INSPECT OVERSIGHT COMMITTEE
Indiana Government Center South
402 West Washington Street, Room W064
Indianapolis, IN 46204

MINUTES OF DECEMBER 8, 2015

Donna Wall, R.Ph., Vice President, Indiana Board of Pharmacy, called the meeting to order at 9:03 a.m. and declared a quorum pursuant to public notice posted at the principal office of the board at least forty-eight (48) hours before the time of the meeting.

Members Present:
Donna Wall, R.Ph., Vice President
Indiana Board of Pharmacy
Eugene Kochert, R.Ph.
Senate Appointee
Larry Turner, Lieutenant Colonel
Indiana State Police
Joan Duwve, M.D., MPH, Chief Medical Officer
Indiana State Department of Health
Gary Jacobi, R.Ph.
Senate Appointee
Matthew Whitmire, J.D., Director
Medicaid Fraud Control Unit
Office of the Attorney General

Staff Present:
Michael Brady, Director of INSPECT
Professional Licensing Agency
Ted Cotterill, J.D., Board Director
Professional Licensing Agency
Jody Edens, Assistant Board Director
Professional Licensing Agency
Kristin Schwartz, Communications Specialist
Professional Licensing Agency
Gordon White, J.D., Deputy Attorney General
Office of the Attorney General

Donna noted that Gary Jacobi began the tradition of reciting the Pledge of Allegiance at Pharmacy Board meetings during his tenure as president during the September 11 attacks in 2001.

Donna asked that everyone at the table would say their name, and that those Committee members who were not at the previous meeting would introduce themselves to the Committee and explain what INSPECT means to them.

Dr. Joan Duwve is the Chief Medical Officer at the Indiana State Department of Health (ISDH), a family practice physician, and the Associate Dean of Public Health Practice at the Richard M. Fairbanks School of Public Health at IUPUI. Dr. Duwve said she was an early adopter of INSPECT. She believes it is a fantastic tool that allowed her to identify doctor shoppers and maximize treatment for those patients who needed opioids.

Donna Wall, R.PH. is the Vice President of the Indiana Board of Pharmacy and has served on the Board for twenty (20) years. She is a practicing pharmacist, and so uses INSEPCT as a practitioner to get appropriate treatment for her patients. She has watched INSPECT grow since she's been on the board. She noted that Indiana was the first state to allow interconnectivity and financing. She said she has a responsibility for INSPECT—that the public must be protected. The Board of Pharmacy has a responsibility to take information and ensure its protection for the patients. We must be sure the information is kept secure and that there is transparency about who wants the information.

Larry Turner is a Lieutenant Colonel at the Indiana State Police, where he has worked for twenty-six (26) years. He oversees the investigative aspects of the force, including drugs, labs, etc. He sat on the Controlled Substance Advisory Committee and remembers INSPECT in its infancy. He believes it is a useful tool for preventing prescription abuse, even more on the front end with the practitioner, and it is a practical application of the database to stop abuse.

Donna noted that the Board of Pharmacy appreciates the State Police lab to help facilitate emergency drug scheduling.

Donna then asked that the Committee take time to review the minutes from the previous meeting. Gary Jacobi moved to approve the minutes. Matt Whitmire seconded. The minutes were approved unanimously.

Donna then asked Mike Brady, Director of INSPECT to offer a progress report.

Mike stated that he would offer both a progress report and a review of action steps for the Committee. He addressed INSPECT staffing, stating that INSPECT benefits from various agency resources. He also introduced Taya Fernandez to the Committee, who will be taking the position of INSPECT's Director of Operations beginning December 21, 2015.

Taya said she started working with INSPECT in 2007. She has held every position with the program except the data analyst position. She left in 2013 to work with Medicaid Fraud, which she said was very helpful training that she will apply as INSPECT's Director of Operations.

Dr. Duwve said Taya has been a tremendous asset to INSPECT. Donna noted that the Board of Pharmacy is excited that Taya is returning to INSPECT. Matt said Medicaid Fraud has appreciated Taya's work for them.

Mike Brady then addressed the action item of reducing barriers to registering for INSPECT. As of the week following the previous IOC meeting, INSPECT is allowing for an automatic registration process for pharmacies when applying for state licensure. In addition, during their November 9th meeting, the Board of Pharmacy voted unanimously to remove the notary requirement for physician registration. INSPECT and PLA staff are now working to make automatic registration possible for practitioners.

