short-acting opiates.
- Patient presents prescriptions for highly abused "cocktails" (combination of opiate, benzodiazepine, and muscle relaxant) of controlled substance medications.[30]

Illicit/Illegal

- Patient indicates that drugs will be shared with others or sold.

[28] If the pharmacist feels physically threatened, dispense the prescription to avoid confrontation; then contact authorities.
[29] Highly abused controlled substances may vary from region to region. Pharmacists should be aware of abuse trends in their area.
[30] This is not in reference to specific medication combinations intended to decrease opioid dose.

Disclaimer – this consensus document should not be construed as establishing any standards of care, but considered as general guidelines and as a reminder that health care practitioners must comply with state and federal laws and regulations and use their professional judgment when confronted with aberrant patient behaviors in regard to controlled substance prescriptions.

- Prescriber's DEA registration or state license has expired/suspended/revoked.
- Patient presents prescription from prescriber who is prescribing outside the scope of his/her practice as defined by state law.
- Patient alters, forges, sells or rewrites prescriptions.[26]
- Patient is diverting/selling medication, or getting drugs from others.

Section 4 – Other Aberrant Medication-Related Behaviors and Factors Potentially Indicative of Substance Abuse or Diversion

A. Prescribers

The population of prescription opioid users is heterogeneous. Among pain patients there are those who are responsive to the medication and adherent, others use the medication to self-treat or as a coping agent, and some develop problems with substance use disorders. Nonmedical users may employ the drug for recreation or have more serious substance use disorders including addiction. Accordingly, other patient characteristics or actions should evoke further scrutiny and must be dealt with, including evaluation of whether an opioid analgesic is indicated for clinical use. These may manifest during the ***initial visit***, eg, patient travels an unexplained long distance for the office visit, is from out of state or "visiting," refuses or is reluctant to present identification, or insists on paying with cash even though health insurance coverage exists, or during the ***pain assessment and history taking***, eg, patient appears to be faking or exaggerating pain severity, offers only a vague medical history, provides old clinical report and/or radiographic image in support of their request for pain medication, is unwilling or not able to provide the name of regular physician, or indicates the physician is unavailable. Certain patterns of ***communication or specific requests*** also warrant further scrutiny, eg, patient demonstrates an unusual knowledge about opioid medications or other controlled substances, uses "street names," requests large quantities, specific drugs, or combinations of controlled substances, or aggressively complains about the need for more drug.

As previously noted, patients who are receiving opioid analgesics may exhibit aberrant drug-related behaviors that exist along a continuum. The factors noted above are more likely to reflect drug abuse, addiction, or diversion. Other aberrant behaviors indicative of non-adherence involve ***medication taking/supply*** such as losing a prescription or claiming that it was stolen, a pattern of early refill requests, using the drug without approval to treat another symptom, or in contrast, exhibiting drug hoarding during periods of reduced symptoms. Aberrant behaviors may emerge related to the ***treatment plan*** including a claim of allergy, intolerance or contraindications to the use of alternative, but appropriate, non-opioid pain medications; refusing to try appropriate non-pharmacologic therapies, eg, cognitive-behavioral, rehabilitative, physical medicine approaches; refusing to taper pain medication when clinically indicated; and, violating an opioid pain care agreement. Patients who are concurrently abusing alcohol or other drugs also are at higher risk of

abusing opioid analgesics.

The emergence of a single, or a few, of these aberrant behaviors does not necessarily confirm the presence of a substance use disorder or illicit/illegal behavior. The presence of multiple aberrant behaviors increases that likelihood. Regardless, when a problematic behavior occurs, it should be evaluated by the treating physician. Because not all aberrant behaviors have the same origins or implications, physicians must consider a differential diagnosis and tailor treatment accordingly.[31,32,33] Management should be pursued based on this interpretation, the seriousness of the behavior(s), and the skills of the clinician, including the need for structured intervention or referral for further treatment.

B. Pharmacists

As previously described, pharmacists must use their professional judgment in order to comply with their corresponding responsibility duty to ensure that controlled substance prescriptions are issued for legitimate medical purposes in the usual course of professional practice. While the above factors or "red flags" are more indicative of substance abuse or diversion, oftentimes more subtle aberrant behaviors exist, that while in and of themselves may not be problematic, may indicate a potential issue that warrants further evaluation prior to dispensing.

Aberrant behaviors that patients may exhibit upon the **presentation of the prescription** include traveling unexplainable and/or unreasonably long distance to a physician office and/or the pharmacy or requesting to pay cash for a controlled substance prescription, when it has been documented that he/she has insurance that would normally cover the prescription.[8,9] Whereas these types of behaviors may be warning signs, they can also be explained by today's specialty practice arena as well as third-party payer reimbursement circumstances.

Additionally, certain **patient behaviors,** which may cause concern, such as asking for a certain drug prone to abuse by color, trade name, or markings and/or uses "street names" when discussing opioid analgesics or other controlled substances (eg, xanibars, purple drank, blues, greens), while not typical, may be explained by the patient having a chronic disease state who has become very familiar with the various medications or just by way of today's drug-savvy culture. Along these lines, other behavior such as a patient claiming to be allergic to other appropriate, non-controlled substance pain medications may very well be a result of a lack of understanding of what constitutes a true allergic reaction versus mere intolerance. Other behaviors that may require additional scrutiny, particularly if they appear to be a pattern include, frequently running out of

[31] Argoff CE, Kahan M, Sellers EM. Preventing and managing aberrant drug-related behavior in primary care: Systematic review of outcomes evidence. *J Opioid Manag.* 2014 Mar-Apr;10(2):119-34. doi: 10.5055/jom.2014.0201.

[32] Chou R, Fanciullo GJ, Fine PG, Miaskowski C, Passik SD, Portenoy RK. Opioids for chronic noncancer pain: prediction and identification of aberrant drug-related behaviors: a review of the evidence for an American Pain Society and American Academy of Pain Medicine clinical practice guideline. *J Pain.* 2009 Feb;10(2):131-46.

[33] Sehgal N, Manchikanti L, Smith HS. Prescription opioid abuse in chronic pain: a review of opioid abuse predictors and strategies to curb opioid abuse. *Pain Physician.* 2012 Jul;15(3 Suppl):ES67-92.

medication for controlled substances early or claiming to lose prescription(s); controlled substance refill patterns being inconsistent with regular refill patterns for non-controlled chronic prescription medications; and repeated claims that a pharmacy dispensed a quantity of a controlled substance that is less than what was prescribed.

Section 5 – Disclaimers

A. Prescribers

While it is generally agreed that it is important to monitor outcomes systematically in patients taking opioids, aberrant medication-related behaviors and other factors potentially indicative of substance abuse or diversion are not definitive markers.[34] They are patient-specific, occur along a continuum of risk, and require a differential diagnosis. They also should not, in and of themselves, be used to establish general standards of care or to inform statutory or regulatory requirements.

B. Pharmacists

Whereas aberrant behaviors may be indicative of potential drug abuse and/or diversion, they are not in and of themselves, positive identifiers that unequivocally result in a pharmacist taking specific actions or be used to establish general standards of care or to inform statutory or regulatory requirements. These types of behavior should however, result in an increased vigilance with taking all patient circumstances into consideration. Pharmacists, on a case-by-case basis, should always use their professional judgment and, when in doubt, exercise due diligence in determining the legitimacy of a controlled substance prescription.

Section 6 – Conclusion

The challenges faced by manufacturers, distributors, physicians and other prescribers, and pharmacists can be overcome through collaboration and broader efforts to prevent the initial diversion of controlled substances. PMPs have proven effective in identifying abuse, misuse, and diversion. Strengthening these programs will help facilitate appropriate clinical decision-making from both prescribers and pharmacists. Similarly, efforts to eliminate "pill mills"– facilities which inappropriately provide access to controlled substances with no regard for medical necessity and are a significant source of diversion – will help to prevent the initial diversion of controlled substances. Finally, appropriate education and collaboration amongst all key stakeholders is essential to addressing this important public health problem. Strengthening these areas will be critical to ensuring all those involved are provided with the information and tools necessary to support the appropriate use of controlled substance medications.

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[34] Meltzer EC, Rybin D, Meshesha LZ, et al. Aberrant drug-related behaviors: unsystematic documentation does not identify prescription drug use disorder. *Pain Med.* 2012 Nov;13(11):1436-43.

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GAO Report Claims DEA to Blame for Many Drug Shortages

Ken Terry | March 17, 2015

The US Drug Enforcement Agency (DEA) and the US Food and Drug Administration (FDA) should work together more closely to prevent shortages of prescription medications containing controlled substances, said a blistering new report from the General Accountability Office (GAO). The DEA should also improve its process for authorizing quotas of the controlled substances used in these drugs, the report recommends.

Shortages of prescription drugs containing controlled substances have increased in recent years, the report notes. Of the 168 shortages from January 2001 to June 2013, nearly 70% began after 2007. Shortages lasted nearly a year on average. Many shortages involved generic pain relievers and drugs with only one manufacturer.

Of the 168 shortages, 87 were identified as critical. More than half of those drug shortages involved analgesics. There were also shortages among this group of antianxiety drugs, sedative hypnotics, and stimulants, among others.

According to the FDA and organizations representing patients and providers, the GAO said, these shortages can lead to less effective care, no treatment, and/or medication errors. Providers spend time and resources mitigating the effects of drug shortages instead of taking care of patients.

One cause of these shortages, pharmaceutical companies charge, is the amount of time it takes the DEA to approve controlled substance quotas. The DEA has created these quotas for each class of controlled substances and for each manufacturer of drugs containing these agents to prevent their diversion to illegal uses.

According to the GAO report, the DEA did not respond to manufacturers' quota applications within the time frames required by the agency's own regulations for any year from 2001 to 2014. Even after the DEA implemented an electronic system to streamline this process in 2011, the report said, it took an average of 58 days to respond to quota applications in 2011 and 2012.

The DEA denied that its lack of adherence to its own quota application processing time frames has caused shortages of drugs, the report said. But the FDA data on the causes of 40 shortages of drugs containing controlled substances from January 2010 to 2013 showed that seven of these shortages "were caused by problems related to quota," the report notes. Other shortages resulted from factors such as manufacturing delays, capacity issues, and product quality issues.

The GAO made several recommendations to improve the DEA's management of the quota application process and to avoid future drug shortages. Among other things, the GAO advised the DEA and the FDA to update their existing memorandum of understanding, which has not been revised since the 1970s.

There is bipartisan interest on Capitol Hill in combatting the increasingly serious problem of medical drug shortages. Sen. Charles Grassley (R-IA) and Sen. Sheldon Whitehouse (D-RI) commissioned the GAO report in 2012, and next month, Grassley and Sen. Dianne Feinstein (D-CA), the leaders of the Caucus on International Narcotics Control, are scheduled to hold a hearing on the report's findings.

Negative Effect on Healthcare

Leaders of medical societies whose members are especially dependent on prescribing drugs containing controlled substances told *Medscape Medical News* that shortages of these medications have grown steadily worse in recent years.

"We are seeing regular and increasing shortages of these drugs," said Beverly Philip, MD, vice president of scientific affairs for the American Society of Anesthesiologists. She cited a 2011 society survey of anesthesiologists showing that 90% of respondents reported they were currently experiencing a shortage of least one anesthesia drug, and that 98% had encountered a shortage within the past year.

As a result of these shortages, 49% of patients experienced a less optimal outcome (eg, postoperative nausea and vomiting), the survey found, and the same percentage of patients had longer operating room or recovery times than they otherwise would have had.

"When one of these drugs go on shortage, we have to look for alternatives," Dr Philip noted. "That's not easy, because there are drugs in the same class, but they're just not the same. They have different strengths, different doses, they last different amounts of time. So we don't have interchangeable drugs."

The current shortage of midazolam, a drug commonly used to relax patients before they have surgery, shows how this problem affects patients, Dr Philip said. There are other drugs in the same category but they are much longer acting, which is not good for the patient, she noted.

Emergency department physicians have less of a problem finding substitutes for most controlled substance drugs, said Robert O'Connor, MD, a member of the board of the American College of Emergency Physicians. "If there's a shortage of morphine, we can use something else to replace it. What has alarmed our members is where a particular drug is the only one in the class and there's no real substitute for it."

He cited etomidate, a sedation agent that is often used in emergency department procedures involving dislocated shoulders or fracture reductions. "There is no real substitute for it, and we've had to use less efficacious agents," he said, adding that patients may suffer as a result. "You may not achieve the desired level of sedation when you're putting somebody's shoulder back in place because you don't have the proper drug."

The shortages of analgesics and sedatives also affect patients and physicians in ambulatory care, observed Lynn Webster, MD, past president of the American Academy of Pain Medicine.

"It compromises our ability to give the patients what they need," he said. "You have to look for an alternative, and sometimes the alternative is not as effective and may also have side effects. It also takes a lot of time, and it adds to the level of frustration for physicians and patients."

Moreover, he said, some shortages have led to patients not getting the medications they need. "We've seen a trend over the past 3 years of physicians not treating or trying to avoid treating patients with opioids. We've seen that with the up-scheduling of hydrocodone. It's a hassle factor, and physicians are just throwing up their hands, and patients are the ones who suffer."

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United States Government Accountability Office

Report to Congressional Requesters

February 2015

DRUG SHORTAGES

Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved

GAO-15-202

February 2015

DRUG SHORTAGES

Better Management of the Quota Process for Controlled Substances Needed; Coordination between DEA and FDA Should Be Improved

GAO Highlights

Highlights of GAO-15-202, a report to congressional requesters

Why GAO Did This Study

In the last decade, shortages of prescription drugs containing controlled substances, such as narcotics and stimulants, have increased nationwide, preventing providers and patients from accessing essential medications for treatment. Controlled substances are regulated by DEA because of the potential for abuse and addiction. To prevent diversion of controlled substances, DEA sets quotas that limit the amount of certain substances that are available in the United States.

GAO was asked to examine shortages of drugs containing controlled substances. This report examines (1) the trends in such shortages, (2) the effect on patients and providers, (3) DEA's administration of the quota process, and (4) coordination between DEA and FDA to prevent and mitigate shortages. GAO analyzed data from 2001 through 2013 from the University of Utah Drug Information Service, which is generally regarded as the most comprehensive source of drug shortage data, and from 2011 and 2012 from YERS/QMS, which is the official record for the quota process. GAO interviewed officials from DEA, FDA, organizations representing patients and providers, and drug manufacturers. GAO reviewed relevant statutes, regulations, and documents.

What GAO Recommends

DEA should take five actions to improve its management of the quota process; DEA and FDA should quickly update their MOU and agree on steps each will take regarding drug shortages. HHS agreed with the applicable recommendations. DEA neither agreed nor disagreed, but raised multiple objections to this report.

View GAO-15-202. For more information, contact Marcia Crosse at (202) 512-7114 or crossem@gao.gov.

What GAO Found

Shortages of prescription drugs containing controlled substances have increased sharply in recent years; of the 168 shortages reported from January 2001 through June 2013, nearly 70 percent began after 2007. Such shortages lasted for nearly a year, on average. Additionally, many shortages involved generic pain relievers and drugs where there was only one manufacturer.

The Food and Drug Administration (FDA), an agency within the Department of Health and Human Services (HHS), and organizations representing patients and providers report that during shortages of drugs containing controlled substances, patients may receive less effective care, experience medication errors, or not receive treatment at all. They said providers are also affected as they spend time and resources mitigating the effects of shortages, rather than providing care.

The Drug Enforcement Administration (DEA), an agency within the Department of Justice (DOJ), has not effectively administered the quota process that limits the amount of controlled substances available for use in the United States. Each year, manufacturers apply to DEA for quota needed to make their drugs. DEA, however, has not responded to them within the time frames required by its regulations for any year from 2001 through 2014. DEA officials attributed this lack of compliance to inadequate staffing. Manufacturers who reported quota-related shortages cited late quota decisions as causing or exacerbating shortages of their drugs. Additionally, DEA's weak internal controls jeopardize the agency's ability to effectively manage the quota process. For instance, agency officials said that DEA does not conduct quality checks to ensure the accuracy of the data in its Year-End Reporting and Quota Management System (YERS/QMS). GAO estimates that 44 percent of YERS/QMS records in 2011 and 10 percent in 2012 had errors. DEA officials said that 2011 was the first year manufacturers applied for quota electronically and they expected data from 2012 and beyond to be more accurate. DEA also lacks critical management information because it does not have performance measures related to setting quotas, nor does it monitor data to assess its performance. Moreover, DEA does not have reasonable assurance that the quotas it sets are in accordance with its requirements and cannot ensure continuity of its operations, as it does not have protocols, policies, training materials, or other documentation to manage the quota process.

Despite statutory provisions requiring DEA and FDA to coordinate certain efforts to address shortages of drugs containing controlled substances, the agencies have not established a sufficiently collaborative relationship. For example, DEA and FDA disagree about what constitutes a shortage. DEA officials also said that they do not believe FDA appropriately validates or investigates the shortage information it posts on its website and that posting this information encourages manufacturers to falsely report shortages to obtain additional quota. However, FDA reports that it takes steps to investigate and confirm the shortages on its website. Given such barriers to coordination, DEA and FDA cannot effectively act to prevent or alleviate shortages. Although DEA and FDA have a memorandum of understanding (MOU) in place, it has not been revised since the 1970s and they have been working for more than two years to update it. Officials from both agencies said an updated MOU could facilitate information sharing and help prevent and mitigate future shortages of drugs containing controlled substances.

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Abbreviations

ADHD	attention deficit hyperactivity disorder
API	active pharmaceutical ingredient
APQ	aggregate production quota
ARCOS	Automation of Reports and Consolidated Orders System
CSA	Controlled Substances Act
DEA	Drug Enforcement Administration
DOJ	Department of Justice
DSS	Drug Shortage Staff
EMS	emergency medical services
FDA	Food and Drug Administration
FDASIA	Food and Drug Administration Safety and Innovation Act
GPRA	Government Performance and Results Act of 1993
HHS	Department of Health and Human Services
MOU	memorandum of understanding
UUDIS	University of Utah Drug Information Service
YERS/QMS	Year-End Reporting and Quota Management System

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
441 G St. N.W.
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February 2, 2015

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
United States Senate

The Honorable Sheldon Whitehouse
Ranking Member
Subcommittee on Crime and Terrorism
Committee on the Judiciary
United States Senate

In the last decade, shortages of prescription drugs have increased nationwide, preventing providers and patients from accessing medications that are essential for treatment. Some shortages involve drugs that contain controlled substances, such as narcotics, stimulants, and sedatives, which play an important role in health care.[1] For example, anesthesia, which is used to sedate patients, is routinely administered prior to surgical procedures and most patients receive some kind of drug containing a controlled substance during inpatient hospital stays. Emergency medical service (EMS) providers also frequently rely on a variety of drugs containing controlled substances to treat patients experiencing heart attacks, seizures, traumatic injuries, and other medical crises. For example, data from the National EMS Information System, a nationwide repository of information collected by EMS organizations, show that fentanyl and morphine—both narcotics that are used to manage pain—were 2 of the 10 most frequently administered medications by such organizations in 2012. In addition, some drugs containing controlled substances are available by prescription for outpatient use as pain relievers or sleep aids, as well as to treat individuals with attention deficit hyperactivity disorder (ADHD) and anxiety. During shortages, providers—including hospitals, physicians, and pharmacists—may have to use alternative medications, if alternatives are available at all. The Food and Drug Administration (FDA), an agency within the Department of

[1]A controlled substance is one that is included in one of five schedules under the Controlled Substances Act. A controlled substance is placed in a respective schedule based on whether it has a currently accepted medical use in the United States and its potential for abuse and physical or psychological dependence. 21 U.S.C. §§ 802(6), 812.

Health and Human Services (HHS), which oversees the safety and effectiveness of drugs marketed in the United States, considers drug shortages to be a serious public health concern and works to prevent, alleviate, and resolve them.[2]

Despite their medical value, prescription drugs containing these substances have the potential for abuse and psychological and physical dependence. They are therefore required to be regulated by the Drug Enforcement Administration (DEA), an agency within the Department of Justice (DOJ), in accordance with the Controlled Substances Act (CSA). The Centers for Disease Control and Prevention has declared that the United States is in the midst of an epidemic of prescription drug overdose deaths. In 2011, more than 22,000 Americans died from drug overdoses attributable to prescription drugs, and most of those deaths—almost 17,000—were due to prescription pain relievers containing controlled substances. To prevent diversion of controlled substances, DEA maintains a closed system of distribution, which includes limiting the amount of certain controlled substances that are available. To do so, DEA establishes quotas for the maximum amount of each basic class of controlled substance—such as amphetamine or morphine—that can be produced each year in the United States, known as aggregate production quotas (APQ). It also establishes quotas for individual manufacturers, who must apply to DEA to obtain quota for specific classes of controlled substances. In setting quotas, DEA is required to provide for the estimated medical, scientific, research, and industrial needs of the United States.[3]

You raised questions about shortages of drugs containing controlled substances and asked us to examine the effect of such shortages on patients. You also asked us to review DEA's administration of the quota process to understand its potential effects on shortages of drugs containing controlled substances, particularly those used by EMS

[2]We have previously reported on trends in the number of drug shortages and types of drugs most often in shortage, the causes of such shortages, and FDA's ability to respond to them. GAO, *Drug Shortages: FDA's Ability to Respond Should Be Strengthened,* GAO-12-116 (Washington, D.C.: Nov. 21, 2011), and *Drug Shortages: Public Health Threat Continues, Despite Efforts to Help Ensure Product Availability,* GAO-14-194 (Washington, D.C.: Feb. 10, 2014).

[3]In addition, DEA is also required to provide for lawful export requirements, and for the establishment and maintenance of reserve stocks. 21 U.S.C. § 826; 21 C.F.R. § 1303.11.

providers and to treat ADHD. This report (1) identifies the trends in shortages of drugs containing controlled substances that occurred from January 2001 through June 2013, (2) describes the reported effects of shortages of drugs containing controlled substances on patients and providers, (3) examines DEA's administration of the quota process for controlled substances, and (4) examines DEA and FDA coordination activities to prevent and mitigate shortages of drugs containing controlled substances.

To identify the trends in shortages of drugs containing controlled substances from January 2001 through June 2013, we analyzed University of Utah Drug Information Service (UUDIS) data during this time period.[4] UUDIS data is generally regarded as the most comprehensive and reliable information on drug shortages for the time period we reviewed and are what we used in preparing our 2011 and 2014 reports on drug shortages.[5] For this report we used an extract of the UUDIS dataset used to prepare our 2011 and 2014 reports, which covered shortages from 2001—the first year available from UUDIS—through June 2013. We also examined the characteristics of drugs containing controlled

[4]UUDIS broadly defines a shortage as a supply issue that affects how pharmacies prepare and dispense a product or that influences patient care when prescribers must choose an alternative therapy because of supply issues. Once UUDIS identifies a shortage, it generally does not consider a shortage to be resolved until the drug is available again in all strengths and package sizes from all manufacturers that currently produce the drug. For example, UUDIS could be notified of a shortage involving three manufacturers: Manufacturer A has no product available; Manufacturers B and C still do, but have limited supply of certain package sizes. According to a UUDIS official, UUDIS would consider the shortage to be resolved (1) when Manufacturers A, B, and C all have all strengths and package sizes back in stock; (2) if Manufacturer A decides to discontinue its product, when Manufacturers B and Manufacturer C both have all strengths and package sizes back in stock; or (3) when UUDIS obtains other information indicating that a shortage has been resolved, such as FDA telling UUDIS that Manufacturers B and C have increased supply and all market need has been met. Our analysis focuses on shortages of prescription drugs, so we excluded shortages of over-the-counter drugs, biologics (including vaccines), medical devices, and orally administered vitamins from our analysis even though UUDIS also tracks and includes these shortages in its data.

[5]See GAO-12-116 and GAO-14-194. At the time we did work for our 2011 report, FDA did not have a database containing information on drug shortages. Since then, FDA developed its own database to track shortages. We reported concerns with FDA's management of this database in 2014, see GAO-14-194. For this report, we used the drug shortage data maintained by UUDIS because the time period we reviewed includes years that predate the development of FDA's database. It also allows us to provide information on the trends and characteristics of drug shortages comparable to that which we presented in our 2011 and 2014 reports.

substances that were in shortage at some point from January 2001 through June 2013 and that UUDIS identified as critical shortages because alternative medications were unavailable, the shortages affected multiple manufacturers, or the shortages were widely reported. These critical shortages were a subset of the total number of shortages reported during this time period.[6] For this subset of shortages, we obtained drug shortage bulletins created by UUDIS, which contain national drug codes associated with each shortage.[7] Using these national drug codes, we analyzed Red Book data to determine the product types, routes of administration, and therapeutic classes.[8] We reviewed all UUDIS data for reasonableness, outliers, and consistency, and based on our review we determined that the data were sufficiently reliable for our purposes. Additionally, to give context to and inform these analyses we interviewed officials at the FDA and UUDIS. For this objective as well as our remaining objectives, the scope of our work was limited to prescription drugs, as opposed to over-the-counter or behind-the-counter medications.

To describe the reported effects of shortages of drugs containing controlled substances on patients and providers, we interviewed officials from provider and patient organizations, such as the American Society of Anesthesiologists and Children and Adults with Attention Deficit/Hyperactivity Disorder. We selected provider and patient organizations that represent populations we determined were likely to be affected by shortages of drugs containing controlled substances. The information that we obtained from these organizations is not generalizable to all provider and patient organizations, but provided us with valuable insights. For a complete list of patient and provider organizations we interviewed, see appendix I. We also interviewed officials from FDA, the

[6]These shortages represented 52 percent of all shortages of drugs containing controlled substances reported during this period.

[7]UUDIS creates a drug shortage bulletin for all shortages that it identifies as critical. Each bulletin is publically posted on the American Society of Health-System Pharmacists' website and describes the reason for the shortage; any estimated resupply dates; any related shortages; and the national drug codes associated with the shortage. A national drug code is a unique identifier, though one drug can have multiple national drug codes associated with it. For example, a drug made by one manufacturer, in one strength, but in three package sizes would have a different national drug code for each of the three package sizes. UUDIS does not consistently track the national drug codes associated with shortages that it has determined are not critical.

[8]Red Book is a compendium published by Truven Health Analytics that includes information about the characteristics of drug products.

Office of the Assistant Secretary for Preparedness and Response within HHS, and the National Highway Traffic Safety Administration's Office of Emergency Medical Services. We reviewed relevant documentation from these organizations and agencies, including the results of surveys they had conducted of their constituencies.

To examine DEA's administration of the quota process for controlled substances, we reviewed the CSA and DEA's regulations and other documentation regarding the agency's process for establishing quotas for certain classes of controlled substances with medical use.[9] See appendix II for the specific substance classes subject to quotas that we considered to have medical use. We also interviewed DEA officials about the quota process, including factors that affect the agency's timeliness and responsiveness to manufacturers' quota applications. In addition, we reviewed DEA's administration of the quota process in light of relevant federal standards for internal controls and our prior work related to the establishment of agency performance measures.[10] To examine the timeliness of DEA's quota decisions for certain classes of controlled substances, we reviewed Federal Register notices for APQs for years 2001 through 2014. From our review of Federal Register notices, we were also able to determine when DEA established annual quotas for individual manufacturers from 2001 through 2014, as these types of quota are established after the APQ has been established in the Federal Register. We also analyzed data from the system DEA uses to track and record quota applications and decisions—the Year-End Reporting and Quota Management System (YERS/QMS). We analyzed data for certain controlled substances with medical use from 2011 and 2012, the most recent years for which data were available when we began our work. We

[9]We consider certain classes of controlled substances with medical use to be those substances subject to quotas that are contained in FDA-approved products that are currently marketed for human use.

[10]See GAO, *Standards for Internal Control in the Federal Government*, GAO/AIMD-00-21.3.1 (Washington, D.C.: November 1999). Among other things, these standards address the need for federal agencies to establish internal controls and to monitor the performance of their programs. The establishment and review of performance measures and indicators is a control activity. Monitoring internal controls allows agencies to assess the quality of performance over time. We have also reported on the importance of establishing performance measures that demonstrate how well a program is achieving its goals. See GAO, *Executive Guide: Effectively Implementing the Government Performance and Results Act*, GAO/GGD-96-118 (Washington, D.C.: June 1996).

analyzed the source documents for a stratified random sample of 440 YERS/QMS records from 2011 and 2012 (15 percent of the total records during these years for certain controlled substances with medical use). We used these source documents to verify YERS/QMS data, each of which includes a manufacturer's quota application for a particular substance and the corresponding decision letter from DEA informing the manufacturer of its quota authorization. We compared the information in these documents with corresponding YERS/QMS records and found many instances of discrepancies between them. We therefore determined the data from YERS/QMS to be unreliable for the purposes of our review, and so we instead are reporting on our analysis of the information contained in the source documents for our sample of YERS/QMS records to determine DEA's timeliness in responding to manufacturers' quota applications. See appendix III for additional information on the sample design and methodology we used to determine the reliability of the data and to report on the source documents. We then compared the timing of DEA's quota decisions, both for the APQs and manufacturers' quotas, to required deadlines in the CSA and DEA's regulations. In addition, we interviewed manufacturers about their experiences with DEA's quota process, including any effect the quota process may have had on shortages of their products. We also reviewed documentation provided by manufacturers about their quota applications and DEA's responses. Specifically, we spoke with 13 dosage form manufacturers, including 7 that had the greatest number of drugs containing controlled substances subject to quota in shortage from January 2010 through June 2013.[11] We also spoke with 2 bulk manufacturers that supplied active pharmaceutical ingredients (API) for some of the drugs containing controlled substances that were in shortage.[12] We identified these manufacturers through our analysis of FDA data on the manufacturer-reported causes of shortages

[11]Dosage form manufacturers produce drugs in finished dosage form, which is a drug product in the form in which it will be administered to a patient, such as a tablet or capsule. Finished dosage forms are manufactured using active pharmaceutical ingredients, such as controlled substances, and excipients, such as fillers or preservatives. An active pharmaceutical ingredient is any element that is intended to provide pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body. An excipient is an inactive ingredient or component that is not the active pharmaceutical ingredient and serves as the vehicle or medium for the active ingredient.

[12]Bulk manufacturers produce API from raw materials for use by dosage form manufacturers in making finished dosage forms for consumption. For example, bulk manufacturers may obtain poppy raw materials to manufacture morphine API.

of drugs containing controlled substances from January 2010 through June 2013, the most recent years for which data were available when we began our analysis. We reviewed FDA's data for reasonableness, outliers, and consistency, and based on our review, determined that the data were sufficiently reliable for our purposes. Lastly, we interviewed DEA and FDA officials about the causes of shortages of drugs containing controlled substances.

To examine DEA and FDA coordination activities to prevent and mitigate shortages of drugs containing controlled substances, we reviewed the relevant provisions of the Food and Drug Administration Safety and Innovation Act (FDASIA) as well as other documentation governing how the two agencies are to coordinate.[13] We interviewed DEA and FDA officials about their coordination activities. In addition, we reviewed our past work related to interagency collaboration and the necessary elements for a collaborative working relationship.[14]

We conducted this performance audit from October 2012 through February 2015 in accordance with generally accepted government auditing standards.[15] Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[13]Pub. L. No. 112-144, tit. X, 126 Stat. 993, 1099-1108 (2012).

[14]See GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies,* GAO-06-15 (Washington, D.C.: Oct. 21, 2005). For that report, we reviewed relevant literature and interviewed experts in the area of collaboration to identify key practices that can help enhance and sustain federal agency collaboration.

[15]Completion of our audit was delayed significantly because of DEA's refusal to comply with our requests for information from and about YERS/QMS for over a year. We requested access to YERS/QMS materials and data starting in January 2013, but did not obtain needed information until March 2014.

Background

DEA's Oversight of Controlled Substances

Within DEA, the Office of Diversion Control is responsible for preventing, detecting, and investigating the diversion of controlled substances. The mission of this Office is dually focused on preventing diversion while ensuring an adequate and uninterrupted supply of these substances for legitimate needs. The CSA requires DEA to maintain a closed system of distribution of controlled substances in the United States from the point of import and manufacture through dispensing to patients or disposal. DEA funds diversion control activities, including the quota process, through fees that it sets for businesses, individuals, or entities that are required to register with DEA to import, export, manufacture, distribute, dispense, or conduct research on controlled substances.[16] The CSA requires that DEA set registration fees at a level that ensures DEA recovers the full costs of operating its Diversion Control Program.[17] DEA adjusts registration fees through the notice and comment rulemaking process and last adjusted registration fees in March 2012.[18]

The CSA places each controlled substance in one of five schedules based on whether the substance has a currently accepted medical use in treatment in the United States, its relative potential for abuse, and the degree of dependence the drug or other substance may cause.[19] Schedule I controlled substances, such as heroin and LSD, have a high potential for abuse and no currently accepted medical use in treatment in

[16]Diversion control activities refer to activities related to the registration and control of the manufacture, distribution, dispensing, importation, and exportation of controlled substances and listed chemicals. 21 U.S.C. § 886a(2)(B). See 21 C.F.R. pt. 1301 for more information on DEA's registration requirements and fees.

[17]21 U.S.C. § 886a.

[18]DEA's March 2012 registration fee adjustment took place nearly 6 years after its prior adjustment. Controlled Substances and List I Chemical Registration and Reregistration Fees, 77 Fed. Reg. 15234-15250 (Mar. 15, 2012).

[19]In addition to DEA's role in regulating controlled substances, states may also establish laws that regulate controlled substances. State laws must be in accordance with the CSA, but may be more restrictive.

the United States.[20] Schedule II controlled substances have a high potential for abuse, which may lead to severe psychological or physical dependence, but also have a currently accepted medical use; for instance, amphetamine is a schedule II controlled substance and is used to treat ADHD. As part of the closed system of distribution to prevent the diversion of controlled substances, the CSA requires DEA to establish quotas for each basic class of schedule I and II controlled substances.[21] Quotas are not established for schedule III, IV, and V controlled substances, which have a currently accepted medical use, a lower potential for abuse, and a lower physical and psychological dependence relative to schedule I and II controlled substances.[22]

DEA's Process for Establishing Quotas for Certain Controlled Substances

Each year the Office of Diversion Control establishes three types of quotas for schedule II substances: APQs, bulk manufacturing quotas, and procurement quotas.[23] Within the Office of Diversion Control, the Quota Unit is responsible for calculating and proposing quotas that are then established by the agency.[24]

Aggregate production quotas, which are established for each basic class of schedule I and II substances—such as amphetamine or

[20]Although schedule I substances have no accepted medical use in the United States, DEA issues quotas for these substances for scientific, industrial, and research purposes, including clinical trials. We do not include schedule I substances in our review of DEA's quota process because they have no accepted medical use in the United States.

[21]In addition to each basic class of schedule I and II substances, DEA is also mandated to establish quotas for list I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine. 21 U.S.C. § 826. In setting quotas for these chemicals, DEA establishes an assessment of annual needs, which is to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. Registrants apply for import quotas to import list I chemicals in to the United States. We did not include quotas for list I chemicals within the scope of this report because DEA officials said that only a small amount of these substances are used to manufacture schedule II substances.

[22]These schedules include drugs such as Tylenol with codeine®, Valium®, and Xanax®.

[23]Although DEA's regulations use the term "individual manufacturing quotas," DEA officials refer to them as "bulk manufacturing quotas." Accordingly, we use the term "bulk manufacturing quotas" throughout our discussion. Companies that obtain bulk manufacturing quotas register with DEA as bulk manufacturers.

[24]In this report, we refer to the Office of Diversion Control's UN Reporting and Quota Section as the Quota Unit.

morphine—specify the maximum amount of each controlled substance that can be manufactured in the United States in a given year to provide for the estimated medical, scientific, research, and industrial needs of the United States, lawful export requirements, and the establishment and maintenance of reserve stocks. APQs limit the amount of bulk materials that may be manufactured or synthesized in the United States, and subsequently available for use in the manufacture of drug products containing schedule I and II controlled substances. In establishing APQs for each basic class of schedule I and II controlled substances, DEA considers information from many sources, including

- manufacturers' production history and anticipated needs;
- estimates from IMS Health on retail consumption based on prescriptions dispensed;[25]
- data from DEA's internal system for tracking controlled substances transactions, known as the Automation of Reports and Consolidated Orders System (ARCOS);
- past histories of quota granted for each substance from YERS/QMS;
- estimates of the projected medical, scientific, and reserve stock needs provided by FDA's Controlled Substances Staff;[26]
- information regarding new and discontinued drug products containing schedule II substances from FDA; and
- data on the diversion of controlled substances, such as information from case seizures and national databases of drug evidence.

