Date: May 15, 2018
Meeting Convened: 1:30 P.M.
Meeting Adjourned: 3:14 P.M.
Location: Chicago: JRTC CBD Rooms 14-612; SPI: Stratton CBD 349C

Roll Call: Philip P. Burgess, MBA, DPh, RPh, Chairperson
Bryan Schneider, Secretary, IDFPR
Adam Bursua, PharmD
Helga Brake, PharmD
Scott Meyers, MS, RPh
Scott A. Reimers
Brian H. Kramer, RPh, MBA
Lemry Al Carter, RPh
Garth Reynolds, RPh

Staff Present: Kathleen Alcorn, IDFPR
Munaza Aman, IDFPR
Lucienne Doler, IDFPR

Guests Present: Tomson George, Walgreens
Rob Karr, IRMA
Joel Baise, Walgreens
Jim Owen, ICHP
Melissa Hogan, Roosevelt University
Denise Scarpelli, University of Chicago
Jason True, United Rx
Bert Stacey, Walgreens
Tasha Polster, Walgreens
Brian Hrad, Symbria Rx Services
Ryan McCann, Jewel Osco
Colleen Jones, Wal-Mart, Safety Culture PSO
Tara Modisett, Alliance for Patient Medical Safety PSO
Michael Callahan, Katten Muchin Rosenman LLP
Cindy Li, ICHP
Laura Licari, IPNA/Roosevelt University
Jan Keresztes, Talent First
John Long, CVS Health
Yash Patel, CVS Health
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| • Phil: Overview of task force; each meeting addresses a new topic to educate task force members. Will make recommendations to the legislature for Pharmacy Practice Act that will be effective in 2020.  
• Topics covered thus far include whistleblower and e-prescribing. Today will focus on Patient Safety Organizations (PSOs). Helga will lead the discussion given her expertise and experience with PSOs. | Presentation from Michael Callahan of Katten Muchin Rosenman: Overview of Patient Safety Act  
• Patient Safety Act is federal. IL has Medical Studies Act, but it does not apply to pharmacies. Pharmacy’s only opportunity to participate in PSO is via federal statute.  
• Congress enacted the Act in 2005 as response to the IOM report re: national concerns over number of preventable errors that were occurring. Goal of Act was to improve safety by encouraging voluntary and confidential reporting of healthcare events that adversely affect patients. The Act provides privilege and confidentiality protections for information when providers work with federally listed PSOs to improve quality, safety, etc.  
• To implement the Act, the Dept. of Health and Human Services issued the Patient Safety and Quality Improvement Rule (Patient Safety Rule). The Act and the Rule authorize the creation of PSOs to improve quality and safety through collection and analysis of aggregated, confidential data. This allows PSOs to more quickly identify patterns of failure and develop best practices.  
  o Providers of all natures are in PSOs: 2/3 of hospitals in state are in PSO. This is extending to physician groups who are not covered by Medical Studies Act but are not being required to track these outcomes.  
• AHRQ created Common Formats to help providers uniformly report to PSOs for aggregation and analysis. PSOs are required to collect/analyze data in a standardized manner using either Common Formats or another system.  
  o In a large pharmacy chain with statistically significant data sets, the data is collected in a standardized format but not necessarily AHRQ common formats-Common Formats only need if PSO reporting to Network of Patient Safety Databases (NPSD)  
• Requires reporting of findings annually in AHRQ’s National Health Quality/Disparities Reports.  
• Revolves around patient safety activities, which is broadly defined as to what can be included.  
• What is Patient Safety Work Product (PSWP)? Data which could improve patient safety, health care quality, or health care outcomes; Data assembled or developed by a provider for reporting to a PSO and are reported to a PSO; analysis and deliberations conducted within a PSES; data developed by a PSO to conduct patient safety activities-e.g. deliberation and analysis, reports, memos, etc.  
• What is not PSWP? Information collected, maintained, or developed separately, or exists separately, from a PSES; data removed from a PSES; data collected for another reason-e.g. medical records, billing information, general patient info, discharge info.  
  o Phil: Is particular info about a specific pharmacist considered work product? Michael: Depends on what the request is. Does Pharm Board know about complaints? We will discuss the Walgreens case where courts found info about pharmacists collected by PSOs was privileged and confidential and not |
subject to discovery or admissibility. This case was under Patient Safety Act, not IL protection of Medical Studies Act.

- Patient Safety Evaluation System (PSES)-collection, management or analysis of info for reporting to or by a PSO. A provider’s PSES is an important determinant of what can and can’t become PSWP-e.g. equipment, virtual/physical space, policies and procedures, staff
  - Balance btwn patient’s right and need to discuss this info in protected environment so that can improve patient care; systems not designed to manage claims or litigation.
  - Phil: No requirement to prove that are actually improving patient care and protecting patients? Michael: Info in amicus brief stated that if courts narrowly interpreting the scope of protection, scope of info available to PSOs will be limited. PSOs provided reports, data and analyses that there were reductions in errors. AHRQ also acts as a watchdog for PSOs.