Mike Brady reminded the Committee of Dr. Trobridge's question about physicians should do after they determine they should notify law enforcement about the concerning patient. Superintendent Carter suggested a fact sheet. Mike mentioned that he had spoken with Dr. Trobridge, and that he is looking for a single point of contact to relay concerns. Mike asked Larry for suggestions.

Larry mentioned that ISP has a 1-800 tip line and the number could be provided to doctors. The tip line is checked every day. They then direct the information to the appropriate people, and it is a statewide tip line.

Mike asked if ISP always handles these types of concerns. Larry responded that they always manage the tip line and may send the information to Medicaid Fraud or DEA if necessary.

Donna mentioned that practitioners can automatically stop prescribing and send person of interest (POI) notifications when they feel it is necessary. She also asked if the tip was confidential.

Turner said it depended on if the doctor called anonymously. If the doctor leaves a number, ISP would probably call back for more information.
Donna suggested that if there was a phone number it could be put on the INSPECT and Board of Pharmacy websites along with a possible FAQ about what to do when reporting something.

Dr. Duwve said she thought it was a good idea, and also mentioned that in situations where practitioners feel unsafe and would call local police it would be helpful to know how to stay within the law as a practitioner.
Mike Brady said the legal implications would need to be addressed.

Mike Reinbold from the Indiana State Medical Association (ISMA), addressed the Committee, saying he wanted to remind everyone about HIPAA requirements. Physicians should take into consideration what exceptions are acceptable before making a report.

Donna suggested this would be a good opportunity for ISMA and the Inspect Oversight Committee to work together to determine what the requirements and considerations should be for physicians who find themselves in this position. The conclusion could be put on the INSPECT and ISMA websites.

Gary asked if, as a pharmacist, he could discuss an INSPECT report with a patient and whether he could hand the report to them.

Donna said it should not be given to the patient.

Ted said the statute lists individuals who can see the report, and the patient is not listed. However, pharmacists are allowed to act within their professional judgment. He would defer to PLA General Counsel, but a pharmacist could say they've consulted the report and choose not to dispense based on the information, but showing them the report would be crossing a line.

Dr. Duwve said an INSPECT report seems like the patient's medical record. She asked if there had been any legal challenges for patient access.

Gordon said it has been challenged in a criminal context and the court of appeals said the report could be accessed in the limited context of a criminal case, with a lot of ifs, ands, and buts. He concurred that patients cannot generally see the record.

Mike Minglin, General Counsel for the PLA, said there have been several civil trial and court of appeals cases. The courts have uniformly held that patients do not have access. The only exception is in criminal proceedings when it is necessary for defense.

Mike Brady then said the process is moving forward to make INSPECT more accessible to practitioners and dispensers, and the PLA is moving forward in exploring the RFI for integration.

Mike Minglin said he has had preliminary discussions with IOT security about possibly going forward with integration. The process was stopped after the pilots ceased, and there was a lot of interest in reopening integration with certain partners. He is working on properly preparing the contracts to go forward, both the RFI and RFP. PLA wants to craft them in such a way that if we move forward it would be available to multiple partners. He suggested that the Committee make a recommendation to the Board of Pharmacy to move forward with the RFI process to investigate the security of the partners' systems, which is critical. It must be ensured that the partners are doing their own penetration tests and have certificates of destruction. We want to know more specifically how they will use the information so that when we craft the proposal our scope can be more specific to make sure we also put security requirements if they do not meet the minimum threshold.

Donna asked if there were any questions or concerns. She asked if the RFI was in place to find out how PLA would know when someone broke security. She asked if that

would come back to the Board of Pharmacy for discipline. Mike Minglin said broken security would mean at the least a breach of contract, and more consequences could be determined.

Dr. Duwve asked whether downloading those records and maintaining them in the EMR belonging to the physician's office would be allowable or a security breach.
Mike Minglin said his personal opinion is that it should be developed so that the INSPECT report is visible on screen when requested, but as soon as the screen is exited the report will disappear and only reappear when requested again. If the INSPECT report were saved in the EMR, there is no ability to police it in someone else's server. Thus, the certificates of destruction would be required. There have also been preliminary discussions with IOT about contract provisions to provide for periodic inspections to make sure everything is as secure as what has been represented.

Donna asked for a motion if there were no other questions.

