MINUTES

KATE BROWN
Governor

Opioid Epidemic Task Force Meeting #7
June 26, 2018
10:00am – 12:00pm
Location: State Library Building, 250 Winter St. NE, Salem, Oregon 97301-3950 -- Room 103

Updates from the Governor's Office:
U.S. House just passed an opioid package of more than 50 bills. 396-14 vote. Included telehealth, reentry, and bills that deal with Fentanyl. Supported by the National Governor's Association. Governor Brown is the Vice-Chair of the Health and Human Services NGA Subcommittee. Bills will move to the Senate.

Federal Health and Human Services funding opportunity announcement for State Opioid Response Grants in the amount of 930 million for states from (Substance Abuse and Mental Health Services Administration (SAMHSA). No state will receive less than 4 million. Due on Aug. 13, 2018. In addition to the 4 million, states will get additional moneys allocated according to certain statistics.

July meeting will focus on DCBS report from HB 4143 will be presented. Rick Blackwell and his team will present a comprehensive overview of the recommendations from that report. The OETF will need to take action on some of the recommendations.

Drug takeback policy discussion:
HB 2645 was a bill from a previous legislative session. The concept is being revisited in light of recent drug take back legislation out of Washington State.

Representative Malstrom – HB 2645 & concept overview;

- Multi-faceted issues – environmental, public health, addiction and public safety.
- 1/3 of all medications purchased in the US go unused.
- Abuse of prescription meds is the leading cause of unintentional injury deaths and common cause of ER visits due to poisoning.
- 70% of those who abuse opioids obtained the drugs from family members.
- 2014 data shows that 87% of adolescent fatalities managed by the poison center at OHSU were linked to prescription drugs.
- The FDA, DEA and EPA all recommend secure medicine take back.
- Oregon's current system is not organized.

What is really needed is an organized, statewide program that has a simple goal – to make unwanted, unused medication as easy to dispose of as it is easy to get. The way to do that is to establish drug take back kiosks at convenient locations.

During the 2017 legislative session, HB 2645 gained bipartisan support but did not emerge from the ways and means committee. Washington State has approved the first in the nation, drug take back program that closely mirrors HB 2645. Oregon should also act to approve a statewide drug take back program.

Presentation: Abby Boudouris and Annalisa Grunwald – DEQ, Product stewardship & statewide efforts

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Background of DEQ's involvement and the concept of product stewardship. DEQ and Abby have been working on the drug take back issue for over a decade. In 2006-2007 DEQ supported and participated in an association of clean water agencies Oregon drug take back project. Goal was to develop stakeholder consensus on the best drug take back program for Oregon. At the time, the group recommended a product stewardship program based on a program that has been operating in British Columbia since 1996.

The growing opioid crisis has changed the focus of the issue from accidental poisonings and environmental concerns to this epidemic. The same solution addresses both.
DEA regulations were adopted in 2014 which removed some barriers to pharmacy take back programs.
13 counties in California and Washington, serving approx. 10 million people, have passed ordinances.
This year, Washington State passed legislation. Last week, New York passed a bill on to their governor's office for signature.

Product stewardship is a concept that says that whoever designs, produces, sells or uses a product, shares in the responsibility of the impacts from that product. That includes, the end of its useful life. Further goes to whoever has the greatest opportunity to impact, has the greatest responsibility.
Oregon has product stewardship programs for paint and electronics. The manufacturer of these products is required to develop, finance and implement the programs, and DEQ oversees for review, approval and inspections. Local government and retailers can voluntarily participate and consumers participate by bringing in their materials to the disposal locations.

Have learned that while the principles are the same, every product is different. Unwanted pharmaceuticals have their own unique challenges and will need to fit in with DEA requirements and other requirements which make this more challenging. DEA has provided us with the framework.
DEQ has submitted a legislative concept to the Governor's office which would create a program to provide for the safe collection, handling and disposal of drugs in the state. It is designed to be strategic about state resources – build on the expertise we already have and be strategic with the Board of Pharmacy and DEQ.

Manufacturers would create a plan to be reviewed and approved by DEQ. That plan must contain:

- A collection system that is safe, secure and operated on an ongoing, year-round basis.
- Provide for the secure handling and disposal of any collected drugs. Including providing and protecting any patient information that may be on the container
- Disposal must occur at a hazardous waste disposal facility or municipal solid waste incinerator that is permitted to accept pharmaceutical waste.
- Include drop off points to provide a convenient and equitable access for everyone across the state.
- Contain a strategy for the promotion and raising of public awareness for these programs.