By May 1 of each year, DEA is required to propose APQs in the Federal Register for the next year and mail a copy of its proposal to persons registered as bulk manufacturers of the basic class.[27] Any interested person may file comments on or objections to the notice, and, after consideration of such comments or objections, DEA must then establish APQs in the Federal Register and mail a copy of its decisions to

[25]DEA obtains prescription data from IMS Health, a company that collects and analyzes health care data, to determine the number of prescriptions and total amount of drugs purchased by retail establishments for dispensing for each substance.

[26]FDA also uses data from IMS Health to develop its estimates of projected use in the United States.

[27]21 C.F.R. § 1303.11.

manufacturers of the basic class.[28] DEA may increase or decrease the APQ at any point due to fluctuations in demand and other factors, such as changes in accepted medical use of a substance for treatment or availability of raw materials for use in manufacturing.[29] DEA monitors the various data sources used to establish the APQ, as well as an FDA website containing information on drug shortages, to identify any possible changes in supply.[30] Generally, the agency revises the APQ midway through the year to account for any of these changes, as well as to account for any changes in anticipated need communicated by quota applicants. The process for revising the APQ is similar to the one used to establish it. Beginning with 2013 APQs, DEA established an additional 25 percent reserve in APQs in the event of natural disaster or other unforeseen event that could result in substantial disruption to the amount of basic classes of schedule II substances available for manufacture.

Bulk manufacturing quotas limit the amount of a basic class of schedule I or II controlled substance that an individual bulk manufacturer can manufacture through the extraction or synthesis of plant material or other controlled substances. Each bulk manufacturer must apply to DEA to obtain bulk manufacturing quota for a specific substance class and the bulk manufacturing quotas granted to manufacturers in sum cannot exceed the APQs established by DEA.

Procurement quotas limit the amount of a basic class of schedule I or II controlled substance that an individual manufacturer can procure from a manufacturer of bulk raw materials in order to manufacture into dosage forms of a drug or into other substances.[31] The sum of procurement quotas determines the amount of bulk material that needs to be produced.

[28]21 C.F.R. § 1303.11. See e.g., Controlled Substances: Established Aggregate Production Quotas for 2012, 76 Fed. Reg. 78044 (Dec. 15, 2011).

[29]21 C.F.R. § 1303.13.

[30]DEA also monitors letters and telephone calls it receives from individuals who indicate that they cannot get their prescriptions filled for specific products or drugs from their local pharmacies.

[31]We refer to companies that obtain procurement quotas as dosage form manufacturers.

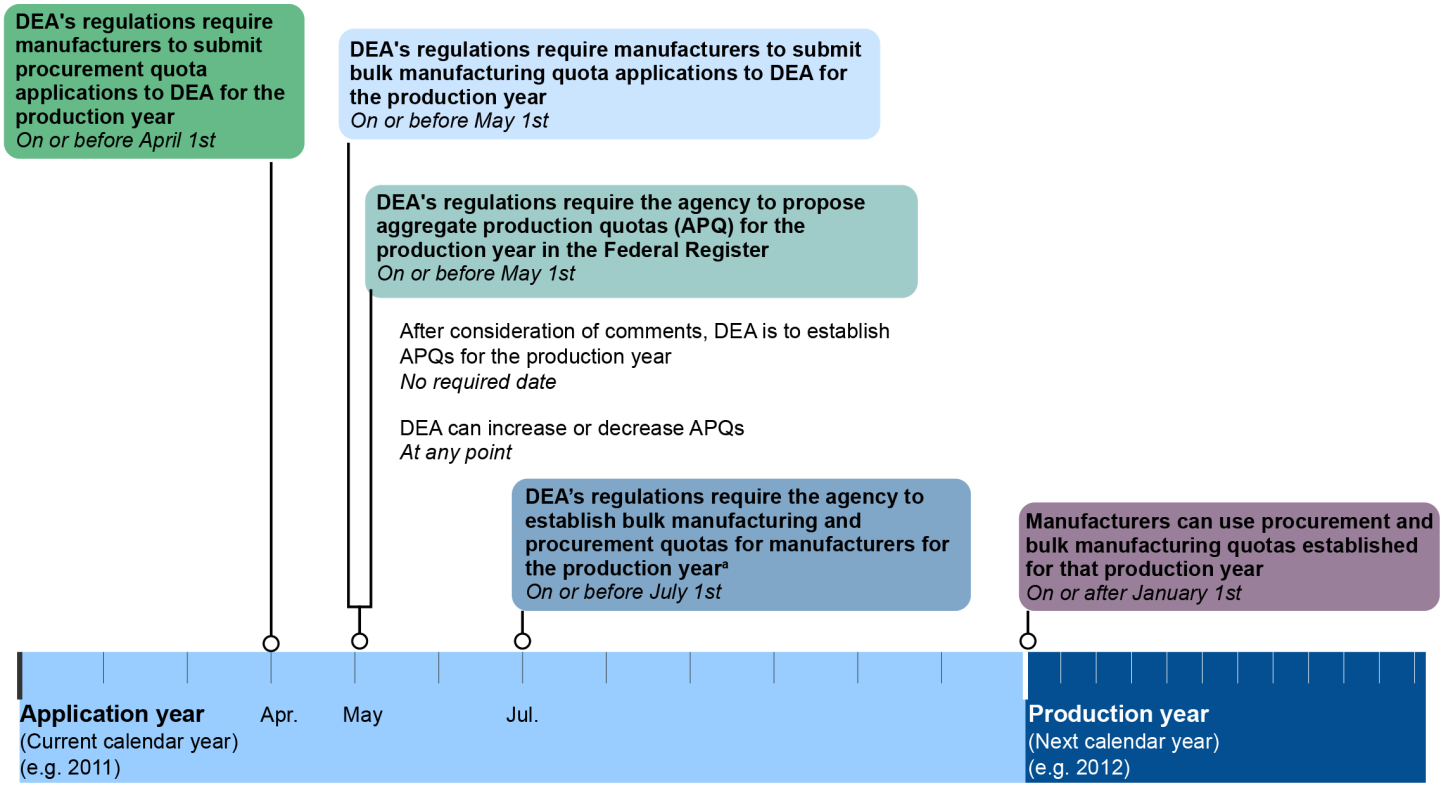
DEA does not have the authority to issue quotas for specific products or to require manufacturers to use their quota for specific products, but rather establishes the quotas for the basic class of controlled substance. For example, DEA may grant a quota of 10,000 grams of amphetamine to a manufacturer, but it is up to the manufacturer to determine how much of that quota will be put towards the various strengths and formulations of its drug products.

In establishing bulk manufacturing and procurement quotas for individual manufacturers, DEA considers the same types of information it uses to establish APQs. However, the agency's focus in reviewing the information is relative to the requesting manufacturer for that particular substance, rather than the total annual need, as is done for the APQ.

The CSA and DEA's implementing regulations designate specific dates by which manufacturers must apply for quotas, as well as dates by which DEA must establish quotas (see fig. 1). Manufacturers apply for quotas in the current year, which we term the application year. Their application is for use of the quota in the next calendar year, which we term the production year. Manufacturers may request a revision to their bulk manufacturing or procurement quota at any point.[32] When manufacturers apply for a revision to their quota during the production year, we term this a supplemental quota application.

[32]21 C.F.R. §§ 1303.12(d), 1303.25(a). DEA also may at any time reduce a manufacturer's bulk manufacturing quota to prevent exceeding the APQ. 21 C.F.R. § 1303.26.

Figure 1: Timeline for Manufacturers to Apply for Quotas and for the Drug Enforcement Administration (DEA) to Propose or Establish Quotas



Source: GAO analysis of the Controlled Substances Act (CSA) and DEA's regulations. | GAO-15-202

Notes: Unused quota from one year cannot be carried over to the following production year. For example, any remaining quota authorized for 2011 cannot be used to obtain controlled substances for procurement quotas and cannot be used to manufacture controlled substances for bulk manufacturing quotas in 2012. A bulk manufacturer, however, may extract or synthesize active pharmaceutical ingredient in one year and hold it in inventory until any subsequent year.

Pursuant to section 1005 of the Food and Drug Administration Safety and Innovation Act, DEA is to review quota requests from manufacturers that relate to shortages of drugs containing schedule II controlled substances and respond within 30 days. Pub. L. No. 112-144, 126 Stat. 993, 1105 (2012) (codified at 21 U.S.C. § 826(h)). Manufacturers can apply to DEA for more quota at any point, but there is no required time frame for DEA to respond to such supplemental quota requests unless a request relates to a drug in shortage.

[a]In contrast to DEA's regulations, the CSA requires DEA to issue bulk manufacturing quotas to manufacturers on or before October 1 for the production year. 21 U.S.C. § 826(c).

DEA launched an electronic system, known as YERS/QMS, in 2008 for manufacturers to submit end of year reports to the agency. Starting in 2011, manufacturers were able to use YERS/QMS to submit quota

applications to the agency electronically.[33] YERS/QMS serves as the official record for the quota process. The system allows DEA to track manufacturers' quota applications—including the date of the quota application, the amount of quota requested, the amount of quota previously authorized by DEA in prior years, and information about the products that will be manufactured with the requested quota—throughout its review process within the Office of Diversion Control. Additionally, YERS/QMS records DEA's decision about how much quota to authorize and the date on which DEA sends a decision letter to the manufacturer notifying it of the agency's quota decision.

FDA's Role in Preventing and Resolving Drug Shortages and Coordination with DEA

Consistent with its mission of protecting public health, FDA established the Drug Shortage Program in 1999—now known as the Drug Shortage Staff (DSS)—to help prevent, alleviate, and resolve shortages. DSS compiles information on drug shortages received from manufacturers and the public, including the reasons for the shortages.[34] FDA defines a shortage as a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug.[35] DSS verifies the existence of a shortage by (1) determining if the current demand for a product is stable or increasing based on historical data from IMS Health; (2) contacting all manufacturers of a given drug to investigate supply issues and to obtain information on inventory, manufacturing schedules, and any changes to ordering patterns; (3) evaluating product distribution at the wholesale level, if needed; and (4) assessing information obtained from IMS Health, manufacturers, and wholesalers for the particular product reported to have a potential or actual shortage

[33]Manufacturers can also submit hard copy paper applications by mail, in which case DEA officials will then manually enter the information from the applications into YERS/QMS.

[34]With the enactment of FDASIA, manufacturers must notify FDA at least 6 months prior to the date of a discontinuance or interruption (or as soon as possible if 6 months is not feasible) in the manufacture of a drug that is life supporting, life sustaining, or used to treat debilitating health issues. Pub. L. No. 112-144, § 1001, 126 Stat. at 1099 (codified at 21 U.S.C. § 356c(a)-(b)).

[35]Pub. L. No. 112-144 § 1001, 126 Stat. at 1100 (codified at 21 U.S.C. § 356c(h)(2)). In September 2014, FDA changed its definition of a drug shortage to be consistent with FDASIA. According to FDA, this is not a substantive change in definition and does not alter how FDA works on matters regarding drug shortages. In general, FDA focuses on shortages of medically necessary drugs that have a significant effect on public health.

and for any acceptable alternative products.[36] DSS tracks drug shortages until their resolution, and posts information on its website about current and resolved shortages. FDA also obtains information from the American Society of Health-System Pharmacists, which becomes aware of drug shortages through voluntary reporting from hospitals, pharmacists, and other health care providers. FDA responds to shortages by taking actions within its authority to address the underlying causes and to enhance product availability. For example, FDA may offer feedback on a manufacturers' proposed approach to responding to quality concerns.

FDASIA, enacted in July 2012, contains several provisions related to drug shortages that require coordination between FDA and DEA. When FDA is notified of a supply disruption of a drug that is life-supporting, life-sustaining, or intended for use in the prevention or treatment of a debilitating disease or condition, and that contains a controlled substance subject to quotas, FDASIA requires that FDA request, if FDA determines that it is necessary, that DEA increase quotas applicable to that controlled substance.[37] Similarly, when FDA has determined that a schedule II drug is in shortage in the United States, manufacturers may also make such requests by submitting quota applications and FDASIA requires that DEA respond to these requests from manufacturers within 30 days.[38] Regardless of whether the request came from FDA or manufacturers, if DEA determines that issuing additional quota is not necessary to address a shortage it must provide a written response, which FDA is to post on its website.[39]

Additionally, FDASIA requires both FDA and DEA to describe their coordination on efforts to prevent or alleviate drug shortages in annual reports to Congress.[40] FDASIA also requires FDA to maintain an up-to-

[36]FDA, *Manual of Policies and Procedures, Drug Shortage Management*, MAPP 4190.1, Rev. 2, (Sept. 3, 2014).

[37]Pub. L. No. 112-144, § 1001, 126 Stat. at 1099-1100 (codified at 21 U.S.C. § 356c).

[38]This requirement applies where the manufacturer's request pertains to a schedule II controlled substance that is on the list of drugs in shortage maintained by FDA under section 506E of the Federal Food, Drug, and Cosmetic Act (established by section 1004 of FDASIA). Pub. L. No. 112-144, § 1005, 126 Stat. at 1105 (codified at 21 U.S.C. § 826(h)).

[39]Id. §§ 1001, 1005, 126 Stat. at 1099-1101, 1105 (codified at 21 U.S.C. §§ 356c(e), 826(h)).

[40]Id. §§ 1002, 1006, 126 Stat. at 1102, 1105-06 (codified at 21 U.S.C. §§ 356c-1, 826a).

date list of drugs that it determines to be in shortage, which, subject to public health, trade secret, and confidentiality provisions, must be publicly available.[41] To meet this requirement, FDA posts information about drug shortages on its website, including the name of the drug and the reason for the shortage.

Performance Measures and Internal Controls

Under the Government Performance and Results Act of 1993 (GPRA), as amended by the GPRA Modernization Act of 2010, agencies are statutorily required to prepare annual performance plans that articulate goals for the upcoming fiscal year and must include indicators that the agency will use to measure its performance.[42] Standards for internal control in the federal government and federal guidance on performance management also call for agencies to establish objectives and performance measures for programs that clearly link to agency-wide goals.[43] As our prior work has shown, performance measures are a key tool to help managers assess progress toward the stated agency-wide strategic goals and program-level objectives.[44] Leading agencies seek to establish clear hierarchies of results-oriented performance measures and targets to ensure that the agency is achieving its mission and strategic goals. Such performance measures help agencies make resource decisions and foster accountability to communicate agency progress to Congress and the public.

Internal control, which is synonymous with management control, comprises the plans, methods, and procedures used to ensure an agency is meeting its missions, goals, and objectives, which supports

[41]Id. § 1004, 126 Stat. at 1104-05 (codified at 21 U.S.C. § 356e).

[42]31 U.S.C. § 1115(b).

[43]GAO/AIMD-00-21.3.1.

[44]For example, see our findings in GAO, *Managing for Results: Enhancing Agency Use of Performance Information for Management Decision Making*, GAO-05-927 (Washington, D.C.; Sept. 9, 2005); *Results-Oriented Cultures: Creating a Clear Linkage between Individual Performance and Organizational Success*, GAO-03-488 (Washington, D.C.; Mar. 14, 2003); *Agencies' Annual Performance Plans Under the Results Act: An Assessment Guide to Facilitate Congressional Decisionmaking*, GAO/GGD/AIMD-10.1.18 (Washington, D.C.; February 1998); and *Program Performance Measures: Federal Agency Collection and Use of Performance Data*, GAO/GGD-92-65 (Washington, D.C.; May 4, 1992).

performance-based management.[45] Such controls help agency program managers achieve desired results and provide reasonable assurance that program objectives are being achieved through, among other things, effective and efficient use of agency resources. In addition, internal control standards in the federal government call for agencies to communicate with and obtain information from external stakeholders, compare actual performance to planned or expected results, review performance measures and indicators, compare and assess different sets of data to establish relationships and then take appropriate action, and to document all internal controls, transactions, and other significant events. In addition, we have previously reported on the importance of interagency collaboration.[46] Collaboration can be broadly defined as any joint activity that is intended to produce more public value than could be produced when organizations act alone.

Shortages of Drugs Containing Controlled Substances Rose Sharply After 2007; Many Involved Generic Pain Relievers and Drugs Manufactured by Few Companies

Shortages of drugs containing controlled substances have increased sharply in recent years; such shortages lasted for nearly a year, on average, and the majority of drugs were in shortage multiple times. Half of the shortages of drugs containing controlled substances identified as critical by UUDIS were analgesics (pain relievers) and most involved generic drugs.

[45]GAO/AIMD-00-21.3.1.

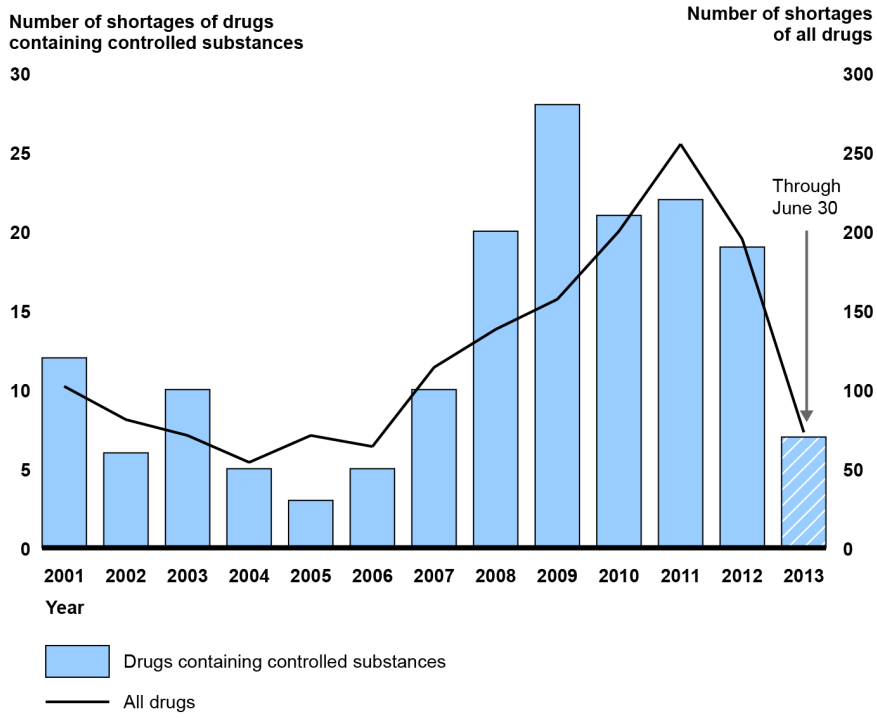
[46]GAO-06-15.

Shortages of Drugs Containing Controlled Substances Have Spiked in Recent Years; Most Were in Shortage Multiple Times and for Nearly 1 Year on Average

Of the 168 shortages of drugs containing controlled substances that were reported from January 2001 through June 2013, nearly 70 percent began between 2008 and 2013.[47] The number of new shortages reported each year peaked in 2009—with 28 that year—and has somewhat declined since then, though the number still remains significantly above pre-2008 levels. (See fig. 2.) The recent increase in these shortages mimics the pattern we have found for shortages of all drugs, which have also sharply increased since 2007 and subsequently declined after peaking in 2011. The 168 shortages of drugs containing controlled substances represent a small percentage of the total 1,575 drug shortages reported from January 2001 through June 2013.

[47]A shortage is counted in the total for "reported" shortages in the year that UUDIS is first notified of the shortage. For example, a shortage reported in July 2010 and resolved in March 2012 would be counted as a reported shortage in 2010. It would not be counted as a reported shortage in either 2011 or 2012.

Figure 2: New Shortages of Drugs Containing Controlled Substances and All Drugs Reported January 2001 through June 2013, by Year



Source: GAO analysis of University of Utah Drug Information Service data. | GAO-15-202

Note: A shortage is counted as "reported" in the year that the University of Utah Drug Information Service is first notified of the shortage. The totals for shortages of all drugs reported for 2007 through 2011 may differ slightly from what we reported in our 2011 report due to minor modifications by the University of Utah Drug Information Service to its data since that report. See GAO-12-116, 16.

The vast majority of shortages of drugs containing controlled substances—96 percent—lasted longer than 1 month and some of these shortages spanned multiple years. (See table 1.) The average duration was nearly 1 year; however, some were much longer. For instance, a single shortage of lorazepam injection, a medication used to treat anxiety, lasted slightly more than 5 years.

Table 1: Summary of the Duration of Shortages of Drugs Containing Controlled Substances, January 2001 through June 2013

Duration of shortages	Number of shortages	Percent[a]	Average duration[a] (in days)
Shortages lasting less than 30 days	6	4	17
Shortages lasting between 30 and 365 days	96	61	160
Shortages lasting more than 365 days	55	35	729
Shortages lasting zero days[a]	11	—	—
Total	**168**	**100**	**354**

Source: GAO analysis of University of Utah Drug Information Service data. I GAO-15-202

Note:

[a]We excluded 11 shortages of the 168 shortages of drugs containing controlled substances identified by the University of Utah Drug Information Service from January 2001 through June 2013 from this analysis because these shortages lasted 0 days, leaving 157 shortages. The majority of these excluded shortages represented manufacturers' decisions to discontinue their production of a drug.

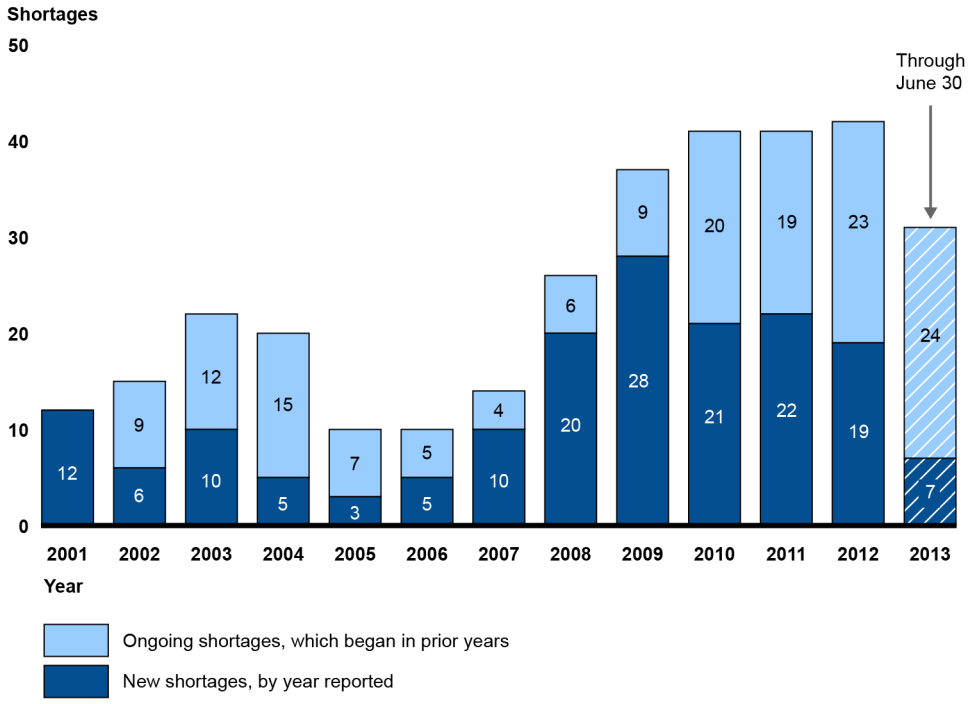
Most shortages—143 of 168—involved drugs that were in short supply multiple times, ranging from two to seven times. Forty-five different drugs containing controlled substances were reported to be in shortage multiple times from January 2001 through June 2013, representing 143 individual shortages. Overall, these 45 different drugs were in short supply for an average of about 3 years. For instance, oxycodone oral solution, a drug that is used to treat moderate to severe pain, was in shortage for the longest combined amount of time over the course of four different shortages, with a combined duration of over 8.5 years.

Drugs containing schedule II substances accounted for more than half of the shortages of drugs containing controlled substances that were reported from January 2001 through June 2013. Fifty-seven percent of shortages involved schedule II substances, while the remaining schedules—schedules III, IV, and V—comprised 15, 26, and 2 percent of shortages, respectively. Shortages of drugs containing schedule II, III, and IV substances ranged on average from 356 days to 359 days. However, shortages of schedule V drugs were shorter, lasting an average of 228 days.

Though the number of shortages reported has declined in recent years, the number of active shortages of drugs containing controlled substances remains high. (See fig. 3.) The active shortage total for each year includes both (1) new shortages reported that year and (2) shortages that started in a prior year that were still ongoing. For example, a shortage reported in July 2010 and resolved in March 2012 would be counted as

an active shortage in three different years (2010, 2011, and 2012). Rather than peaking in 2009, as the number of new shortages reported did, the number of active shortages has remained more or less constant, with 37 to 42 active shortages of drugs containing controlled substances per year from 2009 to 2012. For instance, in 2012, there were 19 new shortages reported that year and another 23 shortages that started in prior years and remained ongoing through some of the year. As of June 2013, there were 31 active shortages of drugs containing controlled substances.

Figure 3: Number of Active Shortages of Drugs Containing Controlled Substances, January 2001 through June 2013, by Year



Source: GAO analysis of University of Utah Drug Information Service data. | GAO-15-202

Note: The active shortage total for each year includes (1) new shortages reported that year and (2) shortages that were reported in a prior year that remained ongoing.

Half of Critical Shortages of Drugs Containing Controlled Substances Were of Pain Relievers and Many Involved Generic Products

Of the 87 shortages of drugs containing controlled substances identified as critical by UUDIS from January 2001 through June 2013, half involved pain relievers (analgesics) (44 of 87). These shortages were identified as critical by UUDIS because alternative medicines were not available, the shortages affected multiple manufacturers, or it received multiple reports of shortages from different provider institutions. There were also shortages of anti-anxiety medications, sedative hypnotic drugs, and stimulants. (See table 2.) All of these types of drugs belong to the broader class of drugs that affect the central nervous system, and are used to treat seizures, manage anxiety, and to provide sedation and pain reduction, among other things.[48]

Table 2: Summary of Critical Shortages of Drugs Containing Controlled Substances by Therapeutic Class, January 2001 through June 2013

Therapeutic class	Number of critical shortages	Percent of critical shortages
Analgesic	44	51
Antianxiety	7	8
Sedative hypnotic	8	9
Stimulant	5	6
Other	23	26
Total	**87**	**100**

Source: GAO analysis of University of Utah Drug Information Service and Truven Health Analytics (Red Book). I GAO-15-202

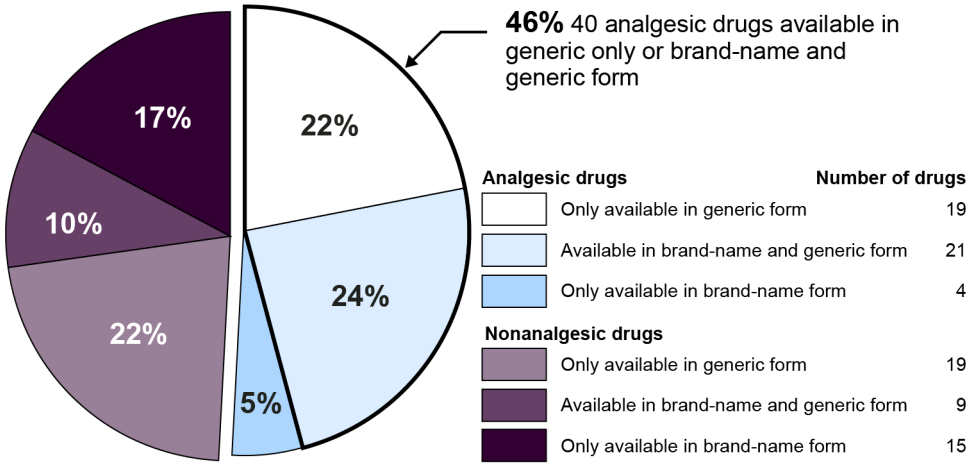
Note: This figure reflects 87 of the 168 (52 percent) shortages of drugs containing controlled substances reported during this time period; it is limited to the shortages the University of Utah Drug Information Service identified as critical. Red Book is a compendium published by Truven Health Analytics that includes information about the characteristics of drug products.

Most critical shortages of drugs containing controlled substances—68 of 87 (78 percent)—involved a generic drug. This 78 percent includes 38 critical shortages of drugs available only in generic form and 30 shortages of drugs available in both brand-name and generic forms. Another 19 critical shortages were of drugs available only in brand-name form (22 percent). Our analysis also showed that 40 critical shortages (46 percent) involved generic pain relievers. These 40 critical shortages include 19 shortages of analgesics only available in generic form

[48]Central nervous system and anesthesia drugs represented the therapeutic class with the highest frequency of all critical drug shortages reported from January 2009 through June 2013. See GAO-12-116 and GAO-14-194.

(22 percent) and 21 shortages of analgesics available in brand-name and generic form (24 percent). (See fig. 4.)

Figure 4: Distribution of Critical Shortages of Drugs Containing Controlled Substances by Therapeutic Class and Product Type, January 2001 through June 2013



Source: GAO analysis of data from the University of Utah Drug Information Service and Truven Health Analytics (Red Book). | GAO-15-202

Note: This figure reflects 87 of the 168 (52 percent) shortages of drugs containing controlled substances reported during this time period; it is limited to the shortages the University of Utah Drug Information Service identified as critical. Non-analgesics include all other therapeutic classes, such as anesthetics and anti-anxiety medications. Red Book is a compendium published by Truven Health Analytics that includes information about the characteristics of drug products.

Most critical shortages of drugs containing controlled substances—79 shortages (91 percent)—involved drugs that were manufactured by four or fewer companies and 39 of those shortages involved drugs manufactured by only one company. The remaining 8 shortages involve drugs that were manufactured by five or more companies (9 percent).

Finally, injectable drugs were in short supply slightly more often than orally administered drugs during this time period, with 44 critical shortages of injectable drugs (51 percent) and 35 critical shortages of orally administered drugs (40 percent). The remaining shortages involved drugs with other routes of administration, such as those administered topically or via the rectum.

Shortages of Drugs Containing Controlled Substances Can Compromise Patient Care and Create Challenges for Providers

According to provider and patient organizations, during shortages of drugs containing controlled substances, patients may receive less effective care, experience medication errors, or not receive treatment at all. Provider organizations also report that providers encounter serious challenges when such drugs are in short supply, requiring them to spend time and resources to mitigate the effects of shortages.

Shortages Can Result in Less Effective Care, Medication Errors, and Delayed or Canceled Treatment

FDA reports that drug shortages can pose a significant threat to the public health by adversely affecting care for patients. According to FDA, drug shortages can delay or deny needed care for patients. Drug shortages can also lead prescribers to use second-line alternatives, which may be less effective or pose additional risks. In addition, provider and patient organizations we spoke with told us that shortages of drugs containing controlled substances have resulted in less effective patient care. For example, representatives from an EMS organization told us that some providers limited the amount of pain medication administered to patients in order to make their supply of the drugs last longer, resulting in patients with unmanaged pain. In addition, some providers often have to use substitutes during shortages that involve undesirable side effects or can be less effective, according to provider organizations.[49] Representatives from the American Society of Anesthesiologists told us that when providers have to use an alternative anesthesia medication that is not the preferred treatment, patients can experience longer recovery times, delayed awakening, or postoperative nausea or vomiting. Medications can affect patients differently and, as a result, finding an effective substitute during a shortage can be complicated. For instance, according to provider and patient organizations focused on mental health issues, providers treating patients with ADHD may need to try different drugs

[49]An American Society of Anesthesiologists' survey revealed that over 95 percent of its members used an alternative medication because of a shortage and another 50 percent modified a procedure in some way because of a shortage. The survey also showed that the anesthesia drugs with the highest reported frequency of shortage were fentanyl and thiopental, both of which are controlled substances, as well as succinylcholine, propofol, and pancuronium, which are not controlled substances. The American Society of Anesthesiologists, *2012 ASA Drug Shortage Survey Results,* accessed January 20, 2015, http://asahq.org/advocacy/federal-activities/regulatory-activity/drug-shortages#Drug%20Shortages%20Survey.

containing other controlled substances and at varied doses to find one that works, although perhaps not as effectively as the patient's usual medication. Even switching from an extended-release formulation to an immediate-release formulation of the same drug can have a significant effect on a child with ADHD if the child's school does not have a nurse to supervise the child taking medication during the day, according to the director of UUDIS. One organization representing patients and families affected by this disorder, Children and Adults with Attention Deficit/Hyperactivity Disorder, found that 18 percent of survey respondents had to change medications during a shortage of ADHD medications. Patients may also be seriously affected by changing to a different route of administration of the same drug during shortages. Patients receiving hospice care or near the end of life may require injections because they cannot swallow a pill for example. Therefore, during a shortage of a morphine injection, clinicians may have to switch the patient to another injectable pain reliever because the patient cannot swallow the morphine tablet, according to the director of UUDIS.

Patients are at increased risk of experiencing medication errors during these shortages. Providers may have to use drugs in unfamiliar dosages or concentrations during shortages of drugs containing controlled substances, which can increase the risk of medication errors and lead to serious consequences for patients. For instance, in its survey of health care practitioners, the Institute for Safe Medication Practices found several instances of overdose and death from providers incorrectly converting doses for pain relievers during a morphine shortage.[50] Errors administering sedatives have also led to patients receiving too much or too little medication, resulting in unintended consciousness during surgery, agitation, and increased recovery times. EMS organizations also noted that the providers they represent are particularly at risk for administering medication incorrectly as they typically have less experience dealing with different medications, doses, or concentrations than hospital-based providers. Additionally, representatives of an EMS organization added that EMS providers deliver care in a mobile environment, which further increases the risk of administering medication incorrectly.

[50]Institute for Safe Medication Practices, *Drug Shortages: National Survey Reveals High Level of Frustration, Low Level of Safety*, accessed October 1, 2012, http://www.ismp.org/newsletters/acutecare/articles/20100923.asp.

Patients may have to delay or forgo care because of shortages of drugs containing controlled substances. For instance, provider organizations told us that providers have had to cancel or delay surgeries and procedures during shortages of anesthesia drugs. EMS associations we spoke with also reported that patients were at risk when drugs that are used to treat seizures were in short supply and there were no available substitutes.

In addition to compromised care, patients faced other hardships. For example, parents spent significant time tracking down ADHD medications that were in shortage for their children, according to provider and patient organizations focused on mental health issues, such as Children and Adults with Attention Deficit/Hyperactivity Disorder and the American Academy of Child and Adolescent Psychiatry. In particular, these organizations reported that some parents of children with ADHD called more than 30 pharmacies to find their children's medication. Representatives of mental health organizations also reported that patients faced increased costs during shortages. Some paid higher prices for their drugs when generic ADHD medications were in short supply and only the more expensive brand-name drug was available. In other instances, patients found they had to visit their physicians more often to obtain new prescriptions when pharmacies with dwindling supplies could only partially fill their orders, which then resulted in additional fees from the physician to obtain a new prescription, according to mental health organizations.[51]

[51]The CSA precludes prescriptions for such schedule II ADHD medications from being refilled, so, according to mental health organizations, patients needed to see their physician more frequently when they were not able to get their prescriptions filled completely. The CSA establishes various requirements that govern prescriptions of controlled substances depending upon the schedule of the drug. For example, schedule II substances, including amphetamine used to treat ADHD, cannot be dispensed without a written prescription of a practitioner, except in emergency situations, and cannot be refilled. 21 U.S.C. § 829(a). Schedule III and IV substances require a prescription; however, the prescription can be filled or refilled for up to 6 months after the date of the prescription and refilled up to five times. 21 U.S.C. § 829(b).

