Maine Prescription Drug Affordability Board
Monday February 24th @ 10:30 am
Microsoft TEAMS Meeting
In Person Location: 109 Capitol St, Augusta Maine, 04330

Board Members in Attendance: Kelsie Snow, Sharon Treat, Peter Hayes, Susan Wehry, Rhonda Selvin, Jennifer Reck
(Total = 6)

Board Members Absent: Noah Nesin, Julia Redding
Vacant Seat(s): 0

Others Present: Benjamin Rome, Maureen Hensley-Quinn
Advisory Council: Kate Ende, Jennifer Kent, Christina Moylan, Jonathan French, Kristy Gould
OAHC: Meg Garratt-Reed, Katie Senechal, Ceilidh Shea
All Others: Maria Lesny, Bren Moreno, Lisa Kimbrough, Rinkal Patel, Zack Friend, Donna Polichemi.

Agenda Item:	Discussion:	Action/Next Steps:
I. Call to Order	**Kelsie Snow** called the meeting to order	
II. Introductions	Board and Advisory Council members were introduced, along with guests joining from PORTAL and NASHP.	
III. Approval of the Minutes	Approval of minutes from the January 27th and February 24th meetings will be reviewed prior to the March 24th meeting, given the February meeting was an additional meeting added out of cadence with usual bimonthly meetings.	
IV. Administrative Update	**1. Presentation from Dr. Benjamin Rome on GLP1s** Dr. Benjamin Rome introduced himself as a health policy researcher and primary care physician at Brigham and Women's Hospital and Harvard Medical School. He shared that he has done a fair amount of research on prescription drug costs and affordability more generally, including on GLP1 receptor agonists. Dr. Rome provided touched on some disclosures, including his work with the National Academy for State Health Policy (NASHP) and direct work with a few other Prescription Drug Affordability	

	Boards, although none of the disclosures are necessarily relevant for his presentation today. Dr. Rome shared an outline of his presentation, which started with a brief history of GLP1s, including clinical data and FDA approvals. He said he will also discuss treatment costs and eligible population before moving on to coverage statuses across different payors, particularly focused on Medicare and Medicaid. He said the last portion of his presentation will explore coverage options. Dr. Rome stated that it is important to remember that although GLP1s have garnered a lot of attention in the past few years, this class of medicines are actually now two decades old. He mentioned that the first daily injectable GLP agonists for diabetes treatment was exenatide, approved in 2005. Liraglutide was then approved in 2010. Both of those drugs were approved based on data that showed they lowered A1c in patients with diabetes, which is how every other diabetes drug was approved before them. He noted that the data is compelling; these drugs do work, lowering A1cs, but they were expensive daily injectables. The mainstay diabetes treatments from around 2009 and 2010 were still metformin, sulfonylureas, and insulin. GLP1s, at the time, were really reserved for second or third-line treatments. Dr. Rome said that this trend began to change in 2016 when we learned these were not just diabetes drugs that lowered blood glucose but were really good diabetes drugs. First, we got weekly injectable GLP1s; dulaglutide (Trulicity) and semaglutide (Ozempic) came out in 2014 and 2017 respectively. This made it much easier to administer the drug and much more tolerable for patients. Secondly, we got a lot of evidence that GLP1 agonists lowered risk of cardiovascular events and death amongst patients with diabetes, not just blood sugar. It became clear that these drugs reduce the complications of diabetes. Trials amongst liraglutide, semaglutide, and dulaglutide showed significant reductions in risks of cardiovascular death. This fundamentally changed the game, along with SGLT2s inhibitors, another class of diabetes drugs that had been developed in the same era,	