Collection points would be placed at drop off sites, and would be required to accept any covered drug. This is where the Board of Pharmacy would come in. They already do the oversite work of pharmacies, so they would be able to inspect the drop off sites at the same time, in the same manner that they already do for regular inspections.

This model is similar to what we saw in 2017 and what we will hear from Washington State.
Q: Does this also count for non-prescription drugs?

A: The way we wrote it, it would be all medications.

Presentation: Margaret Shield (Community Environmental Health Strategies, LLC) – National lens w/ focus on recent efforts in Washington;
Secure drug take back is the service that the community needs:

- How to make it more convenient?
- How to make these programs available to everyone?
- How to make them sustainably financed?

In regards to the opioid crisis, this is part of a comprehensive, primary prevention approach to help shut down the "drug dealer" in the medicine cabinet. Goes hand in hand with other prevention approaches like PDMP, education, prescribing guidelines.

After many years, Washington State just became the first to enact a law that requires the pharmaceutical industry to provide safe and comprehensive take back programs for leftover medicines. Believe the success of the county level laws are what made the difference to get the law passed. Throughout the years of working on this policy concept, we kept building more support with a diverse coalition of organizations. Specifically, law enforcement who were tired of holding the bag on drug take back. Had support from substance abuse prevention groups, suicide prevention groups, doctors, nurses, dentists, Hospice and home care groups and senior groups. Public health officials came out to say that this was a missing component of our opioid prevention efforts.

The pharmaceutical industry had been the sole opponent of this program for many years, but they finally came to the table and negotiated with us. We got them to a neutral position on the bill.

Law was modeled on local board of health ordinances and regulations which were passed between 2013-2018. Each law was similar, and they contained local customization. Modeled the state law on what we knew was working in these localities. Under current state law, the local laws can continue until 12 months after there is an approved statewide program operating, so won't see a drop in services at the local level.

Many California counties have also passed pharmaceutical stewardship ordinances. Several of the laws also require pharmaceutical manufacturers to take back medical SHARPS.
New York has passed state level legislation that is a pharmaceutical stewardship law. Similar to WA. Think WA law has some advantages in being more specific in terms of the services that need to be provided.

Programs have been a patchwork across the state. Some communities have drug take back, others don't. If we are going to be effective, we need programs to be more convenient, available, better promoted, and ensure sustainable funding. Local law enforcement programs have been overwhelmed with the amount of medicines being turned in.

Programs that pharmaceutical manufacturers are providing services in 4 counties (50% of WA population). 400 pharma companies that are participating have formed a stewardship LLC organization called MED-Project. Prior to the project there were no drop boxes in major cities and we were relying on collection events. Went from13-120 drop boxes which are dispersed across city and small towns.
With few exceptions every drop box takes all prescription and over the counter drugs. All take narcotic and controlled substances.

Under local and state law, there have to be pre-paid return mailers provided for those folks that can't get out to a drop box. Can be requested online or through a toll-free number. Can also pick up and libraries in King Co.

Consumers often don't know the differences in drugs, so we make it easy for them to just clean out their medicine cabinet. Drop boxes take pills, liquids, creams.

Manufacturers are required to promote the program. They have a website where public can find drop locations. This ensures that even the rural locations will be promoted. Makes it more standardized. They are also required to distribute promotional materials. We would like to see more public awareness now that these services are available.

Additional collectors can join these programs over time. Critical in that organization that wants to host a drop box can opt in to join. They must be able to follow the DEA security requirements. Once enrolled the manufacturer's MED-Project program services logistics and pays the hard costs. Drop sites continue to increase.

Pharmaceutical stewardship policy accomplishes a systems change for the way we are providing drug take back. Gone from not enough resources and over reliance on law enforcement sites, to Pharma taking responsibility and providing additional drop boxes and more convenient locations. Drug stores are one of the most visited retail environments.

By looking at local programs, you can get a good sense of what is required in the state law. Legislation lays out standards and performance criteria for the programs. Goal of the legislation is to allow flexibility for the manufacturers to design the program in a way that works. Encourage specificity in the legislation. Have learned from local implementation that it is better to be specific and avoid disputes with the pharma industry about what is and isn't required. WA bill lays out clear requirements, specifies the type of drugs that have to be accepted, defines a "convenience standard" for the service that need to be provided to all communities. There is a description of the public education requirements, and standards about how the medicines need to be handled securely and disposed of properly to protect the environment. There are also reporting requirements where the manufacturers have to describe their program activities and report on the amount of medicines they have collected. All of this is being overseen by the WA State Department of Health. They review the plans, oversee the program and conduct periodic public awareness surveys. If the education is not providing enough public awareness they can go back to the manufacturers and require more education be done.