Providers Face Challenges Mitigating the Effects of Shortages of Drugs Containing Controlled Substances

FDA reports and provider organizations told us that shortages of drugs containing controlled substances burden providers, as the providers must spend time and resources addressing such shortages rather than providing care to patients. For example, some providers have had to add full-time staff to manage the effects of shortages and track down medications, according to provider organizations. Officials from a provider organization said that those who could not afford the cost of additional personnel may have had to divert staff from patient care. EMS organizations said that shortages can be particularly challenging for EMS organizations that typically have fewer staff or resources than large hospitals to dedicate to finding drugs that are in short supply. These reports corroborate research on the cost of all drug shortages; researchers at the University of Michigan, in collaboration with the American Society of Health-System Pharmacists, found that the labor costs for managing all drug shortages for U.S. hospitals is approximately $216 million annually.[52]

In trying to mitigate the effects of shortages of drugs containing controlled substances, providers may face situations that pose safety and efficacy concerns, and create ethical dilemmas. For example, providers may opt to turn to expired medications. FDA states that expired medications can be less effective or pose risks due to a change in chemical composition or decrease in potency. In limited cases FDA has exercised enforcement discretion to enable use of expired drugs to alleviate the effect of a shortage. Some states allow the use of expired drugs and providers in those states often pay for expensive tests to assess an expired drug's stability and efficacy, according to provider organizations.[53] Obtaining drugs containing controlled substances in short supply through compounding pharmacies is another avenue providers may take that can pose risks to patients and can cost significantly more than noncompounded drugs.[54] Compounded drugs can raise safety and

[52]R. Kaakeh, B.V. Sweet, C. Reilly, et al., "Impact of Drug Shortages on U.S. Health Systems," *American Journal of Health-System Pharmacy*, vol. 68, no. 19 (2011). This estimate is based on the number of shortages in 2010, when the number of shortages of all drugs was about half of what it was in 2013, according to data from UUDIS.

[53]For instance, in July 2013, Pennsylvania's Bureau of Emergency Medical Services instituted a procedure to allow EMS providers to apply for an exemption that allows them to use certain drugs for 6 months beyond the drugs' expiration date.

[54]Drug compounding is the process by which a pharmacist or doctor combines, mixes, or alters ingredients to create a drug tailored to the needs of an individual patient.

efficacy concerns because the pharmacies that produce such drugs may be exempt from some FDA requirements that apply to drug manufacturers.[55] Provider organizations also said drugs containing controlled substances from compounding pharmacies are significantly more expensive than traditional suppliers and have a shorter shelf live, which can result in wasted product.

EMS providers may face additional challenges during shortages of drugs containing controlled substances, compared to other providers. EMS organizations said that their providers typically obtain medications either through contracts with hospitals or directly from distributors. However, provider organizations said that during periods of short supply, it may be a low priority for hospitals to ensure that EMS providers receive drugs in shortage because hospitals will typically fill their own supply first. EMS organizations added that distributors are more likely to cater to hospitals and other, larger providers because EMS providers are comparatively small purchasers.[56] Additionally, EMS organizations reported some confusion about whether the providers they represent can transfer medications to other affiliated EMS providers because of federal and

[55]Drugs compounded by a licensed pharmacist in a state licensed pharmacy or federal facility, or by a licensed physician, and that meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353a, can qualify for exemptions from the FDA approval requirements, the requirement to label products with adequate directions for use, and the requirement to comply with current good manufacturing practice requirements. The exemptions in section 503A are only available if the licensed pharmacist or licensed physician obtains a valid prescription for an identified individual patient among other things.

Although drug compounding is a traditional component of the practice of pharmacy, concerns have been raised by FDA and others that some pharmacies were going beyond traditional drug compounding for individual patients by producing large quantities of compounded drugs. The Drug Quality and Security Act created a new section 503B of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 353b, under which a compounder can register as an "outsourcing facility." Drugs compounded in an outsourcing facility by or under the direct supervision of a licensed pharmacist, and that meet the conditions in section 503B of the Federal Food, Drug, and Cosmetic Act, can qualify for exemptions from the FDA drug approval requirements and the requirement to label products with adequate directions for use. Such outsourcing facilities remain subject to current good manufacturing practice requirements.

[56]The drug distributors we spoke with told us that during a shortage they generally use an allocation system in which customers receive a percentage of past orders, in order to ensure equitable distribution among their customers. However, one distributor said that customers who buy more drugs may receive a higher percentage of their order than other customers though all customers would be limited in the quantities that they receive.

state laws.[57] In addition, the vast majority of EMS providers are governed by state or local clinical protocols and, in some cases, medication formularies designate the specific doses and concentrations of medications that are permitted for use.[58] As a result, EMS providers in those states and localities are likely to continue to grapple with short supplies, unless state laws or regulations enable them to use different medications, doses, or concentrations than what is allowed under existing formularies or protocols.

DEA Has Not Effectively Administered the Quota Process Due to Missed Time Frames and Weak Internal Controls

DEA did not meet its required time frames for establishing quotas for classes of schedule II substances, and manufacturers report that the lack of timeliness has caused or exacerbated shortages of some of their drugs containing controlled substances. Additionally, our work shows that DEA's lack of internal controls, such as controls to ensure data reliability, performance measures, and monitoring of performance, may hinder the agency's ability to ensure an adequate and uninterrupted supply of controlled substances.

[57]EMS providers must comply with federal laws when handling controlled substances, and may also have to comply with a variety of additional state and local requirements. EMS provider organizations reported confusion among EMS agencies about how to comply with federal requirements related to controlled substances. As a result, officials from the Federal Interagency Committee on EMS said they are working with DEA to clarify DEA regulations and guidance that apply to EMS agencies.

[58]Most EMS providers are required to follow certain protocols that govern how they administer care and, in some cases, adhere to medication formularies, both of which can limit the medications used by these providers. State and local governments regulate the practice of EMS by licensing EMS providers and establishing standards of care, including what medications can be administered by EMS providers. According to the 2011 National EMS Assessment, prepared for the Federal Interagency Committee on Emergency Medical Services, 48 states have either state or locally developed patient care protocols for EMS providers (2 states did not provide information). Additionally, 25 states have medication lists or formularies for EMS professionals, according to this assessment.

DEA Did Not Meet Required Time Frames for Establishing Quotas for Schedule II Substances; Manufacturers Reported Quotas Caused or Exacerbated Shortages of Some of Their Products

Our examination of DEA's Federal Register notices proposing and establishing APQs found that DEA has not met its required time frames for more than a decade. Specifically, DEA has not met the time frames provided in its regulations for proposing APQs for classes of schedule II substances and establishing annual bulk manufacturing and procurement quotas for individual manufacturers since at least 2001.

- Proposing APQs: DEA did not propose APQs in the Federal Register on or before May 1st, as required by DEA's regulations, for any year from 2001 through 2014.[59] On average, DEA proposed APQs about 5 months after the May 1 deadline specified in its regulations. Additionally, though there is no requirement for when DEA must establish the APQ in the Federal Register, for 10 of the 14 years from 2001 through 2014, DEA established APQs in the Federal Register in December of the application year, generally in the last two weeks of the year.[60] For one year (2005), DEA established the APQs in the Federal Register in January of the production year. DEA does not inform manufacturers of their quota authorizations until after APQs have been established for the production year; therefore, the date the APQ is established affects when manufacturers receive their quotas.
- Establishing annual bulk manufacturing and procurement quotas: According to our analysis of Federal Register notices, DEA did not meet the requirements specified in the agency's regulations for establishing bulk manufacturing and procurement quotas by July 1, for any year from 2001 through 2014.[61] From our analysis of a random probability sample of YERS/QMS source documents, we estimate that DEA took an average of 182 days in 2011 and 178 in 2012 beyond July 1 to establish annual bulk manufacturing and procurement

[59]21 C.F.R. § 1303.11. The CSA does not designate when DEA is to propose or establish APQs.

[60]We define "application year" as the year in which manufacturers apply for annual quota for the next calendar year. We define "production year" to be the year in which manufacturers can use their quota.

[61]21 C.F.R. §§ 1303.12 and 1303.21.

quotas.[62] In addition to not meeting the time frames in DEA's regulations, our analysis of Federal Register notices found that neither did DEA meet the CSA requirement for establishing bulk manufacturing quotas by October 1 from 2001 through 2013, though it did meet this deadline recently.[63] For 2014 annual bulk manufacturing quotas, DEA established manufacturers' bulk manufacturing quotas in September 2013.

Moreover, manufacturers have expressed concerns about DEA's timeliness in establishing quotas and have asserted that the amount of time it takes DEA to respond to their quota applications has contributed to shortages of some drugs containing controlled substances. We obtained FDA data on the manufacturer-reported causes of 40 shortages of drugs containing schedule II controlled substances from January 2010 through June 2013.[64] These data show that 10 manufacturers reported to FDA that 7 of the 40 shortages of drugs containing schedule II substances during this time period were caused by problems related to quota.[65] The remaining 33 shortages of drugs containing schedule II substances were caused by other factors, such as manufacturing delays, capacity issues, and product quality issues, according to information reported to FDA by manufacturers.[66] After reviewing this information, we contacted representatives from all of these companies. Many told us that DEA's lack

[62]All percentage estimates from the sample of source documents have margins of error at the 95 percent confidence level of plus or minus 10 percentage points or less, unless otherwise noted. All numerical estimates other than percentages have margins of error of plus or minus 10 percent or less of the value of those numerical estimates, unless otherwise noted. Our sample of YERS/QMS source documents includes the entire population of applications submitted by manufacturers that reported shortages caused by quota to FDA and a probability sample of all other applications within each year (2011 and 2012).

[63]21 U.S.C. § 826(c).

[64]The FDA data reflect information reported by manufacturers to FDA that is subsequently analyzed and categorized by the agency.

[65]These 7 shortages were of drugs that included the substance classes of amphetamine, methylphenidate, or oxycodone, and began in either 2010 or 2011. According to FDA's data, there were several instances of shortages of drugs containing each of these substances between January 2010 and June 2013 and some, but not all, were reportedly caused by quotas.

[66]We previously reported that these are the same factors that cause shortages of drugs generally. See GAO-14-194 for more information on the reasons for shortages of all drugs.

of timeliness in establishing manufacturers' quotas has caused or exacerbated shortages of their products containing schedule II substances. In particular, the representatives said that DEA's timing of establishing annual bulk manufacturing and procurement quotas, which has generally been in late December of the application year, after it establishes the APQ, does not provide manufacturers with enough time to plan for production and order the raw material or API needed to start manufacturing their products at the beginning of the production year in January. Representatives from dosage form manufacturers report that these late decisions leave manufacturers operating solely with what is left in their inventory for the first few months of the production year, which may be limited because manufacturers operate in a lean manufacturing environment where they carry as little inventory as possible.

Additionally, manufacturer representatives said that DEA's lack of timeliness in responding to supplemental quota applications submitted during the production year has also caused or exacerbated shortages of their products. Based on our analysis of a probability sample of YERS/QMS source documents, we estimate that it took DEA an average of 58 days to respond to supplemental quota applications in 2011 and 2012. Within the source documents we reviewed, DEA's fastest response to a supplemental application was 7 days and its longest response took about 5 months. While there are no required time frames for DEA to respond to supplemental applications in the CSA or DEA's regulations, as of July 2012, FDASIA has required DEA to respond to manufacturers' quota requests that relate to shortages caused by quotas within 30 days.[67] Although this 30-day time frame was not yet a requirement in 2011 and much of 2012, it is worth noting that it often took longer for DEA to respond, suggesting this requirement could pose a challenge during a future shortage. We estimate that DEA responded within 30 days to 21 percent of supplemental applications in 2011 and 2012. Furthermore, we found that DEA took 10 days longer, on average, to respond to supplemental quota applications submitted by manufacturers that reported shortages caused by quota to FDA in 2011, the year in which these shortages began, than other supplemental applications (see table 3). In 2012, however, we found no statistical difference between the estimated amount of time DEA took to respond to both groups of supplemental applications.

[67]Pub. L. No. 112-144, § 1005, 126 Stat. at 1105 (codified at 21 U.S.C. § 826(h)).

Table 3: The Drug Enforcement Administration's (DEA) Estimated Response Times for Supplemental Applications in Year-End Reporting and Quota Management System (YERS/QMS) Source Documents, 2011 and 2012

YERS/QMS source documents	Applications submitted by manufacturers who reported shortages caused by quota (Y/N)	Average number of days
2011	Y	73
	N	63[a]
2012	Y	51
	N	54[b]
Both years	Y	59
	N	58[c]

Source: GAO analysis of YERS/QMS source documents. I GAO-15-202

Notes: This table reflects our review of a stratified probability sample of 440 source documents from YERS/QMS. This sample included all of the 146 records in 2011 and 2012 that are associated with drug shortages manufacturers reported to the Food and Drug Administration (FDA) were caused by quotas. We consider YERS/QMS records to be associated with these shortages if the record contains a quota application that was (a) submitted by a manufacturer who reported quota caused a shortage of their product to FDA; (b) for a substance that was used in the products reportedly in shortage because of quota; and (c) was submitted during the time of the reported shortage caused by quota. Manufacturers may or may not have reported to DEA that their quota application was related to a shortage. We also analyzed a random sample of 294 records stratified by year that were not associated with any drug shortages reportedly caused by quotas—180 and 114 records from 2011 and 2012, respectively.

[a]The margin of error at the 95 percent confidence level for supplemental applications submitted by manufacturers who did not report shortages caused by quota in 2011 is plus or minus 10.9 percent.

[b]The margin of error at the 95 percent confidence level for supplemental applications submitted by manufacturers who did not report shortages caused by quota in 2012 is plus or minus 13.7 percent.

[c]The margin of error at the 95 percent confidence level for supplemental applications submitted by manufacturers who did not report shortages caused by quota in 2011 and 2012 combined is plus or minus 8.8 percent.

DEA officials acknowledged that the agency has not met the time frames for proposing and establishing quotas, as required by the agency's regulations. DEA officials cited inadequate staffing of the Quota Unit as the reason why DEA has not met its requirements for proposing APQs and establishing manufacturers' bulk manufacturing and procurement quotas for schedule II substances. In particular, DEA officials noted that the agency's workload with respect to quotas has increased substantially and that drug manufacturing has become more complex since the CSA was enacted and DEA's regulations were established in the 1970s. For example, DEA officials said that when the CSA was enacted and DEA's regulations were initially established, dozens of companies applied for quota each year, whereas now hundreds of companies apply for quota. Additionally, DEA reports that manufacturers submit substantially more

applications to DEA than they have in the past. In 2012, for example, DEA received over 3,000 quota applications, and officials said that each application necessitates its own evaluation and analysis for each substance as it relates to the application. In addition to an increasing workload, DEA officials said that the agency has faced hiring challenges. In particular, it has been unable to hire additional qualified scientists for the Quota Unit because DEA has not found candidates with the right skills who are also able to pass the background checks required for employment. They also said that offers to qualified candidates have been declined. DEA officials noted that as of October 2014, the agency was still in the process of trying to hire two additional scientific staff for the Quota Unit, which would increase the staffing level to 12 (8 quota scientists and 4 administrative staff).

DEA officials added that the quality and timeliness of manufacturers' quota applications affects DEA's ability to meet its required time frames for proposing APQs and establishing manufacturers' quotas. For example, DEA estimates that the agency follows up with manufacturers on about half of the quota applications to get clarification on the information provided or to obtain additional information. DEA officials said that manufacturers also continue to revise their annual applications as manufacturing conditions change throughout the year, such as when manufacturers gain or lose business or encounter a manufacturing problem that destroys part of their inventory of controlled substances and they seek to replace what was lost.[68] From our analysis of a probability sample of YERS/QMS source documents, we estimate that although 80 percent of annual applications in 2011 and 65 percent of annual applications in 2012 were submitted in the first two quarters of the application year, another 19 percent of annual applications in 2011 and 22 percent of annual applications in 2012 were submitted in the fourth quarter of the application year. This may represent the first annual application submitted by a manufacturer for the production year or subsequent revisions because YERS/QMS contains both the first annual application submitted and subsequent revisions. DEA officials said that they do not consider manufacturers to be noncompliant with their time frames when they submit annual quota applications after the deadlines. They said they recognize that it is important for manufacturers to submit

[68]DEA's regulations authorize manufacturers to apply for revisions to their quotas at any point. 21 C.F.R. §§ 1303.12(d) and 1303.25(a).

revisions as conditions change, to ensure they receive appropriate amounts of quota. Our review of a sample of YERS/QMS source documents shows that manufacturers often submit annual bulk manufacturing and procurement quota applications throughout the year. Despite this, DEA officials said that they expect the agency will be compliant with its CSA time frames in the future. DEA officials said that moving to an electronic data system for the quota process—YERS/QMS—has helped the agency to be more compliant with its time frames, as well as the reorganization of staff into a separate Quota Unit in 2011.[69] They noted that the agency has already made progress in meeting its CSA-required time frames for establishing annual bulk manufacturing quotas in 2014.

Although DEA acknowledges it has generally not adhered to the quota setting time frames required by the CSA and the agency's regulations in the last 14 years, agency officials do not agree that quotas can cause shortages of drugs containing schedule II substances. In particular, according to DEA, shortages cannot be related to quotas established by the agency because DEA authorizes quotas at the basic class level for a substance—such as amphetamine or morphine. DEA cannot authorize quota for specific drug products containing those substances, as this is precluded by the CSA. DEA officials said the agency has no control over what specific drug products manufacturers actually produce with the quota authorized. For example, if DEA authorized 10,000 grams of morphine to a manufacturer, the manufacturer—and not DEA—then decides how to authorize the quota amongst its various products that contain different formulations, dosage forms, and concentrations.

We cannot confirm whether DEA's lack of timeliness in establishing annual and supplemental quotas has caused or exacerbated shortages. However, by not responding to annual applications in accordance with the time frames required by its regulations or the CSA and by not acting promptly on supplemental applications, DEA may hinder manufacturers' ability to manufacture drugs that contain schedule II controlled substances that may help prevent or resolve a shortage.

[69]DEA officials report that this change is provisional as it is pending finalization.

DEA's Weak Internal Controls Jeopardize Its Ability to Effectively Manage the Quota Process and Ensure an Adequate Supply of Controlled Substances for Legitimate Medical Use

DEA does not have sufficient internal controls to effectively oversee and manage the quota process and therefore may not be able to appropriately respond to quota applications related to shortages when they arise. In particular, DEA does not have adequate controls to ensure the reliability of the YERS/QMS system that it uses to track manufacturers' quota applications and record its quota decisions. DEA officials told us there are no systematic quality checks to ensure that the data in YERS/QMS are accurate, such as electronic checks for data outliers or manual comparisons of YERS/QMS data to source documents (i.e., manufacturers' quota applications and corresponding DEA decision letters) to identify inconsistent information. Instead, DEA officials said that when manufacturers submit their quota applications electronically, YERS/QMS automatically checks to ensure that the manufacturer applying for quota has a valid DEA registration. Additionally, DEA officials said they added an electronic prompt to YERS/QMS that asks manufacturers to reexamine and confirm quota requests that are for smaller amounts than they have already received for the production year. Officials told us that the Quota Unit also reviews the information submitted by manufacturers and will contact them when information entered looks inconsistent or out of the ordinary. DEA also reports that managers verify that the information entered into YERS/QMS by the Quota Unit is accurate. Though DEA takes some steps to ensure the accuracy of its YERS/QMS data, the agency has not systematically checked to make sure that its efforts are sufficient or having the intended effect. Lacking systematic data checks is inconsistent with federal standards for internal control, which calls for agencies to have appropriate control activities in place, such as periodic data checks, to ensure that the data used by the agency for decision making are accurate.[70] Without controls in place to ensure the accuracy of YERS/QMS data, DEA cannot provide reasonable assurance that it has correct information in its official record of the dates and amounts of its quota decisions beyond the individual electronic and hard copies of decision letters it keeps for retention purposes. Further, inaccuracies in YERS/QMS data will also affect the accuracy of future quota applications submitted by manufacturers, as YERS/QMS automatically populates information on quotas previously authorized by DEA from the prior 2 years into a new quota application.

[70]GAO/AIMD-00-21.3.1.

In our review of YERS/QMS data from 2011 and 2012, we found a large number of errors in 2011 and a significant reduction in the number of errors in 2012. Based on our analysis of a probability sample of YERS/QMS data, we estimate that 44 percent of the records in 2011 and 10 percent of the records in 2012, each of which corresponds to one quota application and DEA decision letter, contained at least one data field with incorrect data, such as incorrect dates or amounts of quota requested or authorized.[71] In particular, we estimate that errors in the quota application fields declined substantially in 2012, with, for example, errors in the total amount of quota requested field dropping from 13 percent of records in 2011 to 3 percent of records in 2012. See table 4 for the specific fields in which we found errors in our review for years 2011 and 2012.

[71]This difference is significant with a margin of error at the 95 percent confidence level of plus or minus 10 percentage points.

Table 4: Estimated Percent of Errors in the Drug Enforcement Administration's (DEA) Year-End Reporting and Quota Management System (YERS/QMS)

	Estimated percent of records with errors[a]	
Data fields	**2011**	**2012**
Quota application		
Application year	0%	0%
Company name	1%	0%
Substance name	0%	1%
Quota type	1%	0%
Date submitted	23%	1%
Total amount of quota	13%	3%
Decision letter		
Application year	0%	0%
Company name	1%	0%
Substance name	1%	0%
Quota type	1%	0%
Date mailed	9%	3%
Total amount of quota	5%	2%
Total	**44%**[b]	**10%**[b]

Source: GAO analysis of YERS/QMS data and source documents obtained from DEA. I GAO-15-202

Notes: This table reflects our review of a stratified random sample of 440 source records from YERS/QMS. The sample included all of the 146 records in 2011 and 2012 that are associated with drug shortages manufacturers reported to the Food and Drug Administration (FDA) were caused by quotas. We consider YERS/QMS records to be associated with these shortages if the record contains a quota application that was (a) submitted by a manufacturer who reported quota caused a shortage of their product to FDA; (b) for a substance that was used in the products reportedly in shortage because of quota; and (c) was submitted during the time of the reported shortage caused by quota. Manufacturers may or may not have reported to DEA that their quota application was related to a shortage. We also analyzed a random sample of 294 records stratified by year that were not associated with any drug shortages reportedly caused by quotas—180 and 114 records from 2011 and 2012, respectively.

[a]All percentage estimates have margins of error at the 95 percent confidence level of plus or minus 10 percentage points or less.

[b]Rows may not sum to total because some records have errors in more than one data field. Therefore, such records are counted towards the total number of errors for multiple data fields but count only once for the total number of records with any error.

DEA officials said 2011 was a transitional year for YERS/QMS as manufacturers first started submitting quota applications electronically, and they expected the information for 2012 and beyond to be more accurate. DEA officials noted that they consider the information submitted to YERS/QMS by manufacturers to belong to the manufacturers and therefore DEA officials do not correct this information, even when they learn that it is not accurate. Instead, DEA officials said that they ask

manufacturers to submit a revised application and they mark the original application as withdrawn, as well as make a note in YERS/QMS that the application will be corrected by manufacturers. Nonetheless, we removed applications marked as withdrawn from our analysis and we still found errors in the YERS/QMS data for manufacturers' quota applications, as well as in the data for DEA's quota decisions. As YERS/QMS data is the official record of how much quota is requested by manufacturers and authorized by DEA, maintaining accurate records is important for the management of the quota setting process.

DEA also does not have agency-wide performance measures related to establishing quotas or ensuring an adequate and uninterrupted supply of controlled substances to assess how well the program is carrying out its responsibilities.[72] Federal internal control standards state that performance measures are an important management tool and that such measures provide critical information to managers about agency performance and program outcomes.[73] Such performance information can demonstrate progress toward goals and help program managers determine how to allocate resources among competing priorities. DEA officials said that performance measures related to establishing quotas or ensuring an adequate and uninterrupted supply of controlled substances would be inappropriate because of the complexity of individual quota applications and the difficulty of projecting the number of quota applications for future years. Nonetheless, performance measures related to quotas—such as the percentage of applications that require follow-up by DEA because of missing documentation—are a critical internal control, without which DEA cannot determine if its process for establishing quotas is having the desired outcome of ensuring an adequate and uninterrupted

[72]DEA does have agency-wide performance measures to assess its performance of reducing the diversion of licit drugs, such as the number of scheduled investigations completed each year. We have previously reported on these measures and recommended that DEA reassess its set of performance measures for the Diversion Control Program to identify ways to enhance the measures' link to the outcome of reducing diversion. See GAO, *Prescription Drug Control: DEA Has Enhanced Efforts to Combat Diversion, but Could Better Assess and Report Program Results,* GAO-11-744 (Washington, D.C.: Aug. 26, 2011).

[73]*Standards for Internal Control for the Federal Government* state that the establishment and review of performance measures and indicators is a control activity and that monitoring internal controls allows agencies to assess the quality of performance over time. See GAO/AIMD-00-21.3.1, 14, 20. We have also reported on the importance of establishing performance measures that demonstrate how well a program is achieving its goals. See GAO/GGD-96-118.

supply of controlled substances for legitimate medical use. In the absence of such performance measures, DEA is missing important information for program managers to use when making decisions about program resources and the agency cannot effectively demonstrate program results.

In addition, DEA officials told us that they do not monitor or analyze available data from YERS/QMS to assess its administration of the quota process, which federal standards for internal control state is an important component of managing a program.[74] DEA officials said that the agency does not monitor or analyze these data and that they do not use YERS/QMS to produce aggregate information on timeliness or other performance metrics and the agency has no plans to do so as of October 2014. Absent such analysis, DEA is unable to evaluate its responses to manufacturers' quota applications or to understand the nature of its workload. For example, whereas DEA previously withheld some of the amphetamine APQ to authorize later in the year, officials told us that the agency initially granted more of the amphetamine APQ in 2012 to manufacturers than it had previously, to see if manufacturers would still claim that there was a shortage of their products. However, DEA officials said they did not monitor the effect of this decision, which they said was unprecedented, and they were therefore unsure if it had an effect on shortages or the agency's workload. Officials were unable to say if this change resulted in manufacturers submitting fewer supplemental applications for amphetamine that year. Additionally, DEA officials cited manufacturers' incomplete applications and frequent revisions as affecting the agency's ability to meet its required time frames. However without monitoring or analyzing data to identify how frequently manufacturers submit incomplete and revised applications, DEA lacks information to assess the effect on the agency's workload. This lack of monitoring also prevents DEA from determining whether a few manufacturers are repeatedly submitting incomplete applications or if there is a larger, systemic issue to address. DEA therefore cannot identify appropriate means to help prevent such issues in the future, such as through in-depth training or guidance.

[74] *Standards for Internal Control for the Federal Government* state that managers need to compare actual performance to planned or expected results throughout the organization and analyze significant differences. See GAO/AIMD-00-21.3.1, 13.

Finally, DEA officials told us that the agency does not have protocols, policies, or other documentation to manage how the agency processes quota applications and establishes APQs and annual and supplemental quotas for individual manufacturers.[75] Instead, DEA officials told us that the agency exclusively relies on its regulations and the CSA to serve as guidance on how to conduct these activities. According to federal internal control standards, agencies should have written documentation, such as detailed policies, procedures, and practices, to fit their agency's operations and to ensure that they are built into, and an integral part of, operations. The absence of written guidance may also pose a risk to the consistency of DEA's future operations in the event of staff turnover, changes in administration, or any other disruption that could lead to a loss of institutional knowledge.[76]

The need for detailed policies, procedures, and practices is particularly important because the activities conducted by Quota Unit staff are very complex, requiring staff to weigh data from at least five different sources and to make recommendations about how to authorize the APQ among various manufacturers. Having additional guidance for these activities is key to help ensure that staff in the Quota Unit process applications consistently and that they are adhering to DEA's regulations and the CSA when setting quotas. For instance, Quota Unit staff analyze and reconcile data from multiple sources in order to recommend quotas that meet estimated legitimate medical need. One such data source is ARCOS, DEA's system for tracking the distribution of controlled substances, which DEA uses in determining how much quota to authorize. Officials told us that there are many instances in which ARCOS data are unreliable and therefore it may contradict information from other sources used by quota scientists, such as the sales information manufacturers provide in their

[75]*Standards for Internal Control for the Federal Government* state that all internal controls, transactions, and other significant events need to be clearly documented, and the documentation should be readily available for examination. The documentation should appear in management directives, administrative policies, or operating manuals and may be in paper or electronic form. See GAO/AIMD-00-21.3.1, 15.

[76]We have previously reported on the risk to the management and operational continuity at agencies due to a lack of written policies and procedures. See, for example, GAO, *Social Security Disability: Management Controls Needed to Strengthen Demonstration Projects,* GAO-08-1053 (Washington, D.C.: Sept. 26, 2008).

quota applications.[77] Although quota scientists may be faced with contradictory information, it is left to the discretion of the Quota Unit staff to determine how to reconcile conflicting data sources, as there are no written policies or guidance and this level of detail is not included in DEA's regulations or the CSA. Moreover, DEA officials told us that the reliability of different data sources can vary based on the substance and the quota applicant. They noted that in some cases, manufacturer-reported sales data may not be as reliable as data on the number of retail prescriptions dispensed, whereas for a different substance or quota applicant, the reverse may be true. Nonetheless, despite the need to consider data sources differently relative to the substance class or quota applicant, there is nothing in the CSA or DEA's regulations about how to do this and DEA has no additional guidance on the matter.

Additionally, when asked how they train new staff if there is no written guidance about the quota process, DEA officials said that they train new Quota Unit staff about the CSA and DEA's regulations through on-the-job training and using presentations created for industry. There are no specific documents developed for the exclusive purposes of training new staff. DEA officials said that the presentations for industry give new Quota Unit staff an overview of the quota process and that everything else must come from on-the-job training, as each function within the Quota Unit is unique and each quota application is different from the next. DEA officials told us that they ensure consistency in their decision-making by having the Deputy Assistant Administrator of the Office of Diversion Control review and authorize every quota decision that is made. However, given the volume of quota applications that DEA processes each year—over 3,000 in 2012—it is unreasonable to expect that the Quota Unit staff can make consistent decisions with no written guidance. Similarly it is not reasonable to assume that one senior manager can devote sufficient time to review these many staff decisions and ensure that quotas are set in accordance with DEA's regulations and the CSA. Further, the lack of written guidance poses a risk to the continuity of the agency's operations should personnel leave or be reassigned.

[77]In the course of our work, DEA officials told us that ARCOS data were unreliable unless verified by DEA officials against source documents located at registrants' place of business.

DEA and FDA Have Not Established a Sufficiently Collaborative Relationship, Which Could Hinder Their Abilities to Effectively Coordinate and Address Future Shortages

FDASIA contains provisions that require DEA and FDA to coordinate their activities where additional quota may be needed to address a shortage of a drug containing controlled substances, though no such opportunity has occurred since the law's enactment in 2012. In addition, FDASIA requires each agency to report to Congress annually describing the coordination between the two agencies on efforts to prevent or alleviate shortages. Although both agencies report that their working relationship has improved in recent years—namely by establishing a point of contact at DEA who is responsible for coordinating with FDA's DSS—the agencies' use of essential collaborative practices to enhance their abilities to successfully coordinate to resolve or mitigate shortages has been limited.[78] We have previously identified key practices that agencies need for enhanced and sustained collaboration, including defining and articulating a common outcome and establishing compatible policies, procedures, and other means to operate across agency boundaries.[79] Running throughout these practices are a number of factors, such as trust, that are important elements for a collaborative working relationship.

One barrier to effective coordination between the two agencies is that DEA and FDA have not defined and articulated a common outcome related to shortages of drugs containing controlled substances. FDASIA gives FDA the authority to create and maintain a list of drug shortages.[80] However, the two agencies sometimes disagree about whether a shortage exists. This is a fundamental concern because FDASIA also contains provisions that require the two agencies to work together to address shortages of drugs subject to quotas. According to DEA, FDA has posted shortages on its website when, from DEA's perspective, there is no shortage. DEA often views drugs containing the same substance class as viable substitutes for one another, even when the drugs are different strengths or formulations. Officials told us that there is no shortage, from DEA's perspective, as long as there is quota available to

[78]Collaboration can be broadly defined as any joint activity that is intended to produce more public value than could be produced when the organizations act alone, including coordination.

[79]See GAO-06-15.

[80]Pub. L. No. 112-144, § 1004, 126 Stat. at 1104-05 (codified at 21 U.S.C. § 356e) (directing the Secretary of Health and Human Services to "maintain an up-to-date list of drugs that are determined by the Secretary to be in shortages in the United States" among other things).

manufacture a given controlled substance, regardless of which manufacturers are producing the product and which strengths or formulations are available. For instance, DEA would not consider there to be a shortage of 1 milliliter vials of hydromorphone in the 10 milligram/milliliter concentration if the 5 milliliter vials were still available. Separately, FDA evaluates potential substitutes on a case by case basis to determine whether drugs are clinically interchangeable in order to assess if there is enough supply of a drug to meet demand. To determine clinical interchangeability, FDA states that it relies upon clinical expertise from within the agency, as well as consultation with outside medical professional associations. For example, for ADHD drugs, both the immediate release and extended release formulations are needed and are not substitutes for each other. According to FDA, some patients are well maintained on the extended release formulation alone, some patients require the immediate release formulation at certain points in the day to treat their specific symptoms, and some patients require both the extended release formulation as well as the immediate release formulation at specific times of the day to control their symptoms. FDA may or may not consider drugs of different strengths or formulations to be substitutes for one another and FDA's determination about whether drugs are clinically interchangeable has not always aligned with DEA's perspective, leading DEA to assert that some of the shortages listed on FDA's website are not actual shortages. By not reaching an agreement about what constitutes a drug shortage, the agencies are lacking a key practice of effective coordination and it is unclear if they will be able to work together to respond to shortages of drugs containing controlled substances caused by quotas.

The agencies' collaboration is further impaired by a lack of trust on the part of DEA regarding the shortages listed on FDA's drug shortage website. DEA officials told us that they do not believe FDA appropriately validates or investigates the shortages it lists on its website, which they believe encourages abuse by manufacturers and distributors. Specifically, DEA officials said that they are concerned that manufacturers may falsely report shortages to FDA when they do not receive the amount of quota they requested, rather than because there are actual supply disruptions. As DEA does not consider FDA to have independently confirmed the existence of a shortage, DEA officials said that it considers FDA's website to be an incentive for manufacturers to file self-serving and misleading reports. As a result, despite the fact that DEA officials told us they monitor FDA's website, they still consider it to be neither useful nor accurate for DEA's purposes. When we spoke to FDA about its drug shortage website, officials told us that the agency takes multiple steps to verify the existence

of a shortage before placing it on its website, including confirming the supply disruption with the manufacturer of the product, checking with manufacturers of related products to confirm that they cannot cover the decrease in supply, and analyzing market sales data to compare current supply with historical demand.[81]

Another barrier to effective collaboration is the lack of compatible policies, procedures, and other means to operate across agency boundaries, including mutually agreed upon time frames for DEA to respond if FDA notifies DEA of a shortage caused by quota. Although FDA established policies and procedures in September 2014 for requesting a quota adjustment from DEA if it determines that it is necessary to address a shortage, DEA officials said that the agency has not and does not plan to establish formal policies or procedures to coordinate the agency's response with FDA.[82] Such actions are not consistent with key practices for effective collaboration. It is important to note that while FDASIA directs DEA to respond within 30 days to manufacturers that request additional quota pertaining to a drug in shortage that is on FDA's drug shortage list, the law does not specify how quickly DEA must respond to a request from FDA to address a shortage of a life-sustaining drug and the agencies do not have an agreement in place regarding this matter. A time frame for DEA to respond to an FDA request is particularly important, given that FDA has determined that there is a shortage of a life-sustaining drug that an increase in quota is necessary to address, and DEA may not necessarily agree with FDA's determination of a shortage. Federal standards for internal control also state that communicating information within a specified time frame that enables entities to carry out their responsibilities is an important control activity.[83] DEA officials told us that the notifications it received from FDA prior to FDASIA were not useful. These notifications included copies of manufacturers' quota applications and FDA's assessment that the application was, or could be, related to a shortage. DEA maintained that, because FDA was not providing it with any new information, FDA's notifications were not helpful. Further, DEA

[81]For more information on the steps that FDA takes to verify the existence of a drug shortage see GAO-14-194.

[82]See FDA, *Manual of Policies and Procedures, Drug Shortage Management*, MAPP 4190.1 Rev. 2 (Sept. 3, 2014).