	becoming the preferred second line treatments (after metformin) for patients with cardiovascular disease, diabetes, and other conditions, including obesity. Dr. Rome then pivoted to the 2021 to 2023 timeframe, during which he said we've come to talk about these drugs for their management of obesity. Even the early trials of GLP1s back in the 2000s showed they caused weight loss in patients with diabetes, so it was a known effect, although the effect for some of the earlier GLP1s is lower than the weight loss potential for some of the newer generations of drugs. In fact, liraglutide, which was already approved for obesity treatment in 2014, predated the obesity era of these drugs, although it only caused an 8% body weight loss – which was comparable to other anti-obesity drugs at the time. It did not take off in the same way as semaglutide and tirzepatide have, because the weight loss from these newer weekly injectable drugs is quite profound (average of 15% body weight loss for semaglutide and 20% for tirzepatide). He said this was new territory for the management of obesity. These types of body weight reductions had not been seen from any other drugs on the market. Previously, the only way to see this kind of clinical weight loss was through bariatric surgery. Dr. Rome also discussed how more recently, in the last year, we've moved into a new stage where even for patients without diabetes, these drugs promote more than just weight loss. He said that semaglutide was tested in the select trial for patients with obesity and high cardiovascular risk and it proved to reduce cardiovascular endpoint (such as strokes or heart attack or death) by twenty percent amongst the non-diabetes population. Tirzepatide was tested and is now approved to treat patients with obesity and obstructive sleep apnea. This signals a move into the era where these drugs don't just lower weight, but they reduce the downstream consequences of obesity. There are more indications on the horizon that companies are testing for these drugs. Dr. Rome said if we step back to look at where we are today, the GLP1s in use today are liraglutide, dulaglutide, semaglutide, and	

	tirzepatide. All of these are made by just two companies. Eli Lilly makes dulaglutide and tirzepatide and Novo Nordisk makes liraglutide and semaglutide. Dulaglutide, semaglutide, and tirzepatide are administered weekly. All of them are approved for diabetes and some are also approved for the cardiovascular risk reduction diabetes, so not just lowering A1c but also reducing risk of cardiovascular events. He said semaglutide also has an indication for reducing progression of kidney disease in patients with diabetes and chronic kidney disease. Liraglutide, semaglutide, and tirzepatide are approved for weight management. Semaglutide has the indication of cardiovascular risk reduction mentioned earlier and tirzepatide has an indication for sleep apnea, also mentioned previously. This will evolve over time as more studies are released. Dr. Rome mentioned that he does not think Eli Lilly has plans to go back and study Trulicity for obesity. Most of the energy has been around semaglutide and tirzepatide as weekly drugs that offer the greatest weight loss. Dr. Rome said that everything included in his presentation up until now has been good news, including the clinical importance of these drugs. He asked, so why not use them? The main issues are cost and how many patients are eligible. From the cost perspective, when looking at the list prices for these drugs, all of these drugs are over a thousand dollars per person per month. In some cases the companies have split the brands, charging higher amounts for the obesity versions than the diabetes versions. Only liraglutide is now lower priced from diabetes treatment, although not for the weight loss version. The list prices are not really what is paid by payors, in fact most payors, including private payors and Medicare, negotiate rebates. He said that in 2022, based on public data, it's estimated that estimated negotiated rebates for the diabetes versions of these drugs were somewhere in the fifty to sixty percent range. Meaning you're taking the price from 1,000 dollars down to somewhere around 500 per month. For the obesity versions, in 2022, the rebates list prices were higher, and rebates were a little bit smaller, at around forty percent, although this may have evolved given up until recently one of the two companies, Novo Nordisk, producing these drugs had weight loss approval. It	

	was when tirzepatide was approved for weight management that we began to see competition between these two companies in the obesity market. He said, I think this forty percent rebate is probably a bit higher now. Dr. Rome stated that the second problem is that lots of patients are eligible to use these drugs for obesity. There are about forty states in the US with a greater than 30% prevalence of obesity, which has increased over time. This data from the CDC leaves you wondering how, even at 500 dollar a month which may not strike you as the most expensive drug on the market, with such high numbers of patients eligible, cost will impact patients. Dr. Rome then transitioned to a discussion of where we are on coverage in Medicare and Medicaid. He said that the Medicaid Drug Rebate Program, that has been around since the early 1990s, entitles states to receive substantial manufacturer discounts on prescription drugs, but in return must cover essentially all FDA-approved drugs. But, if you look at the statute that created this program, there are a lot of drugs that are carved out from this required coverage, including "agents when used for anorexia, weight loss, or weight gain." As a result, coverage for anti-obesity medications has been optional for states. He said that Medicare Part D was actually enacted after this, in 2003, and when Medicare was created, they basically defined a covered drug the same way as Medicaid, using the same list of exclusions. If it was on the list of carve outs, it's not a covered drug, essentially. Currently, under the interpretation of this statute, which could change, coverage for anti-obesity medications is not allowed. Peter Hayes asked whether there is evidence to support claims that these drugs are essentially lifetime prescriptions that when stopped, lead to gaining back weight, if not more than their original BMI? Dr. Rome responded that there is. He said that Novo Nordisk did a study for semaglutide that found that for patients who stopped the medication after about a year, the ensuing weight gain was	

