SCHEDULE:

SUNDAY, AUGUST 6:

3 p.m. – Welcome and Announcements

3:15 p.m. to 5:15 p.m. – Continuing Education ACPE 0205-9999-17-052-L04-P&T

Drug Store Cowboys: Pharmacy Robbery and Burglary
Presented by Tara O'Connor Shelley, PhD Associate Professor
Director of the Institute for Criminal Justice Leadership & Public Policy
Director of the Institute on Violence Against Women and Human Trafficking
School of Criminology, Criminal Justice and Strategic Studies
Tarleton State University-Fort Worth
This is a knowledge based activity for pharmacists and technicians.

5:15 p.m. to 5:45 p.m. AACP Report, David Allen, RPh, PhD, President AACP

5:45 p.m. to 6:15 p.m. NABP Report, Jeanne Waggener, RPh, DPh, President NABP

6:15 p.m. – Welcome reception and supper

MONDAY, AUGUST 7:

7 a.m. – 8 a.m. – Provided breakfast

8 a.m. – 9:30 a.m. – Continuing Education ACPE 0205-9999-17-053-L05-P&T

Current Consideration for Conducting Root Cause Analysis: A Case Study
Presented by Karen Ryle, MS, RPh and Donna Horn, RPh, DPh
Associate Chief of Pharmacy — Director, Patient Safety-Community Pharmacy
Ambulatory Care — ISMP
Massachusetts General Hospital
This is a knowledge based activity for pharmacists and technicians.

9:30 a.m. – 10:00 a.m. – Break

10:00 a.m. – 11:30 a.m. – Continuing Education ACPE 0205-9999-17-054-L03-P&T

Evolution of Pharmacists' Scope of Practice to Support Direct Patient Care Activities
Presented by Trish Freeman, RPh, PhD
Associate Professor, Department of Pharmacy Practice & Science
Director, Center for the Advancement of Pharmacy Practice
University of Kentucky College of Pharmacy
This is a knowledge based activity for pharmacists and technicians.

11:30 a.m. – 12:00 p.m. – NABP and AACP Breakout Business Sessions

AFTERNOON FREE – Suggestions of things to do will be provided

TUESDAY, AUGUST 8:

7 a.m. – 8 a.m. – Provided breakfast

8 a.m. – 10 a.m. – Continuing Education ACPE 0205-9999-17-055-L04-P&T

Lessons Learned From Expanded Scope of Practice in Washington and Other States
Presented by Jenny Arnold, PharmD, BCPS
Director of Practice Development
Washington State Pharmacy Association
This is a knowledge based activity for pharmacists and technicians.

10 a.m. – 10:30 a.m. – Break

10:30 a.m. – 11:30 a.m. – NABP and AACP Breakout Business Sessions

11:30 a.m. – Closing

NABP and the NABP Foundation® are accredited by the Accreditation Council for Pharmacy Education as providers of continuing pharmacy education. ACPE Provider Number: 0205.

Participants may earn ACPE-accredited CPE credit for these knowledge-based activities by completing a Statement of Continuing Pharmacy Education Participation online and submitting it electronically to NABP. Full attendance and completion of the program evaluation and learning assessment for each session are required to receive CPE credit and for the credit to be recorded in the CPE Monitor® system. If you do not submit your CPE claim within 60 days of the date you completed the CPE activity you will be unable to receive credit, as this is the maximum amount of time allowed for providers to transmit CPE claims to ACPE for credit. Please submit your claim as soon as possible to ensure that you receive credit.

Drugstore Cowboys: Pharmacy Robbery & Burglary

Presented by:
Dr. Tara O'Connor Shelley
Associate Professor
School of Criminology, Criminal Justice & Strategic Studies
Tarleton State University

Speaker Information

- **Tara O'Connor Shelley, Ph.D.,** is an Associate Professor and Director of the Institute for Criminal Justice Leadership and Public Policy with the School of Criminology, Criminal Justice and Strategic Studies at Tarleton State University. She wishes to disclose she received a grant from RxPatrol & Purdue Pharma LLC to support some of the expenses associated with this research study. She will present this content in a fair and balanced manner.

Learning Objectives

1. Explain trends in diverting controlled prescription drugs (CPDs), particularly in the form of pharmacy robbery and burglary
2. Identify preventative measures to enhance security of pharmacies and the safety of their staff and customers
3. Outline strategies to reduce pharmacy burglaries and robberies for CPDs
4. Examine the influence of PDMPs/PMPs on robbery of retail pharmacies for CPDs *(if time)*

Question 1

- **True or false. Most pharmacy robbers have been to the same pharmacy to fill a prescription at some point prior to the robbery.**
  - True
  - False

Question 2

- **True or false. Most pharmacy robberies involve an injury to the offender and/or a member of the pharmacy staff.**
  - True
  - False

Question 3

- **Which of the following will reduce pharmacy robbery & burglary?**
  - A=Reduce Target Suitability
  - B=Increase Capable Guardianship
  - C=Reduce Motivated Offenders
  - D=All of the Above
  - E=Only A & B

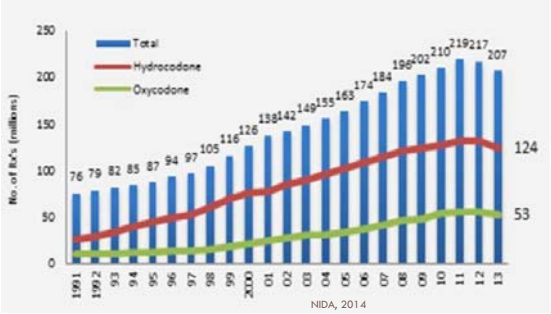
Question 4

- **Which of the following strategies had *the strongest effect* on reducing pharmacy robbery?**
  - A=Bottle tracking
  - B=PMPs/PDMPs
  - C=Abuse deterrent formulations of controlled prescription drugs
  - D=DNA spray security systems

The Pre-Event Context

Exploring Antecedent Factors and Trends

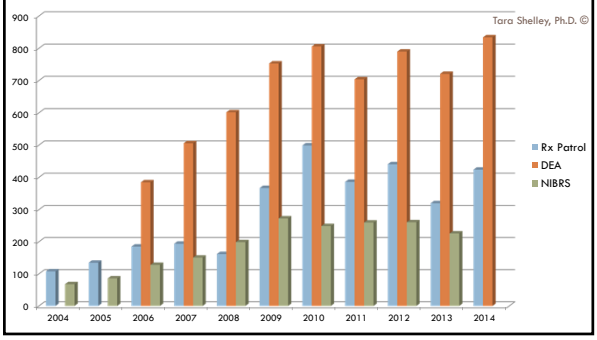
A Change in Routine Activities in Pain Management: US Opioid Prescriptions Dispensed by US Pharmacies



Diversion

- **Definition:** When legitimately manufactured controlled substances are diverted from their lawful purpose to an illicit purpose (DEA, 2013).
- **Trend:** Diversion of prescription drugs on the rise since the 2000's (most common type=pain relievers) (NDIC, 2011).
- **Examples:** Robbery/Burglary of Pharmacies; Fraud; Cargo Theft; Pilferage; Giving/Selling Drugs to Family/Friends.
- *"…data on pharmaceutical abuse and diversion are not reliable, comprehensive or timely."* (US GAO, 2003)

Pharmacy Robberies of CPDs 2006 - 2014



Pharmacy Robberies & Burglaries of CPDs in Kentucky

- **DEA Form 106 (2006-2014)**
  - **120 Robberies**
  - **323 Burglaries**

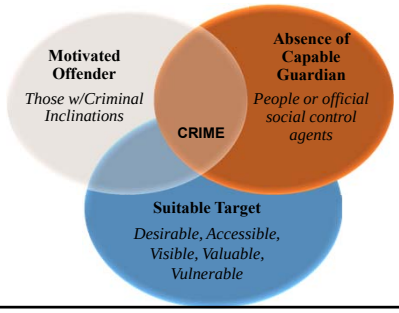
Research Methodology

- **Semi-Structured Interviews w/48 Convicted Offenders in Two Hot Spot Locations identified via diversion data**
  - Ohio & Florida

- Interviews were transcribed verbatim & loaded into NVivo for analysis of open ended responses.

Routine Activities Theory

- Cohen & Felson (1979); Felson (1994)



Theory to Practice: Motivated Offenders

Which of the following best describes the "typical" pharmacy robber for CPDs?

- A=

- C=

- B=

- D=

Meet "Rodney"

- **Criminal History**
  - Fraudulent Prescriptions
  - Pharmacy Robbery
- "Before I started robbin' the pharmacies, I started writin' the prescriptions. It was so easy, because I'd seen so many doctors for my health issues, I thought, '*Now, wait a minute. I know these doctors personally, why not make 'em up?*' So I went to Kinko's and wow, there's cameras everywhere, but who's gonna watch me do this? Those cameras are for robberies and stuff like that. They're not there to watch people like me printing these prescriptions. And it's so easy."

Rodney & Healthcare Facilities

- Dated/Married Nurses = easy access
  - *"My fiancée, she's a nurse. That's all I've ever been married to is nurses."*
- Targeted patients while in a visitor/volunteer capacity; sold medication for patients
  - *"…I went to where my fiancée worked at. She wasn't there at the time, but everybody knew me, 'cause I would come in, the patients loved me to death. I would play guitar, sing to 'em, help 'em do whatever, but I was always high. And some of the patients were alert and young age, they were in there for rehabilitation and stuff like that, and they'd sell me their pills. Literally."*
  - Bribed one patient with fast food for pills

Tara Shelley, Ph.D. ©

Rodney's Desperation/ Escalation Moment

- "The doors weren't locked at night, and the staff all knew me, and they said, '*What are you doin' here?*' I said, '*Who-all wants pizza?*' And I seen that drug cart and I was thinking, '*Hell, if I can get this past these people, it's on.*' It was a pretty good-sized drug cart, and I started pushin' it down the aisle. I get it out one door into the courtyard. I looked behind me and I swear to you, this is my right hand of God, I looked behind me and saw these women, two big black girls about 250 pounds apiece, chasin' my dumb ass, comin' after me. '*What the hell are you doin'?*' So I pushed the cart and it gets on the big stones and falls over and breaks and the stuff goes everywhere, and I take off…I didn't get nothin."

Tara Shelley, Ph.D. ©

Doctors Seen/Doctor Shopping

- **Of those w/Rx, 73% reported seeing more than 1 doctor/healthcare professional**
- **Reported Range of Doctors seen 1-100**

- *"I'd go doctor-shopping. Some doctors won't prescribe it at all. I remember times in ____County…in the emergency room, they knew me by my first name. "Look, we're not givin' you nothin' at all. Don't ask. Go away."*

Tara Shelley, Ph.D. ©

Rodney & The ER

- **ER Visits**
  - "Oh, yeah, I had several doctors. They don't care. '*What do you want?*' You go to an emergency room and you tell 'em you're passing a kidney stone, which I've done hundreds of times, and they want to know the symptoms. That's stupid. I know the symptoms. I've read up on that stuff before I go in. I feel like the doctor in *House*."

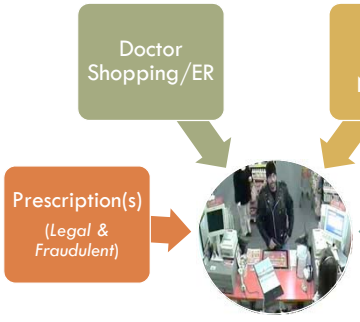
Tara Shelley, Ph.D. ©

Rodney's Doctors

- Q: How many docs do you think you visited?
  - "Fifty."
- Q: And how many did you get a prescription from?
  - *"Everyone. They don't care about it. They always say money talks and walks. It does, but greed is how I look at it. They have everything in the world, but they want that extra."*

Tara Shelley, Ph.D. ©

Pathways to Robbery & Burglary



Tara Shelley, Ph.D. ©

Offender Assessments of Certainty

- **What did offenders most often report as their perceived likelihood of getting caught?**
  - A. 0%
  - B. 10%
  - C. 50%
  - D. 75%
  - E. 100%

Deterrence: Offender Perceptions

- **Perceived likelihood of getting caught:**
  - 44% thought there was 0% chance
  - 17% thought there was a 50% chance
  - 10% thought 100% chance
- **43% knew what their possible sentence might be**
  - *"I had a rough idea of the penalties because of my prior robbery charges, it's **cost** versus **benefit**."*

Pre-Event Indicators: Today's Customer *Could* Be Tomorrow's Offender

- **PREPARATION**
  - **72% of offenders had been to the targeted pharmacy before**…almost all to fill prescriptions
  - **They carefully scout for SITUATIONAL CUES**
- *"I was still goin' to that pharmacy in between the time I robbed it with legit prescriptions. [laughs]."*
- *"Typically CVS carries two drug safes, and if you catch 'em right after a delivery, you can get everything in the safe, that's the best time to hit 'em."*
- *"I'm watching FedEx when they're bringin' all the medications in. You see 'em all the time at every one of these places you go to."*

Pre Event: Commuters or Marauders

- **Are most pharmacy robbers commuters or marauders?**
  - **Commuters**
  - **Marauders**

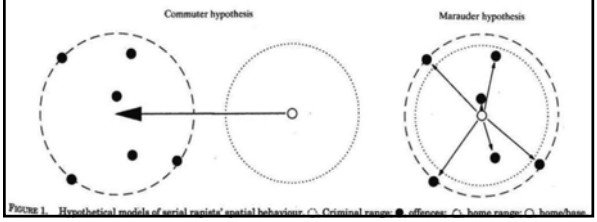
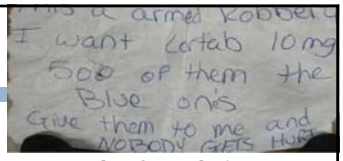


FIGURE 1. Hypothetical models of serial rapists' spatial behaviour. ○, Criminal range; ●, offences; ○, home range; ○, homebase.

Crime Tactics

- **Preparation Tactics**
  - 76% Wore Disguise
  - 16% Use Distraction Techniques
- **The Approach**
  - 30% Jumped



- **The Completion**
  - 23% Passed Note
  - 89% Used or Implied a Weapon
    - *Gun (56%)*
    - *Knife (19%)*
    - *Explosive Device (6%)*
  - 22% Reported Victim Injuries

Typology of Motivated Offenders

- **Pure Addict** (46%)
  - Few crime skills, don't want to hurt people, unstable; don't consider guardianship & target suitability.
- **Hybrids** (44%)
  - Criminals who are also abusers (*sometimes addicts*) and/or dealers, willing to harm as a last resort; do consider guardianship & target suitability.
- **Entrepreneurs** (10%)
  - Pure business, trafficking, rare for abuse, willing to harm; meticulously consider guardianship & target suitability.

Motivated Offenders & Differential Effects

- Motivated offenders are not one in the same in their mindset…a case of **differential effects.**
- Explaining the prevalence of "**Don't Matter**" When Assessing Guardianship and Target Hardening.