[83]See GAO/AIMD-00-21.3.1, 18.

officials said that the applications may or may not be related to a shortage from DEA's perspective.

Finally, both agencies stated that they are subject to restrictions on exchanging the proprietary information they receive from drug manufacturers. Both agencies agree that sharing such information with one another would be helpful in preventing and mitigating shortages of drugs containing controlled substances. For example, DEA officials said that it would be helpful to be informed in advance of FDA's decisions about upcoming drug approvals that may help alleviate a shortage. According to DEA, this could provide it with early notification about the need to quickly verify information provided by manufacturers in quota applications for drugs that appear to be nearing FDA approval. DEA officials added that such information sharing would make it easier for the two agencies to communicate about drug shortages and quotas in a meaningful way.

Although DEA and FDA have long had memorandums of understanding (MOU) in place, these documents do not address the topic of drug shortages. The agencies have been working for more than 2 years on developing a new MOU, which would replace the original documents that were executed in the 1970s. As of January 20, 2015, the new MOU had not been finalized and the two agencies report that they are continuing to work towards outlining mutually agreeable terms. Officials from both agencies explained that they expect the new MOU would establish the terms for sharing and safeguarding the proprietary information that they are currently prohibited from exchanging and that may ultimately allow the agencies to work together more effectively to address shortages. However, DEA officials said that they do not expect the new MOU to specify what types of information may be shared, including information related to a shortage of a drug containing controlled substances or the time frames for sharing such information. FDA officials indicated that once the new MOU is in place the two agencies will still need to take additional steps before they can begin to share information, such as developing a work plan for sharing information related to shortages of drugs containing controlled substances. As the agencies will need to take additional steps before they can begin exchanging information related to shortages after the MOU is in place, it is uncertain whether FDA and DEA will be able to expeditiously address shortages of drugs containing controlled substances, should one occur in the near future.

Conclusions

Prescription drugs containing controlled substances are routinely used in inpatient, outpatient, and emergency settings. DEA is responsible for preventing, detecting, and investigating the diversion of these substances, while nonetheless ensuring an adequate and uninterrupted supply for legitimate needs. Because DEA maintains a closed system of distribution that limits the availability of certain substance classes by establishing aggregate production, bulk manufacturing, and procurement quotas, the agency's management of the quota process is of critical importance to public health.

Our work shows that DEA is not well prepared to expeditiously respond to future shortages. DEA has not met its required time frames for establishing quotas for more than a decade. DEA also lacks sufficient internal controls to ensure the reliability of the data it uses to establish quotas, which we found led to errors in its data system. Moreover, DEA does not monitor the data it collects and has no established performance measures related to either setting quotas in a timely manner or ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical use. Its lack of written policies and procedures for a complex process poses a risk to the continuity of its future operations.

Because FDA also plays a vital role in preventing, mitigating, and resolving drug shortages, its collaboration with DEA is key to responding to shortages. FDA adopted the definition of a drug shortage that is specified in FDASIA and was assigned authority to maintain the list of drugs in shortage. Moreover, FDASIA directs the two agencies to work together to coordinate certain activities related to shortages. However, DEA and FDA are not able to effectively collaborate due to fundamental disagreement over whether any given shortage exists. DEA has made it clear it does not trust FDA's information, as it does not consider many of the shortages that FDA verifies to be legitimate. In addition, DEA has not developed any formal policies or procedures to coordinate its response to a shortage with FDA. The two agencies have been operating under an MOU that has been unchanged for about 40 years and that does not address the topic of drug shortages. Although it is under revision, this process began over 2 years ago and remains incomplete. Despite FDASIA's provisions directing the two agencies to coordinate and report on their responses to drug shortages, it is not clear that the new MOU will facilitate this. Given that the agencies have indicated that they will still need to take additional steps before they can begin exchanging information after the MOU is in place, they may not be able to provide a quick response should a shortage occur in the near future.

While we cannot establish a causal relationship between shortages of drugs containing controlled substances and DEA's management of the quota setting process, the shortcomings we have identified prevent DEA from having reasonable assurance that it is prepared to help ensure an adequate and uninterrupted supply of these drugs for legitimate medical need, and to avert or address future shortages. This approach to the management of an important process is untenable and poses a risk to public health.

Recommendations for Executive Action

To ensure that DEA is best positioned to administer the quota process to ensure an adequate and uninterrupted supply of controlled substances for legitimate medical use and respond to shortages of drugs containing controlled substances, we recommend that the Administrator of DEA take the following five actions:

- establish controls, including periodic data checks, to ensure that the YERS/QMS data accurately reflect both manufacturers' quota submissions and DEA's decisions;
- establish performance measures for DEA related to quotas and ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical use;
- monitor and analyze YERS/QMS data to assess DEA's administration of the quota process;
- establish internal policies for processing quota applications and setting aggregate, annual, and supplemental quotas to ensure that staff conduct these activities consistently and in accordance with the CSA and agency's regulations; and
- expeditiously establish formal policies and procedures to facilitate coordination with FDA as directed by FDASIA, including a specific time frame in which DEA will be expected to respond to FDA requests to expedite shortage-related quota applications.

To strengthen DEA's and FDA's ability to respond to shortages of drugs containing controlled substances, we recommend that the Administrator of DEA and the Commissioner of FDA take the following two actions:

- promptly update the MOU between the two agencies, and
- either in the MOU or in a separate agreement, specifically outline what information the agencies will share, and time frames for sharing such information, in response to a potential or existing drug shortage.

Agency Comments and Our Evaluation

We provided a draft of this report for comment to HHS and DOJ. In addition, we provided excerpts of this report to UUDIS. We received written comments from HHS and DEA, which are reproduced in full in appendix IV and V, respectively. Both agencies also provided technical comments, which we incorporated as appropriate. UUDIS did not have any comments.

HHS agreed with the two recommendations applicable to FDA. Specifically, it agreed with our recommendation that it promptly update its MOU with DEA. It also agreed with our recommendation that it and DEA should specifically outline what information they will share and the time frames for doing so, in response to a potential or existing drug shortage. HHS also stated that FDA is actively working to finalize the new MOU with DEA.

DEA did not explicitly agree or disagree with the seven recommendations we made to it, but commented on each. In some instances, its comments indicate that it is either supportive of strengthening its management of the quota process and improving coordination with FDA, or that it has already taken steps consistent with our recommendations. In one instance, it did not respond directly to our recommendation. DEA also raised multiple objections to our work and described what it characterized as flaws and weaknesses in our draft report. In particular, DEA stated concerns with (1) our understanding of quotas, (2) definition of a shortage, (3) the title of our draft report, (4) our methods of conducting investigation and data analysis, and (5) our conclusions.

Understanding of quotas. DEA stated that we fail to understand that it does not have the authority to issue quotas for individual dosage forms and that it cannot require a manufacturer to manufacture or distribute its products, whether API or final dosage form. This report reflects these facts, specifically stating that “DEA does not have the authority to issue quotas for specific products or to require manufacturers to use their quota for specific products.” DEA concluded that because the agency does not have this authority, its quota decisions have no effect on the availability of individual dosage forms containing substances that are subject to quotas. We disagree with this conclusion because manufacturers must receive authorization from DEA to obtain controlled substances subject to quotas, and so the amounts of quota authorized by DEA and the timing of its decisions directly affect when manufacturers are able to obtain the substances necessary to manufacture their products. We understand that manufacturers are ultimately responsible for what they manufacture with

the quota authorized by DEA, but their decisions are made within the confines of the quota granted by DEA.

Definition of a shortage. DEA stated that our draft report is misleading because we fail to account for the fact that the definition of a "shortage" means different things to different entities. DEA suggested that our approach is flawed because we focus on individual drug products rather than the basic class of controlled substances. We do so because this is the level that affects patients and providers. Thus, we used data from UUDIS and FDA, both of which track shortages of individual drug products. UUDIS is regarded as the most comprehensive and reliable source of drug shortage information between January 2001 through June 2013 and FDA has been mandated by statute to identify and monitor drug shortages. Drugs within the same substance class are not necessarily clinically interchangeable, according to FDA and UUDIS. For example, as we describe in this report, there can be significant implications for patients who have to switch from an extended-release formulation to an immediate-release formulation of the same drug and patients who have trouble swallowing may not be able to use a tablet formulation if an injection is in short supply.

Additionally, DEA criticized our use of FDA's revised definition of a drug shortage, which FDA adopted in September 2014. DEA stated that this definition, which FDA adopted to be consistent with FDAISA, is "materially different" from the definition FDA used from 2006 through 2012. DEA implied that, by doing so, our analysis was flawed in that we inappropriately applied the new definition to our analysis of YERS/QMS records from 2011 and 2012—a period predating FDA's revised definition. We disagree. Our analysis of certain YERS/QMS records was premised on particular shortages of drugs containing controlled substances that occurred between January 2010 and June 2013. We collected data from FDA beginning in October 2012 to specifically identify the manufacturer-reported causes of shortages of drugs containing controlled substances. We completed our collection of FDA's data in August 2013. We could not have applied FDA's revised definition of a drug shortage to our efforts as, at that time, the revised definition was not yet adopted by FDA. We requested the YERS/QMS source documents, including the entire population of records in 2011 and 2012 that were associated with drug shortages manufacturers reported to FDA that were caused by quotas, in June 2014. Therefore, FDA's revised definition had no bearing on our YERS/QMS analysis. However, we include and discuss FDA's revised definition in this report as it is relevant to FDA's and DEA's implementation of FDASIA provisions that require coordination between

both agencies in response to certain drug shortages. It is also important to note that, although DEA asserts that FDA's revised definition is "materially different" than its prior one, as we note in this report, FDA does not consider the revised definition to be substantively different nor does it alter how FDA works to resolve drug shortages.

With respect to DEA's and FDA's different views on when a shortage exists, our report explicitly recognized that DEA and FDA are not able to effectively collaborate due to this fundamental disagreement. In fact, this was the basis for our recommendation that DEA and FDA take steps to improve the coordination required of them under FDASIA.

Title of our draft report. DEA stated that the title of our draft report was inconsistent with the our findings: (1) that a causal relationship could not be established between shortages of drugs containing controlled substances and DEA's lack of timeliness in establishing annual and supplemental quotas and (2) that we could not prove that DEA's collaboration with FDA would hinder their collective abilities to effectively coordinate regarding future shortages. We disagree with DEA's conclusion that the quota process and its collaboration with FDA play no role in, and cannot cause or exacerbate, drug shortages. As this report shows, DEA does not use effective approaches for managing the quota process or collaborating with FDA. We continue to believe that DEA should improve its administration of the quota process and enhance coordination with FDA to be in a position to fulfill its statutory responsibilities. Nevertheless, we modified the title of this report to emphasize the need for process and collaboration improvements, rather than the link between drug shortages and the process and collaboration shortcomings.

Method of conducting investigation and data analysis. DEA stated that our methodology was flawed because we did not attempt to independently determine whether there were shortages of drugs subject to quotas and whether quotas actually caused such shortages. In its comments, DEA stated that two of its data systems—ARCOS and YERS/QMS—would have provided us with such information. This stance contradicts information that DEA consistently provided throughout the course of our work, and we disagree with DEA's position for several reasons.

- First, we sought to obtain ARCOS and YERS/QMS data from DEA early in our review and were met with strong opposition from agency officials. We requested ARCOS data in order to track the drugs that

manufacturers reported to be in shortage to examine their movement through the supply chain before, during, and after the reported shortage and YERS/QMS data to analyze DEA's timeliness and responsiveness in authorizing quota. DEA officials said that ARCOS is used to monitor the diversion of drugs and it is not used nor intended to be used to identify shortages of specific drugs. DEA officials also told us that there is too much complexity in the supply chain to perform a meaningful analysis and that it would be inappropriate to use ARCOS data for our purpose. DEA officials also insisted that supplying us with ARCOS data would be burdensome and an inefficient use of their agency's resources. Similarly, DEA officials objected to providing us with the YERS/QMS data we requested. As DEA stated in its comments, negotiations to obtain these data were "protracted and contentious." Our audit was ultimately delayed for over a year as we attempted to obtain these ARCOS and YERS/QMS data. However, following the intervention of senior DOJ management officials, DEA eventually provided the requested information from both ARCOS and YERS/QMS.

- Second, although DEA indicated in its comments that ARCOS and YERS/QMS data could have provided us with a "full view" of the distribution of schedule II controlled substances throughout the supply chain, this is inconsistent with information the agency provided throughout the course of our work and what we ultimately found through our analyses. DEA officials repeatedly informed us that, apart from their concerns with providing us with the ARCOS data, they objected to our planned analysis because of significant and inherent inaccuracies in the data. Agency officials explained that, because the ARCOS data are self-reported by registrants, the data contain many errors, particularly in the quantity field that records the number of packages, weight, or volume being reported in each transaction. DEA officials told us that they consider these data to be so unreliable they only use data from ARCOS as a preliminary tool when beginning diversion investigations, and that they must ultimately verify the data against source documents available at the registrants' business locations. DEA advised us that ARCOS data were unreliable; however, to maintain our independence, it was necessary for us to obtain a sample of data to complete our own assessment.

  Once we obtained the requested data from both ARCOS and YERS/QMS, we conducted a preliminary analysis on each data set. We identified significant data reliability issues with both sets of data and determined that both ARCOS and YERS/QMS were unreliable for our purposes. Specifically, regarding ARCOS, our analysis of the data sample identified drastically different numbers of transactions and

amounts reported as transferred between manufacturers and distributors for any given quarter between 2010 through 2012. Both manufacturers and distributors are required to report the number of transactions of these substances and the amounts transferred to ARCOS, so we would therefore expect that the number of transactions and amounts reported as transferred between both groups to be similar. DEA officials could not provide explanations for these inconsistencies. In addition, it was not possible for us to use source documents to verify all of the transactions in our sample because it was beyond the two year retention requirement for registrants' original documentation for many of the transactions. Because our tests on the sample we obtained showed the ARCOS data to be unreliable for our purposes, there was no point in further analyzing ARCOS data or in requesting additional data.

Our assessment of YERS/QMS also determined that these data were not reliable for our purposes. However, we were able to analyze a sample of YERS/QMS data by taking certain methodological steps. Specifically, to correct for the errors that we found in the data, we analyzed the information contained in the source documents for our sample of YERS/QMS records for certain fields. Overall this sample represented about 15 percent of the total YERS/QMS records that we obtained from DEA in 2011 and 2012.[84] We found a significant number of errors in the data from 2011 (44 percent overall) and less in the data from 2012 (10 percent overall). Although we had correct information from the source documents, we determined that it was not appropriate for us to use all of the fields contained in those documents because we continued to identify inconsistencies, including in the source documents themselves. For instance, within the source documents associated with a particular supplemental application—a manufacturer's supplemental quota application and DEA's decision letter—the manufacturer may have requested the additional amount of quota it was seeking (e.g., an additional 500 grams in addition to 500 grams it previously received), but DEA's corresponding decision letter authorized the total amount of quota for that year (e.g., 1,000 grams). Therefore, it would appear that DEA authorized 200 percent of the quota requested in this case, according to the source documents, when in fact it authorized 100 percent of the request. Due to these

[84]According to DEA officials, YERS/QMS data prior to 2011 were not available and our data request was made before 2013 was complete.

inconsistencies, we did not pursue analyzing the amount of quota that DEA authorized for manufacturers in 2011 and 2012. DEA states in its comments that we should have analyzed the amounts of quota authorized by DEA for the substance classes that had drugs in shortage in 2011 and 2012 to verify the manufacturers' claims that quotas caused or exacerbated shortages. However, the data reliability concerns we identified within the quota amount fields, particularly for 2011 data when 6 of the 7 quota related shortages began, prevented the feasibility of a meaningful analysis.

In addition to criticizing our methodology for not fully utilizing data from YERS/QMS and ARCOS to independently establish causation between a specific shortage and the quotas DEA established for a basic class of schedule II controlled substance, DEA stated that our draft report was misleading because of our extensive description of the nature and magnitude of drug shortages of all controlled substances and their consequences. We do so because the scope of this report is not limited to drugs containing controlled substances that are subject to quota, but includes other prescription drugs containing controlled substances. It is important to note that we identify specific examples of shortages of schedule II drugs that are subject to quota—such as morphine, fentanyl (anesthesia), amphetamine and methylphenidate (ADHD drugs)—and the impact of these shortages on patients and providers in this report. As we note in this report, quota was not reported to be the primary cause of all shortages of drugs that contain schedule II substances. Indeed, not all drugs containing controlled substances are subject to quota. Other primary causes included manufacturing delays, capacity issues, and product quality issues, which are the same factors that cause shortages of drugs generally. However, because the availability of quota could be a factor in shortages of those drugs that do contain controlled substances subject to quota, we considered it both necessary and relevant to include such information. We therefore provide FDA data on the manufacturer-reported causes of shortages of their products containing schedule II substances, including quota.

Lastly, we believe that DEA may have misconstrued the intent of our study. DEA implies that our purpose was to evaluate whether it authorized adequate amounts of quota and whether manufacturers provided adequate justification for their quota requests. However, our purpose was to examine the trends and characteristics of drug shortages of controlled substance and their affect on patients and providers, as well as assess DEA's administration of the quota process, including its internal controls and compliance with required time frames. The purpose of our

study was not to determine whether DEA's decisions were correct or manufacturers' justifications were sufficient. In using ARCOS and YERS/QMS data, we sought to obtain information about where certain controlled substances were in the supply chain before, during, and after a shortage and DEA's timeliness and responsiveness in responding to manufacturers' quota applications. Data reliability concerns with both data sets prevented us from fully accomplishing such analyses.

Our conclusions. DEA stated that our conclusions unfairly link the quota process to diminished patient care by describing the trends of shortages of drugs containing controlled substances and then evaluating DEA's administration of the quota process that only applies to a subset of those substances. These are two separate issues. This report does not say, nor do we believe, that quotas are the sole cause of shortages of drugs containing schedule II substances. However, we disagree with DEA's contention that the actions it takes in setting quotas at the class level would have no bearing on the drug products that are made with those substances. The shortcomings that we identified in DEA's administration of the quota process prevent it from having reasonable assurance that it is providing for an adequate and uninterrupted supply of these drugs for legitimate medical need, and calls into question DEA's ability to avert or address future shortages of medically necessary products. We agree that there are many factors that affect and ultimately cause drug shortages and include these in this report. However, simply because not all drugs that have been in shortage are subject to quotas does not mean that quotas cannot cause, contribute to, or exacerbate shortages of drugs containing schedule II substances.

DEA also questioned our conclusion that by not acting promptly to respond to supplemental quota applications, it may hinder manufacturers' ability to produce schedule II drugs that may help prevent or resolve a shortage. DEA said this is not possible because manufacturers' business decisions are involved. We recognize that manufacturers must apply for quota, and then use it to manufacture and ultimately distribute the appropriate drugs for there to be any impact on drug shortages. However, DEA's actions also play a part when quota is involved. DEA's lack of timeliness in responding to manufacturers' supplemental quota applications—taking nearly 60 days on average—for both shortage and non-shortage related applications is problematic and not in the interest of public health. We continue to believe DEA should implement our recommendations to ensure that it is positioned to comply with the statutorily mandated time frame of responding to applicable requests within 30 days.

DEA's response to our recommendations. Regarding our first recommendation that DEA establish controls to ensure that the YERS/QMS data accurately reflect both manufacturers' quota submissions and DEA's decisions, DEA described existing flags and reviews in place to ensure the information that is entered by manufacturers and DEA staff is accurate. While we understand that DEA takes some steps to help ensure the accuracy of YERS/QMS data, it does not perform sufficient checks to ensure the accuracy of the information. For example, DEA does not compare a sample of YERS/QMS data to the source documents (manufacturer's application and DEA decision letter) to identify if its existing checks are adequate. Although the accuracy of the data improved from 2011 to 2012, we nonetheless found a 10 percent error rate in the 2012 data. In particular, some of the fields with the highest rates of error in the 2012 data were in the fields for the amount of quota requested or authorized, which have implications for the availability of controlled substances subject to quota. We continue to believe that taking additional steps to reduce this error rate, as we recommended, is important.

Regarding our second recommendation to establish performance measures related to quotas, DEA said it recognizes the value in establishing performance measures for personnel who review quota applications. While we agree that it can be useful to develop performance measures for personnel, our recommendation is intended to be more expansive than that and should include performance measures at the program or agency level. For example, as we note in this report, DEA could set goals and then measure the number of manufacturers who submit incomplete or revised quota applications, both factors that DEA cited as affecting its ability to meet its required time frames. DEA could also establish goals and track the percentage of annual applications that DEA responds to in accordance with its required time frames. It is important that DEA set such measures to assess its performance in achieving its mission of ensuring an adequate and uninterrupted supply of controlled substances as it does for its diversion-related mission.

For our third recommendation about monitoring and analyzing YERS/QMS data, DEA said it agrees that such actions are important to ensuring proper administration of the quota process. DEA also provided examples of how the agency uses YERS/QMS data in setting APQs and bulk manufacturing and procurement quotas. However, the agency did not commit to using the data to monitor its administration of the quota process or its performance. Such information could be of vital importance to determine the feasibility of potential performance measures, as we

recommended, or to evaluate DEA's efforts in meeting its performance measures once developed, such as the extent to which DEA is meeting its required time frames for responding to annual quota applications.

In response to our fourth recommendation that DEA establish internal policies for processing quota applications, DEA stated that it has already established such policies and procedures. However, the agency did not provide documentation of such policies and procedures despite repeated requests. To the contrary, DEA officials told us that the agency relies exclusively on its regulations and the CSA in establishing APQs and manufacturers' quotas. As we state in this report, this is inconsistent with federal standards for internal control, and we believe that policies are still needed because of the complexity of the work involved in setting quotas.

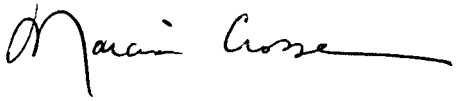
In response to our fifth recommendation that DEA expeditiously establish formal policies and procedures to facilitate coordination with FDA as directed by FDASIA, DEA stated that it will follow the requirements of FDASIA to respond to FDA's requests within 30 days. However, FDASIA does not specify a time frame in which DEA must respond to FDA's requests to increase quota; this 30-day time frame is only applicable to requests that DEA receives from manufacturers. Furthermore, DEA has not historically met its required time frames for establishing quotas from either the CSA or its regulations. Therefore, we believe that policies and procedures are needed to establish such a time frame and specify how DEA will respond to such a request from FDA. We understand that DEA has received no such request from FDA since the enactment of FDASIA; however, we believe that it is imprudent to wait for a shortage that has serious implications for public health before determining how to proceed.

Regarding our sixth recommendation that DEA promptly update the MOU with FDA, DEA stated that it had begun negotiating the terms of the new information sharing agreement when this review began in 2012, which we note in this report. DEA said that the final version of this MOU has been routed for signature within the agency as of December 2014.

Lastly, in response to our seventh recommendation that, either in the MOU or in a separate agreement, DEA and FDA specifically outline what information the agencies will share and the time frames for sharing such information in response to a potential or existing drug shortage, DEA noted that it has already engaged in discussions with FDA to determine the specific procedures for sharing drug shortage related information pursuant to FDASIA. We believe that reaching a specific agreement on information sharing will be beneficial to both agencies.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies of this report to the Secretary of the Department of Health and Human Services and the Attorney General, and other interested parties. In addition, the report will be available at no charge on GAO's website at http://www.gao.gov.

If you or your staff have any questions about this report, please contact me at (202) 512-7114 or at crossem@gao.gov. Contact points for our Office of Congressional Relations and Office of Public Affairs can be found on the last page of this report. Other major contributors to this report are listed in appendix VI.



Marcia Crosse
Director, Health Care

Appendix I: List of Provider and Patient Organizations Interviewed

Provider Organizations

1. American Academy of Child and Adolescent Psychiatry
2. American Academy of Pediatrics
3. American College of Emergency Physicians
4. American Hospital Association
5. American Psychiatric Association
6. American Society of Anesthesiologists
7. American Society of Health-System Pharmacists
8. Association of Critical Care Transport
9. Institute for Safe Medication Practices
10. International Association of Fire Chiefs
11. National Association of Boards of Pharmacy
12. National Association of Emergency Medical Technicians
13. National Association of State EMS Officials
14. National Community Pharmacists Association

Patient Organizations

1. Children and Adults with Attention Deficit/Hyperactivity Disorder
2. National Alliance on Mental Illness

Appendix II: Classes of Schedule II Controlled Substances with Medical Use

The Drug Enforcement Administration (DEA) establishes quotas on the quantity of schedule II substance classes that may be produced in the United States in any given calendar year.[1] We consider classes of schedule II controlled substances with medical use to be those substances that are contained in Food and Drug Administration (FDA) approved products currently marketed for human use, and are not considered precursors, reference standards, or metabolites, as reported by DEA.[2] Those substance classes include the following:

Alfentanil	Hydromorphone	Opium
Amobarbital	Levorphanol	Oxycodone
Amphetamine	Lisdexamfetamine	Oxymorphone
Cocaine	Meperidine	Pentobarbital
Codeine	Methadone	Remifentanil
Dihydrocodeine	Methamphetamine	Secobarbital
Diphenoxylate	Methylphenidate	Sufentanil
Fentanyl	Morphine	Tapentadol
Hydrocodone	Nabilone	

[1]DEA also establishes quotas for schedule I substances, but we did not include them in our report because such substance classes have no currently accepted medical use in treatment in the United States.

[2]A precursor is a chemical that is transformed into another compound as in the course of a chemical reaction. For example, the controlled substance noroxymorphone is a precursor used to manufacture opiates. A metabolite is a substance produced during metabolism or a result of metabolism. For example, the substance ecgonine is a metabolite of cocaine as it is generated in the extraction of cocaine from coca leaf.

Appendix III: Scope and Methodology – Analysis of the Year-End Reporting and Quota Management System Data

As part of our work examining the Drug Enforcement Administration's (DEA) quota process, we analyzed data from DEA's Year-End Reporting and Quota Management System (YERS/QMS) for certain controlled substances with medical use to assess the reliability of the system and DEA's timeliness in responding to manufacturers' quota applications. This appendix provides further detail on our methods for determining the reliability of the data and analyzing the data.

To determine the reliability of data from DEA's YERS/QMS, DEA provided data from the system for 2011 and 2012, the most recent years for which data were available when we began our analysis. We discussed these data with the officials responsible for maintaining YERS/QMS and examined the data for obvious errors and values outside of expected ranges. We removed applications that were marked as "withdrawn," as DEA does not authorize quota for these applications.[1] We also removed applications that appeared to be duplicates, which we identified by searching for applications that had the same registrant, drug, date submitted, and quota type (e.g., bulk manufacturing or procurement). We searched for applications that had the word "duplicate" in the notes field of YERS/QMS as well, which DEA uses to record additional information about quota applications. Additionally, we removed applications that were not for schedule II substance classes with medical use.[2]

We then selected a sample of 442 records, from the total of 2,982 records, from YERS/QMS to verify against source documents, each of which includes a manufacturer's quota application for a particular substance and the corresponding DEA decision letter informing the manufacturer of its quota authorization (see table 5). This sample included the entire population of records in 2011 and 2012 that are associated with drug shortages manufacturers reported to the Food and Drug Administration (FDA) were caused by quotas, of which there were 146. We consider YERS/QMS records to be associated with these shortages if the record contains a quota application that was (a) submitted by a manufacturer who reported to FDA that quota caused a shortage of its product; (b) for a substance that was used in the

[1]DEA told us that manufacturers often withdraw an application if it has an error or if a manufacturer loses a contract and no longer needs quota for a particular substance.

[2]See appendix II for the list of schedule II substances that we consider to have medical use.

products reportedly in shortage because of quota; and (c) was submitted during the time of the reported shortage caused by quota. For instance, if a manufacturer reported a shortage of a drug containing a controlled substance to FDA beginning in 2011 and ending in 2012, and said that the shortage was caused by quota issues, we considered all applications from that manufacturer for that controlled substance in 2011 and 2012 to be related to a shortage reportedly caused by a quota issue. We also selected a random sample of 296 records stratified by year—182 and 114 records from 2011 and 2012, respectively. We included more records from 2011 because we believed those records would be harder for DEA to locate, as DEA told us that there were a larger percentage of hard-copy applications, as opposed to electronic applications, in 2011 than 2012. Because we followed a probability procedure based on random selections, our sample is only one of a large number of samples that we might have drawn. Since each sample could have provided different estimates, we express our confidence in the precision of our particular sample's results as a relative margin of error based on a 95 percent confidence interval (e.g., plus or minus 10 percentage points). This is the interval that would be expected to contain the actual population value for 95 percent of the samples we could have drawn.

Table 5: Records Sampled from the Drug Enforcement Administration's Year-End Reporting and Quota Management System (YERS/QMS) for Schedule II Substances with Medical Use

	Number of records in population	Number of records in sample
Records associated with shortages reportedly due to quota (2011 and 2012)	146	146
Records not associated with shortages reportedly due to quota (2011)	1,419	182
Records not associated with shortages reportedly due to quota (2012)	1,417	114
Total	**2,982**	**442**

Source: GAO analysis of YERS/QMS data. I GAO-15-202

From our sample of 442 YERS/QMS records for which we requested source documents from DEA, we analyzed source documents for 440 records. DEA officials said that they could not locate documents for one record and another record was found to be ineligible based on our review. Noncertainty sample sizes were inflated to account for an expected location rate of 50 percent for 2011 and 80 for 2012, to assure enough located files would be available for analysis. Because DEA told us that some paper applications had been put into storage due to office renovations and were difficult to retrieve, we assumed we would not be able to locate the full sample of records. DEA officials told us that there were more paper records—as opposed to electronic records—submitted

in 2011 than 2012. Based on that information, we assumed a lower location rate in 2011 than 2012. In order to estimate population quantities, we analyzed our sample data using survey analysis software that accounts for our stratified random selection design and uses analysis weights in order to make the results of our sample representative of all YERS/QMS applications for schedule II substances with medical use in 2011 and 2012.

In order to confirm that we were comparing the source documents to the correct record in YERS/QMS, we matched the documents based on the manufacturer and substance, and at least one of the following fields: date application was submitted; total amount requested; date decision letter was mailed; and total amount authorized.[3] Using this methodology, we were able to match 440 records in our sample. To verify the accuracy of the YERS/QMS data for these 440 records, we compared the data in YERS/QMS against the information in DEA's source documents (quota applications and decision letters). We used the following fields in the quota application to validate or correct the data in YERS/QMS: quota year, company name, substance name, quota type (e.g., bulk manufacturing or procurement), the date submitted, and total amount requested. We used the following fields in the decision letters provided by DEA to validate or correct the data in YERS/QMS: quota year, company name, substance name, quota type (e.g., bulk manufacturing or procurement), date mailed, and total amount authorized. We calculated the number of fields with errors (e.g., number of errors in the date submitted field) and the number of records with errors (i.e., a record with an error in any field). We also weighted the results of our error calculations in order to make the results representative of all YERS/QMS records in 2011 and 2012. Based on our review of these source documents, we determined that the YERS/QMS data we obtained from DEA were unreliable for our purposes.

Because of the reliability concerns with the YERS/QMS data, we used the information contained in the 440 YERS/QMS source documents for our analysis of DEA's timeliness in responding to manufacturers' quota applications and when manufacturers submitted annual quota applications. In order to separate annual applications and supplemental

[3]DEA matched source documents to the corresponding YERS/QMS records for 8 of the 440 records for which they provided source documents.

applications, which have different requirements for timeliness, we considered annual applications to be applications submitted in the year prior to when the quota would be used (e.g., an application submitted in May 2010 for 2011 quota). Applications submitted in the same year as when the quota would be used were considered supplemental. For annual applications, we analyzed DEA's compliance with the required deadlines in the Controlled Substances Act and DEA's regulations, including how often DEA met the deadlines for our sample of records and how many days passed when it did not meet the deadlines.[4] We also analyzed when manufacturers submitted their annual quota applications. For supplemental applications, we analyzed the amount of time that it took DEA to respond to supplemental applications in our sample. We used a two-tailed t-test to determine whether there was a statistical difference in the amount of time DEA took to respond to supplemental applications submitted by manufacturers that reported shortages due to quota compared to all other supplemental applications. For our analysis of these 440 YERS/QMS source documents, we express our confidence in the precision of our particular sample's results the same way in which we did for our analysis of the errors in the YERS/QMS data, as we described above.

[4]See 21 U.S.C. § 826(c); 21 C.F.R. §§ 1303.12 and 1303.21.

Appendix IV: Comments from the Department of Health and Human Services

DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

DEC 29 2014

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, "Controlled Substances: Better Management of the Quota Process and Enhanced Coordination between DEA and FDA Needed to Address Drug Shortages" (GAO-15-202).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Jim R. Esquea
Assistant Secretary for Legislation

Attachment

GENERAL COMMENTS OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT ENTITLED: CONTROLLED SUBSTANCES: BETTER MANAGEMENT OF THE QUOTA PROCESS AND ENHANCED COORDINATION BETWEEN DEA AND FDA NEEDED TO ADDRESS DRUG SHORTAGES (GAO-15-202)

The U.S. Department of Health and Human Services (HHS) appreciates the opportunity to review and comment on this draft report.

GAO Recommendation

To strengthen the Drug Enforcement Administration's (DEA) and the U.S. Food and Drug Administration's (FDA) ability to respond to shortages of drugs containing controlled substances, we recommend that the Administrator of DEA and the Commissioner of FDA promptly update the memorandum of understanding (MOU) between the two agencies and either in the MOU or in a separate agreement, specifically outline what information the agencies will share, and timeframes for sharing such information, in response to a potential or existing drug shortage.

HHS Response

HHS concurs with this recommendation and is actively working to finalize the new MOU with the DEA.

Appendix V: Comments from the Drug Enforcement Administration

U. S. Department of Justice
Drug Enforcement Administration

www.dea.gov

DEC 2 9 2014

Marcia Crosse
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Crosse:

The Drug Enforcement Administration (DEA) provides the following comments to the Government Accountability Office (GAO) report entitled "*Controlled Substances: Better Management of the Quota Process and Enhanced Coordination between DEA and FDA Needed to Address Drug Shortages*" (GAO-15-202).

It is important to note that the titled conclusion of the report is inconsistent with the GAO finding that it cannot establish either a "causal relationship between shortages of drugs containing controlled substances and DEA's management of the quota setting process" (Draft, p. 45) or that DEA coordination with the U.S. Food and Drug Administration (FDA) adversely affected the availability of drug products containing controlled substances.[1]

Introduction

The DEA agrees that prescription drug abuse is a nationwide epidemic and more must be done to prevent, detect, and deter the diversion of pharmaceutical controlled substances that supply drug addiction and abuse. The DEA role in this effort is as the primary agency responsible for coordinating the drug law enforcement activities of the United States. The Diversion Control Program (DCP) is a strategic component of the DEA's law enforcement mission. The DEA Office of Diversion Control administers the DCP and implements and enforces Titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, but are collectively referred to as the "Controlled Substances Act" or the "CSA." The CSA and its implementing regulations are designed to prevent, detect, and deter the diversion of controlled substances and listed chemicals into the illicit market while

[1] See Draft, p. 34 (stating GAO "cannot confirm whether DEA's lack of timeliness in establishing annual and supplemental quotas has caused or exacerbated shortages"); p. 40 (stating "DEA and FDA have not established a sufficiently collaborative relationship, which *could* hinder their abilities to effectively coordinate *future* shortages") (emphasis added).

establishing the total quantity of each basic class[2] of controlled substance in schedules I and II and for ephedrine, pseudoephedrine, and phenylpropanolamine to be manufactured each year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. This is a delicate balance.