- Examples in PSES for collecting and reporting to a PSO include medication error and near miss reports, investigative analysis, culture of safety data, proactive risk assessments, root cause analysis, best practice, process improvement plan and corrective actions, risk management (incident reports, investigation notes, etc.) and outcome/quality (procedure changes, clinical protocols, etc.)

- PSWP is privileged. Not subject to subpoenas or court order, discovery, FOIA or other similar law, or request from accrediting bodies or CMS. Not admissible in any state, federal or other legal proceeding, state licensure proceedings, or hospital peer review disciplinary proceedings.

- Patient Safety Act privilege and confidentiality prevail over state law protections. Want environment where people self-report and entities will work with them to get them back on track vs. continuing to make/hide errors.
  - State Peer Review is limited in scope of covered activities/entities. State law protections do not apply in federal claims. State laws usually do not protect info when shared outside the institution (considered waived).
  - Patient Safety Act is a consistent national standard that applies in all state and federal proceedings. Scope of covered activities/providers is broader, protections can never be waived, PSWP can be more freely shared throughout a system, and PSES can include non-provider corporate parent.
  - Question: Would termination of employee based on quality event be protected? State Pharm Law says that if terminated based off quality event it would need to be reported to state pharm board. Michael: Info that report to PSO cannot be used in disciplinary actions, but mandatory reports must continue to be made.

- There are some exceptions under the law e.g. strict privilege never waived, but sometimes have to share materials with lawyer, business associate, accrediting bodies, and other third parties. If improperly disclose and don’t fall under exception, will be fined.

- IDFPR v. Walgreens summary (see notes above).

Panel Discussion: Colleen Johns, Tara Modisett, and Tasha Polster

  - Phil: Once independent joins, their info is protected like anyone else joining a PSO? Tara: Right, we give independents and regional chains what they would get if were a big chain-we group the data so they can learn from each other.

- Colleen-Wal-Mart Safety Culture PSO.
Experience with providers not looking at information because don’t want to find errors and have to pay. This discourages self-auditing and self-reporting.

There is a privilege around the information with the Act that allows us to look at and learn from errors. Factual info not protected; reporting and review is what is protected. Wal-Mart doesn’t punish for human errors.

Good system design is what is least likely to have errors—e.g. multi-point scanning and different eyes on each step. This includes culture of reporting errors so that can learn from information and improve processes, policies, procedures, etc.

- Phil: From State Pharm Board standpoint, inspector going in once complaint has been filed. Inspector has access to materials related to that complaint/error. But if asks what other errors that pharmacist has made, will they have access to that info? Colleen: No, at Wal-Mart those errors only tracked in reporting tools that go back to PSO, so this would be privileged. Phil: How can Dept. ID bad actors to protect the public? Colleen: Importance of just culture idea. In just culture, no incentive to keep bad actors at a pharmacy. Don’t want to punish human error; want to mitigate risks. PSO doesn’t leave room for bad actors to be bad actors. Will still meet mandatory reporting and record keeping requirements, but do not do this for quality improvement purposes because would be redundant. Michael: Can’t get this info on doctors, either.

- Question: Since newest PSO, have you seen huge improvement in quality? Colleen: Since adopted just culture, have info never had before and have been able to create several new processes and procedures.

- Tasha Polster-Vice President, Pharmacy Quality, Compliance and Patient Safety, Walgreens Co.
  - Just culture piece has been big benefit of PSOs. Ability to share info through mandatory monthly peer review meetings is great learning experience. ERx has greatly reduced patient errors because don’t have to interpret physician handwriting. Also can speak freely re: safety with competition via PSO collaborative, and this would never have been the case w/o the privilege.

- Colleen: Still looking at error info through root cause analysis, but won’t share this for punitive reasons

- Tara: Each independent pharmacy has different ways of operating. If sign third party contract, need quality assurance and safety standards. Our org. offers education to these smaller and independent pharmacies to set up these types of programs, run meetings, collect data, etc. 93% of data is near misses for our clients and this is where we can improve. Each pharmacy gets own data, then can aggregate the data to share trends, then share best practices, trends, etc. Idea is for independent/small pharmacies to have the same resources large chains have.

- Phil: On board with concept of root cause analysis, but when we have knowledge of someone who is a danger to the public how do we get them out of there? Colleen: Whole point behind just culture is that don’t fire for human error, but negligence would still have to be reported and hold people accountable for decisions and actions. If not fit to serve and filling scripts, and find out substance abuse issue, this is an HR issue as a blatant disregard for SOP.

