Good afternoon everyone, I would like to thank you for inviting me to attend this House Health Care Committee Meeting to speak a little bit about Step Therapy as per pertains to patients and providers. I am speaking on behalf of myself, the Vermont Academy of Family Physicians, and the Vermont Medical Society. I am not speaking on behalf of my employer.

My name is Anne Morris. I am a family physician at UVM Medical Center – Milton. This clinic is one of the largest primary care offices in the State of Vermont. We complete about 27,000 visits per year. Our staff answer an average of over 5000 telephone calls a month. We are situated in Milton and are the northern most UVMMC clinic, so we straddle the Chittenden, Grand Island, and Franklin County counties. In a time when most primary care practices are closed to new patients, we do our best to see anyone who needs to be seen. At one point within the last year, our new patient waiting list was over three hundred people.

With that said, I think we can all agree that the health care system in Vermont is stretched and stressed but that writing and obtaining a prescription should not be. Prescription drugs are just one of many bottle necks in our system. Whether it be the outright cost of the medication, medication availability due to supply chain issues, prior authorization completion, or step-therapy, the decision to prescribe and the process of actually picking up and starting the medication can be arduous. I would like to urge the Committee today to reform Step Therapy within the State of Vermont.

This time of year is a particularly good time to be talking about prior authorizations and step therapy. You see, it's January, and all our patients are potentially in new insurance plans, insurance formularies have changed, and everyone is starting at $0 in terms of meeting their deductibles. This means that every time I order (or, specifically) re-order a medication, the insurance company has an opportunity to deny my request based on their Step Therapy rules. And every insurance company can have different rules. These rules, as far as I can tell, are based solely on finances and the deals that have been brokered between insurance and pharmaceutical companies. They have limited to no evidence-based logic.

From the patient perspective, this can lead to delays in care. And by delays in care, I mean, many patients won't bother to actually pick-up the medication if they have to return to the

pharmacy multiple times. This delay in care can lead to worsening or uncontrolled health care conditions.

*I would like to use the example of Michael. Michael was a 3-year child with asthma. Come fall, when the first colds start going around, Michael's asthma worsens. He goes from needing just an albuterol inhaler (*one of the most prescribed inhalers for asthma/COPD) to needing controller medication. Controller medications often combine two different long-acting drugs. They help to reduce airway inflammation and relax the airway muscles to improving breathing. They are notorious for either NOT being covered by insurance AT ALL or requiring lengthy step therapies.*

Over the course of two months, Michael's Mom, a mother of four, made ***3 different trips to the pharmacy, had 6-7 phone calls to the doctor's office, 3 calls to the insurance company, and the physician wrote several letters of support*** *for the treatment plan before the medication, Symbicort was approved. In the end, his insurance company would only approve the Brand name (not the generic) of the medication which had logically been prescribed. This family was on BCBS via the Vermont Health Exchange. During this incredible stressful time, the family rationed the medication they had, giving it to Michael once daily instead of twice a day as prescribed. Additionally, they had no extra inhaler to provide to the school as required by the child's asthma action plan. In 2024, they are now on Cigna via the Exchange, and the first refill of the year had to be for GENERIC Symbicort and required an IN-PERSON visit to the pharmacy to fill.*

In this story, I specially mention inhalers used to treat asthma and COPD. These are conditions that when poorly controlled, or untreated, are among the most likely to end in ER visits and hospitalizations because they often require specialized breathing treatments or oxygen as part of the therapy. Did you know that JUST a bed overnight in a hospital is something like $4000? And yet, ALBUTEROL, a generic and one of the most commonly prescribed and effective inhalers has become the victim of step therapy.

In the case of albuterol. I might order it as "albuterol" a generic drug that can often be found on the $4 prescription lists at large corporate pharmacies such as Wal-mart or Walgreens.

But now, when I order albuterol there is a 50% chance (that might be a little embellished) that I will get it returned to me with a denial letter. The denial letter will say, "You must order an alternative such as ALBUTEROL". It doesn't seem to matter if I use my EHRs to help me predict which "albuterol" will be covered. It doesn't matter if I write "okay to substitute" on my prescription. I still must spend the time, going back into the patient's chart, figuring out which "albuterol" I already tried to order, potentially addend the note, and communicate back to my nursing team and the patient that I have to order a new medication. And my only recourse??? The satisfaction I get by forcibly filing the notification into my shred bin.

In this case, as the provider, I can truly say that step therapy rules are increasing my administrative burden and affecting my sense of wellbeing/burnout due to the absolutely ridiculousness of the situation.