One way that DEA provides for the estimated medical, scientific, research, and industrial needs of the United States is to establish an aggregate, nationwide quota for each basic class of schedule I and II controlled substance (referred to as the Aggregate Production Quota, or "APQ") and to authorize individual quotas (referred to as manufacturing quota and procurement quota). It is important to understand that DEA authorizes quota only at the manufacturer level for those entities that manufacture active pharmaceutical ingredients (API), those entities that manufacture substances into dosage forms, and those entities that repackage or re-label drug products that contain schedule I or II controlled substances. Once the aggregate quota is established and a particular manufacturer is

[2] "Basic class" means, as to controlled substances listed in Schedules I and II:
(1) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in §1308.11(b) of this chapter;
(2) Each of the opium derivatives, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(c) of this chapter;
(3) Each of the hallucinogenic substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.11(d) of this chapter;
(4) Each of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis:
(i) Opium, including raw opium, opium extracts, opium fluid extracts, powdered opium, granulated opium, deodorized opium and tincture of opium;
(ii) Apomorphine;
(iii) Codeine;
(iv) Etorphine hydrochloride;
(v) Ethylmorphine;
(vi) Hydrocodone;
(vii) Hydromorphone;
(viii) Metopon;
(ix) Morphine;
(x) Oxycodone;
(xi) Oxymorphone;
(xii) Thebaine;
(xiii) Mixed alkaloids of opium listed in §1308.12(b)(2) of this chapter;
(xiv) Cocaine; and
(xv) Ecgonine;
(5) Each of the opiates, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation, listed in §1308.12(c) of this chapter; and
(6) Methamphetamine, its salts, isomers, and salts of its isomers;
(7) Amphetamine, its salts, optical isomers, and salts of its optical isomers;
(8) Phenmetrazine and its salts;
(9) Methylphenidate;
(10) Each of the substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, listed in §1308.12(e) of this chapter. 21 C.F.R. § 1300.01(b).

authorized to manufacture a specific amount of a basic class of controlled substance, DEA cannot require the manufacturer to manufacture API or a specific drug product, or distribute that substance down through the supply chain. Furthermore, a bulk manufacturer may extract or synthesize API in an authorized calendar year, and hold it in inventory until any subsequent calendar year. Of equal importance, the CSA prohibits DEA from establishing quotas in terms of individual pharmaceutical dosage forms prepared from or containing such a controlled substance. 21 U.S.C. § 826(a). These limitations are critical to understanding the effect that quota can have on the availability of a specific drug product at the retail level or at the emergency medical service (EMS) provider level. The failure to appreciate these limitations is the fatal flaw in the GAO report.

Another fundamental weakness in the GAO report is the failure to account for the fact that "shortage" means different things to different entities, and without accounting for this distinction, the GAO report is misleading with respect to the effect that the DEA quota process can have on patient care. To identify trends in shortages of drugs containing controlled substances, GAO analyzed University of Utah Drug Information Service (UUDIS) data. UUDIS broadly defines a "shortage" as a supply issue that affects how pharmacies prepare and dispense a product or that influences patient care when prescribers must choose an alternative therapy because of a supply issue. A UUDIS "critical shortage" occurs when alternative medications are unavailable, the shortages affect multiple manufacturers, or the shortages are widely reported. In addition, UUDIS information is based on national drug codes (NDCs) rather than the basic class of controlled substance contained within a specific drug product. NDCs are identifiers that are unique to a particular manufacturer, drug product, dosage form, dosage strength, and package size. Accordingly, a single basic class of controlled substance will be represented by many different NDCs. Statistics and analysis based on the NDC, rather than the basic class of controlled substance, could dramatically distort the actual number of shortages that could be attributed to quota.

From September 2006 through July 2012, the FDA defined a "drug shortage" as a "situation in which the total supply of all clinically interchangeable versions of an FDA-regulated drug is inadequate to meet the current or projected demand at the user level."[3] (FDA CDER MAPP 6003.1, Sept. 26, 2006). FDA changed their definition in September 2014 to align with the definition in the 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) to "a period of time when the demand or projected demand for the drug within the United States exceeds the supply of the drug." Although this new definition is materially different from the definition applicable during the period in review (2011 and 2012), the GAO report uses the 2014 definition in its analysis.

In contrast to the UUDIS and FDA, which view shortages in the context of patient-level availability, DEA views shortages in the context of manufacturer-level quota. Accordingly, a shortage within DEA's jurisdiction is the lack of sufficient quota available for bulk or dosage form manufacturers to manufacture a basic class of a schedule I or II controlled substance. This perspective is the result of the CSA prohibition against establishing quotas in terms of individual

[3] The GAO report discusses DEA's concern with the reliability of information posted on FDA's drug shortage website. During the period under review, DEA was concerned that FDA did not adhere to the applicable definition of "drug shortage" because FDA was listing drug products in shortage when clinically interchangeable drug products were available. Other inaccuracies included reporting that some distributors experienced a shortage due to quota or lack of API, yet distributors do not receive quota.

pharmaceutical dosage forms prepared from or containing a controlled substance, together with the mandate to limit the supply of controlled substances available for diversion, and the inability to require a manufacturer to manufacture a specific API or drug product or require the distribution of controlled substance drug products downstream. Accordingly, if alternative forms of a drug product are available (e.g., brand, generic, or other clinically interchangeable drug products), or if manufacturers have quota authorization, the DEA cannot remedy any patient-level shortage (e.g., inadequate supply at the retail level or EMS provider level) by increasing the aggregate or authorizing more quota at the manufacturer level. GAO fails to emphasize and account for these fundamental distinctions in its review of the potential effect of the quota process on the availability of drug products containing schedule II controlled substances.

Some simplified examples can illustrate how the above distinctions can skew shortage conclusions. If there is an unmet patient need for hydromorphone 10 mg/mL, 1 mL vials, UUDIS and FDA would qualify it as a shortage. However, DEA would not consider there to be a shortage within its jurisdiction if the 10 mg/mL, 5 mL vials are available. Similarly, DEA would not consider there to be a shortage if the brand name version of a particular drug product is unavailable, if the generic version of the drug product is available. Also, there would be no shortage in DEA's jurisdiction if there is hydromorphone quota available in the APQ (i.e., the annual APQ has not been exhausted) and manufacturers are not requesting additional quota, or if manufacturers with authorized hydromorphone quota are not manufacturing their quota allotment or are not distributing the manufactured hydromorphone downstream.

Further comments regarding the GAO report are focused on the following three main areas and are discussed below: method of conducting investigation; method of data analysis; and GAO conclusions.

Method of conducting investigation:

Generally, the Congressional requesters sought to "better understand the impact of DEA quotas on patients with emergency medical and critical care conditions and traumatic injuries, and the extent to which DEA policies and regulations may impede the ability of physicians and health care providers to mitigate a shortage of a drug on any of the applicable schedules." Specifically, GAO was asked to particularly focus on shortages of drugs containing controlled substances used by EMS providers and to treat attention deficit hyperactivity disorder (ADHD). GAO did not evaluate the flow of specific controlled substances from the point of quota request and authorization to manufacture, or from the point of manufacture to distribution to the retail level, using available data from the Automation of Reports and Consolidated Orders System (ARCOS) and Year End Reporting and Quota Management System (YERS/QMS).

GAO was aware of which manufacturers self-reported shortages to FDA claiming the shortage was due to quota, and which specific drug products were reported in shortage due to quota, yet GAO did not investigate each manufacturer's quota allotment or usage, the manufacturer's manufacturing and distribution practices, whether the manufacturer provided adequate justification for quota, or if the manufacturer asked for quota before or after reporting the shortage. In fact, GAO did not attempt to determine whether "shortages" actually existed because of a lack of quota. GAO was not without the tools to determine the answer to this question. After a protracted and contentious

negotiation regarding the data that DEA could release to GAO to conduct this investigation, DEA and GAO reached an agreement wherein DEA provided specified information from ARCOS and YERS/QMS. ARCOS and YERS/QMS data could have provided GAO with a full view of the distribution of schedule II controlled substances by manufacturers and distributors, from the point of bulk manufacture, to dosage form manufacture, and down to distribution to the retail level. Instead, GAO simply reported manufacturers' anecdotal complaints about the quota process' effect on shortages.

Amphetamine is a schedule II controlled substance and is used to treat ADHD, among other things, and it was reported to be in shortage during the review period. GAO requested ARCOS information pertaining to 17 specific NDCs, all of the amphetamine basic class. However, the 17 requested NDCs represented only a small fraction of the available market supply. The DEA estimated that there were 48 other amphetamine-containing drug products, 25 of which were manufactured and distributed during the period under review. GAO did not request ARCOS data on the other available amphetamine-containing products on the market, and GAO did not discuss in its report any findings relative to the 17 requested NDCs. The ARCOS information, combined with information from YERS/QMS, is crucial to determining whether sufficient API was manufactured, whether the API was distributed downstream by bulk manufacturers, whether dosage form manufacturers were manufacturing drug products in accordance with their quota applications, whether dosage form manufacturers were distributing drug products downstream and if so, where, and whether controlled substances were being held at the manufacturer level or destroyed rather than placed into the supply chain.

DEA is confident that a review of ARCOS and YERS/QMS data would have established that DEA's administration of the quota process did not cause or exacerbate any shortages of drug products used to treat ADHD in 2011. In 2011, DEA increased the APQ for amphetamine salts by 6,700 kg. A review of the ARCOS and YERS/QMS data for amphetamine salts showed that manufacturers subsequently requested, and DEA authorized, only a very small percentage of this increase. In addition, a significant number of amphetamine dosage units were destroyed throughout 2011, as well as a substantial amount of raw material, and millions of dosage units of ADHD drug treatment products still remained at the distributor and retail level at the end of 2011.

Close review of the ARCOS data would have also refuted manufacturers' assertions about the effects of DEA's timing to establish quotas. For example, manufacturer representatives reported to GAO that the timeline for establishing quotas does not provide manufacturers with enough time to plan for production and order the raw material or API needed to start manufacturing their products at the beginning of the production year. Representatives reported to GAO that they operated solely with what is left in their inventory for the first few months of the production year, "which may be limited because manufacturers operate in a lean manufacturing environment where they carry as little inventory as possible." (Draft, p. 30). This statement from manufacturers is conflicting. Manufacturers complained that they do not have sufficient inventory because of quota and must operate on what is solely remaining in inventory, but then go on to state their business choice to operate in a lean environment where they carry as little inventory as possible. Even so, manufacturers may manufacture API and procure raw material at any time during the year, and not distribute it until the next calendar year because DEA regulations provide for an inventory allowance.

In addition, a review of ARCOS data would have been critical to determining whether the DEA's processing of supplemental quota applications in 2011 caused or exacerbated FDA-reported drug shortages, as alleged by manufacturers. (Draft, p. 30-31). GAO's probability sample of YERS/QMS source documents showed that it took DEA an average of 58 days to respond to supplemental quota applications in 2011 and 2012. (Draft, p. 30-31). GAO also reported that it took DEA 10 days longer, on average, to respond to supplemental quota applications submitted by manufacturers that reported shortages caused by quota in 2011. However, as discussed above, a review of ARCOS and YERS/QMS information would have established that amphetamine manufacturers only sought authorization to manufacture a very small percentage of the mid-year increase.

Method of Data Analysis:

The report's extensive description of the nature and magnitude of shortages (Draft, p. 17) is misleading as it uses a very broad definition of "shortage," using data from two different sources to quantify and explain the consequences of shortages, and then ties these consequences to the very small number of schedule II drug product "shortages" without ever establishing causation between the specific shortage and the quotas for the specific basic class of controlled substance.

GAO found that approximately 10% (168 of 1,575) of the UUDIS shortages from January 2001 through June 2013 involved drug products containing a controlled substance (Draft, p. 17); of these, 57% (96) involved drug products containing schedule II controlled substances (Draft, p. 19), or approximately 6% (96 of 1,575) of the total number of UUDIS shortages. Because UUDIS information is presented according to NDC rather than the basic class, the results (96 shortages of schedule II controlled substances from 2001 to 2013) can dramatically distort the actual number of shortages that could have been attributed to lack of quota in a particular basic class of controlled substance. The results can also be misleading because UUDIS counts a shortage as a period of time; as a result, 45 different drugs containing controlled substances were reported to be in shortage multiple times from January 2001 through June 2013, representing 143 individual shortages. (Draft, p. 19). The data could also be distorted by the fact that GAO analyzed data from YERS/QMS for 2011 and 2012, rather than 2001 to 2013. Analyzing the information regarding the specific drug products and the specific basic class of controlled substance represented by the 96 NDCs, as well as the calendar year that the substances were reported in shortage would have helped to determine the role, if any, that quota played in any shortage.

GAO also reported that critical shortages represented 52% (87 of 168) of all shortages of drugs containing controlled substances. (Draft, p. 4, n.6; p. 21). Of the 87 shortages containing controlled substances identified as critical by UUDIS from January 2001 through June 2013, half (44 of 87) involved pain relievers (analgesics). (Draft, p. 20-21). Analgesics can be controlled in schedule II, III, IV, or V. However, GAO does not state whether these products contained schedule II controlled substances subject to quota, or schedule III through V controlled substances not subject to quota. This information, along with the NDCs and basic class of controlled substance involved, would be important in determining the role, if any, quota played in any shortage, particularly with respect to the UUDIS "critical shortages," because the applicable criteria (alternative medications are unavailable, the shortages affect multiple manufacturers, or the shortages are widely reported) are more likely to implicate quota than a standard shortage (a supply issue that affects how pharmacies

prepare and dispense a product or that influences patient care when prescribers must choose an alternative therapy because of a supply issue).

Even so, for the period January 2010 to June 2013, GAO reported that there were 40 FDA-reported shortages of drug products containing schedule II controlled substances, and of those, only seven were alleged to have been caused or exacerbated by quotas. (Draft, p. 30). The remaining 33 reported shortages of drugs containing schedule II controlled substances were caused by other factors that cause shortages of drugs generally such as manufacturing delays, capacity issues, and product quality issues. (Draft, p.30). GAO does not state whether any of these seven shortages occurred during the period in review, 2011 and 2012, nor does GAO indicate which basic class of controlled substance was involved, or whether each shortage involved a different basic class of controlled substance or if a single basic class of controlled substance was involved in several reported shortages. However, GAO contacted the 10 manufacturers that reported the seven shortages from January 2010 to June 2013, and reported that "many" manufacturers stated DEA's lack of timeliness in establishing quotas caused or exacerbated shortages of their drug products. It does not appear that GAO verified these statements with the data it obtained from YERS/QMS or ARCOS. Rather, the cause of these self-reported shortages was substantiated by collecting anecdotal information from manufacturers.

Some drug products specifically mentioned in the report were in shortage due to reasons other than quota. For example, beginning in 2010, a major manufacturer of injectable drug products containing controlled substances voluntarily shut down certain of its production lines and slowed the release of products in certain manufacturing facilities as a result of certain quality issues cited by the FDA. Such interruptions adversely impacted, and continue to adversely impact, the manufacturer's ability to manufacture and sell its products. The availability of all injectables were adversely affected, including substances specifically mentioned in the GAO report as having significant deleterious effects on patient care as a result of shortage, such as fentanyl, hydromorphone, and morphine—all schedule II substances subject to quota. Review of the quota data would have shown that when new manufacturers submitted quota applications to meet the new demand, DEA verified with FDA the supply disruption and acted quickly to authorize quota to the new manufacturers.

In addition, some drug products emphasized by GAO when it reported the effects of drug shortages on treatment and patient care were not drug products subject to quota. For example, GAO references an American Society of Anesthesiologists' survey regarding the effects of drug shortages on anesthesiologists. (Draft, p.24, n.49). The highest frequency of reported shortages were fentanyl (66%), thiopental (40%), succinylcholine (21%), propofol (19%), and pancuronium (15%). As discussed above, fentanyl shortages were due to manufacturing issues. Thiopental is a schedule III controlled substance and thus not subject to quotas; and the remaining three substances are non-controlled substances. In another example, lorazepam injection is a schedule IV controlled substance, and GAO highlighted the adverse consequences of its shortage, indicating that a single shortage of it lasted slightly more than 5 years. (Draft, p. 18). Another consideration GAO ignores is that the benzodiazepines are primarily imported and not manufactured in the United States. Finally, GAO reports that oxycodone oral solution (Draft, p.19), a drug GAO reports is used to treat moderate to severe pain, was in shortage for the longest combined amount of time from January 2001 through June 2013. However, certain oxycodone oral solution drug products were not FDA-approved drugs and could not be lawfully manufactured or distributed until FDA approval in

September, 2014.

GAO Conclusions:

Failure to utilize the available information as discussed above, and failure to evaluate and analyze the causes of specific controlled substance shortages lead to an analysis that unfairly linked the quota process to diminished patient care. Even though GAO could not find that shortages occurred because of a lack of quota or because of DEA's administration of the quota process, GAO makes several inferences about a relationship between drug shortages and the quota process. This was accomplished because GAO begins its report with identifying trends in shortages from January 2001 through June 2013, and then examines DEA's administration of the quota process, thereby suggesting the effect of the quota process on shortages. However, GAO only evaluated quota data for 2011 and 2012, and its evaluation is not generalizable to other years.

As discussed above, only seven of 40 FDA-reported shortages of drug products containing schedule II controlled substances were alleged to have been caused or exacerbated by quotas. GAO reports that it cannot confirm that DEA's lack of timeliness caused or exacerbated shortages. However, the tools were available to GAO to refute the specific claims that DEA's administration of the quota process caused or exacerbated shortages.

DEA is confident that its administration of the quota process did not affect a shortage during the period in review because drug product shortages are not limited to products that contain schedule II controlled substances. In fact, for the period January 2010 to June 2013, only 18% (7 of 40) of FDA-reported schedule II drug product shortages implicated quotas. Also, UUDIS data shows that from January 2001 through June 2013, approximately 43% of all reported controlled substance shortages were present in schedule III through V drug products, where quotas are not involved. (Draft, p. 19). In addition, GAO found that, from January 2001 through June 2013, the number of new controlled substance shortages reported each year peaked in 2009 and then declined. (Draft, p. 17-18; fig. 2). The increase in these shortages mimics the pattern found for shortages of all drugs, indicating that the same factors affecting shortages of all drugs are also the same factors affecting shortages of drugs containing controlled substances. It is more likely that a common denominator (or a combination of common denominators) are effecting the similar patterns in shortages amongst controlled substances and non-controlled substances; as well as amongst schedule II controlled substances and schedule III through V controlled substances.

GAO concluded that by not acting "promptly" on supplemental applications, DEA may hinder manufacturers' ability to manufacture schedule II drugs that may help prevent or resolve a shortage. However, as explained above, even if DEA increased the APQ or authorized additional manufacturing or procurement quota, manufacturers must apply for it and actually use it to manufacture the drug products in shortage, and then distribute those products downstream—activities that DEA cannot compel.

DEA Response to Recommendations:

GAO Recommendation (1): Establish controls, such as periodic data checks, to ensure that the YERS/QMS data accurately reflect both manufacturers' quota submissions and DEA's decisions.

Response: The GAO report found that the data error rate was substantially improved from the initial year the process became electronic to the second year (2011 to 2012), dropping from 45% to 10%. (Draft, p. 35). DEA has established policies and procedures to ensure data is accurate. In order to determine the timeliness of responses to submitted requests, there are a number of computer-generated dates, including date submitted, date assigned for review, and date review complete. In order to determine accuracy in quota values being requested and granted there are a series of system-generated flags in YERS/QMS. The flags guide and verify data provided by applicants; and there are flags for internal review, including when a quantity greater than requested is entered. Managers review worksheets for accuracy in summarizing the analysis of the data and supporting documentation provided by the applicant. They then verify that the values contained in the working documents are accurately entered into YERS/QMS. Upon final authorization, managers close the application in YERS/QMS after ensuring that the dates mailed are entered as the authorization letters are scanned and sent to the applicant (via email and U.S. Postal mail). YERS/QMS has a flag to ensure that the date entered is correct.

GAO Recommendation (2): Establish performance measures for DEA related to quotas and ensuring an adequate and uninterrupted supply of controlled substances for legitimate medical use.

Response: DEA recognizes the value in establishing performance measures for personnel reviewing quota applications and will determine whether performance is measurable with regard to processing quotas. Many factors determine how quickly and how accurately a quota application is reviewed and a quota recommended. For example, a single quota application is for one specific basic class; however, each quota request may involve quota for more than one specific drug product containing that basic class. The reasonable amount of time to evaluate each application is highly dependent on how many different factors affect a single request.

GAO Recommendation (3): Monitor and analyze YERS/QMS data to assess DEA's administration of the quota process.

Response: DEA agrees that monitoring and analyzing YERS/QMS data is important to ensuring proper administration of the quota process. The YERS/QMS data are integrally related for manufacturing and procurement quotas applications and responses. The data are reviewed and monitored constantly when analyzing each quota application. For example, with the APQ set as the maximum of each basic class to be manufactured each year, the quota review process of every manufacturing quota application checks the APQ, amounts issued, pending and remaining. In addition, the manufacturing quota data are analyzed and used with other sources to establish and revise the annual APQs.

GAO Recommendation (4): Establish internal policies for processing quota applications and setting aggregate, annual, and supplemental quotas to ensure that staff conduct these activities consistently and in accordance with the CSA and agency's regulations.

Response: DEA has established policies and procedures for staff administering the quota

procedures. In addition, beginning with 2013 APQs, DEA included an additional 25% of the estimated medical, scientific, and research needs as part of the amount necessary to ensure the establishment and maintenance of reserve stocks. DEA expects that maintaining this reserve in the aggregate production quotas will mitigate adverse public affects if an unforeseen event results in substantial disruption to the amount of controlled substances available to provide for legitimate public need.

GAO Recommendation (5): Expeditiously establish formal policies and procedures to facilitate coordination with FDA as directed by FDASIA, including a specific timeframe in which DEA will be expected to respond to FDA requests to expedite shortage-related quota applications.

Response: DEA shall follow the requirements of FDASIA to respond to requests within 30 days. It should be noted that no special requests for expedited quota review have been forwarded to DEA since enactment of FDASIA in July, 2012. As previously conveyed to GAO, DEA and FDA began negotiating the terms of a new information sharing agreement before this engagement commenced. As of December 15, 2014, the final memorandum of agreement has been routed for signature within DEA.

GAO Recommendation (6): Promptly update the MOU between the two agencies.

Response: As previously conveyed to GAO, DEA and FDA began negotiating the terms of a new information sharing agreement before this engagement commenced. As of December 15, 2014, the final memorandum of agreement has been routed for signature within DEA.

GAO Recommendation (7): Either in the MOU or in a separate agreement, specifically outline what information the agencies will share, and timeframes for sharing such information, in response to a potential or existing drug shortage.

Response: As previously conveyed to GAO, DEA and FDA began negotiating the terms of a new information sharing agreement before this engagement commenced. As of December 15, 2014, the final memorandum of agreement has been routed for signature within DEA. DEA and FDA have engaged in discussions to determine the specific procedures by which information regarding drug shortages shall be exchanged, pursuant to FDASIA. These procedures will be memorialized in a mutually agreeable workplan.

Conclusion:

There can be no doubt that drug shortages adversely affect the public health. Drug shortages occur across the continuum of pharmaceutical characteristics, e.g., brand, generic, controlled, non-controlled, over-the-counter, dosage forms and dosage strengths, analgesics, sedatives, stimulants. Shortages can be caused by a variety of factors, as GAO previously reported in 2011 and 2014. Determining the relationship between retail and EMS level drug product shortages and manufacturing quota is a multifaceted undertaking that particularly requires an understanding of controlled substance manufacturing and distribution practices, an appreciation of how competitive contractual agreements affect the actions of manufacturers, distributors, and patent owners, and how

these dynamics influence the annual forecasting of quota need.

DEA remains committed to establishing production quotas for each basic class of controlled substance in schedule II to be manufactured each year to provide for the estimated medical, scientific, research, and industrial needs of the United States, for lawful export requirements, and for the establishment and maintenance of reserve stocks. Accordingly, DEA appreciates the GAO finding that it cannot establish a causal relationship between shortages of drugs containing controlled substances and DEA's management of the quota setting process.

Should you have any questions regarding this matter or our comments, please contact Michael A. Dixon, Acting Deputy Chief Inspector, Office of Inspections, at (202) 307-4007.

Sincerely,

FOR

Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control

cc: Richard P. Theis
Director, Audit Liaison Group
Internal Review and Evaluation Office
Justice Management Division

Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

Marcia Crosse, (202) 512-7114 or crossem@gao.gov

Staff Acknowledgments

In addition to the contact named above, Geri Redican-Bigott, Assistant Director; Zhi Boon; Jessica Farb; Cathleen Hamann; Rebecca Hendrickson; Tom Jessor; Eileen Larence; Jan Montgomery; Lisa Motley; Leslie Powell; Dan Ries; Janet Temko-Blinder; Sonya Vartivarian; and Eric Wedum made key contributions to this report.

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(14) DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug

Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgement page must be displayed to confirm receipt. The report must contain the following information:

(a) The federal Drug Enforcement Administration registration number of the wholesale distributing location.

(b) The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.

(c) The transaction code that indicates the type of transaction.

(d) The National Drug Code identifier of the product and the quantity distributed or received.

(e) The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all schedule II transactions.

(f) The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

(15) DUE DILIGENCE OF PURCHASERS.—

(a) Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:

1. A determination of the clinical nature of the receiving entity, including any specialty practice area.

2. A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.

3. A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.

(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious

transactions. A wholesale distributor must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

(c) A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

(d) The department shall assess national data from the Automation of Reports and Consolidated Orders System of the federal Drug Enforcement Administration, excluding Florida data, and identify the national average of grams of hydrocodone, morphine, oxycodone, and methadone distributed per pharmacy registrant per month in the most recent year for which data is

available. The department shall report the average for each of these drugs to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011. The department shall assess the data reported pursuant to subsection (14) and identify the statewide average of grams of each benzodiazapine distributed per community pharmacy per month. The department shall report the average for each benzodiazapine to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011.

Section 19. Paragraphs (o) and (p) are added to subsection (1) of section 499.05, Florida Statutes, to read:

499.05 Rules.—

(1) The department shall adopt rules to implement and enforce this part with respect to:

(o) Wholesale distributor reporting requirements of s. 499.0121(14).

(p) Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

Section 20. Subsections (8) and (9) are added to section 499.067, Florida Statutes, to read:

499.067 Denial, suspension, or revocation of permit, certification, or registration.—

(8) The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9) The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report

64B16-27.830 Standards of Practice - Drug Therapy Management.

(1) "Prescriber Care Plan" means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. The Prescriber Care Plan shall be written by a physician licensed pursuant to Chapter 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication. The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.

(2) "Drug Therapy Management" means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.

(3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient's drug therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:

(a) Drug therapy to be initially dispensed to the patient by the pharmacist; or

(b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist; or

(c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient; or

(d) The conditions under which the pharmacist shall contact or notify the physician.

(4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:

(a) A transferable patient care record that includes:

1. A Prescriber Care Plan that includes a section noted as "orders" from a duly licensed physician for each patient for whom a pharmacist provides Drug Therapy Management services;

2. Progress notes; and

(b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and

(c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

Specific Authority 465.005, 465.0155 FS. Law Implemented 465.003(13), 465.0155, 465.022(1)(b) FS. History–New 4-4-00.

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

(2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

(a) Frequent loss of controlled substance medications,

(b) Only controlled substance medications are prescribed for a patient,

(c) One person presents controlled substance prescriptions with different patient names,

(d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,

(e) Patient always pays cash and always insists on brand name product.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom the medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist's records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person's identity and document on the back of the prescription complete information on which the confirmation is based.

(b) Verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine not to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

(4) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017(2), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(5) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(6) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall be exempt from the requirements to obtain suitable identification.

Specific Authority 465.005, 465.0155 FS. Law Implemented 456.072(1)(i), 465.0155, 465.016(1)(i), (o), 465.017(2) FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

United States Department of Justice
Drug Enforcement Administration
Office of Diversion Control

Pharmacist's Manual

An Informational Outline of the Controlled Substances Act

Revised 2010[1]

[1] This manual replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

Michele Leonhart
Administrator
Drug Enforcement Administration

Joseph T. Rannazzisi
Deputy Assistant Administrator/
Deputy Chief of Operations
Office of Diversion Control

Mark W. Caverly
Chief, Liaison and Policy Section

This manual has been prepared by the Drug Enforcement Administration, Office of Diversion Control, as a guide to assist pharmacists in their understanding of the Federal Controlled Substances Act and its implementing regulations as they pertain to the pharmacy profession.

The 2010 edition replaces all previous editions of the Pharmacist's Manual issued by the Drug Enforcement Administration, both hard copy and electronic.

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Section XIII – Other Controlled Substance Regulations

Section XIV – Combat Methamphetamine Epidemic Act of 2005

Appendices

SECTION I – INTRODUCTION

Disclaimer

This pharmacist's manual is intended to summarize and explain the basic requirements for prescribing, administering, and dispensing controlled substances under the Controlled Substances Act (CSA), Title 21 United States Code (21 U.S.C.) 801-971 and the DEA regulations, Title 21, Code of Federal Regulations (21 C.F.R.), Parts 1300 to End. Pertinent citations to the law and regulations are included in this manual.

Printed copies of the complete regulations implementing the CSA (21 C.F.R. Part 1300 to End) may be obtained from:

Superintendent of Documents
U.S. Government Printing Office
Washington, D.C. 20402

Both the C.F.R. and the Federal Register (which includes proposed and final rules implementing the CSA) are available on the internet through the U.S. Government Printing Office website. This website, which provides information by section, citation, and keywords, can be accessed at:

www.gpoaccess.gov

Unofficial copies of pertinent C.F.R. citations and this pharmacist's manual may be found on the internet at DEA's Diversion website (under "publications"):

www.DEAdiversion.usdoj.gov

Should any pertinent provisions of the law or regulations be modified in the future, DEA will issue a revised electronic version of this document, which will be posted on the DEA Diversion website.

If you encounter errors in this document, please notify:

Drug Enforcement Administration
Attn: Liaison and Policy Section/ODL
8701 Morrissette Drive
Springfield, Virginia 22152

Inquiries regarding topics within this document may be addressed to your local DEA Diversion Field Office (Appendix K) or the address above.

Authorization for Public Dissemination

Message from the Administrator

The Drug Enforcement Administration is pleased to provide you with the 2010 edition of the Pharmacist's Manual to assist you in understanding the provisions of the Controlled Substances Act (CSA) and its implementing regulations. This manual will answer questions you may encounter in the practice of pharmacy and provide guidance in complying with the CSA regulations. This edition has been updated to include information on the provisions of the Combat Methamphetamine Epidemic Act of 2005, the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, and the Interim Final Rule entitled Electronic Prescriptions for Controlled Substances.

Your role in the proper dispensing of controlled substances is critical to the health of patients and helps protect society against drug abuse and diversion. Your adherence to the CSA, together with its objectives and your compliance, is a powerful resource for protecting the public health, assuring patient safety, and preventing the diversion of controlled substances and drug products containing listed chemicals.

Sincerely,

Michele M. Leonhart
Administrator
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Preface

The Drug Enforcement Administration (DEA) was established in 1973 to serve as the primary agency responsible for the enforcement of federal drug laws. The Controlled Substances Act (CSA) and its implementing regulations establish federal requirements regarding both illicit and licit controlled substances. With respect to pharmaceutical controlled substances, DEA's responsibility is twofold: to prevent diversion and abuse of these substances while ensuring an adequate and uninterrupted supply is available to meet the country's legitimate medical, scientific, and research needs. In carrying out this mission, DEA works closely with state and local authorities and other federal agencies.

Under the framework of the CSA, all controlled substance transactions take place within a "closed system" of distribution established by Congress. Within this "closed system" all legitimate handlers of controlled substances – manufacturers, distributors, physicians, pharmacies, and others, must be registered with DEA (unless exempt) and maintain strict accounting for all controlled substance transactions.

To carry out this mission effectively, DEA seeks to educate its registrants regarding their legal obligations. It is DEA's goal to maintain a positive working relationship with all of its registrants, including pharmacies. DEA understands that it can best serve the public interest by working with the pharmacy community to prevent the diversion of pharmaceutical controlled substances and scheduled listed chemical products (SLCPs) into the illicit market.

Federal controlled substance laws are designed to function in tandem with state controlled substance laws. DEA works in cooperation with state professional licensing boards and state and local law enforcement officials to make certain that pharmaceutical controlled substances are prescribed, administered, and dispensed for a legitimate medical purpose in the usual course of professional practice. Within this framework, the majority of investigations into possible violations of controlled substance laws are carried out by state authorities. DEA focuses its investigations on cases involving violators of the highest level or most significant impact.

In the event a state board revokes the license of a pharmacy, DEA will request a voluntary surrender of the pharmacy's DEA registration. If the pharmacy refuses to surrender its registration, DEA will seek administrative action to revoke its DEA registration based on lack of state authorization. Additional administrative remedies that may be utilized to correct a lack of compliance include a letter of admonition or an administrative hearing. DEA may also pursue civil or criminal sanctions if there is sufficient evidence to justify a prosecution. All such actions are designed to protect the public health and safety.

In addition to the diversion of controlled substances, DEA is concerned with the diversion of certain chemicals used in the clandestine manufacture of controlled substances. Chemicals such as ephedrine and pseudoephedrine contained in over the counter and prescription substances are immediate precursors used in the illicit manufacture of methamphetamine and amphetamine. These products may be purchased or stolen from retail outlets, including pharmacies, for use in clandestine laboratories.

Pharmacies that sell over the counter products containing ephedrine and pseudoephedrine must be "self-certified" as required by the Combat Methamphetamine Epidemic Act of 2005 (CMEA). The CMEA created a new category of products designated as SLCPs. SLCPs are products containing ephedrine, pseudoephedrine, or phenylpropanolamine that may be marketed or distributed lawfully in the United States as a non-prescription drug under the Food, Drug, and Cosmetic Act. The retail provisions of the CMEA went into effect on September 30, 2006 and require, among other things, employee training, self certification, placement of SLCPs out of customer reach, required identification, sales logbooks, sales and purchase limits, and others.

DEA and the pharmacy profession have strong common interests in the appropriate use of controlled substances and SLCPs. An effective working relationship to ensure compliance with CSA requirements will continue to produce lasting benefits on a national scale.

SECTION II – SCHEDULES OF CONTROLLED SUBSTANCES

The drugs and other substances that are considered controlled substances under the CSA are divided into five schedules. A listing of the substances and their schedules is found in the DEA regulations, 21 C.F.R. Sections 1308.11 through 1308.15. A controlled substance is placed in its respective schedule based on whether it has a currently accepted medical use in treatment in the United States and its relative abuse potential and likelihood of causing dependence. Some examples of controlled substances in each schedule are outlined below.

NOTE: Drugs listed in schedule I have no currently accepted medical use in treatment in the United States and, therefore, may not be prescribed, administered, or dispensed for medical use. In contrast, drugs listed in schedules II-V have some accepted medical use and may be prescribed, administered, or dispensed for medical use.

Schedule I Controlled Substances

Substances in this schedule have a high potential for abuse, have no currently accepted medical use in treatment in the United States, and there is a lack of accepted safety for use of the drug or other substance under medical supervision.

Some examples of substances listed in schedule I are: heroin, lysergic acid diethylamide (LSD), marijuana (cannabis), peyote, methaqualone, and 3,4-methylenedioxymethamphetamine ("ecstasy").

Schedule II Controlled Substances

Substances in this schedule have a high potential for abuse which may lead to severe psychological or physical dependence.

Examples of single entity schedule II narcotics include morphine and opium. Other schedule II narcotic substances and their common name brand products include: hydromorphone (Dilaudid®), methadone (Dolophine®), meperidine (Demerol®), oxycodone (OxyContin®), and fentanyl (Sublimaze® or Duragesic®).

Examples of schedule II stimulants include: amphetamine (Dexedrine®, Adderall®), methamphetamine (Desoxyn®), and methylphenidate (Ritalin®). Other schedule II substances include: cocaine, amobarbital, glutethimide, and pentobarbital.

Schedule III Controlled Substances

Substances in this schedule have a potential for abuse less than substances in schedules I or II and abuse may lead to moderate or low physical dependence or high psychological dependence.

Examples of schedule III narcotics include combination products containing less than 15 milligrams of hydrocodone per dosage unit (Vicodin®) and products containing not more than 90 milligrams of codeine per dosage unit (Tylenol with codeine®). Also included are buprenorphine products (Suboxone® and Subutex®) used to treat opioid addiction.

Examples of schedule III non-narcotics include benzphetamine (Didrex®), phendimetrazine, ketamine, and anabolic steroids such as oxandrolone (Oxandrin®).

Schedule IV Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances in schedule III.

