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February 11, 2020

House Committee on Health Care
900 Court St. NE
Salem OR 97301

RE: Opposition to HB 4116

Dear Chair Salinas and Members of the Committee,

As Chief of Service for Immune Deficiency at Kaiser Permanente Northwest (KPNW), I am writing to share my deep concerns about HB 4116. While my colleagues at Kaiser Permanente and I support expanding access to both pre-exposure prophylaxis (PrEP) and post-exposure prophylaxis (PEP), I am very concerned that authorizing direct access to PrEP at any pharmacy could inhibit overall HIV prevention efforts, negatively impact patient safety and waste health care resources.

Physicians on my team work very closely with our KPNW pharmacy colleagues in all facets of antiretroviral therapy (ART) use—chronic HIV infection, PrEP and PEP. Pharmacists with expertise in HIV and antiretroviral medications are indispensable members of our care teams. That said, **PrEP drugs should not be furnished outside of a comprehensive PrEP program, which is highly specialized and requires extensive time, training and patient screening and monitoring. There must be a real-time, consistent connection to care with any PrEP program.**

In our practice at KPNW, we have had a protocol in place for providing PrEP since 2013. Patients are referred to us from all over the region. We spend ~ 30 minutes one-on-one with each person referred to us. During this visit (either in the office, by phone, or by video), we review the medications available for PrEP (currently Truvada and Descovy), discuss the available dosing regimens (daily vs 2:1:1), and review side effects and potential long-term toxicities. We also check available information regarding prescription benefit, review anticipated out-of-pocket cost, and discuss resources (including patient assistance programs) for helping with cost. We also discuss vaccinations to help prevent other infections (including hepatitis A and B, HPV, meningococcus), review available health records for prior immunizations or tests for immunity, and order vaccines as indicated. We offer triple site screening for other sexually transmitted infections (including gonorrhea, chlamydia, and hepatitis C) and review history of prior syphilis to help guide screening for new syphilis exposure going forward.

Both Truvada and Descovy, used for PrEP, have the potential for kidney injury. While renal dysfunction from either drug is rare, the standard of care is to assess renal function prior to prescribing. There is a creatine clearance cut off below which prescription of these medications is not recommended. Direct dispensing by pharmacists as allowed under this bill would bypass this important step to protect patient safety.

For the vast majority of persons interested in starting antiviral medication for PrEP, there is no urgency. These are generally people who are well educated regarding risks for HIV exposure and who desire the extra margin of protection afforded by taking PrEP. For a small group, the need for PrEP is arguably more urgent: those who are engaged in higher risk patterns of sexual behavior; those more frequently treated for STD's; those with a higher number of partners. However, people within these categories are the least appropriate candidates for pharmacy-based dispense of PrEP.

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Because very early HIV infection can be missed when screening is performed with a routine HIV antibody/antigen blood test, we also screen those at higher risk for recent exposure using an HIV viral load test. This ensures that we are not inappropriately prescribing *just* Truvada or Descovy to someone already infected with HIV. In addition, PrEP given daily according to FDA approved regimen does not reach effective levels until 7 days into therapy. Those who intend to rely on PrEP to prevent HIV infection immediately may benefit from an alternative dosing strategy that we discuss at the time of visit.

In the public health and HIV/STD treatment communities, there already exists a strong focus on timely provision of antiretrovirals with minimal barriers within multidisciplinary settings. I see no role for allowing pharmacists to dispense PrEP without a prescription, disconnected from a more comprehensive care setting. The use of antiretrovirals for PrEP is expanding, and the addition of newer medications to our armamentarium in the next few years is anticipated. The decisions around deciding what drug to prescribe to whom will become more complex. **A bill such as this, allowing dispensing of all antiretroviral drugs without prescription, becomes increasingly fraught with risk as the scenarios in which we use antiretrovirals become more complex.**

There may, however, be a role for pharmacy dispense of antiretrovirals for post exposure prophylaxis (PEP). In our system, we dispense a four-day supply of antiretrovirals after a person experiences potential exposure. We perform baseline testing for bloodborne pathogens and screen for possible need for hepatitis B PEP. The person is then evaluated by one of our HIV specialists within four days, to review side effects, ensure that medications are being dosed correctly, and discuss schedule for follow up testing. Even in our integrated system, this process is complicated and often leads to some patient confusion.

Requiring health plans to reimburse for PrEP and PEP from out-of-network, non-contracted pharmacies and without utilizing prior authorization or step therapy could result in treatment inconsistencies and misuse of health care dollars. A generic version of Truvada is expected to be released this year. The step therapy provisions of HB 4116 would eliminate our ability to manage drug costs for our members by shifting patients to a therapeutically-equivalent, less expensive drug.

Finally, chronic, established HIV infection is not an “urgent medical condition.” This is a very broad definition that will surely wrap in other drugs and treatments that have not been considered and discussed. Those with advanced immunodeficiency (AIDS) for whom the disease might be an “urgent medical condition” are not appropriate candidates for pharmacy dispensed antiretroviral therapy. They need assessment for active opportunistic infection and monitoring for immune reconstitution syndrome, a condition which can be severe and life threatening, and can occur within the first few weeks of antiretroviral therapy. For these reasons, pharmacy dispense of ART is not appropriate for persons living with established, chronic HIV infection.

Thank you for your attention to these concerns.

Molly Stenzel, MD

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