Effects health and environmental standards so there is a partnership between WA State Department of Health and Department of Ecology in the oversite.

Financing – who is going to pay for the program? In the legislation, drug manufacturers are explicitly required to provide for the specific cost of the program. In doing so, they manage their own funds. The manufacturers pay directly for the program services. The legislation is clear that there cannot be a point of sale or point of return charge. There is also in-kind support coming from the collectors. They give up floor space to host the drop box, they invest staff time in monitoring the box and talking with the public about how to return medications. Most government agency costs are recovered through fee on the manufacturers programs. Trying to recover all of the costs, but there is likely to be some start-up and rule making costs that are being covered through state general funds. When looking at estimated cost of this program to drug manufacturers, it is important to think about the large volume of sales of medicines going on. The cost works out to be about .1% of annual medicine sales. Manufacturers can pass this along through the supply chain, but it is something they can incorporate into their business model and expenses.

There are implementation deadlines in the state law. Have a July 1 2019 deadline for the manufacturers to submit their program proposal. Between now and then, our state agency has started some rule making. The legislation is specific but they will clarify some other requirement. Are also deadlines in the state law whereby program manufacturers have to notify every pharmacy, police station and hospital of the opportunity to host a drop box. The program proposal will be submitted and state agency will review it to check that it meets the criteria of the law. Hope to see the program operating statewide by 2020.

Please visit the following link for WA Secure Drug Take-Back and Local WA Ordinance resources
https://www.cehstrategies.com/wa-drug-take-back-laws

Q: What is the advantage of having an industry driven voluntary program, as opposed to simply requiring pharmacies to do this?

A: It comes down to who has the ability to have a funding source to pay for this. The premise of the pharmaceutical stewardship policy is looking back at who can incorporate this cost of doing business into the product price – that is the manufacturers. Have had many conversations with all types of pharmacies. There is a cost to drug take back but pharmacies operate on a slim margin, so can be limited to how much they can adjust the prices of medicines.

Q: If I could offer you a program where you send the bill to pharma, it's cheaper that what you have described, and you get every pharmacy as opposed to 1/2 or 2/3 of the pharmacies, would that be better>

A: I would like to see every pharmacy participate. What I also know is that some pharmacies have good reasons why it is not possible for them to host a drop box. Can be a space, staffing or storage security reason. In the jurisdictions that have mandated that every pharmacy have a drop box, the pharmacies will come to your elected officials and give all the good reasons why that mandate doesn't work for them. You will then have many pharmacies doing other types of collection rather than the consistency of a drop box. The California counties that have mandated retailer participation, they don't have more drop boxes than with voluntary participation. Still believe the voluntary model with the opt-in is going to end up with better services.

Q: How many retail pharmacies do you have and how many do you expect to be covered by this once you are up and fully running?

A: Approximately 2000 statewide pharmacies. Our state department of health does not give licenses on whether or not they are retail or clinical pharmacies – the list is merged. We do hope that once the program goes statewide, we will see more participation from the national chains. Some of the national chains run their own programs, and they can do that under this law, but we want to see more of them put drop boxes in all of their stores. One of the argument we have heard is that it is challenging for a chain store to comply with the difference in local laws. It should be easier for them to participate once the law is statewide.

Q: Do you have an estimate out of the 2000 pharmacies? What is your goal for coverage?

A: To have it in every store. All of them can participate. The law lays out minimum standards that are less than that, so there is a minimum number of drop boxes that need to be in every city, town and unincorporated areas. Agree that there is a political issue. For drug take back to work well, we believe it needs to be in our pharmacies. We have listened to our pharmacies saying what they need to make the program work, and have worked that into our policies and have been successful. Different issue for the pharma manufacturers. Many of them are going to just cut a check to finance the program. The pharmacies themselves have more complex issues to think about in terms of doing the physical work of collecting the drugs.

Q: For the New York law, is the funding mechanism similar to what you have done in WA?