	substantial. That is on average, which is not to say there are not some patients who, using these drugs, are able to make important lifestyle changes and maintain weight loss once they stop using the medication. On average, though, people do regain weight if they stop taking their medication. Peter Hayes asked whether compliance complications leading to questionable returns on investment (ROI) factors into conversations about whether this should be covered or not? Dr. Rome responded that this is a somewhat circular argument given if you want people to take it, you have to cover it but if you don't cover it people aren't taking it. In general, there is a lot of data on adherence of chronic disease medicines and on average, of all the patients who start a medicine, about half will remain on it a year from starting. That is pretty standard across all cardiovascular drugs, regardless of costs. The other complicating factor is that in recent years these drugs have been in shortage. He noted that as a primary care doctor, it's been hard to get patients the medicine to begin with. A lot of patients have probably fallen off of them because of the shortage, which is self-imposed and self-limited, making it hard to know more about adherence. He said that from his perspective, concerns about non-adherence are a bit overstated given it's not that different than other chronic disease drugs. Jennifer Kent asked that with all of these new approved indications, are those improvements directly related to the drug itself or to the fact that a person who has a lower BMI has a reduced risk of these other comorbidities? Dr. Rome responded that he has the same question. He said he hasn't seen compelling evidence of that yet. It's obviously partly the weight loss, with a lower BMI as a mediating factor, but there question remains whether there is some effect of the medicine above and beyond, that is reducing risk. A good comparison here are statins, which lower cholesterol levels, but there is evidence that suggests that above and beyond that, they also have anti-	

	inflammatory properties that seem to be affecting other pathways that reduce cardiovascular risk. The reduction in cardiovascular doesn't correlate perfectly with the cholesterol reduction, so it would be interesting to see a similar post hoc analysis on evidence we have from GLP1s, we just don't have that yet. Rhonda Selvin shared that from a primary care standpoint, it's difficult to clump everybody together because this is an illness that really affects people. They end up hopeless, but when we find a medication that's tolerable and people see noticeable change, she has observed a subset of people who do very well and do change their lifestyle. They can be remade by this opportunity, which is important not to lose sight of. Dr. Rome said he agrees and that these are good drugs, working better than most others we prescribe on a regular basis. We have even seen evidence in trials that is compelling and noted he has seen patients whose weight loss can be transformative. Dr. Rome reminded the group that coverage for anti-obesity medications is optional in Medicaid and currently prohibited in Medicare. So, what have states done with this optional coverage? He said that according to 2023 data, which is a little outdated now, ten states covered one of the GLP1s for obesity and more states covered them for diabetes treatment. There were some other states where managed care organizations that states contract with seemed to cover them, at least in some capacity. So, on average it was probably more like twenty states that covered them. Coverage amongst states is increasing over time and the Medicaid population has a high prevalence of obesity. Dr. Rome said that there are two caveats to Medicare not covering anti-obesity medication. In March of 2024, when semaglutide got the cardiovascular indication, CMS said that the cardiovascular risk reduction is not on the list of things excluded from coverage, so Part D plans can now cover them for cardiovascular risk reduction. This opened up the possibility that patients who have obesity in addition to cardiovascular disease could get access to these drugs	

	if their Part D plan elected to cover them. Then, in November of 2024 at the end of the Biden administration, a proposed rule was introduced that expanded coverage/allowed coverage for these drugs. They essentially reinterpreted the statute that previously carved out coverage for anti-obesity medication in Medicare. The statute referenced weight loss drugs, but the administration made the argument that these are actually anti-obesity medications, which is widely believed to be a medical condition. The administration understood these drugs as treatments for chronic conditions and not as a weight loss drug or a more cosmetic medicine. Dr. Rome said that this is a proposed rule and CMS under the new administration will have to finalize the rule for it to go into effect. He said he has not heard news about whether that will or will not happen. One reason it might not, though, is that it would be extremely expensive. He said that some researchers from his group examined that March 2024 expansion, looking at coverage for Medicare patients with cardiovascular disease. About 28% of Medicare beneficiaries have a combination of obesity and diabetes – making them eligible based on diabetes not obesity. An additional 14% of beneficiaries would become eligible based on cardiovascular disease. That is a very strict definition of cardiovascular disease and if you were to use a more liberal interpretation, maybe looking at people with high risk for cardiovascular disease then more patients would obviously be eligible. Some researchers (Ippolito, Levy) looked at estimated spending if Medicare were to expand coverage and they got a figure somewhere in the three to six billion range, which would be a large increase in Medicare spending on prescription drugs. This assumes that only about five to ten percent of patients will take the drugs who are eligible. He said that another thing they did in their paper was reemphasize that if they were to take all of the patients on Medicare who have obesity and examined what might happen if they had some other indication, additionally. Even if CMS doesn't change the rule, patients who have diabetes and obesity are eligible and patients with diabetes and cardiovascular disease are eligible. It is important to consider the impacts of expanding	