An example of a schedule IV narcotic is propoxyphene (Darvon® and Darvocet-N 100®).

Other schedule IV substances include: alprazolam (Xanax®), clonazepam (Klonopin®), clorazepate (Tranxene®), diazepam (Valium®), lorazepam (Ativan®), midazolam (Versed®), temazepam (Restoril®), and triazolam (Halcion®).

Schedule V Controlled Substances

Substances in this schedule have a low potential for abuse relative to substances listed in schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. These are generally used for antitussive, antidiarrheal, and analgesic purposes.

Examples include cough preparations containing not more than 200 milligrams of codeine per 100 milliliters or per 100 grams (Robitussin AC® and Phenergan with Codeine®).

Scheduled Listed Chemical Product (SLCP)

An SLCP is defined as a product that contains ephedrine, pseudoephedrine, or phenylpropanolamine and may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug.

SECTION III – REGISTRATION REQUIREMENTS

New Pharmacy Registration

Every pharmacy that dispenses a controlled substance must be registered with the DEA. First, a state license must be obtained.

To register as a new pharmacy, the DEA Form 224 must be completed. The cost of the application fee is indicated on the application form. The certificate of registration must be maintained at the registered location and kept available for official inspection. If a person owns and operates more than one pharmacy, each place of business must be registered.

The DEA Form 224 should be completed online (www.DEAdiversion.usdoj.gov).

A paper version of the DEA Form 224 may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

If a pharmacy needs a duplicate Certificate of Registration (DEA Form 223), a copy may be requested online via DEA's Diversion website, www.DEAdiversion.usdoj.gov, or contact DEA Headquarters at 1-800-882-9539 or via e-mail at DEA.Registration.Help@usdoj.gov.

Renewal of Pharmacy Registration

A pharmacy registration must be renewed every three years utilizing DEA Form 224a, Renewal Application for DEA Registration. The cost of the application fee is indicated on the application form.

To renew a registration, the most current information from the pharmacy's existing registration must be utilized. A registrant can renew online no more than 60 days prior to the current expiration date. The DEA Form 224a should be completed online and can be found at www.DEAdiversion.usdoj.gov.

If the registrant has not renewed online approximately 50 days before the registration expiration date, a renewal application is sent to the registrant at the mailing address listed on the current registration. If the renewal form is not received by the 30th day before the expiration date of the current registration, the pharmacy should contact the local DEA Registration Specialist (Appendix J) or DEA Headquarters at 1-800-882-9539 and request a renewal registration form.

NOTE: Once the expiration date has passed and no renewal has been received by DEA, the pharmacy has no authority to handle controlled substances.

Affidavit for Renewal of Retail Chain Pharmacy Registration

Corporations that own or operate a chain of pharmacies may submit a single DEA Form 224b, Retail Pharmacy Registration Affidavit for Chain Renewal. This affidavit, along with a list of the corporation's registrations, is provided in lieu of a separate registration application for each pharmacy registration. No registration may be issued unless the completed affidavit is received by DEA. The corporation should retain a copy of this affidavit with their readily retrievable records for the duration of the registrations covered by the affidavit. A responsible individual must answer the questions listed on the affidavit on behalf of the corporation as they pertain to each registrant. The original affidavit along with the registration application fee and the list of registrations should be mailed to:

Registration Chain Renewal
Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

Change of Business Address

A pharmacy that moves to a new physical location must request a modification of registration. Modifications are handled in the same manner as applications and must be approved by DEA. A modification of registration can be requested online at www.DEAdiversion.usdoj.gov or in writing to the local DEA Registration Specialist (Appendix J) responsible for the area in which the pharmacy is located. If the change of address involves a change in state, the proper state issued license and, if applicable, controlled substances registration must be obtained prior to the approval of modification of the federal registration. If the modification is approved, DEA will issue a new certificate of registration and, if requested, new schedule II order forms (DEA Form 222). The registrant should maintain the new certificate with the old certificate until expiration. A Renewal Application for Registration (DEA Form 224a) will only be sent to the mailing address on file with DEA. It will not be forwarded.

Termination of Registration

A pharmacy that discontinues business activities either completely or only regarding controlled substances must return its DEA registration certificate and unused official order forms (DEA Form 222) to the local DEA Registration Specialist (Appendix J). In addition, DEA may ask for the location of where inventories, prescriptions, and other required controlled substance records will be stored during the requisite two-year retention period.

Unwanted controlled substances in the pharmacy's possession must be disposed of in accordance with DEA regulations (see Section IV, *Transfer or Disposal of Controlled Substances*).

Transfer of Business

A pharmacy registrant that transfers its business operations to another pharmacy registrant must submit in person or by registered or certified mail, return receipt requested, to the Special Agent in Charge in his/her area, at least 14 days in advance of the date of the proposed transfer (unless the Special Agent in Charge waives this time limitation in individual instances), the following information:

1. The name, address, registration number, and authorized business activity of the registrant discontinuing the business (registrant-transferor);
2. The name, address, registration number, and authorized business activity of the person acquiring the business (registrant-transferee);
3. Whether the business activities will be continued at the location registered by the person discontinuing business, or moved to another location (if the latter, the address of the new location should be listed); and
4. The date on which the transfer of controlled substances will occur.

On the day the controlled substances are transferred, a complete inventory must be taken and a copy of the inventory must be included in the records of both the person transferring the business and the person acquiring the business. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. It is not necessary to send a copy of the inventory to the DEA unless requested by the Special Agent in Charge.

To transfer schedule II controlled substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

All controlled substance records required to be kept by the registrant-transferor shall be transferred to the registrant-transferee. Responsibility for the accuracy of records prior to the date of transfer remains with the transferor, but responsibility for custody and maintenance shall be upon the transferee.

If the registrant acquiring the pharmacy owns at least one other pharmacy licensed in the same state as the pharmacy being transferred, the registrant may apply for a new DEA registration prior to the date of transfer. DEA will issue a registration which will authorize the registrant to obtain controlled substances at the time of transfer, but the registrant may not dispense controlled substances until the pharmacy has been issued a valid state pharmacy license.

A DEA registration application to transfer ownership of an existing pharmacy can be facilitated if the applicant includes an affidavit verifying that the pharmacy has been registered by the state licensing agency. The affidavit verifying the existence of the state license should be attached to the initial application for registration.

Denial, Suspension, or Revocation of Registration

Under the CSA (21 U.S.C. § 824 (a)), DEA has the authority to deny, suspend, or revoke a DEA registration upon a finding that the registrant:

1. Has materially falsified the application;
2. Has been convicted of a felony relating to a controlled substance or a List I chemical;
3. Had a State license or registration suspended, revoked, or denied by a competent State authority and is no longer authorized by State law to engage in the manufacturing, distribution, or dispensing of controlled substances or List I chemicals or has had the suspension, revocation, or denial of a registration recommended by competent State authority;
4. Has committed an act which would render the DEA registration inconsistent with the public interest; or
5. Has been excluded (or directed to be excluded) from participation in a program pursuant to Title 42 U.S.C. § 1320a-7(a), that is, a Medicaid or Medicare program.

Denial of Registration in the Public Interest

In determining the public interest, the CSA states the following factors are to be considered (21 U.S.C. § 823 (f)):

1. The recommendation of the appropriate State licensing board or professional disciplinary authority.
2. The applicant's experience in dispensing or conducting research with respect to controlled substances.
3. The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.
4. Compliance with applicable State, Federal, or local laws relating to controlled substances.
5. Such other conduct which may threaten the public health and safety.

Chemical Registration Requirements

Registration is not required for regulated sellers of SLCPs. However, a regulated seller must self-certify with DEA pursuant to federal law (see Section XIV, *Self-Certification*). A regulated seller is defined as a grocery store, general merchandise store, drug store, or other entity engaged in over-the-counter sales of ephedrine (both single-entity and combination products), pseudoephedrine, or phenylpropanolamine products, directly to walk-in customers or in face-to-face transactions by direct sales. A mobile retail vendor is defined as a person or entity that makes sales at retail from a stand that is intended to be temporary or is capable of being moved from one location to another.

Federal law requires any person who is engaged in the wholesale distribution of an SLCP to obtain a registration as a chemical distributor. A distributor who does not meet all the requirements for a regulated seller of SLCPs, or who does not meet the requirements for distributors required to submit "mail-order" reports, is a wholesale distributor.

Note: this would include those pharmacies that sell quantities of SLCPs to institutions, including long term care facilities, jails, and other institutional-type settings for non-patient specific use. Such pharmacies are often referred to as "closed door" pharmacies.

Retail pharmacies that are registered to handle controlled substances need not obtain a separate DEA chemical registration for retail distribution of SLCPs. If a pharmacy desires to engage in the wholesale distribution of bulk quantities of SLCPs, the pharmacy is required to register with DEA as a chemical distributor because these activities fall outside the definition of a regulated seller. Therefore, the pharmacy would be subject to the registration requirements that apply to wholesale distributors for those distribution activities, and subject to the pharmacy requirements for its pharmacy activities. To obtain a DEA chemical distributor registration, a pharmacy may complete the DEA Form 510 online at www.DEAdiversion.usdoj.gov. A paper version may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

SECTION IV – TRANSFER OR DISPOSAL OF CONTROLLED SUBSTANCES

Transfer of Controlled Substances

A pharmacy may hire an outside firm to inventory, package, and arrange for the transfer of its controlled substances to another pharmacy, the original supplier, or the original manufacturer. The pharmacy is responsible for the actual transfer of the controlled substances and for the accuracy of the inventory and records. The records involving the transfer of controlled substances must be kept readily available by the pharmacy for two years for inspection by the DEA.

To transfer schedule II substances, the receiving registrant must issue an official order form (DEA Form 222) or an electronic equivalent to the registrant transferring the drugs. The transfer of schedules III-V controlled substances must be documented in writing to show the drug name, dosage form, strength, quantity, and date transferred. The document must include the names, addresses, and DEA registration numbers of the parties involved in the transfer of the controlled substances.

Transfer to a Pharmacy

If a pharmacy goes out of business or is acquired by a new pharmacy, it may transfer the controlled substances to another pharmacy. On the day the controlled substances are transferred, a complete inventory must be taken which documents the drug name, dosage form, strength, quantity, and date transferred. In addition, DEA Form 222 or the electronic equivalent must be prepared to document the transfer of schedule II controlled substances. This inventory will serve as the final inventory for the registrant going out of business and transferring the controlled substances. It will also serve as the initial inventory for the registrant acquiring the controlled substances. A copy of the inventory must be included in the records of each pharmacy. It is not necessary to send a copy of the inventory to the DEA. The pharmacy acquiring the controlled substances must maintain all records involved in the transfer of the controlled substances for two years.

Transfer to the Original Supplier or Original Manufacturer

Any pharmacy may transfer controlled substances to the original supplier or the original manufacturer that is appropriately registered with the DEA. The pharmacist must maintain a written record showing:

1. The date of the transaction.
2. The name, strength, dosage form, and quantity of the controlled substance.
3. The supplier or manufacturer's name, address, and registration number.

The DEA Form 222 or the electronic equivalent will be the official record for the transfer of schedule II controlled substances.

Disposal of Controlled Substances

A pharmacy may transfer controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. The pharmacy should contact the local DEA Diversion Field Office (Appendix K) for an updated list of DEA registered reverse distributors. In no case should drugs be forwarded to the DEA unless the registrant has received prior approval from the DEA. The DEA procedures established for the disposal of controlled substances must not be construed as altering in any way the state laws or regulations for the disposal of controlled substances.

Reverse Distributors Authorized to Dispose Controlled Substances

A pharmacy may forward controlled substances to a DEA registered reverse distributor who handles the disposal of controlled substances. When a pharmacy transfers schedule II controlled substances to a reverse distributor for destruction, the reverse distributor must issue an official order form (DEA Form 222) or the electronic equivalent to the pharmacy. When schedules III-V controlled substances are transferred to a reverse distributor for destruction, the pharmacy must maintain a record of distribution that lists the drug name, dosage form, strength, quantity, and date transferred. The DEA registered reverse distributor who will destroy the controlled substances is responsible for submitting a DEA Form 41 (Registrants Inventory of Drugs Surrendered) to the DEA when the controlled substances have been destroyed. A DEA Form 41 should **not** be used to record the transfer of controlled substances between the pharmacy and the reverse distributor disposing of the drugs.

A paper version of the DEA Form 41 may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
P.O. Box 2639
Springfield, Virginia 22152-2639

Disposal of Controlled Substances by Persons Not Registered with DEA

On January 21, 2009, DEA published in the Federal Register an Advance Notice of Proposed Rulemaking (ANPRM), *Disposal of Controlled Substances by Persons Not Registered with the Drug Enforcement Administration*. This ANPRM sought comments on how to address the issue of disposal of dispensed controlled substances held by DEA nonregistrants (i.e., ultimate users, long term care facilities). DEA was interested in the possible options that would enable nonregistrants to dispose of unwanted controlled substances, while also protecting public health and public safety, and minimizing the possibility of diversion. The public comment period for this ANPRM ended on March 23, 2009.

SECTION V – SECURITY REQUIREMENTS

Requests for Employment Waivers for Certain Pharmacy Employees

Under 21 C.F.R. § 1301.76(a), a registrant must not employ in a position which allows access to controlled substances any person who has been convicted of a felony relating to controlled substances, or who, at any time, has had an application for DEA registration denied, revoked, or surrendered for cause. "For cause" means surrendering a registration in lieu of, or as a consequence of, any federal or state administrative, civil, or criminal action resulting from an investigation of the individual's handling of controlled substances.

However, 21 C.F.R. § 1307.03 does permit registrants desiring to employ an individual who meets this definition to request an exception to this requirement. The employer must have a waiver approved before allowing such an employee or prospective employee to have access to controlled substances. A waiver request should be sent by the employer to the following address:

Drug Enforcement Administration
Attn: Regulatory Section/ODG
8701 Morrissette Drive
Springfield, Virginia 22152

A registrant that applies for such a waiver should understand that the following factors will be considered by the DEA in the approval process and should provide details relevant to each factor as part of the waiver request submitted, since a waiver will not be considered unless there are valid reasons to believe that diversion is unlikely to occur:

1. A detailed description of the nature and extent of the individual's past controlled substances violations, including all pertinent documentation;
2. Current status of the individual's state licensure;
3. Extent of individual's proposed access to controlled substances. "Access" is not limited to only physical access to controlled substances, but includes any influence over the handling of controlled substances;
4. Registrant's proposed physical and professional safeguards to prevent diversion by the individual;
5. Status of employing registrant regarding handling of controlled substances;
6. Other pertinent information uncovered by DEA in its investigation of the individual's or registrant's handling of controlled substances; and
7. All other relevant factors or materials.

Controlled Substance Theft or Significant Loss

Should a theft or significant loss of any controlled substance occur at a pharmacy, the following procedures must be implemented within one business day of the discovery of the theft or loss.

A. Notify DEA and Local Police

The theft of controlled substances from a registrant is a criminal act and a source of diversion that requires notification to DEA. A pharmacy must notify in writing the local DEA Diversion Field Office (Appendix K) within one business day of discovery of a theft or significant loss of a controlled substance. Although not specifically required by federal law or regulations, the registrant should also notify local law enforcement and state regulatory agencies. Prompt notification to enforcement agencies will allow them to investigate the incident and prosecute those responsible for the diversion. If there is a question as to whether a theft has occurred or a loss is significant, a registrant should err on the side of caution and report it to DEA and local law enforcement authorities.

DEA must be notified directly. This requirement is not satisfied by reporting the theft or significant loss in any other manner. For example, a corporation which owns or operates multiple registered sites and wishes to channel all notifications through corporate management or any other internal department responsible for security, must still provide notice directly to DEA in writing within one business day upon discovery and keep a copy of that notice for its records. The notice must be signed by an authorized individual of the registrant.

B. Complete DEA Form 106

A pharmacy must also complete a DEA Form 106 (Report of Theft or Loss of Controlled Substances) which can be found online at www.DEAdiversion.usdoj.gov under the Quick Links section. The DEA Form 106 is used to document the actual circumstances of the theft or significant loss and the quantities of controlled substances involved. A paper version of the form can be obtained by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
8701 Morrissette Drive
Springfield, Virginia 22152

If completing the paper version, the pharmacy should send the original DEA Form 106 to the local DEA Diversion Field Office (Appendix K) and keep a copy for its records. Please see the *Guidelines for Completing the DEA Form 106* (Appendix I) for additional guidance.

The DEA Form 106 must include the following information:

1. Name and address of the firm (pharmacy),
2. DEA registration number,
3. Date of theft or loss (or when discovered if not known),
4. Name and telephone number of local police department (if notified),
5. Type of theft (e.g., night break-in, armed robbery),
6. List of identifying marks, symbols, or price codes (if any) used by the pharmacy on the labels of the containers, and
7. A listing of controlled substances missing, including the strength, dosage form, and size of container (in milliliters if liquid form) or corresponding National Drug Code numbers.

C. If Investigation Finds No Theft or Loss

If, after the initial notification to DEA, the investigation of the theft or loss determines no such theft or loss of controlled substances occurred, a DEA Form 106 does not need to be filed. However, the registrant must notify DEA in writing of this fact in order to resolve the initial report and explain why no DEA Form 106 was filed regarding the incident.

D. Registrant's Responsibility for Identifying "Significant Loss"

Although the CSA regulations do not define the term "significant loss," it is the responsibility of the registrant to use his/her best judgment to take appropriate action. Whether a "significant loss" has occurred depends, in large part, on the business of the pharmacy and the likelihood of a rational explanation for a particular occurrence. What would constitute a significant loss for a pharmacy may be viewed as comparatively insignificant for a hospital or manufacturer.

Further, the loss of a small quantity of controlled substances, repeated over a period of time, may indicate a significant problem for a registrant, which must be reported. The burden of responsibility is on the registrant to identify what is a significant loss and make the required report to DEA.

When determining whether a loss is significant, a registrant should consider, among others, the following factors:

1. The actual quantity of controlled substances lost in relation to the type of business;
2. The specific controlled substances;
3. Whether the loss of the controlled substances can be associated with access to those controlled substances by specific individuals, or whether the loss can be attributed to unique activities that may take place involving the controlled substances;
4. A pattern of losses over a specific time period, whether the losses appear to be random, and the results of efforts taken to resolve the losses; and, if known
5. Whether the specific controlled substances are likely candidates for diversion; and
6. Local trends and other indicators of the diversion potential of the missing controlled substances.

If it is determined that the loss is not significant, the registrant should place a record of the occurrence in a theft and loss file for future reference. Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106, but rather should be noted in a separate log at the pharmacy management's discretion.

In-Transit Loss

When all or part of an in-transit shipment of controlled substances fails to reach its intended destination, the supplier is responsible for reporting the in-transit loss of controlled substances to DEA. The purchaser is responsible for reporting any loss of controlled substances after he/she has signed for or taken custody of a shipment. If it is discovered after that point that an in-transit loss or theft has occurred; the purchaser must then submit a DEA Form 106. If the purchaser does not take custody of the shipment and instead returns it to the supplier, it is the supplier's responsibility for reporting any loss of controlled substances in the original shipment.

In-Transit Loss from Central Fill Pharmacy

Central fill pharmacies must comply with 21 C.F.R. § 1301.74(e) when selecting private, common or contract carriers to transport filled prescriptions to a retail pharmacy for delivery to an ultimate user. Pursuant to 21 C.F.R. § 1301.76(d), when a central fill pharmacy contracts with private, common or contract carriers to transport filled prescriptions to a retail pharmacy, the central fill pharmacy is responsible for reporting the in-transit loss upon discovery of such loss by use of a DEA Form 106. In addition, when a retail pharmacy contracts with private, common or contract carriers to retrieve filled prescriptions from a central fill pharmacy, the retail pharmacy is responsible for reporting in-transit losses upon discovery using a DEA Form 106.

Breakage and Spillage

The breakage or spillage of controlled substances does not constitute a "loss" of controlled substances. When there is breakage, damage, or spillage or some other form of destruction, any recoverable controlled substances must be disposed of according to DEA requirements. When this disposal occurs, it must be reported to DEA on a DEA Form 41 (Registrants Inventory of Drugs Surrendered). Damaged goods may also be disposed of through shipment to a reverse distributor or by a DEA approved process as defined in Section IV, *Transfer or Disposal of Controlled Substances*.

A paper version of the DEA Form 41 may be requested by writing to:

Drug Enforcement Administration
Attn: Registration Section/ODR
8701 Morrissette Drive
Springfield, Virginia 22152

Robberies and Burglaries Involving Controlled Substances

The Controlled Substance Registrant Protection Act of 1984 (CSRPA) was enacted to protect DEA registrants against certain crimes (see Title 18 U.S.C. § 2118 for a complete text of CSRPA). The CSRPA provides for the federal investigation of controlled substances thefts and robberies if any of the following conditions are met:

1. The replacement cost of the controlled substances taken is $500 or more.
2. Interstate or foreign commerce was involved in the execution of the crime.
3. A person was killed or suffered significant bodily injury as a result of the crime.

Penalties Upon Conviction - The perpetrator(s) convicted of violating CSRPA's provisions may be subject to the following penalties:

1. Burglary or robbery - a maximum $25,000 fine and/or 20 years imprisonment.
2. If a dangerous weapon was used to carry out the crime - a maximum $35,000 fine and/or 25 years imprisonment.
3. If death resulted from the crime - a maximum $50,000 fine and/or life imprisonment.

SECTION VI – RECORDKEEPING REQUIREMENTS

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance purchased, received, stored, distributed, dispensed, or otherwise disposed of. These records are required to provide accountability of all controlled substances from the manufacturing process through the dispensing pharmacy and to the ultimate user. The closed system reduces the potential for diversion of controlled substances.

All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials. Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant. All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records. Recordkeeping requirements for prescriptions are detailed in Section VI, *Prescription Records*.

Readily retrievable is defined as:

1. Records kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time, and/or
2. Records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Required Records

The records which must be maintained by a pharmacy are:

1. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
2. Power of Attorney authorization to sign order forms
3. Receipts and/or invoices for schedules III, IV, and V controlled substances
4. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
5. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
6. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
7. Reports of Theft or Significant Loss (DEA Form 106), if applicable
8. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
9. Records of transfers of controlled substances between pharmacies
10. DEA registration certificate
11. Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005

Central Recordkeeping

A registrant desiring to maintain shipping and financial records (but not executed official order forms) at a central location rather than the registered location must submit written notification of his/her intention by registered or certified mail, return receipt requested, in triplicate, to the Special Agent in Charge of the local DEA Diversion Field Office in which the registrant is located (Appendix K). Unless the registrant is informed by the DEA that the permission to keep central records is denied, the registrant may begin maintaining central records 14 days after DEA receives this notification. Central recordkeeping requirements are described in 21 C.F.R. § 1304.04. Central recordkeeping permits are no longer issued by the DEA.

Prescription Records

Pharmacies have two options for filing paper prescription records and one option for electronic prescription records. If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the pharmacy must choose a filing system that would comply with both federal and state law. All prescription records must be *readily retrievable* for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:

Paper Prescriptions Records Option 1 (Three separate files):

1. A file for schedule II controlled substances dispensed.
2. A file for schedules III, IV and V controlled substances dispensed.
3. A file for all noncontrolled drugs dispensed.

Paper Prescriptions Records Option 2 (Two separate files):

1. A file for all schedule II controlled substances dispensed.
2. A file for all other drugs dispensed (noncontrolled and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.

Electronic Prescription Records

1. If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.
2. Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to pharmacists or pharmacies.
3. Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of 21 C.F.R. §1311. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the DEA or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sortable by prescriber name, patient name, drug dispensed, and date filled.

SECTION VII – INVENTORY REQUIREMENTS

An "inventory" is a complete and accurate list of all stocks and forms of controlled substances in the possession of the registrant as determined by an actual physical count for schedule II controlled substances and an estimated count or measure of the contents of a schedule III, IV, or V controlled substance (unless the container holds more than 1,000 tablets or capsules in which case an exact count of the contents must be made). The CSA also requires that all inventory records be maintained at the registered location in a readily retrievable manner for at least two years for copying and inspection. In addition, the inventory records of schedule II controlled substances must be kept separate from all other controlled substances.

Initial Inventory

When issued a DEA registration, a registrant must take an initial inventory, which is an actual physical count of all controlled substances in their possession. If there are no stocks of controlled substances on hand, the registrant should make a record showing a zero inventory. There is no requirement to submit a copy of the inventory to the DEA. The C.F.R. requires that the inventory include:

1. The date of the inventory,
2. Whether the inventory was taken at the beginning or close of business,
3. The name of each controlled substance inventoried,
4. The finished form of each of the substances (e.g., 10 milligram tablet),
5. The number of dosage units of each finished form in the commercial container (e.g., 100 tablet bottle),
6. The number of commercial containers of each finished form (e.g., four 100 tablet bottles), and
7. A count of the substance - if the substance is listed in schedule II, an exact count or measure of the contents or if the substance is listed in schedules III, IV, or V, an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case, an exact count of the contents is required.

DEA recommends, but does not require, an inventory record include the name, address, and DEA registration number of the registrant, and the signature of the person or persons responsible for taking the inventory.

Biennial Inventory

Following the initial inventory, the registrant is required to take a biennial inventory (every two years), which requires the same information as the initial inventory (see list above) of all controlled substances on hand. The biennial inventory may be taken on any date which is within two years of the previous inventory date. There is no requirement to submit a copy of the inventory to DEA.

Newly Scheduled Controlled Substance Inventory

When a drug not previously listed as a controlled substance is scheduled or a drug is rescheduled, the drug must be inventoried as of the effective date of scheduling or change in scheduling.

SECTION VIII – ORDERING CONTROLLED SUBSTANCES

Ordering Schedule II Controlled Substances

Only schedules I and II controlled substances are ordered with an official order form, DEA Form 222, or the electronic equivalent (see below, *Controlled Substance Ordering System (CSOS) – Electronic Order Forms*). A DEA Form 222 is required for each distribution, purchase, or transfer of a schedule II controlled substance.

When a controlled substance has been moved by DEA from schedule II to another schedule at the federal level, in many states it may remain a schedule II controlled substance pending any legislative or administrative action that may result from the federal action. Many states require transactions that involve substances they classify as schedule II be made via official order forms (DEA Form 222) or the electronic equivalent. When federal law or regulations differ from state law or regulations, a pharmacy is required to abide by the more stringent aspects of both the federal and state requirements. When the use of DEA Form 222 or the electronic equivalent for the transfer of a controlled substance is not required under federal law, its use as mandated by these states does not violate federal law and is therefore permitted.

Requesting Official Order Forms

The unexecuted DEA Form 222 can be requested initially by checking "block 3" on the application for a new registration (DEA Form 224). The DEA Form 224 can be found online at www.DEAdiversion.usdoj.gov.

Once a registrant has received a DEA registration number, additional DEA Forms 222 may be ordered online at www.DEAdiversion.usdoj.gov. When requesting additional DEA Forms 222 online, a valid DEA registration number, business name, and contact telephone number are required. The registrant may also request DEA Forms 222 by calling the DEA Headquarters Registration Section at 1-800-882-9539 or by contacting the local DEA Registration Specialist (Appendix J).

Each book of DEA Form 222 consists of seven sets of forms. Each pharmacy is provided a maximum of six books at one time unless its needs exceed this limit. In such a case, the pharmacy should contact the local DEA Registration Specialist (Appendix J) to request additional books.

Completing Official Order Forms

When ordering schedule II controlled substances, the purchaser is responsible for filling in the number of packages, the size of the package, and the name of the item. Each DEA Form 222 must be signed and dated by a person authorized to sign a registration application or a person granted power of attorney (see below, *Power of Attorney to Sign an Official Order Form*). When the items are received, the pharmacist must document on the purchaser's copy (copy three) the actual number of packages received and the date received.

The executed DEA Form 222 must be maintained separately from the pharmacy's other business records. However, this does not preclude a registrant from attaching a copy of the supplier's invoice to the related DEA Form 222.

Title 21 C.F.R. § 1305.15(a)(1) requires that, for orders using the DEA Form 222, an order must not be filled if the order is not complete, legible, or properly prepared, executed, or endorsed, or if the order shows any alteration, erasure, or change of any description. For a discussion of the circumstances in which an electronic order must not be filled see below, *Controlled Substance Ordering System (CSOS) – Electronic Order Forms.*

A supplier may refuse to accept an order for any reason as set forth under 21 C.F.R. § 1305.15(c). If a supplier refuses to accept an order, a statement that the order is not accepted is sufficient. If an order is refused, the supplier must return copies one and two of the DEA Form 222 to the purchaser with a statement explaining the reason the order was refused. For electronic orders, the supplier must notify the purchaser and provide a statement as to the reason (see below, *Controlled Substance Ordering System (CSOS) – Electronic Order Forms*).

DEA policy does not preclude the substitution of identical products differing in packaging size from those initially ordered, provided that the actual quantity received does not exceed the amount initially ordered and that the National Drug Code number reflected is that of the actual product shipped. For example, a distributor may substitute five bottles of 100, 2 milligram tablets for one bottle of 500, 2 milligram tablets or any variation thereof.

Cancellation and Voiding an Official Order Form

A purchaser may cancel an order (or partial order) on a DEA Form 222 by notifying the supplier in writing. The supplier must indicate the cancellation on Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing "cancelled" in the space provided for the number of items shipped.

A supplier may void part or all of an order on a DEA Form 222 by notifying the purchaser in writing. The supplier must indicate the voiding in Copies 1 and 2 of the DEA Form 222 by drawing a line through the cancelled item(s) and printing "void" in the space provided for the number of items shipped. For information regarding cancelled electronic orders, see below, *Controlled Substance Ordering System (CSOS) – Electronic Order Forms*.

Power of Attorney to Sign an Official Order Form

Any registrant (pharmacy) may authorize one or more individuals, whether or not they are located at the registered location, to obtain and execute DEA Forms 222 by granting a power of attorney to each such individual. The power of attorney must be signed by the same person who signed the most recent application for registration or renewal registration, as well as the individual being authorized to obtain and execute the DEA Forms 222.

The power of attorney may be revoked at any time by the person who granted and signed the power of attorney. Only if the renewal application is signed by a different person is it necessary to

grant a new power of attorney when the pharmacy completes a renewal registration. The power of attorney should be filed with executed DEA Forms 222 as a readily retrievable record. The power of attorney is not submitted to DEA.

Suggested formats for granting and revoking a power of attorney follow:

Power of Attorney for DEA Forms 222 and Electronic Orders

_____ (Name of registrant)
_____(Address of registrant)
_____(DEA registration number)

I, _____(name of person granting power), the undersigned, who is authorized to sign the current application for registration of the above named registrant under the Controlled Substances Act or Controlled Substances Import and Export Act, have made, constituted, and appointed, and by these presents, do make, constitute, and appoint _____(name of attorney-in-fact), my true and lawful attorney for me in my name, place, and stead, to execute applications for books of official order forms and to sign such order forms in requisition for schedule I and II controlled substances, in accordance with Section 308 of the Controlled Substances Act (21 U.S.C. 828) and part 1305 of Title 21 of the Code of Federal Regulations. I hereby ratify and confirm all that said attorney shall lawfully do or cause to be done by virtue hereof.

_____
(Signature of person granting power)

I, _____(name of attorney-in-fact), hereby affirm that I am the person named herein as attorney-in-fact and that the signature affixed hereto is my signature.

_____
(Signature of attorney-in-fact)

Witnesses:
1. _____
2. _____

Signed and dated on the ___ day of _____in the year____ at _____ .

Notice of Revocation

The foregoing power of attorney is hereby revoked by the undersigned, who is authorized to sign the current application for registration of the above-named registrant under the Controlled Substances Act. Written notice of this revocation has been given to the attorney-in-fact _____ this same day.

_____
(Signature of person revoking power)

Witnesses:
1. _____
2. _____

Signed and dated on the ___ day of _____in the year____ at _____ .

Lost or Stolen Order Forms

When a pharmacist has not received an expected shipment of controlled substances, he/she should first contact the supplier to determine whether the original DEA Form 222 was received. If the original order form has been lost or stolen, the pharmacist must complete a second order form so the supplier can fill the original order. The pharmacist must also prepare a statement which includes the first order form's serial number and date, and verify that the drugs ordered were never received. The pharmacy must attach a copy of the statement to the second order form that is sent to the supplier. In addition, the pharmacist must keep a copy of the statement with copy three from the first and second order forms.

A pharmacy, upon discovery of the loss or theft of used or unused order forms, must immediately report the loss to the local DEA Diversion Field Office (Appendix K) and provide the serial numbers of each lost or stolen order form. If an entire book or multiple books of order forms are lost or stolen, and the serial numbers of the missing forms cannot be identified, the pharmacist must report the approximate date of issuance (in lieu of the serial numbers) to the DEA. If an unused order form reported stolen or lost is later recovered or found, the pharmacy must immediately notify the local DEA Diversion Field Office.

Controlled Substance Ordering System (CSOS) – Electronic Order Forms

Any registrant permitted to order schedule II controlled substances may do so electronically via the DEA Controlled Substance Ordering System (CSOS) and maintain the records of these orders electronically for two years. The use of electronic orders is optional; registrants may continue to issue orders on a paper DEA Form 222. CSOS allows for secure electronic transmission of controlled substance orders without the supporting paper DEA Form 222. The adoption of the CSOS standards is the only allowance for the electronic transmission of schedule II controlled substance orders between controlled substance manufacturers, distributors, pharmacies, and other DEA authorized entities. CSOS uses Public Key Infrastructure (PKI) technology, which requires CSOS users to obtain a CSOS digital certificate for electronic ordering. The electronic orders must be signed using a digital signature issued by a Certification Authority (CA) run by the DEA.

Digital certificates can be obtained only by registrants and individuals granted power of attorney by registrants to sign orders. A registrant must appoint a CSOS coordinator who will serve as that registrant's recognized agent regarding issues pertaining to issuance of, revocation of, and changes to, digital certificates issued under that registrant's DEA registration. A CSOS digital certificate will be valid until the DEA registration under which it is issued expires or until the CSOS CA is notified that the certificate should be revoked. Certificates will be revoked if the certificate holder is no longer authorized to sign schedule II orders for the registrant, if the information on which the certificate is based changes, or if the digital certificate used to sign electronic orders has been compromised, stolen, or lost.

A "Questions and Answers" page about the CSOS certificate is available on the DEA E-Commerce Program website at www.DEAecom.gov. Applicants can download the Diversion PKI CSOS Enrollment document and the CSOS Subscriber's Manual for assistance on the enrollment process. DEA maintains a support line to assist applicants and subscribers with issues pertaining to certificate enrollment, issuance, revocation, and renewal. Staff is available from 8:00 a.m. to 6:00 p.m. (Eastern Time), Monday through Friday at 1-877-332-3266 if further assistance is needed.

Unaccepted and Defective Electronic Orders

An electronic order for controlled substances may not be filled if any of the following occurs:

1. The required data fields have not been completed.
2. The order is not signed using a digital certificate issued by DEA.
3. The digital certificate used has expired or been revoked prior to signature.
4. The purchaser's public key will not validate the digital certificate.
5. The validation of the order shows that the order is invalid for any reason.

If an order cannot be filled, the supplier must notify the purchaser and provide a statement as to the reason (e.g., improperly prepared or altered). A supplier may, for any reason, refuse to accept any order. If a supplier refuses, a statement that the order is not accepted is sufficient.

When a purchaser receives an unaccepted electronic order from the supplier, the purchaser must electronically link the statement of nonacceptance to the original order. The original statement must be retained for two years. Neither a purchaser nor a supplier may correct a defective order. The purchaser must issue a new order for the order to be filled.

Cancellation and Voiding of Electronic Orders

A supplier may void all (or part) of an electronic order by notifying the purchaser of the voiding. If the entire order is voided, the supplier must make an electronic copy of the order and indicate "Void" on the copy and return it to the purchaser. The supplier is not required to retain a record of orders that are not filled. The purchaser must retain an electronic copy of the voided order. Should a supplier partially void an order, the supplier must indicate in the linked record that nothing was shipped for each item voided.