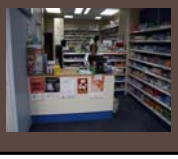
Tara Shelley, Ph.D. ©

Key for Results

- Red = Discourager/Deterrent
- Green = Encourager
- Blue = Does not Matter
  - WHY? Too dope sick or will work around it

Tara Shelley, Ph.D. ©

"Suitable" Targets

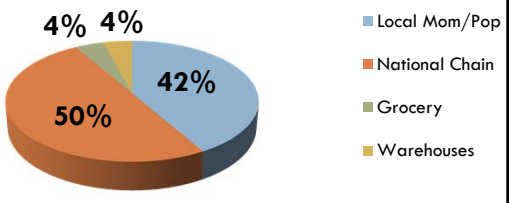




Dimensions of Target Suitability

- **Pharmacies are "suitable" targets**…they have the property that the offender desires, they are accessible, and have a high value (e.g., relief, financial).
- "*…to be honest with you **pharmacies are better than banks**. They are. They're better than banks. **It's the only place of business in today's society that you can go in and steal the product that it offers and get more than what it's worth.**"*


Tara Shelley, Ph.D. ©

"Preparation": Type of Pharmacy Targeted



Tara Shelley, Ph.D. ©

"Preparation": Chain vs. Ma/Pop

Chain	Ma/Pop
"*People tend to rob the Walgreens and CVS more often than anyone* **else…it's a corporate entity. You are not hurting a single person.**"	**Ma/Pops Have Less Security**
"*Nobody wants to see little Suzy blown away at Walgreens because they didn't give up some Roxys*"	*VERSUS*
	Ma/Pop are Armed, Dangerous, Unpredictable
	"*..the mom and pops, that's their livelihood, and apparently they'll fight you for them. So I found out.*"

Tara Shelley, Ph.D. ©

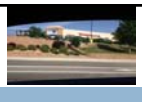
Target Suitability: Ideal vs. Not Ideal?

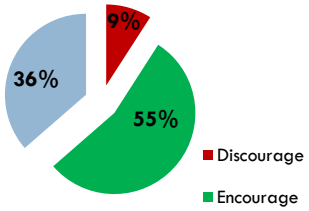
Tara Shelley, Ph.D. ©

Target Suitability: Ideal vs. Not Ideal?

Tara Shelley, Ph.D. ©

Target Suitability: Stand Alone Parking Lot

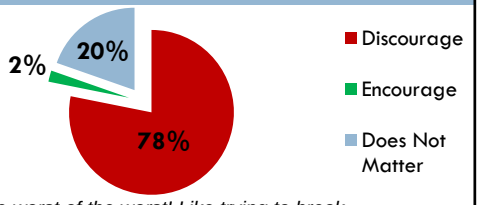




- *"You love those standalones. **ENCOURAGER**! That's exactly what you want."*
- *"So I waited till—it was late. **I remember I kept drivin' around to see how many cars** were in the parking lot."*

Tara Shelley, Ph.D. ©

Worst Pharmacy Location: Grocery Store in Shopping Center



"That's the worst of the worst! Like trying to break into the Vatican."

"I looked at 'em, and there's too many people, too much everything in that place. You can go in there late at night and there's still a dozen people in there."

Tara Shelley, Ph.D. ©

Approaching the Target: Accessibility/Visibility/Open Areas

- *They were probably the most vulnerable out of all of 'em. They're just askin' for it…you could see all the way—the pharmacy's wide open. You could see in there. The pharmacy part of the store is so small, you could see right in there."*
- *"I could see right over it. I could see everything he was doin'."*

Tara Shelley, Ph.D. ©

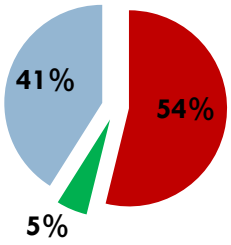
Approaching the Target: Accessibility/Visibility/Open Areas

- *"These drug cabinets are **too close** for the customers' eyes…"*
- *"Yeah, [they were] literally right there, **grabbable**. They grabbed 'em and put 'em in the bag."*
- ***"When I seen 'em pull it off the shelf**, I thought, Why are these people doing this, as bad as this drug is, **keepin' it out in the open like that**? They had bottles of it, I seen 10 or 15 bottles, the 20s, the 40s, the 80s. I thought, **'How easy would it be to just jump over there and just grab 'em?"***

Approaching the Target: Accessibility/Visibility/Open Areas

- *"It was a cabinet by itself that was probably a locking cabinet, and that's where all the stronger narcotic pharmaceuticals were kept.* ***It was unlocked, I just opened it up…"***
- ***"…and they typically keep the safes unlocked, the CVSs do, because they fill so many prescriptions in a day,*** *it's just not efficient to keep dialing them."*

Approaching the Target: High Counter



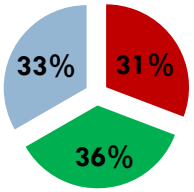
Discourage
Encourage
Does Not Matter

"…she was terse with him and he got mad. ***So he jumped over the counter and this time he had a gun.*** *And he said, "Lady, don't you understand that this is a gun and I'm telling you to get me hydrocodone?"*

Tara Shelley, Ph.D. ©

Pharmacy Counter in Back

"He had no idea, 'cause I got this trash bag. I jumped over and I got this trash bag, and he looked right at me, he looked into my face, and I'm like… 'Hey, what's up, man? I got the trash.' So people are just thinkin', 'Oh, he just works here, he's taking out the trash.' And I walk right out the front, gone. Simple as that."

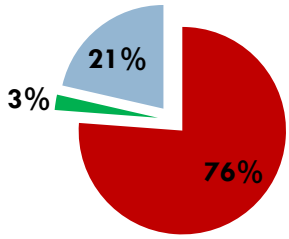


Discourage
Encourage
Does Not Matter

"I just walked out, smiled at the guy at the front and told him to have a nice day. He had no idea."

Tara Shelley, Ph.D. ©

Approaching the Target: Time Delay Safes



Discourage
Encourage
Does Not Matter

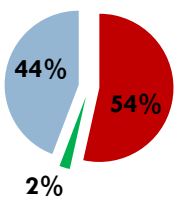
Tara Shelley, Ph.D. ©

Reactions: Time Delay Safes

- ***SOCIAL EDUCATION/MARKETING:*** *"…if you don't advertise it and no one knows about it, there's no sense havin' it,* ***cause then you're just puttin' people's lives at risk."***
- ***"Someone that wants a big shot of dope and you're telling 'em no, that's a dangerous son of a bitch…It would piss them off,*** *but see, that's a buffer, you're goin' Hold on, hold on, hold on. You've only got to wait two minutes. They start sweatin and 99% of 'em are gonna say, Fuck it. Let's get the hell out."*
- ***"I'd probably panic.*** *That would probably cause some people to panic, and then when they panic, it ain't good. Sometimes a person will get scared and run away,* ***but some people start getting' frustrated and start hurtin' people."***

Tara Shelley, Ph.D. ©

Limited Inventory

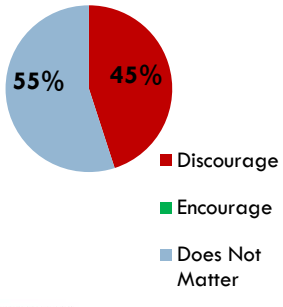


Discourage
Encourage
Does Not Matter

- *"We know so many people got prescriptions, and they gotta get the pills from somewhere. So we figure if they don't have it…we'll leave and go to the next one."*
- *"It doesn't matter. I'm gonna take all the products…I'm gonna get 15 different kinds of Opiates."*

Tara Shelley, Ph.D. ©

Priming the Offender: Camera Surveillance at the Counter

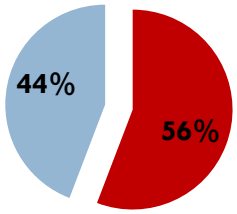


- *"…the Rite-Aid that I was involved in had surveillance system in the inside, **but it was not working.**"*
- *"…the places I robbed had surveillance, and **I didn't care.**"*
- *"…some of 'em, like Walmart, **got the bubbles in the aisles**. I think those are better…"*

Rodney & Cameras

- Robbed multiple pharmacies and never photographed
  - "Because eight of 10 times they don't work…You can tell what cameras work and which don't, sometimes you'll see a light, you'll see a lens dirty."
- His suggestions:
  - INVEST: *"…they need to invest, again, it's money, but they make billions of dollars anyway."*
  - *"I think another thing that would help is a TV monitor in the pharmacy. When you walk up, you're seeing yourself walk up, and it's being recorded from the time you walk up, everybody. You're seein' yourself walk up. Wow! Shit!"*

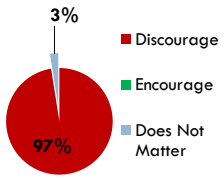
Priming the Potential Offender: Camera Surveillance at Store Entrance



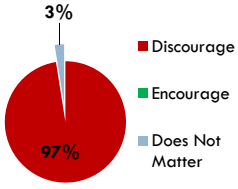
*"**Put a camera outside**. They usually have one on the drive-through, but not the doors on the outside before you walk inside."*

Block Access to Pharmacy

Bullet Resistant Barrier



Pass Through Drawer

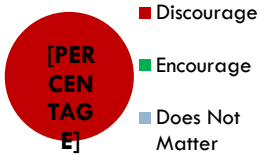


Reactions: Bullet Proof Enclosur /Sliding Pass Through Drawers

- *"But I think they need to go to the way of the gas stations in the ghettos, ya know what I mean? In the hood, fucking like the bullet proof glass in the front so that way you can't just run in, jump over the counter, and force anybody to get 'em."*
- *"The biggest thing is a turnstile for the money and the drugs and bullet proof glass. With that, then you have no way of robbin' it. The only way would be if your slipped in a note and put a shoebox up there and said, "This is a bomb, I'm gonna blow you all to fuckin' hell." Or if you literally grabbed someone in the store and put a gun to their head. You'd have to go to drastic measures."*

CAPABLE GUARDIANS

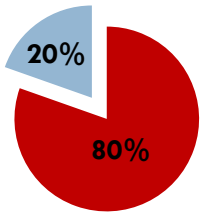
Capable Guardian: Uniformed Armed Guard



- *"It's better than banks because the **security is not the same**…You're not sitting there with an armed guard like banks do."*
- *"If there was a security guard or somethin' out there, yeah, I woulda stopped."* [laughs]

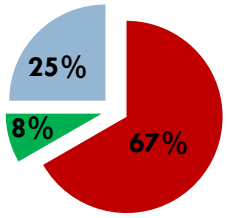
Tara Shelley, Ph.D. ©

Capable Guardian: Uniformed but Unarmed Guard



"No. If I knew he had pepper spray or somethin' like that, I would not have went up there, but if he didn't have nothin', it don't matter. I'd fight him. Who cares?" [laughs]

Capable Guardians: 3 Staff Members in Pharmacy

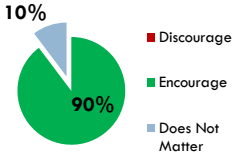


"A lot of people working behind the counter. That's the one thing you don't want…because then you cannot control the situation."

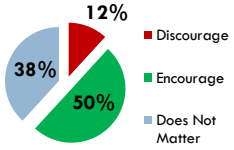
Tara Shelley, Ph.D. ©

Capable Guardian: Staffing in Pharmacy

One Staff Member



Two Staff Members



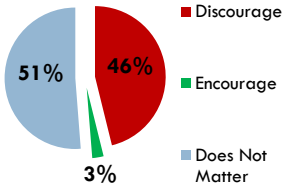
Increase vicarious visibility via radio usage?

Tara Shelley, Ph.D. ©

Capable Guardian: Possible Interference from Staff

"I handed her the note. The lady was like—she said something like, 'are you serious?' I said, 'pretty much.' She said 'get the fuck out of here."

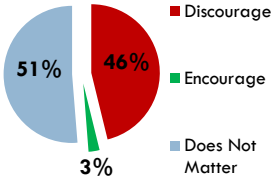
"…she said if you want 'em, come and get 'em."



Tara Shelley, Ph.D. ©

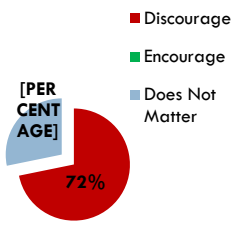
Capable Guardian: Possible Interference from Staff

*"…first thing I'm gonna do is, I'm probably going to shoot him. **I'm gonna show him his own blood first.** I'm not even gonna have to ask for nothin', just take it. If I go into a drug store, I normally pull my gun out and fire it. And instantly when people hear gunshots, they get down."*



Tara Shelley, Ph.D. ©

Capable Guardian: Presence of Customers



- *"**Cops** get their prescriptions filled too and that was my biggest **fear**."*
- ***"I would probably pistol-whip somebody**. Generally a loaded weapon in someone's face, it terrorizes…**That's why we carried the pistols, was for the hero…***

Offender Profiling & Applications of Key Concepts

Offender Typology Refresher

Apply profiles using offender views about guardianship and target "suitability."

Offender Typology: Addict, Hybrid, Entrepreneur?

- ***General View:** "I've dealt (and used) other drugs, so I was like, '**That's good lookin' money.**"*
- ***Target Suitability:** "I stumbled upon a pharmacy one day while picking up a script with a brother of an ex girlfriend. While waiting in the lobby, I noticed 9 or 10 bottles spread out on the front counter labeled "Hydrocodone." Being that I know 90% of the pill heads in _____, I found my next lick. As we left the pharmacy, I told my buddy—Hey did you see all those on the service desk? He stated, That's not even the best part, **they leave those pills there over night after they close.** To myself, I said 'Is that right?'…So began my habit of pharmacy burglary."*
- ***Guardianship:** "You go to like a pain management clinic…and **you don't rob them because the security's so much tighter there.**"*

Offender Typology: Addict, Hybrid, Entrepreneur?

- ***General View:** "Why would anyone rob a gas station when you're facing the exact same time for robbin' a pharmacy, and you could make **$20,000 off of the pills instead of getting' $200 out of a cash register?** Stuff like that would go through my mind."*
- ***Target Suitability:** "…they (community drug stores) don't carry as many drugs, usually. They're usually a smaller operation…if I'm gonna go down for it, I want to get as much as I can…It wasn't worth it to me."*
- ***Guardianship: "You can't teach the street life to pharmacists.** [Laughs] You can walk into a pawn shop and you can look someone in the eye and you can see they know what time it is. But a pharmacist is dumb. They're lost, and you see it all over their faces.[Laughs] When you go in there, you know what you're looking at. **You got you a lame duck, and you're gonna do what you do. That's it. That's the problem. You can't teach that part to people. You have to live it.**"*

Offender Typology: Addict, Hybrid, Entrepreneur?

- ***General View: "I was the first victim in this crime**…I was overmedicated by these doctors."*
- ***Target Suitability***
  - *"So I said, **The first pharmacy I come to, I'm just gonna rob it** and get the OxyContin, eat 'em, and that's it."*
  - *"I was freakin' out, cause I was out of pills and I was gonna get sick, and I didn't know what to do. **So I'm drivin' home, and I get to the corner…and there's a CVS."***
- ***Guardianship***
  - *"I'm **more fearful of the customers** than I am anybody else."*
  - *"I had already made the decision that if they decided not to give me it, I was just gonna leave anyway. **I've never stabbed anybody or hurt anybody in my life…"***

Question 1

- **True or false. Most pharmacy robbers have been to the same pharmacy to fill a prescription at some point prior to the robbery.**
  - True
  - False

Question 2

- **True or false. Most pharmacy robberies involve an injury to the offender and/or a member of the pharmacy staff.**
  - True
  - False

Question 3

- **Which of the following will reduce pharmacy robbery & burglary?**
  - A=Reduce Target Suitability
  - B=Increase Capable Guardianship
  - C=Reduce Motivated Offenders
  - D=All of the Above
  - E=Only A & B

Exploring Deterrence

A Fixed Effect Time Series Analysis for Determinants of CPD Robberies Reported to the DEA (via Form 106) for 2006-2014.