	indications to heart failure or other indications currently under investigation for treatment using GLP1s. It may be that the majority of patients with obesity will gain access to these drugs because of one of their comorbidities even if CMS doesn't make the change. This is going to lead to high spending in Medicare one way or another. Dr. Rome said that another factor to consider is that semaglutide was one of ten drugs selected for the second round of price negotiations under the Inflation Reduction Act. This includes both the diabetes version, Ozempic, and the obesity version, Wegovy. The negotiated price will be announced later this year and would take effect in 2027. Therefore, there would be mandated Medicare Part D coverage for semaglutide, which does have some weird effects given there is a competitor, tirzepatide. Coverage for which would be optional. There isn't an expected direct effect, though. Also, he said, there is no direct effect on the commercial market, although the negotiated price will be made public at the end of the year. Dr. Rome said that other payors are also struggling with coverage decisions for these drugs. He mentioned that North Caroline's statement on direct cost impacts of coverage is important given we rarely see this kind of direct cost impact for coverage of a specific drug. In North Carolina, their State Employee Health Plan estimated that continuing coverage for GLP1s for weight management would result in a nearly fifty dollar increase in premiums per subscriber per month. That's a huge amount, which left the state unable to justify coverage. Dr. Rome stated that fundamentally, the dilemma is that we have a highly effective treatment that addresses a major public health crisis in the U.S., but at the same time, they are both high cost and apply to a large eligible population. The cost of coverage is going to be felt by everybody, including patients who do not take the medicines. Dr. Rome said that some people are accessing these medications without insurance coverage. There has been a higher direct-to-consumer market for these drugs than there has been for many	

	other drugs. Eli Lilly has actually launched this direct-to-consumer portal called LillyDirect. The portal allows you to buy tirzepatide as a vial, without an auto injector, in the 500 dollar range per month, which is probably the real net price of the drug, anyway. So if you want to get a prescription without insurance, patients can have their prescriber send a prescription to Eli Lilly and they will fill it for patients at this price. You've also probably seen that there are a lot of compounded versions of these drugs that are made by other companies. Technically, the FDA only allows companies to make compounded versions of FDA approved drugs while they're in shortage. Both tirzepatide and semaglutide, as of this month, are out of shortage. The FDA says they will begin enforcement in the middle of this year. Dr. Rome said he expects this compounded production market to go away, although it is an interesting conversation to explore how compounders are going to fight to maintain their ability to produce these products. They do tend to be much cheaper, somewhere in the 300 to 400 range. However, there has been some concern about quality control and who is making them. Dr. Rome explained the coverage options for payors. The first option is simple, which is not to cover the drugs for obesity. He said that most everyone has agreed to cover them for diabetes and then you can continue allowing people who can afford it, to pay prices in the 500 dollar range. Another option is coverage, but with high cost sharing with partial coverage, essentially. The concerns about these options are equitable access. Only patients with the financial meant access these drugs will be able to take them. He also said that these options aren't applicable to Medicare or Medicaid. Medicare has a 2,000 dollar cap as of this year so cost sharing is no longer as much of a barrier. And then for Medicaid, if a state's Medicaid plan chooses to cover these drugs, cost sharing is very low. Dr. Rome said that another option is coverage for limited populations, choosing to focus on who is most likely to benefit (such as those with severe obesity or obesity with comorbidities). Dr. Rome shared that he thinks defining this is very hard. It's hard	