A: Yes. It is very clear that the pharmaceutical manufacturers need to pay for the collection, transportation and disposal of the medicines. The bill also lays out requirements for them to do promotion. They did not include the opt-in. Worry that the way they've written it isn't clear how much service needs to be provided to all communities. Worry that the manufacturers would indicate they have met the minimum criteria, and they don't have to include other pharmacies who choose to opt in later.
Comment: Pharmacy representatives in Oregon are absolutely behind a similar program. WA has been a great model. Should be easy to get groups of pharmacists to be advocates for the program and to reach out to the public when it is voluntary. When it is a mandate, I think you see less of that positive energy about trying to promote the program.

Q: You mentioned that the pharmaceutical industry has gone to neutral on this bill. Can you give some insight into those discussions?

A: Worked with WA Representative Peterson. In our years of work on this issue, the concerns of stakeholder groups had already been addressed in the legislation. Pharma lobbyist eventually approached Rep. Peterson and I think they could see that we had the votes to move the bill forward. They then came forward and said they wanted to talk about specific details of the bill. In all of our years of work on the county laws, the pharma industry had been in just say "no" position. Some of the things pharma asked Rep. Peterson for, he could not agree to because we wanted to have a bill that provided great services. Pharma was asking to limit the number of drop boxes, and

to limit other types of services. Rep. Peterson listened to all of those requests, but was consistent in saying we need a comprehensive program that serves all communities in the state. There were some accommodations made to pharma requests – around timing of implementation, details about their responsibilities vs state agency responsibilities. There was a lot of back and forth about the types of drugs that would be accepted and to clarify that used Sharps should not be going into these boxes. Don't think pharma got everything they wanted in these negotiations, but I am glad to say that they had enough accommodation that they were able to shift to a neutral position.

Q: To Rep Malstrom – How closely do you think that what you had last time mimics what WA passed?

A: It is very close. There are some tweaks, but the bulk of it is the same thing.

Comment: When we crafted 2645 we relied on two sources; we had the WA bill and blended with the CA ordinances and made it fit into Oregon statute. It is close, but it needs more tweaks. Especially regarding the compromises with pharma. We may need to do the same.

Q: Are the pockets of resistance from last time more likely to move based on cost and administrative overhead, or challenges around mandates? Ironically, it is probably cheaper to do every pharmacy because you don't have to have formulas for figuring out whether or not you have sufficient and equitable coverage and staff to oversee. I don't have a good sense about where that resistance lies in our legislature:

Q: When you asked the question about everyone can opt in and there has to be sufficient provision. Are you saying still that you think requiring every single pharmacy to have one is the right way to go?
Comment: I think it is cheaper. There is education value that is hard to put a price tag on. PSU just did a study of pharmacies that have boxes and those that don't. The clients at the pharmacies that have boxes are 3 times more likely to understand the risks of opioids, and 3 times more likely to understand the importance of proper disposal. When you are picking and choosing which pharmacies are going to have it and which aren't, we are going to get different education. I think it is substantively better. Politically, my question is can we figure out a way to accommodate pharmacists concerns about the mandates to keep them on board. At the same time, have reduced cost and reduced administrative overhead. You get the politics and the substance aligned.

A: Regarding costs, there are various pharmacies that are using these turn-key systems like Assured Waste or SHARPS compliance. They provide a kiosk, then they do a mail back service for their drugs. Skeptical when I hear folks say that it is $2000 per year per pharmacy. The cost of these programs is driven by the amount of medicines that come in. In a well promoted program, the bins (33 gallon box) fill up every week. The cost of disposing of that year-round is going to be more than $2000. Skeptical that it is going to be cheaper to just say that it will be a flat rate per pharmacy.

A: Also to consider is who is paying the cost. Pharmacies? How are they being reimbursed? Think it is key whether it's the pharmaceutical industry paying the whole cost vs a more distributed cost that many pay.

Comment: Assured Waste has the contract in Colorado where they have 120 boxes. Do an RFP that allows contractors to become certified providers. If they are, then you collect the revenue on the revenue side. Put in the fund with DAS or other state agency who manages. Then pharmacies arrange with the certified contractors to get the boxes installed and have the system up and running, then they tap the fund.

A: That is really what MED-Project is doing on behalf of the pharmaceutical manufacturers. They developed the system, they have kiosks designed, and they form a contract with each potential collector. Boxes are shipped through a common carrier which is allowed by DEA regulations and is probably the most cost effective way to do it.

Q: If you had to do it over again in WA, would there be anything with your legislation that you would have tweaked the second time around?