I have one more example that I would like to discuss. I'd like to talk about Diabetes. According to the CDC:

- About 38 million people in the United States have diabetes, and 1 in 5 of them don't know they have it.
- Diabetes is the 8th leading cause of death in the United States
- In the last 20 years, the number of adults diagnosed with diabetes has more than double as the American Population has aged and become more overweight or obese.
- Medical Costs and lost work and wages for people diagnosed with diabetes total $431 **billion** yearly.
- Medical costs for people with diabetes are more than twice as high as for people who don't have diabetes. (CDC.gov)

All the same concerns about being lost to treatment, delayed treatment, condition destabilization and physician administrative burden and burnout *still apply.* But I would also like to add, **loss of physician autonomy and the ability to apply best practice/evidence-based care.**

The realm of diabetes drugs has been revolutionized in the last decade. The new SGLT2

and GLP-1a drugs such as Farxiga (dapagliflozin) and Ozempic (semaglutide) have completed changed the way the American Diabetes Association ADA guidelines tell us to approach diabetes. These drugs are being touted because they improve health outcomes – they reduce morbidity and mortality (disease complications and death). They reduce blood sugars, help to protect the heart and kidneys, and, yes, also cause weight loss. The problem is that they are they are still under patent and therefore are Brand name only and expensive. Insurance companies have quickly put in place step therapy protocols that dictate I use older generic drugs like metformin and sulfonylureas (glipizide) whose side effects include: GI side effects such as chronic diarrhea, low blood sugars and weight gain.

George is a 37 year male. He is coming to the PCP to establish care becuase he is worried about his risk of diabetes and heart attack. Two years ago, his father, who had diabetes had a massive cardiac event and died during a traumatic hospital course. Clearly, affected by this, George brings up his father's death and fear of following down the same path numerous times throughout our visits. Last year, George's A1c was 5.8% (prediabetic). This year, his A1c is 7.4% (solidly diabetic). He is also obese with a BMI of 38. George's wife is also diabetic and is on Trulicity, one of the GLP-1a drugs. She tolerates it well, has no problem with the weekly injections, and as a bonus, has lost weight. George is ready to start this medication. Almost immediately, the denial comes back in. George must try and fail the other diabetes classes before I can prescribe the medication that has the best evidence to support its' use.

What happens to George in the process of trying and failing medications? – why must George try and fail when recommendations when my clinical judgement and expertise tell me he should be on a different medication?

In summary, Section 1 of H. 766 does not eliminate step therapy but creates a pathway for common sense exemptions to be requested by a patient or health care professional. For example, if the patient is already stable on a prescription drug or step therapy would likely worsen a comorbid condition. This language is modeled off of legislation already passed in both Massachusetts and New York that include nearly identical lists of clear exceptions to step

therapy protocols. Our neighboring states have done this – and it will greatly improve care for patients and reduce the burden on health care professionals – please move Section 1 forward.

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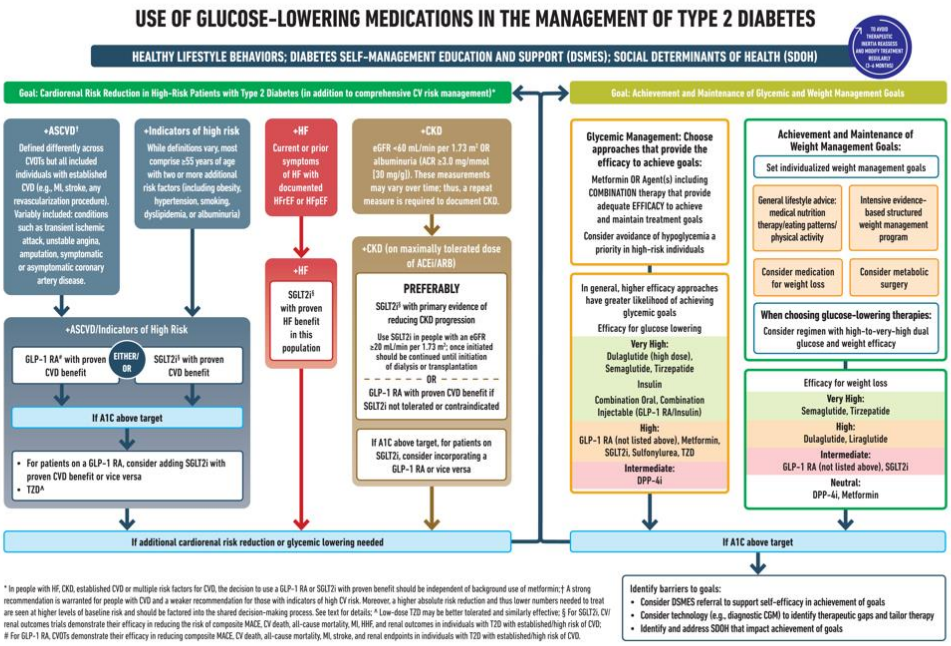

 Adapted from Davies MJ, Aroda VR, Collins BS, et al. Diabetes Care 2022;45:2753–2786.