TARLETON STATE UNIVERSITY

Fixed-Effects Time Series Coefficients (b) & Standard Errors (SE) for Determinants of Pharmacy CPD Robberies

	Model 1		Model 2		Model 3	
	b	SE	*b*	SE	*b*	SE
Reformulation	**-5.12***	2.40	3.97	3.22	**-3.94#**	2.02
Population	**8.7*10^8*** **	2.5*10^8	-6.7*10^7	4.5*10^8	**8.7*10^8*** **	2.4*10^8
Age	**4.37****	1.62	0.65	2.45	**3.97****	1.38
% White	-98.54	66.14	-17.05	98.02	**-116.06#**	62.46
% Unemployed	**124.66***	56.5	**202.89#**	111.70	**106.18****	37.99
% Single parent	63.79	74.88	7.16	109.82	-	-
% Male	**353.33#**	197.22	-85.97	299.99	**336.27#**	190.03
% Food stamps	-57.23	46.59	-79.22	75.18	-	-
Family income	.0001	.0002	**.0004#**	.0002	0.0002	0.0002
Household migration	-4.16	94.06	-81.64	156.09	-	-
Education	-1.21	7.15	-0.08	9.83	-	-
Non-medical pain reliever use	-	-	1.60	1.49	**3.19****	1.17
LEOs trained	-	-	0.004	0.004	-	-
HCPs trained	-	-	0.004	0.004	-	-
Bottle tracking	-	-	2.00	2.97	-	-
Time delay	-	-	0.40	4.04	-	-
PDMP	-	-	**-11.61*****	2.58	**-4.59***	1.87
Chain pharmacies	-	-	-0.02	0.04	-	-
Independent pharmacies	-	-	-0.04	0.03	-	-
Constant	-327.55*	127.79	41.80	198.13	-303.40**	115.42
N	453		283		435	
F	**9.34*****		**2.22****		**12.98*****	
R^2 *within*	**0.216**		**0.164**		**0.237**	

Notes: ***$p<0.001$, **$p<0.01$, *$p<0.05$, #$p<0.10$ significance (two-tailed).

Question 4

- **Which of the following strategies had *the strongest effect* on reducing pharmacy robbery?**
  - A=Bottle tracking
  - B=PMPs/PDMPs
  - C=Abuse deterrent formulations of controlled prescription drugs
  - D=DNA spray security systems

Concluding Remarks

- **Reduce Target Suitability, Increase Guardianship, Decrease Motivated Offenders***
  - Diminish by getting offenders to NOTICE reduced target suitability/increased guardianship & UNDERSTAND how this adversely impacts facilitation of **crime…but this is NOT a silver bullet solution due to…DIFFERENTIAL EFFECTS.**
  - *"It's a shame that a pharmacist would have to attend classes or do things to prevent crime from happening or even to turn him from wantin' to even enter that profession. It's a twisted situation."*

Thank you!

Tara O'Connor Shelley, Ph.D.
Associate Professor & Director of the Institute for Criminal Justice Leadership & Public Policy
School of Criminology, Criminal Justice and Strategic Studies
Tarleton State University
Shelley@Tarleton.Edu

"You're Gonna Get 'Em"

- *"If the drugs are on hand, there's nothing, if you're determined, **whether you have to put a gun to someone's head or shoot 'em to get a key or a combination or blow a safe**—whatever you want to do, **if you're determined you're gonna get 'em."***
- *"Really, this is gonna go down, **this is gonna happen no matter what security you've got. And until they figure out a way to fight the drug addiction totally** and completely, it'll never go away."*
- *"If the **drugs are addictive and euphoric**, people are going to go for them. It doesn't matter."*

Displacement: Pharmacy Staff Home Invasion

- *"You're sought-after. They need to take more precautions. I think all of 'em should carry pistols. They should. That's what's comin next. The home invasions, that's what's comin next on the pharmacies."*
- *"If I was desperate enough or that evil enough, I could see your name, and I could watch when you leave and be like, 'Oh, she's the manager,' and then just follow you home…break into your house at night, tie the family up. 'You're gonna come. We're gonna go open that up. You're gonna take the alarm off. We're gonna walk in the back. You're gonna give me the fuckin' drugs and we're gonna leave.'"*

Bottle Tracking

- *"They should have dummy bottles, fake bottles with the dye packs. When they come, give 'em them bottles and let 'em go. That is the best thing. They think they got somethin', and then once they get out of the parkin' lot or whatever, it blows up and they are marked."*
- *"If they could design some kind of sensor on the pharmaceutical bottles, that would be like On-Star in the car…and once they left that store, that sensor would go off, that would discourage just about everybody, once they knew about that. I don't see where that would be much of a problem doin' it with all the technology they've got out there now."*

Current Consideration for Conducting a Root Cause Analysis: a case study

Donna Horn, M.S., R.Ph., D.Ph.
Karen Ryle M.S., R.Ph., D.Ph

1

Disclosures

- Donna Horn and Karen Ryle declare no conflicts of interest.

2

Learning Objectives

- Describe how to analyze a medication error using a specific set of steps and associated tools to identify the contributing factors and root causes of the event.
- Prepare an action plan from the Root Cause Analysis (RCA) which includes risk-reduction strategies, communication, and implementation strategies as well as ways to measure effectiveness.
- Identify common pitfalls that may occur when conducting an RCA.

3

Self Assessment Question 1

- What is the first step for conducting a Root Cause Analysis?

A. Create a flow chart
B. Formulate a team
C. Develop an Action Plan
D. Identify root cause reduction strategies

4

Self-Assessment Question 2

- All adverse events that occur at the pharmacy must be investigated using the RCA method.

A. True
B. False

5

Self-Assessment Question 3

- Which statement is false in regards to a successful RCA?

A. Continuously asks “why” until all root causes have been identified
B. Focuses primarily on individual performance
C. Identifies changes to reduce the risk of recurrences or close calls
D. The RCA team includes organization’s leadership and individuals closely involved in the incident

6

Self-Assessment Question 4

- All of the following basic questions must be asked during the RCA process, but which is the most critical to answer?

A. What happened?
B. What normally happens?
C. What do the policies and procedures require?
D. Why did it happen?

7

Self-Assessment Question 5

- When an event involves staff who cut corners, breach a policy, or did not follow a procedure, the RCA process can be stopped since the root cause leading to the error event has been discovered.

A. True
B. False

8

It's the System…Not the People

"Incompetent people are, at most, 1% of the problem. The other 99% are good people trying to do a good job who make very simple mistakes and it's the processes that set them up to make these mistakes."

Dr. Lucian Leape
Harvard School of Public Health

9

Case Study

- "Shannon" is a 15 year old
- Prescribed Amitriptyline 10 mg for prophylaxis of migraines
- Directions to take 2 tablets at bedtime
- Rx was for #60 with 5 refills
- Original Rx was dispensed correctly
- She is currently a junior residing in a boarding school
- Currently studying in an advanced program

10

Case Study

- On the 1st refill, she received Amitriptyline 100 mg
- Directions to take 2 tablets at bedtime
- Her daily medication was distributed every morning by the school nurse
- Shannon notices the pills looked different
- Shannon sends an e-mail to the school nurse
- "Thank you for being so diligent"
- Nurse responded that it was a new batch and it is the same medication, different company
- Shannon takes the medication for 7 days

11

Amitriptyline

- Amitriptyline is a Tricyclic Antidepressant
- Used for the treatment of depression
- Off label use for migraines
- FDA boxed warning:
  - Increased risk of suicidal thinking and behavior in children, adolescents and young adults
  - Need close observation for suicidality or unusual changes in behavior
- Shannon experiences dizziness, syncope, cardiac issues, hypotension and abnormal heart rate
- Admitted to the hospital for suspected seizures
- Adverse Outcome -- short term memory loss -- can no longer attend college and become a research scientist as was her dream

12

Case Study

- Shannon is discharged from the hospital
- Following day, she boards a plane to Ireland to visit her grandmother
- Shannon's mother noticed the different color pill when packing her medicine
- Shannon's mother looks up the medicine in WebMD and discovers that the medication in the bottle is Amitriptyline 100 mg
- The label indicates 10 mg
- She notifies her daughter to stop the medication and contacts the pharmacy

13

The Pharmacy

- "Home Town Pharmacy" filled Shannon's refill with Amitriptyline 100 mg instead of 10 mg
- Home Town Pharmacy provides a wide variety of pharmacy services
  - Specialty Pharmacy Services
  - Medication Therapy Management
  - Disease State Management
  - Long Term Care Facilities
  - Compliance packaging

14

The Pharmacy

- The pharmacy did have appropriate safeguards in place including appropriate technology
  - Prescription scanning
  - Pill imaging
  - Bar code scanning
- The pharmacy system does have an appropriate drug dictionary with drug utilization review screening
  - High dose
  - Drug-drug interactions
  - Drug-disease interactions
  - Drug-allergy interactions
  - Drug-age appropriateness
  - High dose alerts

15

The Technician

- Home Town pharmacy did have appropriate training and policies and procedures in place
- The pharmacy technician "Rob" has been working for Home Town for 8 months
- He was going through a messy divorce
- He had 20 years experience using the pharmacy system
- He prepared the refill
- He pulled the wrong bottle off the shelf

16

The Technician

- He overrode the bar code scanning
- When a mismatch occurs a red X appears on the screen that states "QA scan failed", to move to the next step, he has to hit override
- He does not recall the incident
- Store policy is to alert the pharmacist when you override the bar code scan
- Rob knows he is not allowed to override on QA scan without notifying the pharmacist
- Rob was terminated after the incident was discovered

17

The Pharmacist

- The pharmacist "Mary" verified the medication
- Her routine is to always open and look inside the bottle and match the pills with the pill image
- The pharmacy system does have an alert warning her that there was a bad QA scan override
- She acknowledges that this message appears on the screen
- She did not "see" the message and also recognizes that there is "so much stuff on the computer screen"
- She completed the scanning function by hitting the enter button
- No "hard stop"

18

The Pharmacist

- Mary would not intentionally ignore a warning of a bad scan
- She looked at the stock bottle of 100 mg and then looked at the tablets inside, they matched
- She failed to notice that the label indicated 10 mg rather than 100 mg
- Look at the label first, then the bottle?
- Confirmation Bias?
- Human Error?

19

The School Nurse

- What role did the nurse have in this error?
- Shannon did alert the nurse that the medication looked different
- The nurse now has "special knowledge" in the difference in the appearance of the medication
- She claims to have called the pharmacy and was told the medication was a different manufacturer
- Pharmacy does not acknowledge speaking with anyone from the school regarding Shannon's medication
- Phone records do not indicate that a call took place

20

Definitions

- Confirmation Bias is the tendency to search for, interpret, favor, and recall information in a way that confirms one's preexisting beliefs or hypotheses
- Human Error is defined as an inadvertent action; inadvertently doing other than what should have been done; slip, lapse, mistake

21

What Type of Behavior?

- *Human Error:* mistakes, slips, lapses, and unintentional deviations from accuracy and correctness
  - Most errors are in this category
  - Action: Console
- *At-Risk Behavior:* Behavioral choices that increase risk where risk is not recognized, or is mistakenly believed to be justified
  - Increase situational awareness
  - Action: Coach
- *Reckless Behavior:* Conscious disregard of a risk of causing harm
  - Remedial and punitive action
  - Action: Punish

Patient Safety and the "Just Culture" David Marx JD

22

Human Error

23

At Risk Behavior

24

Reckless Behavior

25

What is RCA?

- A systematic process to identify the causal factors contributing to the occurrence of a sentinel event
- Goal - find out **what** happened, **why** it happened and what to do to **prevent** it from happening again
- Focus on pharmacy systems and processes - not individuals; does not assign blame
- Conducted by team of interdisciplinary individuals
- Recognizes the underlying and fundamental conditions that increase the risk of adverse events
- Implements effective strategies that target root causes

26

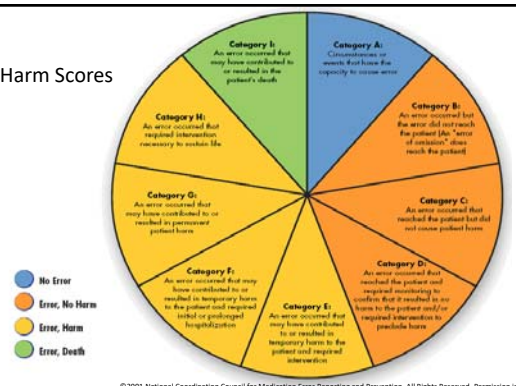
When is RCA Necessary?

- Not every adverse event
- Organizations should specify/define "require RCA?" or "investigate through case reviews or investigative techniques?"*
- NOTE: If the event is thought to be the result of a criminal or purposefully unsafe act or related to alcohol or substance abuse, stop the RCA process and report individual(s) to organization leader

*http://www.ismp.org/Tools/Community_AssessERR/default.asp

27

Harm Scores



28

Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy

- Describe the root cause analysis (RCA) process
- Prompt users to create an action plan from the RCA, including implementation strategies
- Describe common pitfalls when conducting RCA
- Provide examples of RCA with actual errors

29

Basic Questions

Basic Questions to Answer During RCA
1. What happened?
2. What normally happens?
3. What do policies/procedures require?
4. Why did it happen?
5. How was the organization managing the risk before the event?

30

Definitions

- **Root Cause**: Most fundamental reason an event has occurred
- **Contributing Factor**: Additional reasons, not necessarily the most basic reason that an event has occurred

31

Definitions

- **Sentinel Event**: an unexpected occurrence involving death or serious physical or psychological injury or risk thereof
- **Medication Error:** any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer

32

Case Study: the Error

- Patient received Amitriptyline 100 mg instead of the 10 mg
- Experiences dizziness, syncope, cardiac issues, hypotension and abnormal heart rate
- Admitted to the hospital for suspected seizures
- Adverse Outcome -- short term memory loss -- can no longer attend college and become a research scientist as was her dream

33

Sentinel Event?

a. Yes
b. No

34

Step 1 Formulate a Team

Step 1 - RCA Name: Amitriptyline 100 mg dispensed in error
Date of Event: 11/14/2016
Problem Statement: Patient ingested the incorrect medication and suffers from permanent short term memory loss as a result
Team Members
Team Leader: Ross Geller, Director of Pharmacy
Event expert (person involved in event): Chandler Bing, CPhT
Front line worker familiar with process: Rachel Green, RN
Non-pharmacy personnel: Joseph Tribianni
Technical RCA expert (optional): Phoebe Buffay

35

Step 2 Determine What Happened

- Review documentation
- Interview pharmacy staff involved in incident

Which is why termination should not be the preventative action

36

Review Documentation

- Prescription for Amitriptyline 10 mg filled with Amitriptyline 100 mg at Home Town Pharmacy
- Stock bottles
- Tablet imaging
- Patient counseling log; counseling not offered (delivery)
- Computer records: barcode scan was overridden
- Review of previous incident reports shows 3 out of 10 errors involved bar code scanning overrides
- No records of CQI meetings taking place (CQI is required by Board regulations)

CQI= Continuous Quality Improvement

37

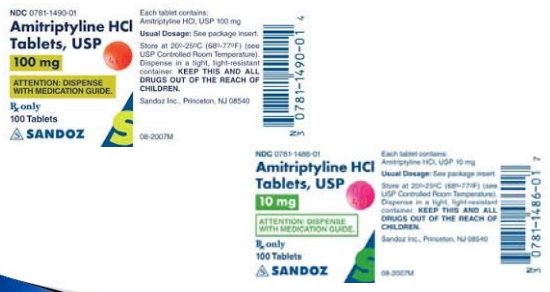
Amitriptyline Image

Amitriptyline 100 mg
NDC 00781-1490-01
Manufacturer- Sandoz
GG461

Amitriptyline 10 mg
NDC 00781-1486-01
Manufacturer- Sandoz
GG40

38

Amitriptyline Stock Bottles



39

Interview Staff

- Use proper interviewing techniques without assessing blame
  - Seek system issues; do not judge or interrupt
  - Make staff comfortable
  - Active listening: reflect, restate, summarize
  - Body posture, eye contact, nod appropriately
- Use interview to create timeline of events
  - Broad open-ended questions
  - If recall issues, ask to describe what they usually do
- Create workflow chart

40

Interview Staff: Tech

- It was a busy Monday morning
- Knows that he is not supposed to override the bar code scan
- Knows he is to notify the pharmacist if there was a bar code scan override
- He did override the bar code scan but he did not notify Mary

Questions for RCA: why does the system allow overrides if the policy is not to override and why does the policy say not to, but then says "however if you do…."