	to know who is going to benefit the most long term: is it older patients? Younger patients? It introduces a lot of questions for payors that go beyond the clinical data we have available. Dr. Rome said you could also impose other coverage restrictions. He mentioned that he has seen a lot of private plans require concurrent or trial weight loss management programs, like behavioral interventions, either in addition to or before using a GLP1. This is not based on evidence, given the drugs were not tested alongside clinical weight loss programs. They were tested as the drug versus placebo. A lot of this tactic is really just a restriction to encourage patients to be invested in behavioral changes as well. You could also make patients trial a less expensive anti-obesity medication. In the Massachusetts Medicaid program, patients are required to try another, older drug before GLP1s. Dr. Rome said that the best thing to do would be to negotiate lower prices. If you can get the prices down, broadening coverage becomes much more feasible. This tactic relies on leveraging competition between the two dominant manufacturers, Eli Lilly and Novo Nordisk. If other competitors enter the space in the coming years, as expected, that would help too. **2. Presentation from Maureen Hensely-Quinn on GLP1 Coverage in State Employee Health Plans** Maureen Hensely-Quinn said she planned to highlight what the National Academy for State Health Policy had heard on this issue from the most vocal states participating in the larger conversation. These states include Connecticut, North Carolina, and Massachusetts. Maureen Hensely-Quinn noted she agrees with Dr. Rome on his description of coverage options, although she noted that there are a couple of important points that states have brought forward that complicate the options.	

	Starting with Connecticut, Maureen Hensely-Quinn said that in their network of state employee health plans (SEHP), Connecticut was one of the first states to voice concern. And although size of SEHPs can vary, Connecticut has a relatively large group of enrollees. She said that they were tracking their pharmacy trend and began noticing substantial increases in 2020. There was significant cost growth, and the state pinned it on GLP1s in particular. They saw an increased cost of 50% per year, reaching 30 million just for GLP1s in 2023. One third of the utilization was from members without a diagnosis of diabetes, so they assumed it was for weight loss and confirmed this after tracking things more closely. They were covering GLP1s but not expressly for weight loss. The state also realized how important these drugs are to enrollees taking them. She said the state then looked into creating a program for weight loss and included GLP1s in that program. They contracted with a telehealth clinical weight loss program, which is something a lot of other SEHPs are considering. The program, called Flyte, provides access to clinicians to help with lifestyle management training. The purpose is to help enrollees understand what is available to them. If there are other interventions they might be able to try, those are used first. The plan does include guidance for GLP1s, though. Maureen Hensley-Quinn said that she had attended meetings where people have highlighted concerns on return on investment. There are also questions about adherence. Anecdotally, we know there are reasons for non-adherence. We know many of the drugs don't make people feel very good. Some people stop taking them because of the side effects. People may also start taking GLP1s then with one particular payor and when they change insurance, their new plan may not cover them anymore. So part of the telehealth clinical weight loss program is to provide patients with support in trying to stay on these drugs or to flag what they may experience. Maureen Hensley-Quinn said that Connecticut, so far, has seen some stabilization in cost and utilization. Although, this is still a pilot program and results are yet to be seen in full. She noted that	

	there is some cost to the Flyte program but the state has weighed the cost of not offering the program and decided to keep it. Maureen Hensley-Quinn then moved on to North Carolina's SEHP, which had explicitly approved coverage of GLP1s for weight loss. They found that in 2023, their overall prescription drug spend had increased by 10% just for the GLP1s. The North Caroline SEHP is a larger health program, they had 1 billion in Rx expenditures in a year and over 125 million of that was specifically on GLP1s for weight loss, not inclusive of diabetes. They did try to add some criteria in order to hopefully curb utilization. The plan wanted to tie coverage for GLP1s to a certain BMI. However, both of the manufacturers said they would withhold rebates if the state chose to do so. Therefore, the plan couldn't afford that option. According to North Carolina, they were paying $809 per month per GLP1 prescription with the rebate. Without the rebate they were paying around $1,300 or more. Maureen Hensley-Quinn shared that North Carolina had decided to work with manufacturers to take a more creative approach. The Treasurer offered to participate in an innovate financing solution so the state could pay over time. This proposal was declined. The state also tried to enter into an exclusive agreement with one manufacturer over another but that was also declined. The plan ended up needing 100 million dollars for continuing coverage. Their board of trustees met and decided that they needed to go to the members before authorizing something like that, because as Dr. Rome shared, that was going to increase per member rates by almost 50 dollars. The plan members decided that they did not want to move in this direction. Their state budget also could not make up that difference. They grandfathered in people who were already taking the drug and while they do have some exclusions, they are essentially no longer covering it for weight loss. She said that we do know that there are around four or five other states that currently cover GLP1s for weight loss within their SEHP, but that is being debated right now as they've seen their rates rise. NASHP anticipates that there will be other states who have to roll back coverage. Some have made the decision not to cover them.	