Dr. Duwve asked if there was a way for something to be embedded in the record to say that the physician accessed the report. She said this was required for the chronic pain prescribing rule and wondered if embedding would eliminate the downloading behavior. Mike Minglin said there is already an audit trail and PLA would have to explore that question with the vendor. Matt Whitmire said it would be helpful to have any documentation that the doctor had accessed the report. Mike Minglin said there would have to be discussions with Appriss (INSPECT vendor) to see how it could be accomplished.

Dr. Duwve moved to recommend that the Board of Pharmacy explore the RFI process.

Matt Whitmire seconded the motion, which passed unanimously.

Mike Brady presented the INSPECT report to the Committee featuring the most recent numbers from December 1. The number of practitioners from INSPECT is in the fifteen thousands (15,000). Forty-seven percent (47%) of those eligible are using the program. MDs are the largest population using the program.

Dr. Duwve asked if all the eligible users added up to thirty thousand (30,000). Mike Brady said he would check that. Dr. Duwve wanted to know who is in the eligible category since some CSRs are not used to prescribe to people. Mike Brady said that could account for the difference.

Mike Brady also noted that the registered pharmacy users of INSPECT has increased by twenty-nine percent (29%) since 2013 to five thousand, six hundred (5,600).
Dr. Duwve asked if there was a way for INSPECT to track the number of people who are registered for the program versus the number of people actually querying the program. Mike Brady said he would look into how to get those numbers.

Donna asked whether there was any other information the Committee wanted to see.

Dr. Duwve asked if they could see numbers pre- and post-2013 when the emergency rules for chronic prescribing were put in place. Gary asked whether the queries to INSPECT could be broken down by scope of practice. Dr. Duwve also asked whether there could be a short survey sent to find out why some registered users were not querying the program and also asked whether there was information about what practice-type each query was from. Mike Brady answered that INSPECT does not have a mechanism for collecting that information, and Mike Minglin added that it is because the PLA does not give specialty licenses beyond the medical license. Mike Reinbold added that ISDH collected some of that data, but Debbie noted that because the survey ISDH used was voluntary, the data was not reliable. Taya said collecting specialty data is very difficult and national organizations have not discovered yet how to do it.

Seeing no further discussion on the INSPECT report, Donna opened the discussion to any new business.

Matt presented three points on Person of Interest alerts (POIs). He noted first that the threshold for a POI alert to be issued is when the patient has a combination of ten (10) unique visits to prescribers or dispensers within a certain period. He said they would like to see the number lowered to seven (7). Lower than seven (7) would mean too many alerts were sent to doctors, but seven (7) is better than ten (10) because at that number the person could have already gotten five (5) controlled substance prescriptions in a month. Lowering the number to seven (7) would let notify the doctor and allow them to not check INSPECT every day.

Donna asked whether the new number was based on a national standard. Matt answered that he thought it was from a study.

Taya said she did a study based on each number up to nine (9) alerts. Eight to ten (8-10) was a high threshold, but lower than five (5) produced too many alerts. She said the numbers could be run again, but the sweet spot was around six (6) or seven (7). Matt noted that if a patient saw the same doctor three (3) times it would not add to the alert, but three (3) different doctors would. Taya suggested running new numbers for more current data.

Donna suggested the Committee look at the POI numbers at the next meeting. Matt asked if they could be broken down for ten (10) and seven (7) alerts. Taya suggested that the Committee might want to look at how many patients are affected and how many reports are being sent out to doctors and dispensers. Dr. Duwve asked if the alerts could be tracked over time to see if there was a difference in prescribing behavior. Amanda
Matt suggested also that the reports should be reviewed for HIPAA compliance.
Mike Reinbold, Dr. Duwve and Donna agreed that POIs were useful to practitioners.
Matt moved that the POI reports be moved to a threshold of seven (7) rather than ten (10). Larry seconded the motion. The motion passed unanimously to recommend to the Board of Pharmacy to set the POI threshold for INSPECT at seven (7) instead of ten (10).

Commented [A1]: No clear answer to this question—just leave it out?

Matt brought up alerts for doctors prescribing over a certain limit. Dr. Duwve said it came up at the medical board about three (3) years ago, but not much has happened since then. Donna said it had never come before the Board of Pharmacy. Mike Reinbold suggested that caution would be good when considering that suggestion. Dr. Duwve agreed, saying there was room for education among prescribers, but physicians prescribe for many valid reasons. Donna suggested that the topic be an item for further discussion rather than an action item.

Matt's third point was about HIPAA compliance, which fit into his first point.