41

Interview Staff: Tech

- Mismatch in the bar code scan of the label and the bottle, a red X appeared on the screen that states "QA scan failed"
- To move to the next step, he hit "O" for override
- He did not document the reason for the override
- He does not recall any part of the process
- He did not consciously override the scan knowing it was going to bring harm to Shannon
- He was not aware of previous incident reports showing 3 out of 10 errors involved bar code scanning overrides; two errors occurred on his shift

42

Interview Staff: RPh

- Mary received a message in the upper right hand corner on the screen alerting her to a warning of a bad QA scan override
- She did not "see" this message
- She stated there is "so much stuff on the computer screen"
- She verified and completed the scanning function by hitting the enter button, deposited the medication in the bag and prepared the bag for delivery

43

Step 2 (cont.) Details of Event

Step 2 - What Happened	
Question	**Finding**
What are the details of the event? (i.e., event description)	Wrong stock bottle selected Mismatch in the bar code scan of the label and the bottle, a red X appeared on the screen that states "QA scan failed" System allows user to hit "O" for override Policy requires pharmacist be notified of override; pharmacist not notified System does not require documenting the reason for the override A message appears in the upper right hand corner on the pharmacist verification screen with a warning of a bad QA scan override The pharmacist is not required to acknowledge the message Previous incidents not discussed with staff
When did the event occur?(e.g., date, day of week, time)	Medication was refilled and dispensed on a busy Monday morning in November Patient took the wrong dose for 7 days then admitted to the hospital for seizures

44

Step 3 Flow Chart

Step 3 – Flowchart Steps in the Process	
In this step, describe how the event happened using a flowchart to illustrate. ***Tip:*** *When developing the flow chart of events, don't jump to conclusions. It is essential to stay focused on what* ***actually*** *happened – not what the team* ***thinks*** *happened; construct a basic "time series" of the facts leading up to and including the adverse outcome.*	
Question	**Finding**
What are the steps in the process? (complete a flowchart)	*Attach process flow chart to template*
Why did it happen? What events were involved in (contributed to) the event?	?

45

Step 3 (cont.) Flow Chart

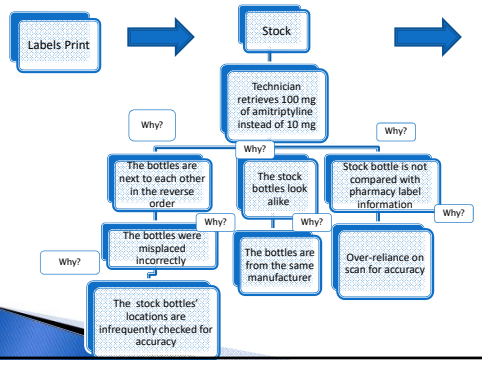
- Diagram the flow of events
  - Describe how the event happened using a flowchart to illustrate
  - Attach flow chart to RCA

Remember: When developing the flow chart of events, don't jump to conclusions. It is essential to stay focused on what **actually** happened – not what the team **thinks** happened; construct a basic "time series" of the facts leading up to and including the adverse outcome

http://www.ismp.org/communityRx/aroc/

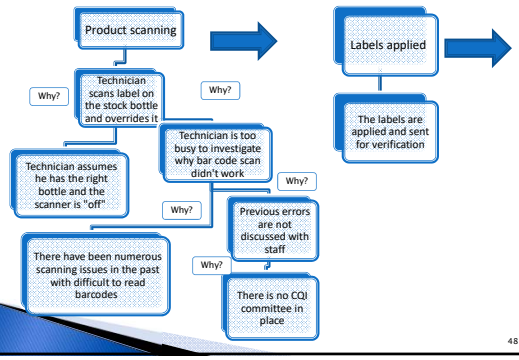
46

Review of the Event: Flow Chart



47

Flow Chart (cont.)



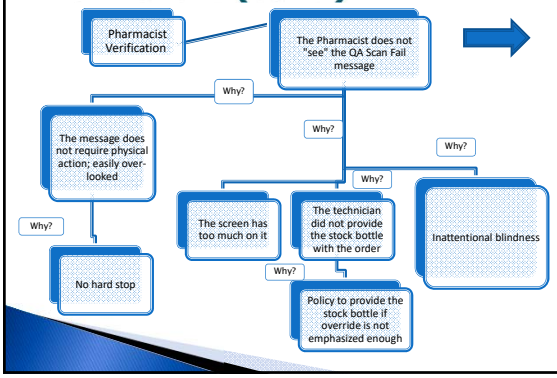
48

From the Interview

- Mary testified that she would not intentionally ignore a warning of a bad scan
- She failed to see the warning on the HBS system alerting her to the QA scan override

49

Flow Chart (cont.)



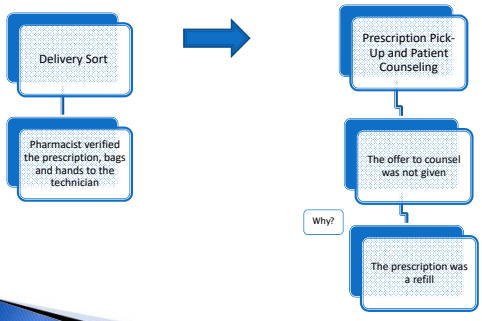
50

Inattentional Blindness

- *The person performing the task fails to see what should have been plainly visible, and later, they cannot explain the lapse*
- In many cases, people involved in the errors have been labeled as careless and negligent
- But these types of accidents are common—even with intelligent, vigilant, and attentive people

51

Flow Chart (cont.)



52

Step 3 Flow Chart

Step 3 – Flowchart Steps in the Process	
In this step, describe how the event happened using a flowchart to illustrate. ***Tip:*** *When developing the flow chart of events, don't jump to conclusions. It is essential to stay focused on what* ***actually*** *happened – not what the team* ***thinks*** *happened; construct a basic "time series" of the facts leading up to and including the adverse outcome.*	
Question	**Finding**
What are the steps in the process? (complete a flowchart)	*Attach process flow chart to template*
Why did it happen? What events were involved in (contributed to) the event?	Wrong drug selected for refill Barcode scan overridden Override not detected

53

Key Elements of Medication Use

1. Patient information
2. Drug information
3. Communication of drug information
4. Labeling, packaging, and nomenclature
5. Drug storage, stock, standardization, and distribution
6. Device acquisition, use, and monitoring
7. Environmental factors
8. Staff competency and education
9. Patient education
10. Quality and risk management issues

54

Which Key Elements ?

a. Drug information (2) and Environmental factors (7)
b. Staff competency (8) and Labeling/packaging (4)
c. Patient information (1) and Patient Education (9)
d. Drug information (2), Labeling/packaging (4), Environmental factors (7), and Quality and risk management issues (10)

55

Step 4 Identify Root Causes

- Study the problem
  - Identify which elements/systems are involved from flow chart (2, 4, 7 and 10)
  - Review key element #2, 4, 7, and 10 and *contributing factors* charts
- Complete Step 4 (1-10 key elements)
  - Indicate if "contributing factor" or "root cause" and check "take action" if root cause

http://www.ismp.org/communityRx/aroc

56

Step 4 – Identify Proximate (Contributing) Factors and Root Causes

As an aid to avoiding "loose ends," the last three columns on the right are provided to be checked off for later reference:

* *"Root cause?" should be answered "Yes" or "No" for each finding. Each finding that is identified as a root cause should be considered for an action and addressed in the action plan. Number each finding that is identified as a root cause.*
* *"Contributing factor?" should be answered "Yes" or "No" for each finding.*
* *"Take action?" should be checked off for each finding that can reasonably be considered for a risk reduction strategy. Each item checked in this column should be addressed later in the action plan.*

Tip: *Contributing factor statements must clearly address why something has occurred and there must be a* ***clear focus on process and system vulnerabilities, never on individuals****.*

57

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contri-buting Factor?	Take Action?
1. Was critical patient information missing? *(e.g., age; sex; weight, allergies; pregnancy; patient identity; address; indication for use or health conditions)*				

58

Proximate Factor Questions	Findings/Proximate Factors	Root Cause? (If yes, assign #)	Contri-buting Factor?	Take Action?
1. Was critical patient information missing? *(e.g., age; sex; weight, allergies; pregnancy; patient identity; address; indication for use or health conditions)*		No	No	

59

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
2. Was critical drug information missing? *(e.g., inadequate computer alerts; typical dose; maximum dose; route; contraindications; precautions; special warnings; drug interactions; cross allergies; outdated or absent references)*	Override alert appears but does not require action			

60

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
2. Was critical drug information missing? *(e.g., inadequate computer alerts; typical dose; maximum dose; route; contraindications; precautions; special warnings; drug interactions; cross allergies; outdated or absent references)*	Override alert appears but does not require action	Yes 1		Yes

61

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
3. Miscommunication of drug order? *(e.g., illegible; ambiguous; incomplete; misheard or misunderstood spoken prescription; poor fax quality; unable to clarify with prescriber; teamwork issues; warnings bypassed; error-prone abbreviations or dose expressions)*				

62

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
3. Miscommunication of drug order? *(e.g., illegible; ambiguous; incomplete; misheard or misunderstood spoken prescription; poor fax quality; unable to clarify with prescriber; teamwork issues; warnings bypassed; error-prone abbreviations or dose expressions)*		No	No	

63

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
4. Drug name, label, packaging problem? *(e.g., look- and sound-alike names; look-alike packaging; no drug image; pharmacy labeling issue; label that obscures information; label not visible; warning labels missing or inconsistently applied; NDC or barcode not available or not used; faulty drug identification)*	Look-alike packaging from same manufacturer Tablets similar color and strength			

64

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action?
4. Drug name, label, packaging problem? *(e.g., look- and sound-alike names; look-alike packaging; no drug image; pharmacy labeling issue; label that obscures information; label not visible; warning labels missing or inconsistently applied; NDC or barcode not available or not used; faulty drug identification)*	Look-alike packaging from same manufacturer Tablets similar color and strength		Yes Yes	Yes No

65

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
5. Drug storage or delivery problem? *(e.g., drug stocked incorrectly; crowded shelves; look-alike products stored next to each other; adult dosage forms for neonatal or pediatric patients)*	The bottles are often misplaced in the reverse order on the shelf (the 100 mg is often on the left of 10 mg bottle)			

66

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
5. Drug storage or delivery problem? *(e.g., drug stocked incorrectly; crowded shelves; look-alike products stored next to each other; adult dosage forms for neonatal or pediatric patients)*	The bottles are often misplaced in the reverse order on the shelf (the 100 mg is often on the left of 10 mg bottle)		Yes	Yes

67

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
6. Drug delivery device problem? *(e.g., automated dispensing devices not calibrated or maintained; oral measuring device not dispensed)*				

68

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
6. Drug delivery device problem? *(e.g., automated dispensing devices not calibrated or maintained; oral measuring device not dispensed)*		No	No	

69

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
7. Environmental, staffing or workflow problems? *(e.g., poor lighting; excessive noise; clutter; foot traffic interruptions; human factors; workload; inefficient workflow; breaks not scheduled; staffing levels and skills; work schedules; inadequate supervision)*	Busy Monday morning The order was rushed because the deliveries needed to get out			

70

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
7. Environmental, staffing or workflow problems? *(e.g., poor lighting; excessive noise; clutter; foot traffic interruptions; human factors; workload; inefficient workflow; breaks not scheduled; staffing levels and skills; work schedules; inadequate supervision)*	Busy Monday morning The order was rushed because the deliveries needed to get out		Yes Yes	No No

71

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
8. Lack of staff education? *(e.g., competency validation; new or unfamiliar drugs or devices; orientation process; feedback about errors and prevention; inexperience; orientation; low compliance with mandatory education; required certification; support for advanced certification and education)*				

72

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor?	Take Action ?
8. Lack of staff education? *(e.g., competency validation; new or unfamiliar drugs or devices; orientation process; feedback about errors and prevention; inexperience; orientation; low compliance with mandatory education; required certification; support for advanced certification and education)*		No	No	

73

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor ?	Take Action ?
9. Patient education problem? *(e.g., lack of information; non-adherence; not encouraged to ask questions; lack of investigating patient inquiries; patient barriers; complex drug regimen; medication reconciliation problem; health literacy; language barrier or other communication problem; intimidated by staff; mental health issue)*	Patient's issues not addressed adequately by school nurse			

74

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor ?	Take Action ?
9. Patient education problem? *(e.g., lack of information; non-adherence; not encouraged to ask questions; lack of investigating patient inquiries; patient barriers; complex drug regimen; medication reconciliation problem; health literacy; language barrier or other communication problem; intimidated by staff; mental health issue)*	Patient's issues not addressed adequately by school nurse		Yes	No

75

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor ?	Take Action ?
10. Quality process and risk management? *(e.g., no culture of safety; fear of error reporting; system-based causes not analyzed; lack of equipment quality control checks; focus on productivity and volume; financial resources or constraints; organizational structure and priorities conflict; technology workaround and/or malfunction; design flaw; technology user error; technology and devices not meeting needs)* ***(human factors issues:** task and information complexity; ergonomics; time urgency; familiarity with task, product, or equipment; mental and physical health of staff; fatigue; fitness for duty; stress; motivation)*	Technician is "allowed" to bypass barcode scan and still have medication moved to next station; Previous scan overrides resulting in errors not investigated			

76

Proximate Factor Questions	Findings/ Proximate Factors	Root Cause? (If yes, assign #)	Contributing Factor ?	Take Action ?
10. Quality process and risk management? *(e.g., no culture of safety; fear of error reporting; system-based causes not analyzed; lack of equipment quality control checks; focus on productivity and volume; financial resources or constraints; organizational structure and priorities conflict; technology workaround and/or malfunction; design flaw; technology user error; technology and devices not meeting needs)* ***(human factors issues:** task and information complexity; ergonomics; time urgency; familiarity with task, product, or equipment; mental and physical health of staff; fatigue; fitness for duty; stress; motivation)*	Technician is "allowed" to bypass barcode scan and still have medication moved to next station Previous scan overrides resulting in errors not investigated	Yes 2 Yes 3		Yes Yes

77

Step 5 Write Root Cause Statements

- Focus on system-level vulnerabilities
- Read and apply the five rules of causation
  1. Causal Statements must clearly show the "cause and effect" relationship
     - "Technician was overwhelmed" is deficient without description of how and why this led to a mistake
  2. Negative descriptors (e.g., poorly, inadequate) are not used in causal statements
     - Broad, negative judgments that do little to describe the actual conditions or behaviors that led to the error
     - **Wrong**: The technician was careless in overriding the bar code scan
     - **Right**: Barcode scanning technology can easily be overridden resulting in wrong drug being dispensed

78

Step 5 Write Root Cause Statements

3. Each human error must have a preceding cause
   - Investigate to determine WHY the human error occurred
   - System-induced error (e.g., step not included in procedure)
   - At-risk behavior (doing task by memory, instead of a checklist)
   - **Wrong**: The technician overrode the barcode scan
   - Right: Since barcode scanning frequently needs to be overridden and had never resulted in an error, the technician was in the practice of overriding barcode scans
   - Workarounds and violations are outcomes of human error -- not causes

79

Step 5 Write Root Cause Statements

4. Each procedural deviation must have a preceding cause
   - It is the cause of the procedural violation that we can manage
   - If a technician is missing steps in a procedure because he is not aware of the safety value, work on education
   - **Wrong**: The technician failed to alert the pharmacist of the barcode scan override
   - **Right**: The written procedure to alert the pharmacist was not enforced
5. Failure to act is only causal when there was a pre-existing duty to act
   - The duty to perform may arise from standards and guidelines for practice
   - Pharmacist is required to acknowledge alert messages during verification
   - **Wrong:** The pharmacist did not see the alert message
   - **Right**: The system does not require alert messages be acknowledged resulting in messages being "missed" during verification

80

Root Cause Statements

Step 5 – Root Cause Statements

Using the findings identified as root causes in Step 4 above, write concise descriptions of the cause-and-effect relationship. Ensure that the team has not focused on the actions of individuals or in any way placed blame.