- Q: How to maintain just culture when someone not fit to be there/other negligence going on, but rest of the culture doesn’t know this. How to encourage reporting and taking these things public when emphasis is on confidentiality? Michael: People know when these things are going on. Organizations develop cultures and processes so that this information is known.
• Q: Back to Colleen’s scenario, someone not fit to serve would have to report that to the Board? Colleen: Will meet mandatory record reporting requirements. “Fit to serve” is its own issue-better not find out about this because of an error, this should be found out long before something happens in an active safety culture. Team members should be holding each other accountable and be encouraged to point out to someone any concerns they have about them on a particular day, etc. If have to report details of an error to a board, it can’t be PSWP anymore and is not protected. We all have the same goal-to keep patients safe and create safe environments. Better to prevent errors before with just culture model vs. punitive punishment.

• Q: PSWS-what if collecting data unrelated to an error. Are these things also protected and do you have to report it to make it protected? A: Considered PSWS if do a study on an issue such as why so many re-dos. If make changes, corrective actions and outcomes of studies are not protected. Don’t have to tell POS about the study.

• Q: How is a “near miss” defined? Colleen: Reporting of errors by COB day it happens for all things that leave the pharmacy or things that get caught at counseling (Wal-Mart definition). Also request info even earlier for mandatory reporting and want info even if just patient perceived error. A: near miss is anything patient doesn’t know about. Some debate around the exact definition, but term is well known.

• Q: Tara, you have pharmacies in all 50 states participating in PSOs? Tara: Yes, all 50 states and Puerto Rico. Q: Which state has the model language that is best for pharmacy practice? Tara: Virginia and North Dakota-have to show evidence of working with PSO or, if not, proof of continuous improvement programs to the Boards in those states.

• Phil: The 16 areas task force charged with addressing are things related to stress, workload, limiting tech hours, breaks, hours, etc. Is anyone looking at these types of issues as part of PSOs? A: Yes, have done analysis and changed hours of pharmacy. When changed hours, didn’t see a difference in errors going up in those locations. Job of pharmacy chain to make the right decisions and create an effective system. Michael: Would these types of issues find their way into a report? Colleen: In root cause analysis these things will often come up when looking at it from quality perspective. Phil: Any data showing that pharmacies with mandatory breaks have less errors than pharmacies without mandatory breaks? Speakers: Don’t know of any data on this. Tara: For independents, hard part about mandating something is the varying sizes/staffing of the members. Michael: Doesn’t the explanation given for the error get collected? Tara: This should be part of culture of safety. Everyone should be able to say that environment is not good for working right now. Independents will go out of business if they have major errors.

• Phil: We have to go back to the legislature with recommendations. How would we justify not recommending mandatory breaks or shorter hours? Colleen: Entities have their own staffing models that should address what works for their employees and the effectiveness of their work. Government entities should not mandate to pharmacies how to staff.

• Q from audience: Assume that mediation errors wouldn’t increase with 10 vs. 8-hour shift, but did personal satisfaction of pharmacist decrease when mandated 12-hour shift? Colleen: Agree that happier you are in your job the better you will perform. Want people to believe they are supported even when make an error. Use AHRQ survey. Phil: We just need good reasons to act on any suggestions we make.
- Comment from audience: Public perception problem—want to fix this the right way. Concerns we hear anecdotally are valid even if no formal study.
- Q from audience: Info gathered by PSO—Can we only take action if we self-report? Is all info protected? Colleen: Can take action on any information, just issue of what is protected or not. Michael: Have to break down corrective action—lots of things you can do. Q follow up: can we use the info to set standards? Michael: Yes, can use this info however you want. Colleen: This is just culture, which is different than how the PSO works. Group will take this offline.
- Helga: Reminder that PSOs offer another way we can go other than mandates and reporting. Would like to see studies on whether mandatory breaks, etc. do make a big difference. Next step is to justify some of the task force action items.
- Phil: Tribune expose focused on chains. Look at 16 areas and not sure how an independent pharmacist could implement. These things aren’t applicable to everyone, so how to address it in the Act. Colleen: Every business runs differently, not sure if detailed regulations are the way to go.
- Q: Any data on what is spent on litigation re: errors vs. if had hired more tech help? Phil: Garth, how would these work for smaller pharmacy? Garth: Basic tenants we can agree to as recommendations regardless of size of pharmacy.
- Colleen: Would like to see us working with NABP on some models. Comment: All of us are working with New Hampshire, who is working on regulations. Need to meet all of our requirements and have Boards be active partners. 14 states with CQI (?) laws. Some of these are very onerous and create excessive record keeping requirements.
- Phil: Next meeting to discuss technician training and education. How to maximize use of techs and what educational requirements? Over next two meetings let’s discuss these items. June will be tech education.

| Adjournment       | Adjourned 3:20 p.m. |