	Everybody wants to be able to cover these drugs and their cost is a true struggle for payors who have to balance these things. Maureen Hensley-Quinn said that in Massachusetts, there is a relatively new decision to cover GLP1s for weight loss in Medicaid. They use what, in their language, is a step therapy approach. They try to see if another drug could be used first. She shared that in meetings she's been in, there have been clinicians from Massachusetts who do not like this approach. Some of them, and certainly not all, view the GLP1s as a safer option even though it is a more expensive option. Maureen Hensley-Quinn also shared that NASHP has had other discussions with others in the industry to understand whether North Carolina's experience working with the manufacturers is unique or if manufacturers are currently willing to provide rebates even when there are some prior authorization requirements or some level of criteria that are in place. NASHP has heard that no, as far as folks know, and Medicaid is a different situation, manufacturers are pretty staunch in not providing rebates when there are some criteria in place to mitigate coverage. **3. Q&A with Dr. Rome and Maureen Hensley-Quinn** Jennifer Reck asked Dr. Rome if he could speak more to the selection of a GLP1 for the second round of price negotiations in Medicare and how that may impact the market? Dr. Rome responded that it doesn't directly impact anything outside of Medicare. We know that the price will be at least a 25% discount off of the current list price. He said it will probably be somewhere at least in the 700 dollar range, but it also has to be lower than the current net prices. So a price will be put out, how aggressively CMS negotiates under this new administration is still up in the air, in addition to how manufacturers are willing to negotiate. It may effect other markets outside of Medicare to have a public price benchmark. He said he could imagine states and private payors and employers pointing to that benchmark price. He	

	added that in terms of North Carolina's experience, but tirzepatide for weight loss is relatively new, so the fact that there is this duopoly where you can do an exclusive agreement is new. So states that may have started negotiations earlier on might have been only talking with Novo Nordisk because that was the only company providing products at the time. If a third manufacturer comes in that could provide more competition and pressure. Based on what we've seen in Massachusetts, manufacturers do seem willing to do exclusive agreements to get higher rebates. Obviously, it is in their best interest to have as many patients covered as possible. They are still somewhat capacity constrained even though the shortages are formerly over. He said he thinks manufacturers are probably willing to play the long game and hold a hard line and maybe if they're really struggling in a few years, they can circle back and renegotiate with some payors. A duopoly is not a very strong market, so it's not surprising to hear what Maureen has said. Peter Hayes asked Maureen Hensley-Quinn if she had a sense of the time frame for seeing an ROI and is it just for people that remain compliant, or does it include the entire population? He also asked about projections for employer coverage. Maureen Hensley-Quinn responded that, in Connecticut's situation, the state is hoping for an ROI but they do not yet have any data to show that that has been achieved yet. That's what they're trying to understand from their pilot program. There is evidence that people stop taking these drugs but we don't really understand why. Some people share that it is a short-term fix but we don't know if that is true. We do not that the side effects can be challenging. We also know that people shift coverage. The SEHP is really trying to get at retention by using their health benefits to achieve that ROI. We don't know what that looks like yet. Maureen Hensley-Quinn responded to Peter Hayes second questions, saying that it depends on the payor. What the increase was in North Carolina, early on, was a 10% increase on their gross Rx spend, which was surprising. That 10% increase was over $125	

	million dollars. It caused them to investigate the cause of such an increase, which led them to GLP1s. She said she has also heard that some payors are experiencing a 25% increase or even higher. There's just not enough information to understand what the ROI for long-term coverage is, especially given North Carolina has to rollback coverage pretty quickly. But yes, other payors have been sharing that increases are higher than 10%. Dr. Rome shared that he has not seen a lot of great cost effectiveness and budget impact work. Presumed savings are not evidence based at this stage. There is a lot of evidence that patients with obesity have higher healthcare spending than patients who are not obese, but that does not mean that if you take the same patients who are obese and cure their obesity, that their spending will go down. Until we have hard evidence, the ROI is not just distant but we also have not seen evidence that these are going to be cost saving long term. You would have to have major offsets in healthcare cost to justify the very high Rx spend. He said he had a paper come out on Entresto, a drug for heart failure, finding that in Medicare patients, that the price of the drug was pretty much offset by the reductions in hospitalizations for heart failure. But it's pretty rare that you find drugs where reductions in other health care spending and services are enough that they lower costs. Meg Garratt-Reed asked about state's ability to do something like the subscription model for Hepatitis C in Louisiana? She also asked whether there are any other factors to that might influence manufacturers openness to negotiation? If more states are moving towards no coverage at all that hopefully strengthens leverage, for example. Dr. Rome responded that he thinks this year will be somewhat of a turning point. Up until this year, some of the drugs have been in shortage. From the manufacturer's perspective, that means that every dose they were producing was selling instantly, so it really didn't matter if a state like North Carolina covered the drugs or not. If they truly are not no longer capacity constrained, their only	