***Tip:** To determine whether a statement is effective, ask, "If this is corrected, will it reduce the likelihood of another adverse event?" The answer should be yes.*

Root Cause #	Statement of Cause
1	The system does not require alert messages be acknowledged resulting in messages being "missed" during verification
2	Barcode scanning technology can easily be overridden resulting in wrong drug being dispensed
3	Previous incidents not discussed with staff, resulting in errors repeated

81

Step 6A Develop Actions

- Formulate improvement actions for each identified root cause in Step 5
- Consider quality improvement actions for identified contributing factors
- Review key elements and suggested *risk-reduction* strategy charts (AROC) http://www.ismp.org/communityRx/aroc/
- Employ a mix of higher- and lower-leverage strategies that focus on system issues and address human issues

82

Rank Order of Error Reduction Strategies

Forcing Functions and Constraints

↓

Automation and Computerization

↓

Standardization and Protocols

↓

Checklists and Double Checks

↓

Rules and Policies

↓

Education and Information

Select high-leverage error prevention tools that are designed to fix the system, not just people, whenever possible

83

Brainstorming Action Plan, RCA Team asks:

- How can we decrease the chance of the event occurring again?
- How can we decrease the degree of harm if the event were to occur again?
- When considering changing procedures or rules, ask: What is best practice?
- How can devices, software, work processes, or workspace be redesigned using a human factors approach?
- How can we reduce reliance on memory and vigilance by improving processes in the workplace?
- Does the organization have resources for the proposals?

84

Step 6B Establish Outcome Measures

- Establish a way to measure effectiveness of action plan over time
- Record methods to measure effectiveness over time

Tip: *Discuss the proposed risk reduction strategies with the person who reported the incident to see if they believe that the RCA team is on the right track.*
Ask: If these recommendations were in place at the time of the incident, do you think it likely that the incident may have been prevented from occurring?

85

Action Plan - Root Causes

Step 6 – Action Plan		
Root Causes		
For each of the root causes identified in Step 5 above as needing an action, complete the following table. Check to be sure the selected measure will provide data that will permit assessment of effectiveness over time.		
Root Cause#	Risk-reduction Strategy	Measure of Effectiveness
1	Create a hard stop requiring alert messages for barcode scan overrides be acknowledged (forcing function)	Run and review scan override reports
2	Remove overriding functionality of bar code scanning at tech station (constraint)	Look for "wrong selection drug" error incidents to decrease
3	Create a CQI team leader and committee to analyze and communicate error reduction strategies (policy, education)	Review CQI meeting notes

86

Action Plan

Contributing Factors		
For each of the contributing factors identified in Step 4 above as needing an action, complete the following table.		
Contributing factor	Risk-reduction Strategy	Measure of Effectiveness
The use of same manufacturers for amitriptyline 10 mg and 100 mg caused the wrong stock bottle to be grabbed	Buy same named drugs with different strengths from different manufacturers and provide shelf dividers/ talkers (standardization, protocol)	Ask pharmacy manager to fulfill this as soon as possible and then monitor patterns of effectiveness
The reversal of order of the amitriptyline 10 mg and 100 mg caused the wrong stock bottle to be grabbed	Check for right locations of stock bottle during down time (procedure, education)	Daily to weekly checks

87

Almost Done! Review Common Errors in RCA

- Avoid Common Pitfalls
  - Start with accurate sequence of events and timeline to help uncover all gaps
  - Don't rely on policies and procedures; illustrate what actually happens
  - Investigate ***why*** staff skipped steps
  - Uncover more deep-seated latent failures in the system
  - Uncover how human errors get through the system

88

Review Common Errors in RCA (cont.)

- Seek outside knowledge
  - Professional literature, regulations, standards, professional guidelines
- Each intervention should be clearly linked to one or more causative factors
- Effective risk-reduction strategies involve redesigning systems; don't rely on:
  - Developing new rules, educating staff, double checks, "be more careful"
- Have realistic plans and measure outcomes
- Resist punitive action

89

Step 7 Communicate the Results

- Provide leadership recommendations for improvement and preventative action plan
- Share with the entire organization as a learning tool and to get buy-in to changes

90

Key Takeaway #1

- RCA is intended to determine three things:
  - What happened?
  - Why did it happen?
  - What can be done to reduce the likelihood of a reoccurrence?

91

Key Takeaway #2

- The RCA framework manageable steps:
  - Form a team
  - Review all documentation (written prescription, data entry, logs, policies, etc.)
  - Review physical environment
  - Review product labeling and packaging
  - Interview those involved in the incident
  - Determine sequence of events through flow charting on the medication use system
  - Ask "why?"
  - Determine contributing factors and root causes
  - Develop an action plan for each identified root cause
  - Communicate results
  - Measure effectiveness of action plan over time

92

Key Takeaway #3

- RCA does not assign blame
  - RCA is an outcome-directed process emphasizing specific, high-leverage actions that take into account the need to integrate safeguards into system design and the need to consider human capabilities and limitations

93

Self Assessment Question 1

- What is the first step for conducting a Root Cause Analysis?

A. Create a flow chart
B. Formulate a team
C. Develop an Action Plan
D. Identify root cause reduction strategies

94

Self-Assessment Question 2

- All adverse events that occur at the pharmacy must be investigated using the RCA method.

A. True
B. False

95

Self-Assessment Question 3

- Which statement is false in regards to a successful RCA?

A. Continuously asks "why" until all root causes have been identified
B. Focuses primarily on individual performance
C. Identifies changes to reduce the risk of recurrences or close calls
D. The RCA team includes organization's leadership and individuals closely involved in the incident

96

Self-Assessment Question 4

- All of the following basic questions must be asked during the RCA process, but which is the most critical to answer?

A. What happened?
B. What normally happens?
C. What do the policies and procedures require?
D. Why did it happen?

97

Self-Assessment Question 5

- When an event involves staff who cut corners, breach a policy, or did not follow a procedure; the RCA process can be stopped since the root cause leading to the error event has been discovered.

A. True
B. False

98

Evolution of Pharmacists' Scope of Practice to Support Direct Patient Care Activities

AACP-NABP District III Meeting
August 7, 2017

Patricia R. Freeman, RPh, PhD
Clinical Associate Professor
Director, Center for the Advancement of Pharmacy Practice
University of Kentucky

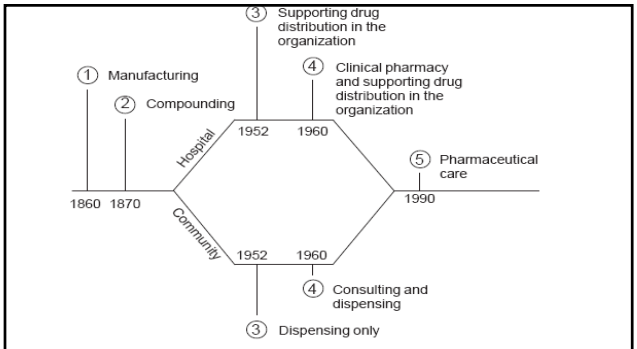
Learning Objectives

- At the end of the session, the participant will be able to:
  - Describe the evolution of pharmacists' scope of practice from product-focused to patient care
  - Discuss regulatory approaches taken by states to support this evolution
  - Identify barriers and challenges to full utilization of pharmacists as healthcare providers

Historical Perspective

- 1820 - 1940: Pharmacist as *compounder* of prescriptions; rise of the classic American drugstore
- 1940 - 1965: Initial development of hospital pharmacy specialty; movement from compounder to *dispenser*; development of the chain drug industry
- 1965 - 1990: Clinical pharmacy era with significant diversification of the profession; focus begins to shift to patient care in hospitals but remains product-focused in community pharmacies
- 1990 - 2005: Pharmaceutical care era; initial focus on the pharmacist as direct care provider in all settings; pharmacists must assume responsibility for patient outcomes of drug therapy
- 2005 - Present: Medication therapy management era; focus on need for provider status to assure pharmacists role as direct care providers

https://pharmacy.wisc.edu/wp-content/uploads/AIHPTeachingGuidelines.pdf



Vol 56 Sep 1 1999 Am J Health-Syst Pharm **1759**

Holland and Nimmo, *Transitions in Pharmacy Practice, part 1: Beyond Pharmaceutical Care*, Am J Health-Syst Pharm. 1999; 56:1758-64

University of Kentucky

Hepler and Strand: 1990

Opportunities and Responsibilities in Pharmaceutical Care

"Pharmacists must abandon factionalism and adopt patient-centered pharmaceutical care as their philosophy of practice.

"Pharmacy's re-professionalization will be completed only when all pharmacists accept their social mandate to ensure the safe and effective drug therapy of the individual patient."

American Journal of Health-System Pharmacy March 1990, 47 (3) 533-543;

National Influence on Practice Change

- ASHP
  - Historical support of clinical pharmacy services in hospitals; 50 years of residency accreditation
  - Pharmacy practice model initiative (PMMI) summit (2010)
  - Ambulatory Care summit (2014)
  - Together these led to what is now known as the Practice Advancement Initiative (PAI).
- APhA
  - Partnered w ASHP to establish accreditation standards for community pharmacy residencies in 1999
  - Collaborated w NACDS to develop Core Elements of MTM (2005)
  - Led development of the Pharmacist Patient Care Process with other pharmacy organizations (2014)
- ACCP
  - White Paper: A vision of Pharmacy's Future Roles, Responsibilities, and Manpower Needs in the US (2000)
  - *"The time has come to unify the profession in pursuit of its patient care mission. Pharmacy is maturing as a clinical profession and presently is well position to transform itself form a product-oriented to a patient-oriented profession*
- \

National Influence on Practice Change

- ACPE/AACP
  - Adopted accreditation Standards and Guidelines for the Professional Program in Pharmacy Leading to the Doctor of Pharmacy Degree (1997)
    - Last student graduates from BSPharm program in 2005
  - Adopted updated accreditation standards and guidelines *"to ensure development of students who can contribute to the care of patients and to the profession by practicing with competence and confidence in collaboration with other health care providers"* (2006)
- Council on Credentialing in Pharmacy
  - Resource Paper *Scope of Contemporary Pharmacy Practice: Roles, Responsibilities and Functions of Pharmacists and Pharmacy Technicians* (2009)

Improving Patient and Health System Outcomes through Advanced Pharmacy Practice

A Report to the U.S. Surgeon General 2011

Office of the Chief Pharmacist

Joint Commission of Pharmacy Practitioners

Vision for Pharmacists' Practice

(adopted by JCPP November 2013)

Patients achieve optimal health and medication outcomes with pharmacists as essential and accountable providers within patient-centered, team-based healthcare.

*JCPP was established in 1977 and serves as a forum on matters of common interest and concern to national organizations of pharmacy practitioners and invited liaison members. JCPP Members are: AMCP, AACP, ACA, ACCP, ACPE, APhA, ASCP, ASHP, NABP, NCPA, and NASPA.

CDC PUBLIC HEALTH GRAND ROUNDS

How Pharmacists Can Improve Our Nation's Health

October 21, 2014

U.S. Department of Health and Human Services Centers for Disease Control and Prevention

NGA PAPER

The Expanding Role of Pharmacists in a Transformed Health Care System

- Published in 2015
- Encourages states seeking to integrate pharmacists more fully into the health care delivery system to:
  - examine state laws and regulations governing pharmacy practice
  - address the challenges to pharmacists practicing to the full scope of their professional training

https://www.nga.org/files/live/sites/NGA/files/pdf/2015/1501TheExpandingRoleOfPharmacists.pdf

State Regulatory Approaches

University of Kentucky

Regulatory Approaches

- Advanced practice designations
- Collaborate practice agreements
- Protocols
  - Statewide protocols
  - Prescriber-approved protocols

Advanced Practice Designations

- New Mexico
  - Pharmacist Prescriptive Authority Act (1993)
    - Creates Pharmacist Clinicians (PhC)
    - Recognizes pharmacists as mid-level practitioners who can manage primary care patients independently in written collaboration with a physician
    - Can prescribe and dispense medications under the CPA

Advanced Practice Designations

- North Carolina
  - Clinical Pharmacist Practitioner Act (2000)
    - Authorizes a CPP to implement predetermined drug therapies as outlined by a CDTM agreement
    - CPPs are in essentially the same position as a physician assistant or nurse practitioner
      - Same supervision and consulting w physician as required for APRNs and Pas (2016)
    - Medical acts which can be performed include prescribing and CPPs who have controlled substances in their protocol can obtain a DEA registration

http://www.ncbop.org/faqs/pharmacist/faq_CPPs.html

Geographic Location of Active Clinical Pharmacist Practitioners (CPPs) in North Carolina, by County.

Jonathan C. Hale et al. North Carolina Medical Journal 2015;76:205-210

Advanced Practice Designations

- California
  - Advanced practice pharmacist (2013)
    - Authorizes expanded scope of practice through CPAs, including authority to perform patient assessments, order and interpret all drug therapy-related tests, refer patients to other healthcare providers, participate in the evaluation and management of disease and health conditions in collaboration with other healthcare providers, and initiate, adjust/modify, and discontinue drug therapy

http://www.cphanet.com/Advocacy/Expanding-Pharmacist-Services

Collaborative Practice Agreements

University of Kentucky

Task Force on
Collaborative Practice Agreements

Members Present:

Sharlea M. Leatherwood, *Chair* (MO); Michael J. Ayotte (VA); Winifred A. Landis (IN); Jeffery Lindoo (MN); C. Ann Perry (GA); Charles R. Young (MA).

Others Present:

Joseph A. Whaley, Jr., *Executive Committee Liaison*; Carmen A. Catizone, *NABP Executive Director/Secretary*; Melissa Madigan, *NABP Staff*.

Introduction:

The Task Force on Collaborative Practice Agreements (TFCPA) met December 3, 1998, at the Marriott Suites Hotel in Rosemont, Illinois. The Task Force was established by the NABP Executive Committee in response to recent increases in the number of prescribers and pharmacists entering into collaborative practice agreements and requests that boards of pharmacy define the elements of an appropriate collaborative practice agreement.

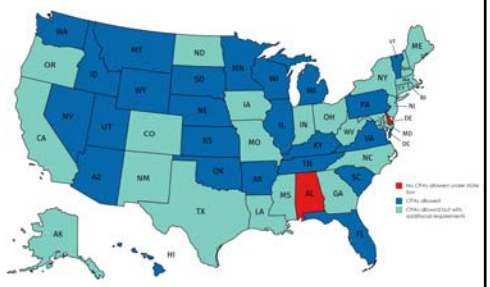
Charge of the Task Force on Collaborative Practice Agreements

Task Force members reviewed their charge and, proposing no changes, accepted it as follows:

- Review the available literature and information pertaining to collaborative practice agreements between prescribers and pharmacists.
- Develop national model guidelines for writing and implementing uniform collaborative practice agreements that can be utilized by the state boards of pharmacy.

