Committee on Health Coverage, Insurance and Financial Services

RE: LD 1577 An Act to Require Health Insurance Coverage for Biomarker Testing

May 5, 2023

Dear Senator Bailey, Representative Perry and members of the Committee on Health Coverage, Insurance and Financial Services

My name is Susan Folk, a Family Nurse Practitioner and Member of the Maine Nurse Practitioner Association's Board of Directors. I am writing in support of LD 1577: An act to Require Health Insurance Coverage for Biomarker Testing. I begin with my professional testimony on the critical importance of biomarker testing that informs clinicians on providing precise evidence-based care for Maine citizens. My testimony goes on to relate a very personal example of how this critical testing affects constituents and communities here in Maine.

Biomarkers are characteristics of the body you can measure, like blood pressure, white blood cell count, cardiac troponins and PDL-1 to name only a few. FDA-NIH biomarker working group define a biomarker as "A defined characteristic that is measured as an indicator of normal biological processes, pathogenic processes or responses to an exposure or intervention." (1) Biomarker testing is already routinely used to identify many things, including damage to heart muscle to identify if a patient is having a heart attack. Routinely when patients enter the ED with complaints of chest pain, cardiac troponins are measured initially and serially to help diagnose an MI (Myocardial Infarction or heart attack) and rush a patient to treatment to save heart muscle and life.

Monitoring Biomarkers is already routinely used when we measure at interval HgAIC to track diabetes and effectiveness of blood glucose lowering medications, or blood pressure to track effectiveness of anti-hypertensive medications. Results of these biomarker test are used by clinicians to track the safety of medication administration, such as monitoring the potassium and serum creatinine to ensure we are not harming a patient's kidneys with a treatment.

The presence or change in the biomarker can predict if an individual or group of individuals more likely to experience a favorable response or effect; an example is in the emerging field of cancer biomarkers. Cancer immunotherapy currently benefits only a small subset of patients. Because not all patients benefit, and some experience serious adverse immune responses (such as life threatening pneumonitis, colitis, and others), it is important to identify those who will have a potential benefit and response to the medication; assuring the remaining 80% are not exposed to potentially life threatening reaction requiring prolonged hospitalizations, halting of their other cancer treatment medications, or treatment of an adverse reaction. Also ensured is that new and expensive medications are not prescribed as last-ditch efforts to every cancer patient who has suffered disease progression despite multiple lines of cancer treatment only to receive an expensive medication with little to no chance of benefit and great risk of deleterious side effects, including death.

On a personal and Maine community noted, my friend and coworker was in the delivery room when her grandchild was born on Thursday. Two days later, she was in the ER and was diagnosed with metastatic Lung cancer. As she goes through CT, PET SCAN, MRI for complete staging of her disease, we sit and wait for tissue type from a bronchoscopy as this will determine the specific "cocktail" of therapies she will need to treat her cancer. Her tissue sample will have the gold mine of information of biomarkers that

will direct her treatment, let her and her medical team know if her tumor will or will not respond to specific medications. These biomarkers are the key to the treatment plans. First line, second line, if immunotherapy will be effective or harmful. (2)

Biomarkers should be useful and validated tools. This bill endorses the use of approved, evidence based biomarkers that are imperative for not only identifying many different types of disease, their management, tracking effectiveness of treatments, but also minimizing harms to patients, reducing costs and disease and treatment burdens.

Thank you for the opportunity to provide testimony based on my experiences, both professional and personal.

Susan Folk, MSN, FNP-C, ACHPN

MNPA Board Member

References:

1. Califf, RM. Biomarker definitions and their applications. *Experimental Biology and Medicine.* 2018; 243: 213-221.
2. Riely, GL. What, When and How of Biomarker Testing in Non-Small Cell Lung Cancer. *Journal of the National Comprehensive Cancer Network.* 2017; 15(5.5):686-688.