	way to generate additional revenue will be to expand coverage. So up to this point, manufacturers have not been super concerned about coverage. They're more concerned about maintaining the price point they have. That may change, but it is hard to know. Just because the shortage is over also does not necessarily mean more people won't start using them, sending them back into shortage. Peter Hayes asked Maureen Hensley-Quinn whether she had heard anything about coverage for these drugs leading to fewer services need downstream, which could lead to hospitals to cost shift? Maureen Hensley-Quinn responded that NASHP has not had discussions with hospitals about GLP1s. She said she is not shocked to hear about potential cost shifting and this is why so many states that NASHP is working with are looking at prescription drugs and hospital costs at the same time. States consistently identify from their own data that it's pharmacy costs and hospital costs that are driving their overall spend. Kelsie Snow said that having worked in a number of clinical settings, it is important to point out that we are doing everything that we can to prevent heart attacks and strokes. In Maine, health care access is also a huge concern and we frequently have hospitals in some of our smaller communities in critical diversion because they're out of space. We sometimes have to find other places for patients to go, sometimes hours away in different states. So if there is a way er can try to optimize an ROI, even if it won't be realized for decades to come. Peter Hayes said that policy makers and the board need to be eyes wide open that there need to be brutally honest conversations. Hospital funding is another major issue, especially for rural hospitals. He noted that we keep trying to solve the healthcare problem in silos when in reality it is a much more complex problem. Pushing the balloon in one place means it will often balloon out somewhere else. He said he thinks it is important to	

	have the policies for prescription drugs and hospital pricing in one bucket to ensure intended consequences actually take place. Dr. Rome said that one other factor that is dynamic and difficult is that in five to seven years there may be generic versions of these drugs. Compounders are already making them, so they aren't hard to produce. It's also hard to know what's going to happen with newer drugs that come out, for example, will there be some with fewer side effects? Suan Wehry states that part of the demand for a drug comes from the fact that it treats a given indication and part of the demand also comes from advertising. She said she remembers a time when direct to consumer was not permitted and it is currently not permitted in some other countries. She wonders whether or not anybody has an appetite for or is looking at restrictions on direct-to-consumer marketing for GLP1s. Clinicians may justify the medication for an obesity condition, which is very different than weight loss. But when patients come in, they want the weight loss drug and that is a marketing phenomenon not a medical phenomenon. She asked if any states are grappling with this or whether there is a case to be make for restricting direct to consumer marketing? Sharon Treat responded that a state would likely run into serious issues with the Commerce Clause trying to regulate advertising. It would probably have to be a federal policy. But, related to that, some states, including Vermont and Maine, used to have this, but it was repealed. Maine did have requirements to track the spending on advertising and marketing and used the data to support public education around drugs and negotiations for rebates. Often the claim has been that the cost of these drugs is primarily because of the cost of developing and researching them as opposed to the costs being spent on marketing. Susan Wehry responded that she has never understood why it used to be ok to pluck advertising, it's ok not to promote cigarettes anymore. She said she doesn't quite understand that in regards to	