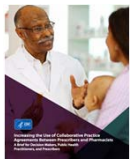
https://nabp.pharmacy/wp-content/uploads/2016/07/TFCollaborativePracticeAgreements_AM95_Dec1998.pdf

States that allow CPAs



CDC's Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team, DHHS, 2017, Appendix A

Support for Pharmacist Collaborative Practice



Collaborative Practice Agreements and Pharmacists' Patient Care Services

A RESOURCE FOR DOCTORS, NURSES, PHYSICIAN ASSISTANTS, AND OTHER PROVIDERS

Collaborative Practice Agreements and Pharmacists' Patient Care Services

A RESOURCE FOR DECISION MAKERS

Pharmacist Collaborative Practice Agreements: Key Elements for Legislative and Regulatory Authority

What is a **CPA?**

A collaborative practice agreement (CPA):

- Creates a formal relationship between pharmacists and physicians or other providers
- Defines certain patient care functions that a pharmacist can autonomously provide under specified situations and conditions
- Many are used to expand the depth and breadth of services the pharmacist can provide to patients and the healthcare team

https://naspa.us/wp-content/uploads/2015/08/CPA-Infographic-PDF.pdf

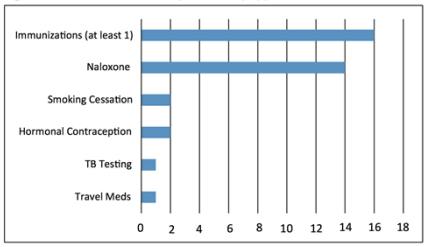
Protocols

University of Kentucky

Statewide Protocols

- Authorize pharmacist prescribing/administration of select medications to address public health needs
  - Codified in statute or refer to BoP as authorizing source
  - Over half of states authorize some type of statewide protocol
- Examples include:
  - Tobacco cessation products
  - Naloxone
  - Immunizations
  - Contraception
  - Travel medication

Figure 1. Number of statewide protocols by application



Source: National Alliance of State Pharmacy Associations

http://pharmacytoday.org/article/S1042-0991(16)30537-0/pdf

Prescriber-approved Protocols

- Authorize pharmacist to act as prescriber delegate
- KY example
  - Immunizations (2004)
  - Naloxone (SB 192, 2015)
- KY BoP recently filed regulations to for "board authorized protocols" (201 KAR 2:380)
  - Modeled after CCA and naloxone statutes/regulations
  - Would not require referral from MD as CCAs do
  - Do not specify what therapy can be initiated under protocol

What's Happening in Your State Regarding CPAs and/or Protocols?

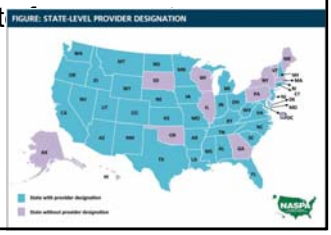
University of Kentucky

Barriers and Challenges

- Payment for pharmacist care services
- Variability in state law governing CPAs and protocols
- Culture - within the profession, the pharmacy and the broader community
- Workflow/use of ancillary help
- Access to health information technology systems

Payment for Pharmacist Care Services

- National push for provider status to address
- Some states already have 'provider status' in state law, but no mandat



Examples of State Provider Status Laws that Facilitate Payment for Pharmacist Services

- Washington – will hear details from Jenny Arnold tomorrow
- Oregon HB 2028 "permits health insurers to provide payment or reimbursement for services provided by pharmacist[s] through [the] practice of clinical pharmacy or pursuant to statewide drug therapy management protocol"

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-26-12
Baltimore, MD 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

CMCS Informational Bulletin

DATE: January 17, 2017

FROM: Vikki Wachino, Director
Center for Medicaid and CHIP Services (CMCS)

SUBJECT: **State Flexibility to Facilitate Timely Access to Drug Therapy by Expanding the Scope of Pharmacy Practice using Collaborative Practice Agreements, Standing Orders or Other Predetermined Protocols.**

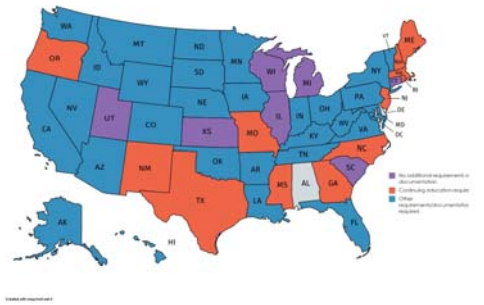
This guidance addresses flexibilities that states may have to facilitate timely access to specific drugs by expanding the scope of practice and services that can be provided by pharmacists, including dispensing drugs based on their own independently initiated prescriptions, collaborative practice agreements (CPA) with other licensed prescribing healthcare providers like physicians, "standing orders" issued by the state, or other predetermined protocols. These practices can facilitate easier access to medically necessary and time-sensitive drugs for Medicaid beneficiaries.

https://www.medicaid.gov/federal-policy-guidance/downloads/cib011717.pdf

Variability in State Law

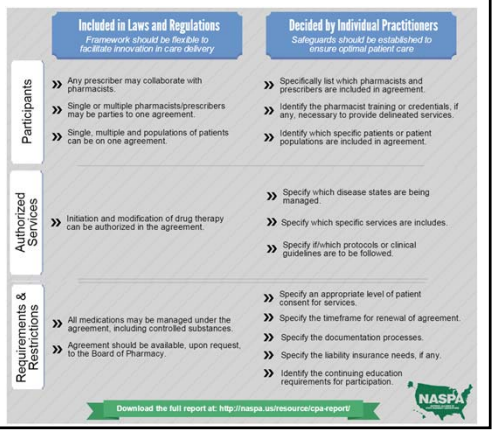
University of Kentucky

State CPA requirements



CDC's Advancing Team-Based Care Through Collaborative Practice Agreements: A Resource and Implementation Guide for Adding Pharmacists to the Care Team, DHHS, 2017. Appendix A

Recommendations from NASPA



PHARMACIST STATEWIDE PROTOCOLS: KEY ELEMENTS FOR LEGISLATIVE AND REGULATORY AUTHORITY

A REPORT OF THE STATEWIDE PROTOCOL WORKGROUP
CONVENED BY THE NATIONAL ALLIANCE OF STATE PHARMACY ASSOCIATIONS
AND THE NATIONAL ASSOCIATION OF BOARDS OF PHARMACY

March 2017

Statewide Protocol Policy Elements and Model Language

- Phase 1: Develop a consensus-based document outlining the model elements of state policies for statewide protocol authority. The report will include a delineation between collaborative practice agreements and statewide protocols and clearly articulate that the elements can be adapted to fit the definitions and construct of individual states' laws and regulations. *This work is to be done by a group of stakeholders through a consensus-based process.*
- Phase 2: Develop model legislative and/or regulatory language based on the consensus-based elements developed in phase 1. *This work is to be done by content experts as part of a working group, informed by the guiding principles of the consensus document.*

Model Statewide Protocols Development

- Phase 1: Develop a template for the elements that should be included in a statewide protocol for pharmacist prescriptive authority.
- Phase 2: Develop examples of specific statewide protocols (e.g., hormonal contraceptives, smoking cessation medications, vaccines, etc.) to serve as templates that can be implemented by state policy makers with the authority to issue statewide protocols for pharmacist prescribing. *This work is to be done by content experts as part of a working group, informed by the guiding principles of the consensus document. The working group will review and leverage existing protocols when available.*

Culture

University of Kentucky

Culture

- Internal – Pharmacist Attitudes

PRACTICE REVIEW
PEER-REVIEWED

Are pharmacists the ultimate barrier to pharmacy practice change?

Meagen Rosenthal, MA; Zubin Austin, BSc(Phm, MBA, MIS, PhD; Ross T. Tsuyuki, BSc(Pharm), PharmD, MSc, FCSHP, FACC

- External – Patient Expectations

It's Not Just the Money: Why Consumers Do Not Purchase Pharmacist-Provided Services

Patricia R. Freeman[1,2], Mikael Jones[1,2], Karen Blumenschein[1,2,3]

[1]Department of Pharmacy Practice and Science, University of Kentucky College of Pharmacy, Lexington, USA
[2]Center for the Advancement of Pharmacy Practice, University of Kentucky College of Pharmacy, Lexington, USA
[3]Martin School of Public Policy and Administration, University of Kentucky, Lexington, USA
Email: kblum1@email.uky.edu

Culture

- Acceptance by other healthcare providers
  - Survey of advanced practice pharmacists in NM and NC
  - Over 40% perceive lack of provider 'buy in' as barrier to implementing advanced practice

Murawski M, et al. Am J Health-Syst Pharm 2011;68:2341-50

Workflow and HIT Access

University of Kentucky

Workflow

- Can be significant barrier, especially in community pharmacy practices
- Optimize use of technicians and other ancillary staff to support pharmacists' direct patient care activity
  - Regulatory changes likely necessary to optimize use of technicians/interns

HIT Access

- Must have access to patient information to safely provide patient care
  - Universal access to patients' labs, medication lists, etc
- Many current dispensing systems lack ability to interface seamlessly with state health information exchanges
  - Often limited to immunization registry access

What do you see as barriers and challenges in your state?

How are you addressing them?

University of Kentucky

Patient Access to Pharmacist-Prescribed Medications

2017 Policy Statement adopted at APhA Annual Meeting

1. APhA asserts that pharmacists' patient care services and related prescribing by pharmacists help improve patient access to care, patient outcomes, and community health, and they align with coordinated, team-based care.
2. APhA supports increased patient access to care through pharmacist prescriptive authority models.
3. APhA opposes requirements and restrictions that impede patient access to pharmacist-prescribed medications and related services.
4. APhA urges prescribing pharmacists to coordinate care with patients' other health care providers through appropriate documentation, communication, and referral.
5. APhA advocates that medications and services associated with prescribing by pharmacists must be covered and compensated in the same manner as for other prescribers.
6. APhA supports the right of patients to receive pharmacist-prescribed medications at the pharmacy of their choice

Vision for the Future?

What can we learn from our colleagues in *"The Eye Care Team"?*

https://www.aao.org/about/eye-care-team

Ophthalmologists (MD)

Specialist for all aspects of eye care; completed medical school plus residency in ophthalmology and often subspecialty residency training.

Optometrists (OD)

Examine eyes to diagnose and treat visual problems and manage diseases, injuries and other disorders of the eye. Prescribe eyeglasses or contact lenses, as well as medications for uncomplicated eye conditions. Dubbed the "Primary eye care provider"; completed Doctor of Optometry 4 year program after undergraduate, or 7-year combined program.

Opticians

Technicians trained to design, verify and fit eyeglasses and contacts using prescriptions issued by optometrists or ophthalmologists; not permitted to diagnose or treat eye diseases or write prescriptions for visual corrections.

Vision for the Future?

The "Pharmacist Care Team"

Clinical Pharmacist Specialist (PharmD plus PGY2 residency training)

Specialist for all aspects of complex, drug-related care for a particular specialty area; e.g. transplant, infectious disease, oncology, etc. Prescribes medications within specialty area.

Pharmacist (PharmD/RPh)

Healthcare team member responsible for ensuring appropriate medication therapy and outcomes in all patients; authorizes the dispensing and administration of medications by CPhTs (PhAs?); engages in health promotion and disease prevention activities to improve patient and public health; assesses and manages chronic disease in collaboration with other healthcare providers; provides basic primary care and prescribes medications for uncomplicated conditions; refers to specialists as appropriate.

Pharmacy Technicians (Pharmacist Assistant or PhA?)

CPhT (consider 4 year degree and licensure?)

Technicians (PhA) trained to assist pharmacists by independently processing, preparing, dispensing and/or administering medications in response to prescriptions or other medication orders that have been reviewed and authorized by pharmacists.

Questions?

University of Kentucky

Lessons Learned from Expanded Scope of Practice in Washington and Other States

Jenny Arnold, Pharm.D., BCPS
Director of Practice Developmetn Washington State Pharmacy Association

Disclosures

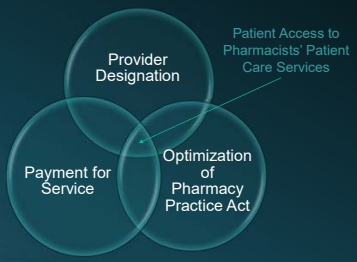
Jenny Arnold has no financial relationships to disclose. She is employed by the Washington State Pharmacy Association.

Learning Objectives

At the completion of this knowledge-based activity, participants will be able to:

- Describe Washington's experience with expanded scope of pharmacist practice
- Discuss impact of expanded practice in Washington and other states
- Identify future opportunities for expanded scope of practice

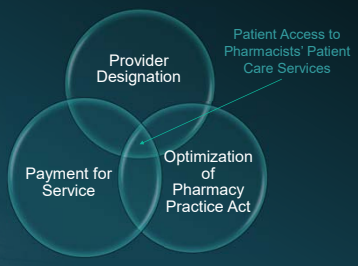
Achieving Provider Status



4

Image: National Alliance of State Pharmacy Association (NASPA)

Achieving Provider Status *Patient Access*



5

The Wave is Cresting….

- State level legislative efforts have been successful
- Federal "Provider Status" legislation is a huge focus
- Pharmacy practice moving forward across the nation but many different approaches

"The tipping point is that magic moment when an idea, trend, or social behavior crosses a threshold, tips, and spreads like wildfire."

—Malcolm Gladwell,

The Tipping Point: How Little Things Can Make a Big Difference

The Washington State Experience

8

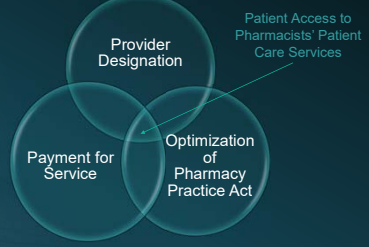
One Vision, One Voice

- 2000-2001

Washington Pharmacists Association merged with the Washington Society of Health System Pharmacy

WSPA
WASHINGTON STATE PHARMACY ASSOCIATION

Achieving Patient Access



10

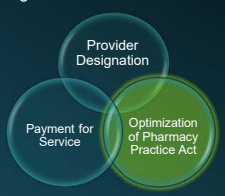
Image: National Alliance of State Pharmacy Association (NASPA)

Provider Designation

- Pharmacists are healthcare providers in Washington State Law
  - Incorporated in appropriate practitioner and healthcare provider definitions
  - Review of statutes and rules
  - Took multiple efforts over the years

Scope of Practice

- RCW 18.64.011
- Definition of "Practice of Pharmacy" includes:
  - "initiating and modifying drug therapy through written protocols and guidelines"
  - "administering" of drugs and devices
  - "monitoring of drug therapy and use"



12

Health System Practice in Washington

- Pain
- TPN, Nutrition
- Renal Dosing
- Antibiotic Dosing
- Narrow therapeutic window dosing
- Oncology
- Formulary Interchanges
- Protocol development
- Code response, medication administration
- Discharge Counseling, reducing readmissions

Long Term Care

- Consultant Pharmacist role in SNFs
- Home Infusion
- Hospice Care, palliative care
- Antimicrobial stewardship
- Administering and reading TB Skin Tests

Community Practice

- Immunizations
- Emergency Contraception (Ella, Plan B for Rx)
- Travel Medicine (yellow fever stamp, TD and malaria, etc)
- Tobacco Cessation (NRT, varenicline, buproprion)
- Naloxone
- TB Testing
- Strep Testing and prescribing
- Influenza testing and prescribing
- Lipid, blood sugar and HgA1C testing
- Clozapine monitoring
- Anticoagulation testing and dosing
- Medication administration
- Hormonal Contraception
- Clinical Community Pharmacist

Clinical Community Pharmacist

- Training on disease identification and treatment
- To avoid ED visits, urgent care visits

- Bronchospasm
- Burns
- Headaches
- Bites
- Stings
- Oral fluoride
- Swimmer's ear
- Cold sores
- Vaginal Yeast Infection
- Uncomplicated UTI
- Contraception
- Insulin
- Epinephrine autoinjector
- And more to come…

Ambulatory Care

- Anticoagulation
- Refill requests
- Heart failure
- Diabetes
- Hypertension
- Dyslipidemia
- Pain
- Depression
- Transplant
- Oncology

→ Moving to a culture of limitations, not permissive

Collaborative Practice in Washington

Public Health
- Immunizations
- Emergency Contraception
- Tobacco Cessation
- Emergency Prep Antiviral
- Opioid Overdose Prevention
- Contraception
- Tuberculosis Screening
- Travel Medications
- Pre-Exposure Prophylaxis

Chronic Disease
- Anticoagulation
- Dyslipidemia
- Diabetes
- Hypertension
- Asthma
- Pain
- Heart Failure
- Oncology
- Comprehensive Med Reviews

**More than 10,000 active CPA's on file with Pharmacy Quality Assurance Commission

18

WSPA

Despite "Legal" Victories… Not Done

Provider Designation √

Scope of Practice √

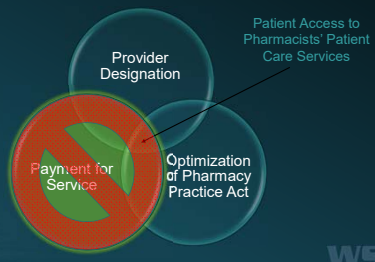
….But we still didn't have "provider status" recognition in the eyes of the insurers

Billing limited to:

- PHARMACY contracts with PBM's for "professional services"
- "Incident to" or "Facility Only" billing
- Individual specifically identified pharmacist provided services

19

We Were Still Lacking Recognition by Payers



OPENING THE DOOR TO THE PROVIDER KINGDOM

How do we fix this?