Lost Electronic Orders

If a purchaser determines that an unfilled electronic order has been lost before or after receipt, the purchaser must provide, to the supplier, a signed statement. This statement must include the unique tracking number and date of the lost order and state that the goods covered by the first order were not received through loss of that order. If the purchaser executes a new order to replace the lost order, the purchaser must electronically link an electronic record of the second order and a copy of the statement with the record of the first order and retain them both. If the supplier to whom the order was directed subsequently receives the first order, the supplier must indicate that it is "not accepted" and return it to the purchaser. The purchaser must link the returned order to the record of that order and the statement.

Ordering Schedules III-V Controlled Substances

The registrant must keep a receipt (invoice or packing slip) on which it records the date the drugs were received and confirm that the order is accurate. These receipts must also contain the name of each controlled substance, the finished form, the number of dosage units of finished form in each commercial container, and the number of commercial containers ordered and received. In addition, these receipts must be maintained in a readily retrievable manner for inspection by the DEA.

SECTION IX – VALID PRESCRIPTION REQUIREMENTS

To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number.

The prescription must also include:

1. Drug name
2. Strength
3. Dosage form
4. Quantity prescribed
5. Directions for use
6. Number of refills authorized (if any)

A prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (i.e., secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature. The practitioner is responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state.

Who May Issue

A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice, and
2. Registered with DEA or exempted from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners), or
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered, provided that additional requirements as set forth in the C.F.R. are met.

Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances.

A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Corresponding Responsibility

A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA (21 U.S.C. § 829). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional license (see *United States v. Kershman*, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]).

Electronic Prescriptions

On March 31, 2010 the DEA published in the Federal Register an interim final rule *Electronic Prescriptions for Controlled Substances* which became effective June 1, 2010. The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules.

Persons who wish to dispense controlled substances using electronic prescriptions must select software that meets the requirements of this rule. As of June 1, 2010, only those electronic pharmacy applications that comply with all of DEA's requirements as set forth in 21 C.F.R. §1311 may be used by DEA-registered pharmacies to electronically receive and archive controlled substances prescriptions and dispense controlled substances based on those prescriptions.

A registered pharmacy may process electronic prescriptions for controlled substances only if the following conditions are met:

1. The pharmacy uses a pharmacy application that meets all of the applicable requirements of 21 C.F.R. §1311, and
2. The prescription is otherwise in conformity with the requirements of the CSA and 21 C.F.R. §1311.

A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy. The audit report the pharmacy will receive from the pharmacy application provider will indicate if the application is capable of importing, displaying, and storing DEA-required prescription information accurately and consistently. If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display the information related to the name, address, and registration number of the practitioner, patient name and address, and prescription information (drug name, strength, quantity, directions for use), the indication of signing, and the number of refills, the pharmacy must not accept electronic prescriptions for the controlled substance.

If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display **other information** required for prescriptions, the pharmacy must not accept electronic prescriptions for controlled substances that are subject to the additional information requirements. For example, until the audit or certification report indicates that the pharmacy application can import, display, and store both a hospital DEA number and the individual practitioner's extension number, the pharmacy must not accept electronic prescriptions that include only a hospital DEA registration number. The pharmacy may, however, use the application to process other controlled substance prescriptions if the audit or certification report has found that the pharmacy application meets all other requirements.

The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions (to the extent such alterations are permitted under DEA regulations). The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions.

When a pharmacist fills a prescription in a manner that would require, under 21 C.F.R. §1306, the pharmacist to make notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or linked files. ***When a prescription is received electronically, the prescription and all required annotations must be stored electronically.***

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist must check the pharmacy's records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy must mark the electronic version as void or cancelled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

Verification of Practitioner Registration

A pharmacist has a responsibility to ensure that a prescription has been issued by an appropriately registered or exempt practitioner (see above, *Who May Issue*). As such, it is helpful to be familiar with how a DEA registration number is constructed and to whom such registrations are issued.

Construction of Valid DEA Registration Number for Practitioners

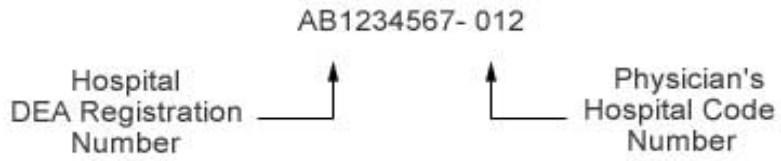
Knowing how a DEA registration number is constructed can be a useful tool for recognizing a forged prescription (see Appendix D, *Pharmacist's Guide to Prescription Fraud*). Prior to October 1, 1985, DEA registration numbers for physicians, dentists, veterinarians, and other practitioners started with the letter A. New registration numbers issued to practitioners after that date begin with the letter B or F. Registration numbers issued to mid-level practitioners begin with the letter M. The first letter of the registration number is almost always followed by the first letter of the registrant's last name (e.g., J for Jones or S for Smith) and then a computer generated sequence of seven numbers (such as MJ3614511).

Practitioner's Use of a Hospital's DEA Registration Number

Practitioners (e.g., intern, resident, staff physician, mid-level practitioner) who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that:

1. The dispensing, administering, or prescribing is in the usual course of professional practice.
2. The practitioner is authorized to do so by the state in which they practice.
3. The hospital or institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state.
4. The practitioner acts only within the scope of employment in the hospital or institution.
5. The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner.

An example of a specific internal code number is depicted below:



A current list of internal codes and the corresponding individual practitioners is to be maintained by the hospital or other institution. This list is to be available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. Pharmacists should contact the hospital or other institution for verification if they have any doubts in filling such a prescription.

Exemption of Federal Government Practitioners from Registration

The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons, who is authorized to administer, dispense, or prescribe, but not to procure or purchase controlled substances in the course of his or her official duties. Such officials must follow procedures set forth in 21 C.F.R. part 1306 regarding prescriptions, but must also state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his or her Social Security identification number.

If federal government practitioners wish to maintain a DEA registration for a private practice, which would include prescribing for private patients, these practitioners must be fully licensed to handle controlled substances by the state in which they are located.

Registration Requirements for Mid-Level Practitioners

Mid-level practitioners (MLPs) are registered and authorized by the DEA and the state in which they practice to dispense, administer, and prescribe controlled substances in the course of professional practice (see Appendix B, *Definitions*). Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, physician assistants, optometrists, ambulance services, animal shelters, euthanasia technicians, nursing homes, and homeopathic physicians.

MLPs may apply for an individual DEA registration granting controlled substance privileges. However, such registration is contingent upon the authority granted by the state in which they are licensed. The DEA may register MLPs whose states clearly authorize them to prescribe, dispense, and administer controlled substances in one or more schedules.

It is incumbent upon the pharmacist who fills the prescription to ensure that the MLP is prescribing within the parameters established by the state in which he/she practices. MLP authority to prescribe controlled substances varies greatly by state. Pharmacists should check with the state licensing or controlled substances authority to determine which MLP disciplines are authorized to prescribe controlled substances in the state. Pharmacists may also visit the DEA Diversion website at www.DEAdiversion.usdoj.gov for a chart indicating the prescribing authority of MLPs by state (click on *Registration Support* and scroll down to *Mid-Level Practitioners Authorization by State*).

For electronic prescriptions written by mid-level practitioners, if required by State law, a supervisor's name and DEA number may be listed on the prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

Schedule II Controlled Substances

Schedule II controlled substances require a written prescription which must be manually signed by the practitioner or an electronic prescription that meets all DEA requirements for electronic prescriptions for controlled substances. There is no federal time limit within which a schedule II

prescription must be filled after being signed by the practitioner. However, the pharmacist must determine that the prescription is still needed by the patient. While some states and many insurance carriers limit the quantity of controlled substances dispensed to a 30-day supply, there are no express federal limits with respect to the quantities of drugs dispensed via a prescription. However, the amount dispensed must be consistent with the requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. For a schedule II controlled substance, an oral order is only permitted in an emergency situation (see Section X, *Emergency Dispensing*).

Refills

The refilling of a prescription for a controlled substance listed in schedule II is prohibited (21 U.S.C. § 829(a)).

Issuance of Multiple Prescriptions for Schedule II Controlled Substances

The DEA has revised its regulations regarding the issuance of multiple prescriptions for schedule II controlled substances. Under the new regulation, which became effective December 19, 2007, an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each prescription must be issued on a separate prescription blank.
2. Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
3. The individual practitioner must provide written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.
4. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.
5. The issuance of multiple prescriptions is permissible under applicable state laws.
6. The individual practitioner complies fully with all other applicable requirements under the CSA and C.F.R., as well as any additional requirements under state law.

It should be noted that the implementation of this change in the regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Facsimile Prescriptions for Schedule II Controlled Substances

In order to expedite the filling of a prescription, a prescriber may transmit a schedule II prescription to the pharmacy by facsimile. The original schedule II prescription must be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually

dispensed. The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept.

Exceptions for Schedule II Facsimile Prescriptions

DEA has granted three exceptions to the facsimile prescription requirements for schedule II controlled substances. The facsimile of a schedule II prescription may serve as the original prescription as follows:

1. A practitioner prescribing a schedule II narcotic controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription a "written prescription" and no further documentation is required. All normal requirements of a legal prescription must be followed.
2. Practitioners prescribing schedule II controlled substances for residents of Long Term Care Facilities may transmit a prescription by facsimile to the dispensing pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy. No further documentation is required.
3. A practitioner prescribing a schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state, may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription. No further documentation is required.

Schedules III-V Controlled Substances

A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or a call-in as indicated below (see *Telephone Authorization for Schedules III-V Controlled Substances)*.

Refills

Schedules III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date of issue. After five refills or after six months, whichever occurs first, a new prescription is required.

When a prescription for any controlled substance in schedules III or IV is refilled, the following information must be entered on the back of the prescription: the dispensing pharmacist's initials, the date the prescription was refilled, and the amount of drug dispensed on the refill. If the pharmacist only initials and dates the back of the prescription, the pharmacist will be deemed to have dispensed a refill for the full face amount of the prescription.

Electronic Recordkeeping of Schedules III-IV Prescription Information

A pharmacy is permitted to use an electronic recordkeeping system for documenting refills as an alternative to the manual method for the storage and retrieval of original paper prescription orders for schedules III and IV controlled substances.

The electronic system must provide online retrieval of original prescription information for those prescriptions which are currently authorized for refill. The information must include, but is not limited to: the original prescription number; date of issuance; full name and address of the patient; the prescriber's name, address, and DEA registration number; the name, strength, dosage form and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed); and the total number of refills authorized by the prescriber.

In addition, the electronic system must provide online retrieval of the current refill history for schedules III or IV controlled substance prescriptions. This information must include, but is not limited to: the name of the controlled substance, the date of refill, the quantity dispensed, the dispensing pharmacist's identification code or name/initials for each refill, and the total number of refills dispensed to date for that prescription.

The pharmacist must verify and document that the refill data entered into the system is correct. All computer generated prescription/refill documentation must be stored in a separate file at the pharmacy and must be maintained for a period of two years from the dispensing date. To meet the C.F.R. recordkeeping requirements, the pharmacy's electronic system must comply with the following guidelines:

1. If the system provides a hard copy printout of each day's controlled substance prescription refills, each pharmacist who refilled those prescriptions must verify his/her accuracy by signing and dating the printout as he/she would sign a check or legal document.
2. The printout must be provided to each pharmacy that uses the computer system within 72 hours of the date on which the refill was dispensed. The printout must be verified and signed by each pharmacist who dispensed the refills.
3. In lieu of such a printout, the pharmacy must maintain a bound logbook or a separate file in which each pharmacist involved in the day's dispensing signs a statement, verifying that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown.
4. A pharmacy's electronic system must have the capability of printing out any refill data which the pharmacy must maintain under the CSA. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance, by either brand or generic name or both, dispensed by the pharmacy. Such a printout must include:

    - Prescribing practitioner's name
    - Patient's name and address
    - Quantity and date dispensed on each refill
    - Name or identification code of the dispensing pharmacist
    - Original prescription number

In any electronic system employed by a user pharmacy, the central recordkeeping location must be capable of providing a printout to a requesting pharmacy of the above information within 48 hours.

5. In case a pharmacy's electronic system experiences downtime, the pharmacy must have a back-up procedure to document in writing refills of schedules III or IV controlled substances. This procedure must ensure that refills are authorized by the original prescription, that the maximum number of refills has not been exceeded, and that all required data is retained for online entry as soon as possible.

A pharmacy may use only one of the two systems described (i.e., manual or electronic) for storage and retrieval of prescription order refill information of schedules III or IV controlled substances.

Facsimile Prescriptions for Schedules III-V Controlled Substances

Prescriptions for schedules III-V controlled substances may be transmitted by facsimile from the practitioner or the practitioner's agent to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription as long as the practitioner has manually signed the prescription.

Telephone Authorization for Schedules III-V Prescriptions

A pharmacist may dispense a controlled substance listed in schedules III, IV, or V pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription except for the signature of the practitioner (see Appendix D, *Pharmacist's Guide to Prescription Fraud*).

Transfer of Schedules III-V Prescription Information

A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one time basis only. However, pharmacies electronically sharing a real-time, on-line database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

Transfers are subject to the following requirements:

The transfer must be communicated directly between two licensed pharmacists and the transferring pharmacist must record the following information:

1. Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.
2. Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.

3. Record the date of the transfer and the name of the pharmacist transferring the information.

For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to be on a prescription and include:

1. Date of issuance of original prescription.
2. Original number of refills authorized on original prescription.
3. Date of original dispensing
4. Number of valid refills remaining and date(s) and locations of previous refill(s).
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
6. Name of pharmacist who transferred the prescription.
7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

For electronic prescriptions being transferred electronically, the transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

1. The date of the original dispensing
2. The number of refills remaining and the date(s) and locations of previous refills
3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
4. The name of the pharmacist transferring the prescription.
5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription (listed above).

The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.

The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

Prescription Monitoring Programs

A prescription monitoring program is a state-administered data collection system used to gather prescription information. This information may be made available to state and federal investigators on a need-to-know basis.

Many states have established an electronic prescription drug monitoring program because it has proven to be an effective tool for detecting pharmaceutical diversion and for developing pharmacist and physician medical education programs. These programs heighten awareness about diversion, prescription drug abuse, drug trends, and are useful for tracking prescription medication dispensed within a state. In some states, the data can be used by pharmacists to identify potential "doctor shoppers" and those who attempt to obtain controlled substances by fraud, forgery, or deceit.

In the states that have adopted these programs, a large part of their success has been attributed to the pharmacists' participation. The DEA strongly endorses prescription monitoring programs.

SECTION X – DISPENSING REQUIREMENTS

Required Information for Prescription Labels

The pharmacist dispensing a prescription for a controlled substance listed in schedules II, III, IV, or V must affix to the package a label showing date of filling, the pharmacy name and address, the serial (prescription) number, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law. If a prescription is filled at a central fill pharmacy, the central fill pharmacy must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy.

Federal Food and Drug Administration regulations require that the label of any drug listed as a "controlled substance" in schedules II, III, or IV of the CSA must, when dispensed to or for a patient, contain the following warning: *CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.* In addition, a pharmacist who receives a prescription for a controlled substance must dispense that prescription to the patient or a member of the patient's household. To provide the controlled substance to anyone other than the patient or a member of the patient's household is distribution, not dispensing.

Schedule II Controlled Substance Prescriptions

A pharmacist may dispense a schedule II controlled substance, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except in an emergency situation as described below.

Emergency Dispensing

An "emergency prescription" in this context, is defined to mean that the immediate administration of the drug is necessary for proper treatment of the intended ultimate user, that no alternative treatment is available (including a drug which is not a schedule II controlled substance), and it is not possible for the prescribing practitioner to provide a written prescription for the drug at that time. In a bona fide emergency, a practitioner may telephone a schedule II prescription to the pharmacist who may then dispense the prescription. The prescribing practitioner must provide a written and signed prescription to the pharmacy within seven days and meet the below requirements:

1. The drug prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription order.
2. The prescription order must be immediately reduced to writing by the pharmacist and must contain all information, except for the prescribing practitioner's signature.
3. If the prescribing individual practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using his or her telephone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity.

4. Within seven days after authorizing an emergency telephone prescription, the prescribing practitioner must furnish the pharmacist a written, signed prescription for the controlled substance prescribed. The prescription must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven day period. Upon receipt, the dispensing pharmacist must attach this written prescription to the oral emergency prescription which had earlier been reduced to writing by the pharmacist. By regulation, the pharmacist must notify the local DEA Diversion Field Office (Appendix K) if the prescriber fails to provide a written prescription within seven days. Failure of the pharmacist to do so will void the authority conferred on the pharmacy to dispense the controlled substance without a written prescription of a prescribing practitioner.
5. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order.

Partial Dispensing

A prescription for a schedule II controlled substance may be partially dispensed if the pharmacist is unable to supply the full quantity of a written or emergency oral (telephone) prescription, provided the pharmacist notes the quantity supplied on the front of the written prescription, on a written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion may be dispensed within 72 hours of the first partial dispensing. However, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

Partial Filling of Schedule II Prescriptions for Terminally Ill or Long Term Care Facility Patients

A prescription for a schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.

The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" must be deemed to have been filled in violation of the CSA. For each partial filling, the dispensing pharmacist must record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or terminally ill patients are valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

Schedules III-V Controlled Substance Prescriptions

A pharmacist may dispense a controlled substance in schedules III, IV, or V having received either a paper prescription signed by a practitioner, a facsimile of that prescription transmitted by the practitioner or their agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or an oral prescription made by an individual practitioner. The pharmacist must promptly reduce the oral prescription to writing, including all required information except the signature of the prescribing practitioner.

Partial Dispensing

A pharmacist may partially dispense a prescription for schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued.

Dispensing Without a Prescription

Dispensing a controlled substance without a prescription is outlined in 21 C.F.R. § 1306.26. The regulation states that a controlled substance listed in schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:

1. Such dispensing is made only by a pharmacist and not by a non-pharmacist employee even if under the supervision of a pharmacist (although after the pharmacist has fulfilled his or her professional and legal responsibilities, the actual cash, credit transaction, or delivery, may be completed by a non-pharmacist);
2. Not more than 240 cc. (8 ounces) of any such controlled substance containing opium, nor more than 120 cc. (4 ounces) of any other such controlled substance, nor more than 48 dosage units of any such controlled substance containing opium, nor more than 24 dosage units of any other such controlled substance, may be dispensed at retail to the same purchaser in any given 48-hour period;
3. The purchaser is at least 18 years of age and the pharmacist requires every purchaser of a controlled substance under this section not known to him or her to furnish suitable identification (including proof of age where appropriate);
4. A bound record book (which must be maintained in accordance with the recordkeeping requirement of 21 C.F.R. § 1304.04) for dispensing of controlled substances is maintained by the pharmacist, which contains the name and address of the purchaser, the name and quantity of the controlled substance purchased, the date of each purchase, and the name or initials of the pharmacist who dispensed the substance to the purchaser;
5. The prescription is not required for distribution or dispensing of the substance pursuant to any other Federal, State or local law; and
6. Central fill pharmacies may not dispense controlled substances at the retail level to a purchaser.

Delivery of a Controlled Substance to Persons in Other Countries

Controlled substances that are dispensed pursuant to a legitimate prescription may not be delivered or shipped to individuals in other countries without proper authorization. Any such delivery or shipment is an export under the CSA and cannot be conducted unless the person sending the controlled substances:

1. Has registered with DEA as an "exporter" (see 21 C.F.R. §§ 1301 and 1309).
2. Has obtained the necessary permit(s), or submitted the necessary declaration(s) for export (21 C.F.R. §§ 1312 or 1313).

SECTION XI – Ryan Haight Online Pharmacy Consumer Protection Act of 2008

Summary of the Act's Major Provisions

On October 15, 2008, the President signed into law the *Ryan Haight Online Pharmacy Consumer Protection Act of 2008*, often referred to as the *Ryan Haight Act*. This law amends the CSA by adding a series of new regulatory requirements and criminal provisions designed to combat the proliferation of so-called "rogue Internet sites" that unlawfully dispense controlled substances by means of the Internet. The *Ryan Haight Act* applies to all controlled substances in all schedules.

This law became effective April 13, 2009. As of that date, it is illegal under federal law to deliver, distribute, or dispense a controlled substance by means of the Internet unless the online pharmacy holds a modification of DEA registration authorizing it to operate as an online pharmacy. Thus, any person who knowingly or intentionally dispenses a controlled substance by means of the Internet that does not have a modification of DEA registration allowing such activity is in violation of 21 U.S.C. § 841(h)(1) and subject to potential criminal prosecution and (in the case of DEA registrants) loss of DEA registration.

Note: The information contained in this section is meant to summarize the Ryan Haight Act but should not be relied upon as setting forth all the requirements. As is always the case, pharmacies are responsible for complying with the actual text of the CSA and DEA regulations.

Definition of an Online Pharmacy

An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet. Examples of an online pharmacy include (but are not limited to) the following:

- Any website that sells, or offers to sell, any controlled substance or a prescription therefor to a person in the United States.
- Any person who operates such a website.
- Any person who pays a practitioner to write prescriptions for controlled substances for customers of such a website.
- Any person who pays a pharmacy to fill prescriptions for controlled substances that were issued to customers of such a website.
- Any pharmacy that knowingly or intentionally fills prescriptions for controlled substances that were issued to customers of such a website.
- Any person who sends an e-mail that:

  (1) offers to sell a controlled substance or a prescription for a controlled substance in a manner not authorized by the Act;

(2) directs buyers to a website operating in violation of the Act;
(3) or otherwise causes or facilitates the delivery, distribution, or dispensing of a controlled substance in a manner not authorized by the Act.

Online Pharmacy Registration Exemptions

The following are exempt from the Ryan Haight Act's definition of an "online pharmacy" so long as their activities are limited solely to the exemptions provided:

- Manufacturers or distributors registered under 21 U.S.C. § 823(a), (b), (d), or (e) who do not dispense controlled substances to nonregistrants.

- Nonpharmacy practitioners who are registered under 21 U.S.C. § 823(f) and whose activities are authorized by that registration, provided that any website operated by such nonpharmacy practitioners complies with 21 C.F.R.§ 1304.50, which requires the website to post in a visible and clear manner on its homepage, or on a page directly linked thereto in which the hyperlink is also visible and clear on the homepage, a list of the DEA-registered nonpharmacy practitioners who are affiliated with the website.

- Any hospital or other medical facility registered under 21 U.S.C. § 823(f) that is operated by an agency of the United States (including the Armed Forces).

- A health care facility owned or operated by an Indian tribe or tribal organization carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act.

- Any agent or employee of any hospital or facility that is operated by an agency of the United States, and any agent or employee of any hospital or facility owned or operated by an Indian tribe or tribal organization carrying out a contract or compact under the Indian Self-Determination and Education Assistance Act, provided such agent or employee is lawfully acting in the usual course of business or employment, and within the scope of the official duties of such agent or employee, with such hospital or facility, and, with respect to agents or employees of such health care facilities only to the extent such individuals are furnishing services pursuant to those contracts or compacts.

- Mere advertisements that do not attempt to facilitate an actual transaction involving a controlled substance.

- A person, entity, or Internet site that is not in the United States and does not facilitate the delivery, distribution, or dispensing of a controlled substance by means of the Internet to any person in the United States.

- A pharmacy registered under 21 U.S.C. § 823(f) whose dispensing of controlled substances via the Internet consists solely of "refilling prescriptions for controlled substances in schedule III, IV, or V," as that term is defined in 21 C.F.R. § 1300.04(k). (This definition is set forth at the end of this section.)

- A pharmacy registered under 21 U.S.C. § 823(f) whose dispensing of controlled substances via the Internet consists solely of "filling new prescriptions for controlled substances in schedule III, IV, or V," as that term is defined in 21 C.F.R. § 1300.04(d). (This definition is set forth at the end of this section.)

- Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of filling prescriptions that were electronically prescribed in a manner authorized by the CSA.

- Any registered pharmacy whose delivery, distribution, or dispensing of controlled substances by means of the Internet consists solely of the transmission of prescription information between a pharmacy and an automated dispensing system located in a Long Term Care Facility when the registration of the automated dispensing system is held by that pharmacy as described in 21 C.F.R §§ 1301.17 and 1301.27 and the pharmacy is otherwise complying with the DEA regulations.

Notification Requirements

Thirty days prior to offering a controlled substance for sale, delivery, distribution, or dispensing by means of the Internet, the online pharmacy shall notify DEA and the State boards of pharmacy in any States in which the online pharmacy offers to sell, deliver, distribute, or dispense controlled substances. Completion of the *Application for Modification of Registration for Online Pharmacies* serves as the notification requirement to DEA.

The online pharmacy must make a separate thirty-day advance notice to the State boards of pharmacy in each State in which it intends to offer to sell, deliver, distribute, or dispense controlled substances. Online pharmacies that apply for the modification of registration are required to certify that the applicable State boards of pharmacy have been notified.

How to Register as an Online Pharmacy

To operate legally as an online pharmacy, the online pharmacy must first be registered with DEA as a pharmacy. Once registered with DEA as a pharmacy, the pharmacy may apply for a modification of registration to operate as an online pharmacy. To apply for a modification of registration, complete the *Application for Modification of Registration for Online Pharmacies* online at www.DEAdiversion.usdoj.gov. There is no fee to apply to modify a DEA registration to an online pharmacy.

If the modification of registration is approved, the pharmacy will be issued a modified DEA Certificate of Registration with the new business activity listed as online pharmacy. The registrant will keep the same DEA registration number. A pharmacy may perform the activities of a retail pharmacy and an online pharmacy at the same time.

State Licensure Requirements

An online pharmacy must comply with the requirements of all applicable State laws concerning the licensure of pharmacies in each State from which it, and in each State to which it, delivers,

distributes, or dispenses, or offers to deliver, distribute, or dispense, controlled substances by means of the Internet. In addition, online pharmacies must certify they are in compliance with these requirements when completing the *Application for Modification of Registration for Online Pharmacies.*

The requirement that an online pharmacy list the States in which it is licensed to dispense controlled substances is designed to ensure that an online pharmacy only dispenses controlled substances to patients in States in which it is authorized to practice pharmacy. Dispensing beyond the scope of State licensure is one of the recurring transgressions of some rogue online pharmacies and generally violates State law. Under this Act, a State may bring civil action in federal court to enjoin any violation of the Ryan Haight Act – not merely those violations of State law – and to obtain other appropriate legal or equitable relief. 21 U.S.C. § 882(c).

Online Pharmacy Website Requirements

When a pharmacy applies for a modification of registration to become an online pharmacy, it must display on its homepage a declaration that it has done so. This declaration must state the following:

> *"In accordance with the Controlled Substances Act and the DEA regulations, this online pharmacy has made the notifications to the DEA Administrator required by 21 U.S.C. § 831 and 21 C.F.R. § 1304.40."*

Once approved to operate as an online pharmacy, the online pharmacy must display at all times on the homepage of its Internet site a declaration of compliance with the requirements of 21 U.S.C. § 831 with respect to the delivery or sale or offer for sale of controlled substances. This statement must include the name of the pharmacy as it appears on the DEA Certificate of Registration.

An online pharmacy is required to post Internet Pharmacy Site Disclosure Information on the homepage of each Internet site it operates. It must be posted in a visible and clear manner and contain the following information:

1. The name and address of the pharmacy as it appears on the pharmacy's DEA Certificate of Registration.
2. The pharmacy's telephone number and e-mail address.
3. Name of pharmacist-in-charge, professional degree, States of licensure, and telephone number.
4. List of State(s) in which the pharmacy is licensed to dispense controlled substances.
5. Certification that the pharmacy is registered to deliver, distribute, or dispense controlled substances by means of the Internet.
6. The name, address, telephone number, professional degree, and States of licensure of any practitioner who has a contractual relationship to provide medical evaluations or issue prescriptions for controlled substances, through referrals from the website or at the request of the owner or operator of the website, or any employee or agent thereof.
7. The following statement must be visible on the website:

> "*This online pharmacy is obligated to comply fully with the Controlled Substances Act and DEA regulations. As part of this obligation, this online pharmacy has obtained a modified DEA registration authorizing it to operate as an online pharmacy. In addition, this online pharmacy will only dispense a controlled substance to a person who has a valid prescription issued for a legitimate medical purpose based upon a medical relationship with a prescribing practitioner. This includes at least one prior in-person medical evaluation in accordance with section 309 of the Controlled Substances Act (21 U.S.C. § 829), or a medical evaluation via telemedicine in accordance with section 102(54) of the Controlled Substances Act (21 U.S.C. § 802(54)).*"

If at any time an online pharmacy should change its Internet site web address, the online pharmacy must notify DEA at least thirty days in advance of this change.

Reporting Requirements

Each online pharmacy must submit a monthly report to DEA of the total quantity of each controlled substance that the online pharmacy has dispensed the previous calendar month. The report is required for every month in which the total amount of dispensing of controlled substances by the pharmacy is either (i) over 100 prescriptions filled or (ii) 5,000 or more dosage units dispensed of all controlled substances combined. Should an online pharmacy's total quantity of dispensed controlled substances fall below both of the thresholds listed above, a report is still required that indicates a negative response for that given month.

The report must include the total amount of such dispensing by any means including all controlled substances dispensed via Internet transactions, mail-order transactions, face-to-face transactions, or any other means. It is not required that the online pharmacy identify the means of the dispensing in its report. Reporting will be by National Drug Code (NDC) numbers. Report the total number of dosage units dispensed for each NDC number.

This report is due on or before the 15th day of the following month. For example, an online pharmacy would submit its report for the month of January no later than February 15th. Reports must be submitted electronically via online reporting, electronic upload, or other means as approved by DEA. All reports must be kept for at least two years and be readily retrievable for inspection.

Should an online pharmacy revert back to a retail pharmacy, the pharmacy is still required to report the monthly sales for the month in which it changes back to a retail pharmacy.

Prescription Requirements

In order for a prescription to be valid, it must be issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted at least one in-person medical evaluation of the patient or by a covering practitioner. An in-person medical evaluation is a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other health professionals.

Definition of Prescription Terms

A pharmacy website is exempted from the Ryan Haight Act's definition of an "online pharmacy" if its Internet-facilitated activity relating to controlled substances is limited to filling new and/or refilling prescriptions for controlled substances in schedules III, IV, or V. If the pharmacy is so exempted from the definition of an "online pharmacy," it is not required under the Act to obtain a modification of its DEA registration authorizing it to operate as an online pharmacy. Thus, it is important to understand precisely the definitions of the following terms.

Filling New Prescriptions for Controlled Substances in Schedules III-V

As stated in 21 C.F.R. § 1300.04 (d), the term "**filling new prescriptions for controlled substances in schedule III, IV, or V**" means filling a prescription for an individual for a controlled substance in schedule III, IV, or V, if:

1. The pharmacy dispensing that prescription has previously dispensed to the patient a controlled substance other than by means of the Internet and pursuant to the valid prescription of a practitioner that meets the applicable requirements of [21 U.S.C. § 829(b) and (c)] and [21 C.F.R. §§ 1306.21 and 1306.22] (for purposes of this definition, such a prescription shall be referred to as the "original prescription");
2. The pharmacy contacts the practitioner who issued the original prescription at the request of that individual to determine whether the practitioner will authorize the issuance of a new prescription for that individual for the controlled substance described in [paragraph (1) of this definition] (i.e., the same controlled substance as described in [paragraph (1)]); and
3. The practitioner, acting in the usual course of professional practice, determines there is a legitimate medical purpose for the issuance of the new prescription.

Refilling Prescriptions for Controlled Substances in Schedules III-V

As stated in 21 C.F.R. § 1300.04(k), the term "**refilling prescriptions for controlled substances in schedule III, IV, or V"**:

1. Means the dispensing of a controlled substance in schedule III, IV, or V in accordance with refill instructions issued by a practitioner as part of a valid prescription that meets the requirements of [21 U.S.C. § 829(b) and (c)] and [21 C.F.R. §§ 1306.21 and 1306.22], as appropriate; and
2. Does not include the issuance of a new prescription to an individual for a controlled substance that individual was previously prescribed.

SECTION XII – OTHER PHARMACY OPERATIONS

Central Fill Pharmacy

A "central fill pharmacy" (see Appendix B, *Definitions*) fills prescriptions for controlled substances on behalf of retail pharmacies with which it has a contractual agreement to provide such services or with pharmacies who share a common owner. When one retail pharmacy receives a prescription and a second pharmacy prepares and subsequently delivers the controlled substance medication to the first retail pharmacy for dispensing to the patient, the second pharmacy is engaging in a "central fill" activity. Records must be maintained by both the central fill pharmacy and the retail pharmacy that completely reflect the disposition of all controlled substance prescriptions dispensed. Central fill pharmacies are required to comply with the same security requirements applicable to retail pharmacies including the general requirement to maintain effective controls and procedures to guard against theft and diversion of controlled substances. Retail pharmacies that also perform central fill activities are allowed to do so without a separate DEA registration, separate inventories, or separate records.

Central fill pharmacies are permitted to prepare both initial and refill prescriptions, subject to all applicable state and federal regulations. Only a licensed pharmacist may fill the prescription. Both the retail and central fill pharmacists have a corresponding responsibility to ensure that the prescription was issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice and otherwise in the manner specified by DEA regulations.

Prescription information may be provided to an authorized central fill pharmacy by a retail pharmacy for dispensing purposes. Prescriptions for controlled substances listed in schedules II, III, IV, or V may be transmitted electronically from a retail pharmacy to a central fill pharmacy including via facsimile. The retail pharmacy transmitting the prescription information must:

1. Write the word "CENTRAL FILL" on the face of the original prescription and record the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted and the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal;
2. Ensure that all information required to be on a prescription is transmitted to the central fill pharmacy (either on the face of the prescription or in the electronic transmission of information);
3. Maintain the original prescription for a period of two years from the date the prescription was last refilled;
4. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common, or contract carrier) and the name of the retail pharmacy employee accepting delivery;
5. For schedules III-V prescriptions, indicate in the information transmitted the number of refills already dispensed and the number of refills remaining (refills for schedule II prescriptions are not permitted).

The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription (if sent via facsimile) or an electronic record of all the information transmitted by the retail pharmacy, including the name, address, and the DEA registration number of the retail pharmacy transmitting the prescription;
2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription; and
3. Keep a record of the date the filled prescription was delivered to the retail pharmacy and the method of delivery (i.e. private, common, or contract carrier).

Central fill pharmacies must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e. the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy. Central fill pharmacies must comply with the provisions of the C.F.R. when selecting private, common, or contract carriers to transport filled prescriptions to a retail pharmacy (and likewise for retail pharmacies retrieving filled prescriptions from a central fill pharmacy) for delivery to the ultimate user.

For electronic prescriptions, the name, address, and DEA registration number of the central fill pharmacy to which the prescription has been transmitted, the name of the retail pharmacy pharmacist transmitting the prescription, and the date of transmittal must be added to the electronic prescription record.

Long Term Care Facilities

A Long Term Care Facility (LTCF) is defined in the C.F.R. as a nursing home, retirement care, mental care, or other facility or institution, which provides extended health care to resident patients. In most cases, these facilities are not registered with DEA, yet these health care facilities routinely maintain controlled substances issued via prescription to their residents. These controlled substances are already outside the CSA's closed drug distribution system since they have been dispensed to the ultimate user.

LTCFs frequently need to dispose of unused medications due to a change in the resident's medication or the resident's death. Accordingly, LTCFs should contact the local DEA Diversion Field Office (Appendix K) for drug disposal instructions. The DEA is aware of issues currently facing LTCFs concerning the dispensing and handling of controlled substances, which are affected by a variety of state laws and circumstances. Pharmacists should check with their state agency for guidelines concerning controlled substances at LTCFs.

Regulations concerning LTCFs can also be found under:

- Section IX, *Exceptions for Schedule II Facsimile Prescriptions*
- Section X, *Partial Filling of Schedule II Prescriptions for Terminally Ill or Long Term Care Facility Patients*

Use of Automated Dispensing Systems by Retail Pharmacies at Long Term Care Facilities

If state law or regulations permit, the DEA will allow a retail pharmacy to register at the site of the LTCF and store controlled substances in an Automated Dispensing System (ADS) as outlined in 21 C.F.R. § 1301.27. In an ADS, a pharmacy stores bulk drugs in the machine in separate bins or containers. The pharmacy programs and controls the ADS remotely. Only authorized LTCF staff are allowed access to its contents, which are dispensed on a single-dose basis at the time of administration pursuant to a valid prescription. The ADS electronically records each dispensing, thus maintaining dispensing records for the pharmacy. Because the drugs are not considered dispensed until the system provides them, drugs in the ADS are counted as pharmacy stock. A registered retail pharmacy that possesses additional registrations for ADS machines at LTCFs may keep all records required for those additional registered sites at the retail pharmacy or other approved central location.