	the marketplace. Conversations in Vermont at the time they were collecting data, in response to claims that list prices were reflective of research and development, did lead to interest in exposing the amount spent on advertising. Initially, Vermont responded by restricting detailing with doctors. Doctors could not be funded by the pharmaceutical industry to give talks. So there has been some pushback, but it has never centered around the airwaves. Somehow, we got marketing for cigarettes off the airwaves, so to speak, so it's hard to understand when you can and can't regulate advertisers. But this is a perfect indication of wherein lies a major problem, particularly, with many people going on and then coming off. That would be data worth tracking as well. She asked if anyone knew anything about what Vermont might be doing to restrict advertising? Sharon Treat responded that we could revert back to having more robust rules like we used to have that were revealed back in 2010. She added that the legislation the PDAB is supporting includes a requirement for the board to look at a variety of strategies which include that sort of thing. So, this could be the kind of thing that we consider taking on, if that passes as part of our responsibility, in terms of looking at whether that kind of a program would be useful or not going forward to reduce costs or improve outcomes. Dr. Rome said he agrees with Susan Wehry's general sentiment about pharmaceutical advertising being a challenge in the United States. However, he said he is not sure it would solve the problem for GLP1s, particularly because the data is so compelling. Doctors want to use these drugs as well, right. In his experience as a PCP, he does see patients come into the office and ask specifically for GLP1s and if they qualify he is not going to stand in their way. But more often, it's him raising that health problems for a patient may all link back to weight. So it's not totally convincing that this will make or break spending in terms of GLP1s because they are such good drugs. They treat a common disease and are effective. He said he is not trying to steer the PDAB away from talking about direct-to-consumer advertising but he does not see it as the primary problem for GLP1s. In fact, most of the direct-to-consumer	

	advertising we've been for these drugs has been for the compounded versions, where they're asking patients to pay full price. Kelsie Snow said that she wonders about the liability if, having the evidence-based information on the efficacy of these drugs, whether there are issues around not prescribing them for whatever reason when they may benefit from them. Dr. Rome responded that this is also very challenging on the payor side is that companies have basically split the diabetes and non-diabetes market. But there are a lot of patients with diabetes and an A1C of 6.6%. They technically have diabetes but almost any clinician in the room would say, let's just put them on metformin. Or they could do nothing and be fine. If you have diabetes and qualify for the diabetes versions of these drugs, you can often get coverage. But are they really on it for diabetes? It's a spectrum and picking out who is going to benefit the most is difficult. If we are going to draw lines of who should and shouldn't have access, there needs to be clear guiding principles. Some of that principle may just be that we can't afford to do it for everybody right now so we may have to try picking out who may need them the most. At the moment, those restrictions aren't in place, so you end up with challenging situations, like in North Carolina. Meg Garratt-Reed thanked Dr. Rome and Maureen Hensley-Quinn for their time and willingness to present to the board. **4. Other Business** Kelsie Snow updated the group that the bill has been printed and thanked Sharon Treat for circulating the language. Sharon Treat said that the bill could be scheduled for a hearing at any point. She said we need to keep track of it and hope that members will be willing to attend the hearing and testify. Meg Garratt-Reed said she wanted to check in on bill tracking.	

	Ceilidh Shea said there have been a few bills that have been added to the tracker and a few who have had language printed or released. Those have all been linked to in the document. The document links to actual bill text and to committee pages where members can view schedules for hearings and work sessions. She said she wanted to touch base with the group about communication and frequency of communication on bill tracking and updates. It's not always possible to be emailing with every update. She asked how the group felt about treating the tracker as a living document members can return to throughout session. Sharon Treat responded that that would be helpful. She asked whether board members are able to identify priority legislation. She had questions about whether there are coverage mandate bills for GLP1s. Ceilidh Shea said that there are two bills mandating coverage. Sharon Treat responded that she wants to make sure the board has the opportunity to weigh in, if the group decides that is important. Meg Garratt-Reed responded that it would be helpful for the OAHC if the board could identify a few priority bills so the office can provide additional communication on their status. The challenge is that things move quickly in the legislature. She said she is unsure how the board handled the process of deciding on legislation before she was working at the OAHC. For many of these bills, it may be difficult for the board to agree on a position in time to testify. Sharon Treat agreed that they may not, but it would be helpful to be able to hold quick check ins on the boards position for certain bills. Meg Garratt-Reed said that maybe at the next meeting, after reviewing the bill tracker, the board could discuss positions on some of them.	• **Ceilidh Shea will re-share the bill tracker.** • **Board members will identify priority legislation.**

	Kelsie Snow said that she follows the Maine Pharmacy Association, who sends out advocacy updates where they cover some relevant bills. She asked if we could keep a consistent subject line so information is easy to find. Meg Garratt-Reed said that for the next meeting, the plan is to revisit the 340B presentations.	
VII. Open Discussion		
VIII. Adjourn	Sharon Treat made a motion to adjourn, and Peter Hayes seconded. The meeting was adjourned.	

Next meeting: March 24th, 2025