1. Identify stakeholders, partners and champions
2. Propose solution(s)
3. Identify barrier(s)
4. Address barrier(s)

22

Identify Stakeholders/Champions

- Individual Members
- Pharmacy, Hospital, Clinic, LTC Leadership
- Legislators
- Agency leadership
- Universities
- Provider Organizations
- Payers and Consultants
- Business Decision Makers
- Patient Advocacy Groups
- Others?

23

Potential Solution:

"Every Category of Provider" Law

- RCW 48.43.045(1)
  - Requires health plans to **include access to every type or "every category" of licensed medical provider**
- WAC 284-43-205
  - health carriers shall **not exclude any category of provider** who provide health care services or care within the scope of their practice

24

Overcoming Obstacle #1

BARRIER:

Law NOT enforced by Insurance Commissioner

- Interpretation of current law: did NOT include pharmacists

SOLUTION:

Requested and obtained AG informal opinion stating:

"Pharmacists are health care providers and must be compensated for services included in the basic health plan that are within the scope of the pharmacist's practice…."

25

Overcoming Obstacle #2

BARRIER:

Legal loophole allowing health plan contracts with pharma*cies* through the PBM to suffice for contracts with pharma*cists*

SOLUTION:

Legislative fix (SB 5557)

26

Legislative Victory

ESSB 5557 introduced by Senator Linda Evans Parlette (R-12)

May 11, 2015: Governor Inslee signed bill into law

27

Keys to Passage

- Attorney General Opinion
- Patient Access/Equality
- Not an expansion of scope just payment for currently covered services
- Support of Hospital Association and Medical Association
- Champions in Agencies
  - OIC
  - DOH
- Addressed concerns of potential opponents

28

SB 5557 Highlights:
Pharmacists as Patient Care Providers

- Health plans must recognize pharmacists as patient care providers of covered medical benefits
- **Adequate** number of pharmacists in their networks
- Includes services **within scope of practice**
  - **covered** services within essential health benefit requirements
- Clarified that pharmacies in health plans' drug benefit networks **DOES NOT** satisfy new requirements
- Required for commercial carriers covering large group, small group, individual and family plans

29

The Path to Provider Status

Legislation
Signed into law by May 2015

Implementation Advisory Committee
Summer 2015

Deliverables to OIC
Recommendations due by December 2015

Implementation
Jan 2016: Health plans enroll pharmacists in health-systems with delegated credentialing agreements
Jan 2017: Health plans enroll pharmacists in all settings

SB 5557 Highlights: Tiered Implementation Dates

2016

Health plans who **delegate credentialing to health facilities** must accept pharmacists employed or contracted by those facilities in their participating provider networks

2017

Health plans must accept **adequate number of pharmacists** in their participating provider networks

SB 5557 Highlights: Advisory Committee Process

- OIC designated a lead organization (One Health Port)
- Lead organization formed Advisory Committee
- TASK:
  - Develop best practice recommendations for standards on credentialing, privileging, billing and payment for pharmacist provided services

32

SB 5557 Highlights: Advisory Committee Participants

- Representative(s) from:
  - Lead organization facilitator
  - State agencies
  - Provider associations
  - Health carriers
  - Health care system that coordinates care and coverage
  - Hospital with internal credentialing process
  - Health facilities with pharmacists providing medical services
  - Pharmacy schools

33

ESSB 5557 Advisory Committee Work

- **Intent**:
  - Ensure that pharmacists will be treated as any other provider as it relates to health plan :
    - billing
    - processing
    - payment of claims for medical services
- **Specific deliverables**:
  - FAQ
  - Health Plan Policy Directives
  - Pharmacists and Other Provider Expectations

34

Key Takeaways

- Components of "Provider Status":
  - provider designation
  - scope of practice optimization
  - payer recognition
- Highlighting patient choice of providers laws is a viable solution.
- Sometimes a judicial branch approach is helpful.
- Patient centered message essential.
- Hard to refute equal treatment of pharmacists.
- Collaboration with stakeholders is essential.

35

Time to celebrate!?!

Now What?!

Where do we go from here?

- Passed law
- Guidance from Advisory Committee Deliverables
  - *FAQ* document
  - *Health Plan Policy Directives* document
  - *Pharmacists and Other Provider Expectations* document
- Goal of equal treatment achieved

Where do we go from here?

- Passed law
- Guidance from Advisory Committee Deliverables
  - *FAQ* document
  - *Health Plan Policy Directives* document
  - *Pharmacists and Other Provider Expectations* document
- Goal of equal treatment achieved
- BUT we found major gaps in our guidance

Completed

Excitement and challenges

- Finally… EQUALITY
- Held to the same standards as other providers means there is much to learn
- Billing medical claims is very different than billing pharmacy claims
- No direction on business processes/work flow, coding, documentation, and clinical record management/billing systems

Our Next Steps

- Work with members and partners to put the other pieces together
  - Identify and address knowledge gaps
  - Advocate for appropriate integration of pharmacists into provider networks
  - Demystify the medical billing process
  - Collect and share data supporting value of pharmacists provided services
  - Share with colleagues throughout the country

42

Identified Knowledge Gaps

- How to enroll in participating provider networks
  - Contracting, Credentialing, Privileging
- Understand medical benefit coverage
- Medical billing processes
- Health information technology
  - Health Information Exchange
  - Practice Management

43

Implementation Workgroups

WSPA Washington State Pharmacy Association

- Contracting, Credentialing & Privileging
- Billing, Coding & Documentation
- Technology & Communication
- Outcomes & Research

Brave New World

- Provider Status is deserved and it makes our skills more relevant in the changing healthcare landscape

…but it comes with:

- New responsibilities
- New obligations
- and more accountability

http://clipart-library.com/clipart/zTX5kxTEc.htm

Roadmap

1. Provider Network Enrollment
2. Identify coding, billing and documentation for specific services
3. Fill technology gaps
4. Submit medical claims

Step 1: Recognition by Health Plans

- Inclusion in provider networks make providers eligible to bill for covered services
- Identify which health plans cover patients in your practice
  - Commercial plans: Large group, Small Group, Individual, Family, Self-Insured
  - Public: Medicaid FFS, Medicaid Managed Care, Medicare
- Enroll in provider networks

Provider Network Enrollment Processes

- Already exist for other health care providers
- Health plans have similar processes but they can differ in requirements for enrollment
- Some can be done by a delegated staff member
- Nothing prohibits commercial health plans from including pharmacists

So, what is a credential?

- A credential is documented evidence of professional qualifications
- Such evidence includes:
  - academic degrees
  - state licensure
  - residency
  - fellowship
  - training certificates
  - statements of continuing education (CE) credit
  - and board certifications

OK…Then what is a certificate?

- A document issued to an individual when achieving a predetermined performance level
- Used as credentials within the credentialing process

Recognized Certifications for Pharmacists

- The Council on Credentialing in Pharmacy developed list of pharmacist certifications
- New certifications are developed, so the list is not complete
- Evolving…there are no certifications available for many areas of pharmacy practice

COUNCIL ON CREDENTIALING IN PHARMACY

What is Credentialing?

A process that documents and demonstrates that the health care professional has attained the credentials and qualifications to provide the scope of care expected for patient care services in a particular setting

Principles for Credentialing of Pharmacists

- Required for enrollment in health plan provider networks
- Includes measures to assess attainment of competencies
- Enables pharmacists to defend patient care privileges
- Based on a demonstrated patient/societal need
- Should emulate other healthcare provider credentialing
- Eventually established profession-wide through consensus

Which Credentialing Process?

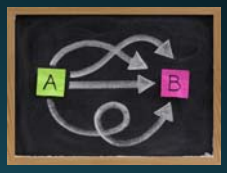
Refers to one of two processes:

1) granting a credential designating that an individual has qualifications in a subject or area
   - granting a license or board certification to practice pharmacy

2) health plan, organization, or institution obtains, verifies, and assesses an individual's qualifications to provide patient care services

Credentialing Pathways

- Credentialing can be done via two major pathways:
  - Direct credentialing
  - Delegated credentialing



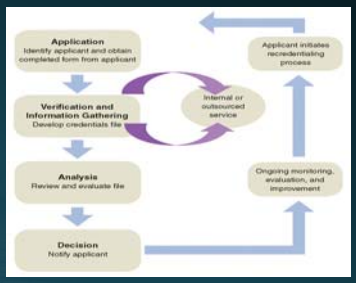
Direct Credentialing

- Places responsibility on the individual provider to initiate the credentialing process with multiple health plans
- Most common

Delegated Credentialing

- Allows **provider organization** to internally credential their providers based on health plan requirements
- Requires agreement between provider organization and health plan
- Typically faster and more efficient process than direct credentialing

The Credentialing Process



Am J Hlth-Syst Pharm, Vol 71, Nov. 1, 2014, p. 1893. Adapted from, Deutsch & Mobley. The Credentialing Handbook, Burlington, MA:Jones and Bartlett, 1999.

Council on Credentialing in Pharmacy (CCP)

- Established in 1999 to guide the professions credentialing programs
- Supported by numerous pharmacy organizations
- Resources available at: *http://www.pharmacycredentialing.org/*

What is a privilege?

- Granted by a health care institution to a provider
- Authority to render specific diagnostic, procedural, or therapeutic services
- Include:
  - **Admitting privileges**: rights to admit patients
  - **Clinical privileges**: rights to treat
    - Clinical privileges are both facility and individual specific

What is privileging?

- The process by which a health care organization grants privileges to perform a specific scope of patient care services **within** that organization

Privileging Process

- Process is organization dependent but includes:
  - review of provider's credentials and performance
  - establishing provider has demonstrated competence to provide these services
  - services are within the scope of provision of the organization
  - organization can support their delivery

Sample Privileging Process

- Initial privileges
  - Request Application
  - Reviewed by committee of peers
  - Approval or modification
- Reappraisal of privileges
  - Common review over designated period of time
  - CQI process
  - Liability issues
  - Provider should keep own records

Purpose of Privileging Process

- Integral part of the quality assurance review process
  - Quality safeguards
  - Competency assurance
- Mechanism for health care organizations to govern who provides which services and who does not
- Assurance that health care professional has specific competencies and experience for specific services

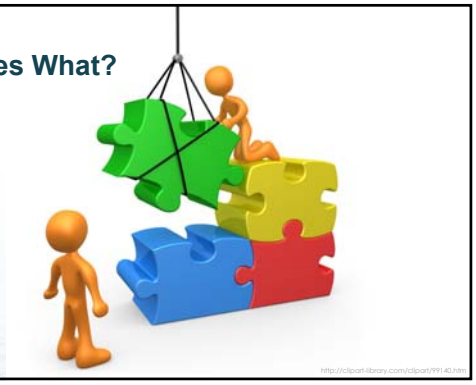
Designing Privileging Processes

- Pharmacists should parallel and coordinate with existing processes
- Define the quality standards and competencies that will be required of pharmacists

Relationship to Reimbursement

- Public expectation of competence underscores the authority to obtain payment for services
- Quality improvement expectations hinge on willingness of providers to undergo peer-assessment and mentoring
- Alignment with value-based performance measures (e.g. HEDIS, PQRS, Star Ratings, ACO measures, etc.)
- Link to employer values and public reporting
- Conditions of participation include payer authority for auditing of care provided

Who Does What?



Role of Health Plans

- Health plans ONLY credential providers
  - they do not privilege providers
- Credentials gathered and verified for a provider do not vary based on the specific services that a provider of that type delivers in the course of their work

Role of Provider Organizations

- Provider organizations may:
  - Credential only, or
  - Credential AND Privilege their providers
- For provider organizations that privilege their providers:
  - The credentials gathered and verified for a provider **may vary** based on the specific services that a provider of that type delivers in the course of their work

Role of Provider/Health Plan Organizations

- Organizations that are provider organization AND health plan
  - Provide patient care and take on financial risk for providing care
- May credential only or
- May credential AND privilege their providers.
- The credentials for a provider **may vary** based on the specific services that a provider of that type delivers in the course of their work

Enrollment in Provider Networks

- Primarily online through the health plans provider enrollment webpage
- Some plans require a phone call
- Involves:
  - Completion of Practitioner Application for each health plans
    - Starts credentialing processes
  - Contracting as individual with health plans

Provider Network Enrollment Requirements

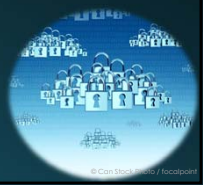
Every Pharmacist Needs Their Own National Provider Identification (NPI)

- Pharmacies and pharmacists who transmit health information in an electronic format must obtain an NPI number
- Apply for your NPI: National Plan and Provider Enumeration System (NPPES) https://nppes.cms.hhs.gov/NPPES/Welcome.do

NPPES
National Plan & Provider Enumeration System

Taxonomy Codes

- Attached to individual NPI numbers
- The codes you select can impact the way the health plan designates you and might affect your billable moments
- https://www.cms.gov/medicare/provider-enrollment-and-certification/medicareprovidersupenroll/taxonomy.html



Provider Network Enrollment Requirements

Get Your Personal Professional Liability Insurance

- To become credentialed, medical insurance companies **mandate** that each health care provider is covered under individual professional liability insurance
- Make sure the coverage includes the entire scope of pharmacy practice in your state

Provider Network Enrollment Requirements

Begin Credentialing Process

- Individual pharmacists must contract and credential with health plans (not PBM's) as providers
- Detemine which process for your practice setting?
  - Direct or Delegated internal

Provider Network Enrollment Requirements

Credentialing Process

- For direct contracting and credentialing
  - Identify health plans covering your patients

OR

- For delegated credentialing
  - Identify internal process within organization that usually involves a medical staffing office

Provider Network Enrollment Requirements

Credentialing Process

For direct contracting and credentialing

- Start enrollment process for each health plan
- Complete and submit provider/practitioner application

OR

For delegated credentialing

- Start enrollment process for providers within healthcare institution
- Complete and submit required information

Provider/Practitioner Application

Provider/Practitioner Application or a version specific to the health plan

- Robust document of credentials

Current copies of the following documents must be submitted with this application:

Provider/Practitioner Application

- State Professional License(s)
- DEA Certificate (if applicable)
- Face Sheet of Professional Liability Policy or Certificate
- Curriculum Vitae
  - Not an acceptable substitute for completing the application
- Practitioner Information
  - Individual NPI
  - Medicaid, L&I and Medicare numbers
  - Specialties/Sub-Specialties

Provider/Practitioner Application

- Practice Information (Primary and Secondary locations)
  - Practice Setting
  - PCP or Specialist
  - Tax ID numbers
  - Supervising responsibility
  - Accepting new patients
  - Wheel chair accessible
  - Languages fluently spoken
  - Hours of operation
  - Inpatient Coverage Plan
  - Call Group

Provider/Practitioner Application

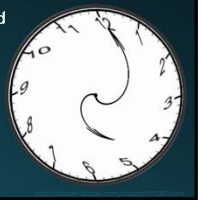
- Professional Licensure, Registrations, Certificates
- Undergraduate Education
- Medical/Professional Education
- Master Degree/Post Graduate Education
- Internship
- Residencies
- Fellowship
- Preceptorship
- Faculty/Teaching Appointments
- Board Certification

Provider/Practitioner Application

- Hospital Affiliations
- Military Affiliations
- Work History
- Peer References
- Professional Affiliations
- Professional Liability
- Attestations (Sanctions, Criminal, Affirmation of Abilities, Litigation and Malpractice, professional liability action)
- Individual CDTA/CPA part of attestation

Hurry up and wait….