Matt then brought up the Rx Committee, a meeting sponsored by the Attorney General's office to discuss legislative issues the AG's office might prioritize. He listed five (5) highlights of the proposed INSPECT legislation and asked for suggestions from the Committee.

1. Require prescribers to check INSPECT initially upon prescribing Schedule II or III controlled substances and quarterly thereafter. The mandatory usage is modeled after Kentucky. Twenty-two (22) states require some kind of mandatory use of PMPs.
   Donna noted that some states are reversing their mandatory usage policies due to push back from physicians. Matt answered that the legislation wouldn't require the physician to check INSPECT every time.
2. Require pharmacists to check INSPECT initially when dispensing Schedule II or III controlled substances and upon red flags that would be specified in the legislation, tied to geography, etc.
3. Allow coroners to have access to INSPECT, as legal opinions have said they do not have access currently.
4. Allow Behavioral Health treatment providers to have access to INSPECT. He was unsure of the exact population of practitioners targeted. Psychiatrists?
   Mike Minglin said licensed alcohol abuse and treatment counselors are probably the targeted group. Donna requested that Matt be more specific about the practitioners being addressed in the legislation.
5. Allow (not require) INSPECT reports to be placed in patient charts. There would be no penalty for placing the report in the chart.
   Donna asked whether there would be anything in the legislation granting patient access to the chart. Matt said no. Mike Minglin pointed out that under Title 16, the medical chart is available to the patient. If the INSPECT report is placed in the chart, the patient will have access. Donna said patients must be allowed to have access or not, but allowing the INSPECT report to be in the chart does not give clarity on that point.

Donna also mentioned regarding Matt's first point that each time a physician writes a Schedule II prescription, it is considered a new prescription, meaning that the doctor would have to check INSPECT each time before writing any Schedule II prescription. She asked if the AG's office meant at the beginning of a new treatment regimen, rather than at the beginning of every prescription.

Matt said it was not the intent to make a physician check INSPECT each time before writing a prescription, so treatment regimen or change would be better.

Dr. Duwve suggested that there must be a way to meet in the middle between mandatory INSPECT usage and low usage. She offered to provide provisional numbers about PMP usage and decreased mortality at the next meeting.

Gordon suggested that on the topic of expanding usage to other practitioners, it would be useful if the statute were clearer about whether INSPECT is available to those people working in substance abuse treatment and recover who do not have prescriptive authority but are working in the program. Donna said the statute needs to be as clear as possible so that when the INSPECT staff get a request they know whether the person meets the requirements. Something generic in the statute would not be helpful.

Mike Reinbold said there was not consensus in the Rx Committee meeting, and said that of the states that have mandatory usage, there is no one-size-fits-all approach. ISMA wants there to be more clarity in the state and issues surrounding Title 16.

Matt acknowledged that there was no one-size-fits-all and asked what ISMA would be comfortable with as far as medical professionals checking INSPECT.

Mike Reinbold said physicians have only had access since 2008, noted that integrity of data was important, and that the issues surrounding INSPECT statute and switching over to 24-hr reporting should be dealt with. More can be accomplished by cleaning other issues rather than imposing mandatory usage.

Matt asked whether less physicians would use the program when mandatory usage was imposed rather than more.

Mike Reinbold said they are different views of the issue. The goal is to have doctors pursue the information because it is valuable to their practice, rather than because they are forced to. INSPECT data has been used in disciplinary hearings of the medical board. ISMA does not have a position because they have not seen a bill on the subject of mandatory usage, but he does offer caution any time there is discussion of a mandate.

Matt asked about the integrity of the INSPECT data.

Donna mentioned that sometimes the handwriting on the prescriptions is hard to read, or the DEA number for prescribing is not unique to one physician. This has always been a disclaimer for INSPECT, that it is a helpful tool to start with, but all the information should be checked at the original sources. It is not that anyone is trying to tamper with the data, but human nature always causes unavoidable errors such as bad handwriting.

Gary mentioned that sometimes physicians prescribe to patients from other states and that can cause confusion.

Donna said it might be helpful to check the requirements across different states for prescribing practice.

Gordon suggested that if the INSPECT statute was going to be opened, there should be a language clean up at the same time.

Donna said that in one of the upcoming Committee meetings, the Committee would study the statutory language surrounding the INSPECT program and review it so everyone is clear about what it says. Mike Brady will lead this discussion.

Discussion of the next meeting date would be held through email later.

There being no further business the INSPECT Oversight Committee adjourned at 10:37 a.m.

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William J. Cover, R.Ph., President