A: Pleased that it mirrors the local ordinances. Can be problems around collecting certain groups of drug produces, i.e. inhalers, about whether or not gas inhalers can go into a drop box. The minimum number of boxes required by population in each city is a bit lower. County laws had a stronger minimum standard for urban areas. State law is a bit weaker. The fact that we have the opt-in of any pharmacy and requirements that all areas are served equitably, I think it will be alright in the end.

Group discussion
Comment: Is pharma ready, willing and able to sit down and negotiate with Rep. Malstrom and the other stakeholders in light of 2645 and the WA bill?

Comment: Given the work on price transparency, pharma is pretty aware that there are a lot of us who are willing to hold their feet to the fire.

Comment: Understanding the funding part is where pharma comes in and then the program implementation. If you don't have core funding, it won't go anywhere.

Comment: Programs for collecting paint and electronics have worked. They are cost neutral to most and relatively small for manufacturers. Why shouldn't we hold pharmaceuticals to the same standard? We have examples of product stewardship in Oregon that have been functioning for years.

Comment: Some of our counties are talking about doing their own county ordinance if the stated program doesn't go.

Comment: This is not just about getting opioids out of the house. Disposal of all drugs is a benefit.

Comment: Some heartburn around DEQ being the agency that does this work. DEQ doesn't have the ability to run the programs it has now. Why is it not the OHA? There are some things to work out in the language of the legislation.

Debrief of Vancouver trip regarding safe injection facilities
Some OETF members went to Vancouver BC last week to visit safe injection site facilities. There is a lot to report to this group but in the interest of time, will have debrief next meeting.

Impact of opioid policy on pain patients, Allan F. Chino, Ph.D.
Jeff previously met with a group of pain patients who are struggling with chronic pain. He invited them to come to the meeting to give a brief update.

Dr. Allan Chino represents the Oregon Pain Action Group, speaking for pain patients and as a clinician. Dr. Chino provides his credentials and background. Discusses customized pain medication protocols, pain rehabilitation model, mindfulness, acupuncture, meditation. Challenges widely held conclusions that chronic opioid therapy is only appropriate for end-of-life patients and that it is harmful to those in non-cancer pain situations. States that this conclusion is not true. We have the capacity and technology to help people with chronic pain live better lives, suffer less and get back to work. We have to be smart about it. A one size fits all approach does not work. There is currently fear among the physicians who prescribe and the chronic pain patients who receive opioids. Doctors are retreating from treating pain patients because they are afraid of sanctions from the State Medical Board and others. They are tapering back on medications. The result of that for pain patients is that they are scared, worried and anxious. It has shifted the focus of pain therapy to fear. Most patients are able to taper, but some are not. This amplifies their fear. This is happening to chronic pain patients and it is in the shadows. When looking for solutions to solve the opioid issue, we must consider this piece of reality and factor it in. The American Academy

of Pain Management came out against the CDC guidelines, or at least gave a critical look at their conclusions. Pain experts are not happy with what is going on. I advocate for integrity in our healthcare system for reaching for the maximum outcome, rather than basing our treatment guidelines on the lowest common denominator. Recommend that we all personally examine our assumptions and taking a second look on whether or not they are valid.

Comment: Important information because 3440 did originally contemplate having representatives from pain patients on the task force that was originally in that bill. We are here under a different bill now, but wanted to make certain that pain patients had the opportunity to address this group and let them know what they are thinking.

Whiteboarding exercise on ideas for 2019 legislation
Will be getting a report from DCBS at next meeting that will have some hefty recommendations regarding barriers to access and treatment. Will want to also look at those items as well. Will be more to add to this exercise after that discussion.

Treatment

- Treatment capacity – Accredited treatment providers
- Foster care systems & intergenerational treatment
- Jails & prisons must offer treatment (medical assisted treatment)
    - "Menu" of options
    - "Pre-treatment" & tele-treatment
- Network adequacy & payment parity
- Naloxone
    - Into the hands of first responders – Funding mechanism? (Fentanyl contamination).
    - Strategic stockpile
- Acute prescribing limits
- Testing for Chronic pain to prevent abuse
- Overdose prevention strategies – Fentanyl contamination
    - Training – Oxygen, etc.
- Chronic illness paradigm & public awareness

PDMP

- Oregon as outlier
- Privacy protection update
- Public health lens
    - No "report card"
- Medical cannabis guidance
- Comprehensive disposal
- Treatment "connection centers"
- Workforce – Building work class medical service
    - Turnover rates too high
    - Stigma reduction
    - Measuring success
- Supportive housing and other social determinates

Meeting closed