- The process and timeline after application completion and health plan notification varies between plans
- Providers can expect:
  - Notification that plans are reviewing completed application
  - Notification of approval



Practitioner Contracts

- Most health plans appear to have similar practitioner contracts
- In Washington, plans are required submit a template to the Office of the Insurance Commissioner (without rates)
- Can be viewed prior to application

The New Pharmacist Musts

- Most pharmacies are already internally credentialing and privileging in some capacity
- Lesson learned: it takes time and should be started prior to provider status
- Parallel quality assurance as other healthcare providers
- Policy and procedure work should expedite contracting with health plans

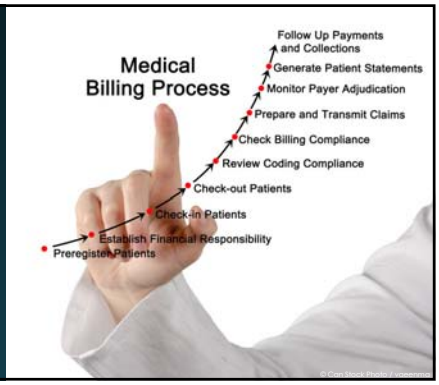
Don't wait… Prepare now!

Contracting, Credentialing, Privileging Resources

- WSPA Contracting and Credentialing Resource Center
  - Guidance on credentialing processes and plan variability
  - Contact information for health plan provider network enrollment
  - Sample provider contracts
- Enrolling in Provider Networks Online Webinar
- ProviderSource Credentialing Portal Online Webinar

Once your in the network…

- It's time to provide care and submit claims



What and How to Bill?

- AMA CPT (Current Procedural Terminology)
- ICD-10 (International Statistical Classification of Diseases and Related Health Problems)
- HCPCS (Healthcare Common Procedure Coding System)
- CMS medical billing standards apply
- And SNOMED CT documentation codes

Essentials for Billing Medical Claims

Preparation to document, code, and bill for medical services requires understanding the following:

- Medical billing and coding systems with documentation processes
- 'Incident to' rule
  - supervision requirements
  - associated risks in pharmacy practice

Essentials for Billing Medical Claims continued

- Consultation codes such as Evaluation and Management (E/M) Codes
- Time-based method of coding and billing
- Complexity-based method of coding and billing using
  - components of history
  - components of examination
  - components of Medical Decision Making

Essentials for Billing Medical Claims continued

- Audits of medical records
- Compliance laws and regulations
- Medical revenue cycle management

Medical Billing Process Key Steps

- Pre-Visit
- Patient Care
- Medical Claims Submission to Insurance Companies
- Post Medical Claim Transmission to Insurance Companies
- After Receiving Insurance Payment
- Invoicing Patients

Medical Billing Process Key Steps

Pre-Visit

- Obtain patient demographics
- Verify patient insurance and eligibility
- Collect co-payments
- Obtain additional documents (medical release, financial, privacy, prior authorization, if needed)

Medical Billing Process Key Steps

Patient Care

- Provide patient care
- Ensure appropriate documentation in medical record to justify code & severity
- Transmit necessary documentation to other providers, as needed

Medical Billing Process Key Steps

Medical Claims Submission to Insurance Companies

- Re-verify patient, provider, and insurance information for accuracy
- Select diagnosis and procedure codes (ICD-10/CPT) based on documentation in medical record
- Submit claim

Medical Billing Process Key Steps

Post Medical Claim Transmission to Insurance Companies

- Check status daily
- Resolve denials
- Resubmit claim with right insurance, prior authorization number attached or CCD attached

Medical Billing Process Key Steps

After Receiving Insurance Payment

- Verify deposits match remittances with contract agreement
- Reconcile
  - co-insurance/co-payments
  - withholdings, offsets, and credit balance forwards due to prior overpayment or adjustment on another claim

Medical Billing Process Key Steps

Invoicing Patients

- Review contract limitations and restrictions on amounts and services patients can be billed
- Bill patient for payments, deductible (if not collected upfront) and co-insurance, if applies
- Follow up with patients

Medical Billing Implementation Resources

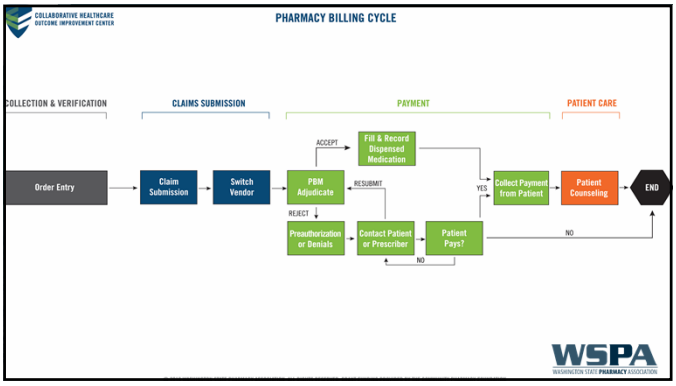
November 2016
- **On-Demand Training**:
- Ten online CE courses on billing, coding, documentation, and compliance

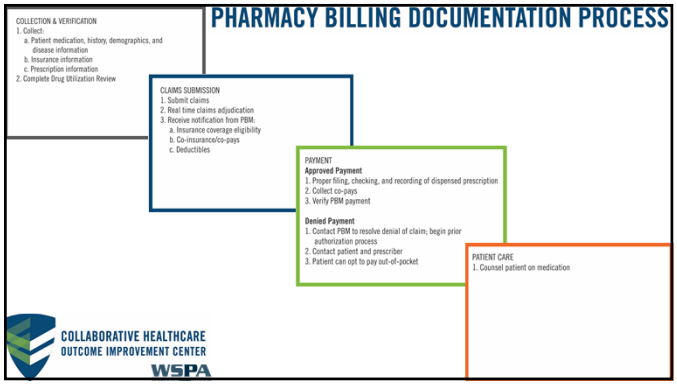
2016-2017
- **Live Trainings**:
- Medical Billing Workshop for Pharmacy Professionals

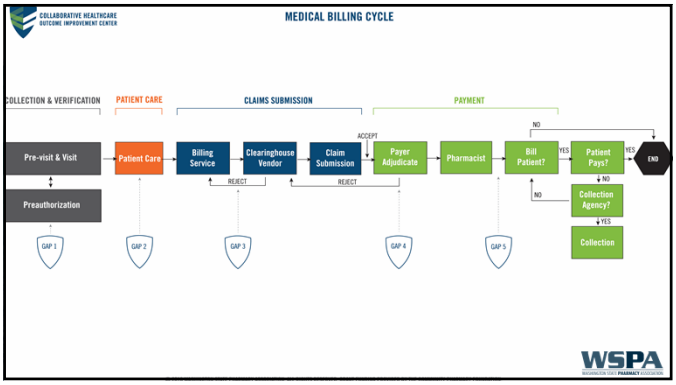
2017
- **Guidebook**: Medical billing, coding and documentation
- **Additional On-Demand Training**: 6-8 Online CEs
  - Disease/clinical focus and case studies

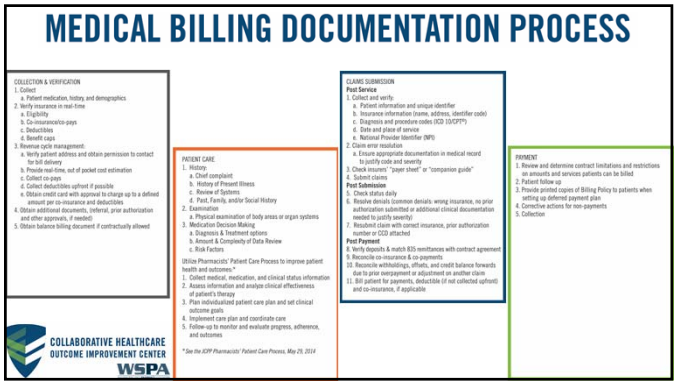
Demystify the technology differences

- Pharmacy claim vs Medical claim




PHARMACY BILLING DOCUMENTATION PROCESS
COLLECTION & VERIFICATION
1. Collect:
a. Patient medication, history, demographics, and disease information
b. Insurance information
c. Prescription information
2. Complete Drug Utilization Review
CLAIMS SUBMISSION
1. Submit claims
2. Real time claims adjudication
3. Receive notification from PBM:
a. Insurance coverage eligibility
b. Co-insurance/co-pays
c. Deductibles
PAYMENT
Approved Payment
1. Proper filing, checking, and recording of dispensed prescription
2. Collect co-pays
3. Verify PBM payment
Denied Payment
1. Contact PBM to resolve denial of claim; begin prior authorization process
2. Contact patient and prescriber
3. Patient can opt to pay out-of-pocket
PATIENT CARE
1. Counsel patient on medication
COLLABORATIVE HEALTHCARE OUTCOME IMPROVEMENT CENTER
WSPA


COLLABORATIVE HEALTHCARE OUTCOME IMPROVEMENT CENTER
MEDICAL BILLING CYCLE
COLLECTION & VERIFICATION
PATIENT CARE
CLAIMS SUBMISSION
PAYMENT
Pre-visit & Visit
Preauthorization
Patient Care
Billing Service
Clearinghouse Vendor
Claim Submission
Payer Adjudicate
Pharmacist
Bill Patient?
Patient Pays?
END
Collection Agency?
Collection
ACCEPT
REJECT
REJECT
NO
YES
NO
YES
NO
GAP 1
GAP 2
GAP 3
GAP 4
GAP 5
WSPA


MEDICAL BILLING DOCUMENTATION PROCESS
COLLECTION & VERIFICATION
1. Collect
a. Patient medication, history, and demographics
2. Verify insurance in real-time
a. Eligibility
b. Co-insurance/co-pays
c. Deductibles
d. Benefit caps
3. Revenue cycle management:
a. Verify patient address and obtain permission to contact for bill delivery
b. Provide real-time, out of pocket cost estimation
c. Collect co-pays
d. Collect deductibles upfront if possible
e. Obtain credit card with approval to charge up to a defined amount per co-insurance and deductibles
4. Obtain additional documents, referral, prior authorization and other approvals, if needed)
5. Obtain balance billing document if contractually allowed
PATIENT CARE
1. History
a. Chief complaint
b. History of Present Illness
c. Review of Systems
d. Past, Family, and/or Social History
2. Examination
a. Physical examination of body areas or organ systems
3. Medication Decision Making
a. Diagnosis & Treatment options
b. Amount & Complexity of Data Review
c. Risk Factors
Utilize Pharmacists' Patient Care Process to improve patient health and outcomes:*
1. Collect medical, medication, and clinical status information
2. Assess information and analyze clinical effectiveness of patient's therapy
3. Plan individualized patient care plan and set clinical outcome goals
4. Implement care plan and coordinate care
5. Follow-up to monitor and evaluate progress, adherence, and outcomes
*See the JCPP Pharmacists' Patient Care Process, May 29, 2014
CLAIMS SUBMISSION
Post Service
1. Collect and verify:
a. Patient information and unique identifier
b. Insurance information (name, address, identifier code)
c. Diagnosis and procedure codes (ICD 10/CPT®)
d. Date and place of service
e. National Provider Identifier (NPI)
2. Claim error resolution
a. Ensure appropriate documentation in medical record to justify code and severity
3. Check insurers' "payer sheet" or "companion guide"
4. Submit claims
Post Submission
5. Check status daily
6. Resolve denials (common denials: wrong insurance, no prior authorization submitted or additional clinical documentation needed to justify severity)
7. Resubmit claim with correct insurance, prior authorization number or CCD attached
Post Payment
8. Verify deposits & match 835 remittances with contract agreement
9. Reconcile co-insurance & co-payments
10. Reconcile withholdings, offsets, and credit balance forwards due to prior overpayment or adjustment on another claim
11. Bill patient for payments, deductible (if not collected upfront) and co-insurance, if applicable
PAYMENT
1. Review and determine contract limitations and restrictions on amounts and services patients can be billed
2. Patient follow up
3. Provide printed copies of Billing Policy to patients when setting up deferred payment plan
4. Corrective actions for non-payments
5. Collection
COLLABORATIVE HEALTHCARE OUTCOME IMPROVEMENT CENTER
WSPA


New Vendor Relationships Needed
Electronic Health Record System
Stand Alone, Integrated, C-CDA Certified
Practice Management System
Scheduling, patient billing and collection
Clearinghouse and Intermediaries
Revenue Cycle Management
Integrated System
EHR/EMR, Practice Management System
WSPA


Outcomes and Research Planning
Tactics:
Prove the need to have pharmacists in provider networks
Need to equate services to value for health plans
Health Plans graded by metrics
Align value to metrics
Ongoing work
WSPA


WSPA created CHOICE
COLLABORATIVE HEALTHCARE
OUTCOME IMPROVEMENT CENTER

Collaborative Healthcare Outcomes Improvement Center (CHOICE)

- Developed as a home for:
  - Shared branding for implementation tools and resources
  - Data analytics, outcomes measures and performance metrics
  - Research work
- Not a state specific or profession specific voice

COLLABORATIVE HEALTHCARE OUTCOME IMPROVEMENT CENTER

WSPA WASHINGTON STATE PHARMACY ASSOCIATION

The Road (Treasure) Map Works…

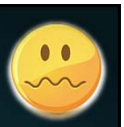
- **Pharmacists are successfully enrolled in provider networks**
- **Medical claims submitted by pharmacists in hospitals, clinics, and community pharmacies**
- **Billing medical claims for services**
  - **Mainly E/M consultation codes**
- **…and they are getting paid!**

WSPA WASHINGTON STATE PHARMACY ASSOCIATION

http://clipart-library.com/clipart/521259.htm

Now is it time to celebrate?

Not so fast…



- Assist with education of health plans
- Help facilitate implementation in community settings
- Identify billing solutions that work for community pharmacists
- Address barriers to implementation
- Establish a viable business model of community pharmacies with contracted pharmacists providing care
  - Overhead- Cost of implementation
  - Revenue delays with medical billing
  - Workflow and staffing changes

We are not slowing down until…

© Can Stock Photo / zlikovec

Our Challenge is Adapting…

"Enjoying success requires the ability to adapt. Only by being open to change will you have a true opportunity to get the most from your talent"

-Nolan Ryan

Hall of Fame Baseball Player

Change is hard but WSPA is here to help!

- We are working hard to help answer your questions and provide resources to assist pharmacists in their pursuit to be included in health plan provider networks.
- **www.wsparx.org**
- **WSPA Pharmacists as Providers Implementation -Getting Started**

References

- Credentialing and privileging of pharmacists: A resource paper from the Council on Credentialing in Pharmacy
  - http://www.pharmacycredentialing.org/Files/CCP_Special_Feature.pdf
- SB5557 Advisory Work Group materials
  - https://www.onehealthport.com/essb-5557

Washington State Pharmacy Association

- Get Started Checklist
  - www.wsparx.org/?page=GetStarted
- Contracting and Credentialing Resource Center
  - www.wsparx.org/?page=ContractCredentialin
- Billing for Patient Care Services Resource Center
  - www.wsparx.org/?page=PatientCare

Thank you!

Community Pharmacy Foundation

Questions?

Jenny Arnold, PharmD, BCPS

Washington State Pharmacy Association

www.wsparx.org

jenny@wsparx.org