DEA registered pharmacies wishing to operate an ADS at an LTCF must contact the DEA Office of Diversion Control, Registration Section, at 1-800-882-9539 for registration instructions. Additional requirements for maintaining an ADS can be found online at www.DEAdiversion.usdoj.gov.

Emergency Kits for Long Term Care Facilities

The DEA has issued a policy statement which provides individual state licensing and regulatory boards with general guidelines for establishing specific rules concerning controlled substances used in emergency kits at Long Term Care Facilities (see Appendix H*, Guidelines for Emergency Kits in Long Term Care Facilities*).

Opioid (Narcotic) Addiction Treatment Programs

The Narcotic Addiction Treatment Act of 1974 and the Drug Addiction Treatment Act (DATA) of 2000 amended the CSA with respect to the use of controlled substances in the medical treatment of opioid addiction. These laws established the procedures for approving and licensing practitioners involved in the treatment of opioid addiction as well as improving the quality and delivery of that treatment to the segment of society in need.

Practitioners wishing to prescribe and dispense FDA approved schedule II controlled substances (i.e., methadone) for maintenance and detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program via a DEA Form 363 which may be completed online at www.DEAdiversion.usdoj.gov. In addition to obtaining this separate DEA registration, this type of activity also requires the approval and certification by the Center for Substance Abuse Treatment (CSAT) within the Substance Abuse and Mental Health Services Administration (SAMHSA) of the U.S. Department of Health and Human Services as well as the applicable state methadone authority.

If a practitioner wishes to prescribe or dispense schedules III, IV, or V controlled substances approved by the FDA for addiction treatment (i.e., Suboxone® or Subutex® drug products), the practitioner must request a waiver from CSAT which will then notify DEA of all waiver requests. These practitioners are referred to as DATA waived practitioners.

DATA waived practitioners may treat 30 or 100 patients at any one time, dependent on individual authorization from CSAT. Upon authorization by CSAT, DEA will issue a new DEA certificate of registration bearing (1) the DEA registration number, (2) a unique identification number, and (3) the corresponding business activity to identify whether the physician is authorized to treat 30 or 100 patients. Pursuant to 21 C.F.R. §1301.28(d), the practitioner is required to include the identification number on all records when dispensing and on all prescriptions when prescribing Schedules III, IV, or V narcotic controlled drugs for use in maintenance or detoxification treatment. The listing of the identification number on a prescription is in addition to all other information required on a valid prescription to include the practitioner's DEA registration number (see Section IX, *Valid Prescription Requirements*).

Dispensing Controlled Substances for the Treatment of Pain

On September 6, 2006, the DEA published in the Federal Register a Policy Statement, *Dispensing Controlled Substances for the Treatment of Pain*. The purpose of the Policy Statement was to make clear the longstanding requirement under the law that physicians may prescribe controlled substances only for a legitimate medical purpose in the usual course of professional practice. In no way should this interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate pain treatment. The second purpose of the Policy Statement was for the DEA to dispel the mistaken notion among a small number of medical professionals that the agency has embarked on a campaign to "target" physicians who prescribe controlled substances for the treatment of pain or that physicians must curb their legitimate prescribing of pain medications to avoid legal liability.

To achieve these aims, the document summarized the relevant legal principles and provided an explanation of DEA's role with respect to the regulation of controlled substances. The document also addressed specific issues and questions that have been raised on a recurring basis by physicians who seek guidance on the subject of dispensing controlled substances for the treatment of pain.

To review the Policy Statement, it may be accessed at www.DEAdiversion.usdoj.gov. Click on *Info & Legal Resources,* then *Federal Register Notices*, then *Notices 2006*, then *Policy Statement: Dispensing Controlled Substances for the Treatment of Pain, September 6, 2006.* For additional guidance on the responsibilities of the pharmacist where it pertains to the treatment of pain, see Section IX, *Corresponding Responsibility.*

SECTION XIII - OTHER CONTROLLED SUBSTANCE REGULATIONS

Controlled Substance Distribution by a Pharmacy – "Five Percent Rule"

A pharmacy registered to dispense controlled substances may distribute such substances (without being registered as a distributor) to another pharmacy or to a registered practitioner for the purpose of general dispensing by the practitioner to patients, provided that the following conditions are met:

1. The pharmacy or practitioner that will receive the controlled substances is registered under the CSA to dispense controlled substances;
2. The distribution is recorded by the distributing practitioner in accordance with 21 C.F.R. § 1304.22(c) and the receipt is recorded by the receiving practitioner in accordance with 21 C.F.R. § 1304.22(c);
3. If the pharmacy distributes a schedule II controlled substance, it must document the transfer on an official order form (DEA Form 222) or the electronic equivalent. For instructions on completing this form, see Section VIII, *Ordering Controlled Substances*.
4. **"Five Percent Rule"** - total number of dosage units of all controlled substances distributed by a pharmacy may not exceed five percent of all controlled substances dispensed by the pharmacy during a calendar year. If at any time the controlled substances distributed exceed five percent, the pharmacy is required to register as a distributor.

United States Postal Service Mailing Requirements for Controlled Substances

United States Postal Services regulations permit the mailing of controlled substances by drug manufacturers or their agents, pharmacies, or other authorized handlers when distribution is lawful under DEA regulations and if the mailer or the addressee meets one of the following conditions:

1. The mailer or the addressee is registered with DEA.
2. The mailer or the addressee is exempt from DEA registration as permissible by law.

United States Postal Service regulations permit mailing of any controlled substance, provided it is not outwardly dangerous and will not cause injury to a person's life or health, and if the following preparation and packaging standards are met:

1. The inner container of any parcel containing controlled substances is marked and sealed as required by the provisions of the CSA and its implementing regulations, and is placed in a plain outer container or securely wrapped in plain paper.
2. If the controlled substance consists of prescription medicines, the inner container is also labeled to show the name and address of the pharmacy, practitioner, or other person dispensing the prescription.
3. The outside wrapper or container is free of markings that would indicate the nature of the contents.

SECTION XIV – COMBAT METHAMPHETAMINE EPIDEMIC ACT OF 2005

Summary of the Act's Major Provisions

In March 2006, the President signed the *Combat Methamphetamine Epidemic Act of 2005* (CMEA). As a result of the new law, the DEA issued an Interim Final Rule in the Federal Register on September 26, 2006, which outlined the retail provisions of the CMEA.

Under the CMEA, regulated sellers must follow new requirements for retail sales of over-the-counter products containing the List I chemicals ephedrine, pseudoephedrine, and phenylpropanolamine (PPA), which can be used to manufacture methamphetamine illegally. The CMEA defined "*regulated seller*" to mean a retail distributor (including a pharmacy and mobile retail vendors) and "*at retail*" to mean sale or purchase for personal use.

Scheduled Listed Chemical Products

The CMEA created a new category of products called "*scheduled listed chemical product (SLCP).*" It includes any product that may be marketed or distributed lawfully in the United States under the Federal Food, Drug, and Cosmetic Act as a nonprescription drug that contains ephedrine, pseudoephedrine, or PPA (includes salts, optical isomers, and salts of optical isomers) (21 U.S.C. § 802(45)). This applies to nonprescription drug products only, not prescription drug products. Retail sales of SLCPs are excluded from the definition of a "regulated transaction" and from the registration requirement under 21 U.S.C. § 823, but are subject to a separate system of retail sales controls under 21 U.S.C. § 830.

Other requirements of the law include:

- Requirement of regulated sellers to place the products behind the counter or in locked cabinets.
- Requirement of regulated sellers to check the identity of purchasers and maintain a log of each sale that includes the purchaser's name and address, signature of the purchaser, product sold, quantity sold, date, and time.
- Requirement of regulated sellers to maintain the logbook for at least two years.
- Requirement of regulated sellers to train employees in the requirements of the law and certify to DEA that the training has occurred.
- Places a quantity limit of each of the chemicals that may be sold to an individual in a day to 3.6 grams of the chemical (base) without regard to the number of transactions.
- For nonliquids, product packaging is limited to blister packs containing no more than 2 dosage units per blister. Where blister packs are not technically feasible, the product must be packaged in unit dose packets or pouches.
- For individuals, purchases in a 30-day period are limited to 9 grams, of which not more than 7.5 grams may be imported by means of a common or contract carrier or the U.S. Postal Service.

While many states have enacted their own legislation regarding the regulation of these products, the federal law also requires regulated sellers to complete a self-certification process with the DEA that includes training their employees on the new regulations and procedures. The self-certification

process must be completed online at www.DEAdiversion.usdoj.gov. If state law differs from federal law regarding the regulation of these products, retail outlets are to adhere to the stricter provisions of both.

Copies of the Interim Final Rule are available at www.DEAdiversion.usdoj.gov (click on the *Combat Meth Act of 2005*, then *Interim Final Rule – Retail Sales of Scheduled Listed Chemical Products)*. Details on specific provisions of the CMEA that may impact a pharmacy that engages in retail sales of SLCPs are outlined below.

Recordkeeping Requirements

Regulated sellers are required to maintain a written (bound logbook) or electronic list of sales that identifies the transactions with the following information:

1. The name of the purchaser
2. The address of the purchaser
3. The date and time of the sale
4. The amount of product sold

The logbook requirement does not apply to any purchase by an individual of a single sales package that contains not more than 60 milligrams of pseudoephedrine.

Concurrently, purchasers are required to:

1. Present a photo identification issued by a State or the Federal Government (see *Proof of Identity Requirements* below for a complete list of acceptable forms of identification).
2. Sign a logbook and enter his or her name, address, date, and time of sale.

Once identification of the purchaser is presented to the seller, the seller is required to:

1. Determine that the name in the logbook corresponds to the name on the identification and that the date and time are correct.
2. Enter into the logbook the name of the product and the quantity sold.

The logbook must include a notice to purchasers that entering false statements or misrepresentations in the logbook may subject purchasers to criminal penalties under 18 U.S.C. § 1001. Sellers must maintain each entry in the logbook for not fewer than two years after the date on which the entry is made.

Loss or Theft of Scheduled Listed Chemical Products

A report should be made orally to the local DEA Diversion Field Office (Appendix K) in the area where the pharmacy is located. Per 21 C.F.R. § 1314.15(c), a written report of losses must be filed within 15 days after the pharmacist becomes aware of the loss or theft. A written report should include the DEA registration number (if applicable), name, business address, date of loss, type of loss, and a description of the circumstances of the loss (e.g., in-transit, theft from premises).

Proof of Identity Requirements

The CMEA requires an individual to present an identification card that includes a photograph and is issued by a State or the Federal Government or a document considered acceptable under 8 C.F.R. § 274a.2(b)(1)(v)(A) and (B). Those documents currently include the following:

- United States passport;
- Alien Registration Receipt Card or Permanent Resident Card, Form I-551;
- An unexpired foreign passport that contains a temporary I-551 stamp, or temporary I-551 printed notation on a machine-readable immigrant visa;
- An Employment Authorization Document which contains a photograph (Form I-766);
- In the case of a nonimmigrant alien authorized to work for a specific employer incident to status, a foreign passport with form I-94 or Form I-94A bearing the same name as the passport and containing an endorsement of the alien's nonimmigrant status, as long as the period of endorsement has not yet expired and the proposed employment is not in conflict with any restrictions or limitations identified on the Form;
- A passport from the Federated States of Micronesia (FSM) or the Republic of the Marshall Islands (RMI) with Form I-94 or Form I-94A indicating nonimmigrant admission under the Compact of Free Association Between the United States and the FSM or RMI;
- In the case of an individual lawfully enlisted for military service in the Armed Forces under 10 U.S.C. § 504, a military identification card issued to such individual may be accepted only by the Armed Forces.

For individuals 16 years of age or older:

- A driver's license or identification card containing a photograph, issued by a state or an outlying possession of the United States. If the driver's license or identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address;
- School identification card with a photograph;
- Voter's registration card;
- U.S. military card or draft record;
- Identification card issued by federal, state, or local government agencies or entities. If the identification card does not contain a photograph, identifying information shall be included such as: name, date of birth, sex, height, color of eyes, and address;
- Military dependent's identification card;
- Native American tribal documents;
- United States Coast Guard Merchant Mariner Card;
- Driver's license issued by a Canadian government authority.

For individuals under age 18 who are unable to produce a document from the list above, the following documents are acceptable to establish identity only:

- School record or report card;
- Clinic doctor or hospital record;
- Daycare or nursery school record.

NOTE: The list of acceptable forms of identification, as cited in the CMEA, may change ("in effect on or after the date of enactment"). The DEA has no discretion to alter the list.

Product Placement

SLCPs must be stored behind the counter or, if in an area where the public has access, in a locked cabinet. Although DEA is not including cabinet specifications in the rule, a locked cabinet should be substantial enough that it cannot be easily picked up and removed. In a store setting, the cabinet should be similar to those used to store items, such as cigarettes, that can be accessed only by sales staff.

Self-Certification

As part of the requirements of CMEA, an annual self-certification is required for all regulated sellers of SLCPs. A regulated seller must not sell SLCPs unless it has self-certified with DEA. In self-certifying, the regulated seller is confirming:

- The employees who will be engaged in the sale of SLCPs have undergone training regarding provisions of CMEA.
- Records of the training are maintained.
- Sales to individuals do not exceed 3.6 grams of ephedrine, pseudoephedrine, or phenylpropanolamine per day.
- Nonliquid forms are packaged as required.
- SLCPs are stored behind the counter or in a locked cabinet.
- A written or electronic logbook containing the required information on sales of these products is properly maintained.
- The logbook information will be disclosed only to Federal, State, or local law enforcement and only to ensure compliance with Title 21 of the United States Code or to facilitate a product recall.

The only way to self-certify is through DEA's Diversion website at www.DEAdiversion.usdoj.gov. Self-certification can be accomplished on any computer (e.g., at the store, at home, at the library, or at any other location).

A certificate will be generated by DEA upon receipt of the self-certification application. The regulated seller may print this certificate, or if the regulated seller is unable to print it, DEA will print and mail the certificate to the regulated seller. Chain stores wishing to file self-certifications for more than 10 locations must print or copy the form electronically and submit the information to DEA by mail. DEA will work with these persons to facilitate this process. Persons interested in this self-certification option should contact DEA for assistance at 1-800-882-9539. For current DEA registrants, the system will pre-populate the form with basic information if the registrant enters his DEA registration number in the field provided.

The regulated seller must self-certify to DEA as described above on an **annual basis**. It is the responsibility of the regulated seller to ensure that all employees have been trained prior to self-certifying each time.

It is the regulated seller's responsibility to annually renew before the certificate expires if the regulated seller intends to continue selling SLCPs at retail. The certificate contains a self-certification number in the upper right corner. The expiration date of the certificate is listed under the self-certification number. Regulated sellers may verify the expiration date of their certificate at www.DEAdiversion.usdoj.gov.

The self-certification requirement is subject to the provisions of 18 U.S.C. § 1001. A regulated seller who knowingly or willfully certifies to facts that are not true is subject to fines and imprisonment.

Required Training

Training materials designed by DEA must be used, although a regulated seller may include information in addition to that provided by DEA. DEA training materials may be found at www.DEAdiversion.usdoj.gov.

Training Records

Each employee of a regulated seller who is responsible for delivering SLCPs to purchasers or who deals directly with purchasers by obtaining payment for the SLCPs must undergo training and must sign an acknowledgement of training received prior to selling SLCPs. This record must be kept in the employee's personnel file.

Self-Certification Fee

On December 29, 2008, the DEA published a Final Rule in the Federal Register entitled *Combat Methamphetamine Epidemic Act of 2005: Fee for Self-Certification for Regulated Sellers of Scheduled Listed Chemical Products*. The rule established a self-certification fee for regulated sellers of SLCPs that are not DEA pharmacy registrants.

APPENDICES

APPENDIX A

This summary is provided as a quick reference to the provisions of the Controlled Substances Act. It is not intended to replace any statutory or regulatory requirement thereof. For complete guidance as to the provisions of each area indicated below, please check the appropriate section of this manual.

Summary of Controlled Substances Act Requirements

	Schedule II	Schedules III & IV	Schedule V
Registration	Required	Required	Required
Receiving Records	DEA Form 222	Invoices, readily retrievable	Invoices, readily retrievable
Prescriptions	Written[1] prescriptions[2]	Written, oral, or fax	Written, oral, or fax
Refills	No	No more than 5 within 6 months	As authorized when prescription is issued or if renewed by a practitioner
Maintenance of Prescriptions	Separate file	Separate file or readily retrievable	Separate file or readily retrievable[3]
Distribution Between Registrants	DEA Form 222	Invoices	Invoices
Security	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals	Locked cabinet or dispersed among non-controlled pharmaceuticals
Theft or Significant Loss	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106	Report to DEA and complete DEA Form 106

Note: ***All records*** must be maintained for 2 years, unless state law requires a longer period.

[1] Written prescriptions include paper prescriptions and electronic prescriptions that meet DEA's requirements for such prescriptions.

[2] Emergency prescriptions require a signed follow-up prescription within seven days.
Exceptions: A facsimile prescription serves as the original prescription when issued to residents of Long Term Care Facilities, hospice patients, or patients with a diagnosed terminal illness, or for immediate administration (21 C.F.R. § 1306.11(e), (f) and (g)).

[3] The record of dispensing can also be a schedule V logbook, if state law allows.

APPENDIX B

Definitions Based on the Controlled Substances Act and the Code of Federal Regulations

Administer
The direct application of a controlled substance to the body of a patient or research subject by 1) a practitioner or (in his/her presence) by his/her authorized agent, or 2) the patient or research subject at the direction and in the presence of the practitioner, whether such application is by injection, inhalation, ingestion, or any other means.

Central Fill Pharmacy
A pharmacy which is permitted by the state in which it is located to prepare controlled substance orders for dispensing pursuant to a valid prescription transmitted to it by a registered retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user. Such central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a retail pharmacy only if the retail pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

Chemicals
Please see the definitions for List I Chemical, Retail Distributor and Scheduled Listed Chemical Product.

Dispense
To deliver a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling, or compounding necessary to prepare the substance for such delivery.

Individual Practitioner
A physician, dentist, veterinarian, or other individual licensed, registered or otherwise permitted, by the United States or the jurisdiction in which they practice, to dispense a controlled substance in the course of professional practice, but does not include a pharmacist, a pharmacy, or an institutional practitioner.

Institutional Practitioner
A hospital or other person (other than an individual) licensed, registered or otherwise permitted, by the United States or the jurisdiction in which it practices, to dispense a controlled substance in the course of professional practice, but does not include a pharmacy.

Inventory
All factory and branch stocks in finished form of a basic class of controlled substance manufactured or otherwise acquired by a registrant, whether in bulk, commercial containers, or contained in pharmaceutical preparations in the possession of the registrant (including stocks held by the registrant under separate registration as a manufacturer, importer, exporter, or distributor).

List I Chemical

A chemical specifically designated by the [DEA] Administrator in 21 C.F.R. § 1310.02(a)… that, in addition to legitimate uses, is used in manufacturing a controlled substance in violation of the [Controlled Substances] Act and is important to the manufacture of a controlled substance.

Long Term Care Facility (LTCF)

A nursing home, retirement care, mental care, or other facility or institution that provides extended health care to resident patients.

Mid-level Practitioner (MLP)

An individual practitioner, other than a physician, dentist, veterinarian, or podiatrist, who is licensed, registered or otherwise permitted by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in the course of professional practice. Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants who are authorized to dispense controlled substances by the state in which they practice. Because this authority varies greatly by state, check with the state licensing authority to determine which MLP disciplines are authorized to dispense controlled substances in a particular state or visit, www.DEAdiversion.usdoj.gov (click on *Registration Support*, then *Resources*, then *Mid-level Practitioners Authorization by State*).

Online Pharmacy

An online pharmacy is a person, entity, or Internet site, whether in the United States or abroad, that knowingly or intentionally delivers, distributes, or dispenses, or offers or attempts to deliver, distribute, or dispense, a controlled substance by means of the Internet.

Pharmacist

Any pharmacist licensed by a state to dispense controlled substances, and shall include any other person (e.g., pharmacist intern) authorized by a state to dispense controlled substances under the supervision of a pharmacist licensed by such state.

Prescription

An order for medication which is dispensed to or for an ultimate user but does not include an order for medication which is dispensed for immediate administration to the ultimate user (e.g., an order to dispense a drug to a bed patient for immediate administration in a hospital is not a prescription).

Readily Retrievable

Certain records which are kept by automatic data processing systems or other electronic or mechanized recordkeeping systems in such a manner that they can be separated out from all other records in a reasonable time and/or records kept in such a manner that certain items are asterisked, redlined, or in some other manner visually identifiable apart from other items appearing on the records.

Regulated Seller

A retail distributor (including a pharmacy or a mobile retail vendor), except that the term does not include an employee or agent of the distributor.

Retail Distributor

A grocery store, general merchandise store, drug store, or other entity or person whose activities as a distributor relating to drug products containing ephedrine, pseudoephedrine or phenylpropanolamine are limited almost exclusively to sales for personal use, both in number of sales and volume of sales, either directly to walk-in customers or in face-to-face transactions by direct sales.

Scheduled Listed Chemical Product (SLCP)

A product that contains ephedrine, pseudoephedrine, or phenylpropanolamine which may be marketed or distributed lawfully in the United States under the Federal, Food, Drug, and Cosmetic Act as a nonprescription drug. Ephedrine, pseudoephedrine, and phenylpropanolamine include their salts, optical isomers, and salts of optical isomers.

Ultimate User

A person who has lawfully obtained, and who possesses, a controlled substance for his [her] own use or for the use of a member of his [her] household or for an animal owned by him [her] or by a member of his [her] household.

APPENDIX C

Definitions of Abbreviations

C.F.R. ..... Code of Federal Regulations

CMEA ..... Combat Methamphetamine Epidemic Act of 2005

CSA ..... Controlled Substances Act

CSAT ..... Center for Substance Abuse Treatment

CSOS ..... Controlled Substance Ordering System

CSRPA ..... Controlled Substance Registrant Protection Act of 1984

DEA ..... Drug Enforcement Administration

FDA ..... Food and Drug Administration

HHS ..... Department of Health and Human Services

SAMHSA ..... Substance Abuse and Mental Health Services Administration

U.S.C. ..... United States Code

APPENDIX D

Pharmacist's Guide to Prescription Fraud

The purpose of this guide is to ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing diversion into the illicit market. It is not the intent of this publication to discourage or prohibit the use of controlled substances where medically indicated. However, nothing in this guide should be construed as authorizing or permitting any person to conduct any act that is not authorized or permitted under federal or state laws.

Pharmacist's Responsibilities

The abuse of prescription drugs—especially controlled substances—is a serious social and health problem in the United States today. As a healthcare professional, pharmacists share responsibility for preventing prescription drug abuse and diversion.

- Pharmacists have a personal responsibility to protect their practice from becoming an easy target for drug diversion. They need to know of the potential situations where drug diversion can occur, and establish safeguards to prevent drug diversion.
- The dispensing pharmacist must maintain a constant vigilance against forged or altered prescriptions. The CSA holds the pharmacist responsible for knowingly dispensing a prescription that was not issued in the usual course of professional treatment.

Types of Fraudulent Prescriptions

Pharmacists should be aware of the various kinds of forged prescriptions that may be presented for dispensing. Some patients, in an effort to obtain additional amounts of legitimately prescribed drugs, alter the practitioner's prescription. They may have prescription pads printed using a legitimate doctor's name, but with a different call back number that is answered by an accomplice to verify the prescription. Drug seeking individuals may also call in their own prescriptions and give their own telephone number as a call-back for confirmation. Drug abusers sometimes steal legitimate prescription pads from practitioner's offices and/or hospitals and prescriptions are written using fictitious patient names and addresses.

In addition, individuals may go to emergency rooms complaining of pain in the hopes of receiving a controlled substance prescription. The prescription can then be altered or copied to be used again. Computers are often used to create prescriptions for nonexistent doctors or to copy legitimate doctors' prescriptions. The quantity of drugs prescribed and frequency of prescriptions filled are not lone indications of fraud or improper prescribing, especially if a patient is being treated with opioids for pain management. Pharmacists should also recognize that drug tolerance and physical dependence may develop as a consequence of a patient's sustained use of opioid analgesics for the legitimate treatment of chronic pain.

The following criteria may indicate that a prescription was not issued for a legitimate medical purpose:

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area.
- The patient appears to be returning too frequently. A prescription which should last for a month in legitimate use is being refilled on a biweekly, weekly or even a daily basis.
- The prescriber writes prescriptions for antagonistic drugs, such as depressants and stimulants, at the same time. Drug abusers often request prescriptions for "uppers and downers" at the same time.
- The patient presents prescriptions written in the names of other people.
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician.
- People who are not regular patrons or residents of the community, show up with prescriptions from the same physician.

The following criteria may indicate a forged prescription:

- Prescription looks "too good". The prescriber's handwriting is too legible.
- Quantities, directions, or dosages differ from usual medical usage.
- Prescription does not comply with the acceptable standard abbreviations or appears to be textbook presentations.
- Prescription appears to be photocopied.
- Directions are written in full with no abbreviations.
- Prescription is written in different color inks or written in different handwriting.

Prevention Techniques

- Know the prescriber and his/her signature.
- Know the prescriber's DEA registration number.
- Know the patient.
- Check the date on the prescription order to determine if it has been presented in a reasonable length of time since being issued by the prescriber.

When there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification.

If at any time a pharmacist is in doubt, he /she should require proper identification. Although this procedure is not foolproof (identification papers can also be stolen/forged), it does increase the drug abuser's risk. If a pharmacist believes the prescription is forged or altered, he/she should not dispense it and call the local police. If a pharmacist believes he/she has discovered a pattern of prescription abuse, he/she should contact the state Board of Pharmacy or the local DEA Diversion Field Office (Appendix K). Both DEA and state authorities consider retail-level diversion a priority issue.

Proper Controls

Dispensing procedures without control and professional caution are an invitation to the drug abuser. Proper controls can be accomplished by following common sense, sound professional practice, and proper dispensing procedures. In addition, pharmacy staff should have knowledge of these safeguards, as it will help prevent and protect the pharmacy from becoming a source of diversion.

Most drug abusers seek out areas where communication and cooperation between health care professionals are minimal because it makes the drug abuser's work easier. Thus, a pharmacist should encourage other local pharmacists and physicians to develop a working relationship which will promote teamwork and camaraderie. In addition, the pharmacist should become familiar with those controlled substances that are popular for abuse and resale on the streets in the area and should discuss those findings with other pharmacists and practitioners in the community.

APPENDIX E

Affidavit for a New Pharmacy[1]

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) at _____ (Number and Street), _____ (City) _____ (State) _____ (Zip Code), hereby certify that said store was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ on _____ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. § 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. § 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than $30,000.00 or both.

_____

Signature (Person who signs Application for Registration)

State of _____ County of _____ Subscribed to and sworn before me this _____ day of _____, 20_____.

_____

Notary Public

[1] 21 C.F.R. § 1301.17(a)

APPENDIX F

Affidavit for Transfer of a Pharmacy[1]

I, _____, the _____ (Title of officer, official, partner, or other position) of _____ (Corporation, partnership, or sole proprietor), doing business as _____ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. _____ by the _____ (Board of Pharmacy or Licensing Agency) of the State of _____ and a DEA Registration Number _____ for a pharmacy located at _____ (Number and Street), _____(City) _____ (State) _____ (Zip Code); and

(2) That said company is acquiring the pharmacy business of _____ (Name of Seller) doing business as _____ with DEA Registration Number _____ on or about _____ (Date of Transfer) and that said company has applied (or will apply on _____ (Date)) for a pharmacy permit from the Board of Pharmacy (or Licensing Agency) of the State of _____ to do business as _____ (Store name) at _____ (Number and Street) _____ (City) _____ (State) _____ (Zip Code).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number.

I understand that if a DEA registration number is issued, the pharmacy may acquire controlled substances but may not dispense them until a pharmacy permit or license is issued by the State board of pharmacy or licensing agency.

I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. § 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. § 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than $30,000.00 or both.

_____
Signature (Person who signs Application for Registration)

State of _____ County of _____ Subscribed to and sworn before me this _____ day of _____, 20_____.

_____
Notary Public

[1] 21 C.F.R. § 1301.17(b)

APPENDIX G

Equivalency Tables for Ephedrine, Pseudoephedrine, and Phenylpropanolamine Under the Combat Methamphetamine Epidemic Act of 2005

RETAIL DAILY SALE LIMITS ARE NOT TO EXCEED THE FOLLOWING AMOUNTS PER PURCHASER	
Ingredient	Number of Tablets = 3.6 grams
25 mg Ephedrine HCl	175
25 mg Ephedrine Sulfate	186
30 mg Pseudoephedrine HCl	146
60 mg Pseudoephedrine HCl	73
120 mg Pseudoephedrine HCl	36
30 mg Pseudoephedrine Sulfate	155
60 mg Pseudoephedrine Sulfate	77
120 mg Pseudoephedrine Sulfate	38
Phenylpropanolamine (PPA)	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.

30-DAY SALE LIMITS ARE NOT TO EXCEED THE FOLLOWING AMOUNTS PER PURCHASER		
Ingredient	Number of tablets at retail = 9 grams	Number of tablets for mail orders = 7.5 grams
25 mg Ephedrine HCl	439	366
25 mg Ephedrine Sulfate	466	389
30 mg Pseudoephedrine HCl	366	305
60 mg Pseudoephedrine HCl	183	152
120 mg Pseudoephedrine HCl	91	76
30 mg Pseudoephedrine Sulfate	389	324
60 mg Pseudoephedrine Sulfate	194	162
120 mg Pseudoephedrine Sulfate	97	81
Phenylpropanolamine (PPA)	The Food and Drug Administration issued a voluntary recall of this ingredient as being unsafe for human consumption. Veterinary use is by prescription only.	

APPENDIX H

Guidelines for Emergency Kits in Long Term Care Facilities

A pharmacy may place an emergency kit with controlled substances in a non-DEA registered Long Term Care Facility (LTCF), if the appropriate state agency or regulatory authority specifically approves the placement and promulgates procedures that delineate:

1. The source from which the LTCF may obtain controlled substances for emergency kits and that the source of supply is a DEA-registered hospital/clinic, pharmacy, or practitioner.
2. The security safeguards for each emergency kit stored at the LTCF, including who may have access to the emergency kit, and specific limitation of the type and quantity of controlled substances permitted in the kit.
3. The responsibility for proper control and accountability of the emergency kit within the LTCF, including the requirement that the LTCF and the supplying registrant maintain complete and accurate records of the controlled substances placed in the emergency kit, the disposition of the controlled substances, and the requirement to take and maintain periodic physical inventories.
4. The emergency medical conditions under which the controlled substances may be administered to LTCF patients, including the requirement that controlled substances be administered by authorized personnel only as expressly authorized by an individual practitioner and in compliance with the provisions of 21 C.F.R. §§ 1306.11 and 1306.21.
5. The prohibited activities that if violated could result in state revocation, denial, or suspension of the privilege to supply or possess emergency kits containing controlled substances.

The requirements for emergency kits in LTCFs were published in a *Federal Register* notice on April 9, 1980 (45 FR 24128). Pharmacies and LTCFs may wish to consult the notice to ensure compliance with the requirements.

APPENDIX I

Guidelines for Completing the DEA Form 106

Instructions for completing the DEA Form 106 are provided when filling out either the paper or electronic version of the form. Listed below are additional guidelines:

- Do not use a DEA Form 106 to report an accidental spillage. Save the broken bottles, salvage the product if possible, and contact the local DEA Diversion Field Office (Appendix K) for additional instructions. This type of a loss must be reported on a DEA Form 41, Registrants Inventory of Drugs Surrendered.

- If thefts have occurred due to employee pilferage over a period of time, document on the DEA Form 106 the date of discovery in block 4. Provide estimated beginning and ending dates of the thefts in box 17 with an explanation.

- If there are multiple thefts or losses on the same day (e.g. mail-order pharmacy), report each theft or loss on a separate DEA Form 106.

- Miscounts or adjustments to inventory involving clerical errors on the part of the pharmacy should not be reported on a DEA Form 106. A separate log documenting the discrepancies may be kept at the management's discretion.

- In block 9, enter the number of thefts or losses experienced in the last 24 months, but do not include the current theft or loss being reported. If the current theft or loss was the only theft or loss in the last 24 months, enter 0 (zero).

- In block 12, enter the amount the pharmacy paid for the controlled substances, not the retail value.

- In blocks 14 b & c, if the customer accepted the controlled substance before discovering a loss in transit, identify the supplier and its DEA registration number.

- In block 14f, when explaining how many losses occurred from the same carrier, do not include the current loss.

- The date next to the signature and title on page 2 should be the date the form was completed, signed, and sent to the local DEA Diversion Field Office (Appendix K).

- Document the National Drug Code (NDC) number of the controlled substance, and if the loss was a partial container, document the actual amount of theft or loss within the container.

Guidelines for Completing the DEA Form 106 (continued)

- If the controlled substance contains hydrocodone, oxycodone or a similar controlled substance and contains acetaminophen, aspirin or ibuprofen, indicate the strength of the non-controlled substance as well as the strength of the controlled substance contained in the product.

- If amending a paper version of a prior DEA Form 106, print **Amended** in the upper front page margin, with the date of the theft.

APPENDIX J

DEA Registration Specialists in Field Divisions

Registration assistants are available during normal business hours to provide information about new applications, renewals, order forms, or changes to a DEA registration. Addresses and telephone numbers are subject to change. Please refer to the DEA's Diversion website, www.DEAdiversion.usdoj.gov, for the most current listing.

APPENDIX K

DRUG ENFORCEMENT ADMINISTRATION
DIVERSION FIELD OFFICE LOCATIONS

Visit www.DEAdiversion.usdoj.gov for current addresses and telephone numbers.

APPENDIX L

Internet Resources

DEA's Diversion Control Program Website
www.DEAdiversion.usdoj.gov

DEA Homepage
www.dea.gov

U.S. Government Printing Office
www.gpoaccess.gov/cfr/index.html

Provides access to the C.F.R., Parts 1300 to end, primary source for the Pharmacist's Manual, and the Federal Register which contains proposed and finalized amendments to the C.F.R.

Office of National Drug Control Policy (ONDCP)
www.whitehousedrugpolicy.gov

Food and Drug Administration
www.FDA.gov

HHS & SAMHSA's National Clearinghouse for Alcohol and Drug Information
www.health.org

SAMHSA/CSAT
www.csat.samhsa.gov

Federation of State Medical Boards
www.FSMB.org

National Association of Boards of Pharmacy
www.nabp.net

National Association of State Controlled Substances Authorities
www.nascsa.org

APPENDIX M

Small Business and Agriculture Regulatory Enforcement Ombudsman

The Small Business and Agriculture Regulatory Enforcement Ombudsman and 10 Regional Fairness Boards were established to receive comments from small businesses about federal agency enforcement actions. The Ombudsman will annually evaluate the enforcement activities and rate each agency's responsiveness to small business. If you wish to comment on DEA enforcement actions, you may contact the Ombudsman at 1-888-REG-FAIR (1-888-734-3247).

APPENDIX N

Additional Assistance

This publication is intended to provide guidance and information on the requirements of the CSA and its implementing regulations. If you require additional clarification or assistance, or wish to comment on any matter regarding the DEA's requirements or regulatory activities, please contact your local DEA Diversion Field Office (Appendix K). Every effort will be made to respond promptly to your inquiry.

Plain Language

The Drug Enforcement Administration has made every effort to write this manual in clear, plain language. If you have suggestions as to how to improve the clarity of this manual, please contact us at:

Drug Enforcement Administration
Attn: Liaison and Policy Section/ODL
8701 Morrissette Drive
Springfield, Virginia 22152
Telephone: 1-202-307-7297