A Report to the Joint Standing Committee on Health Coverage, Insurance and Financial Services of the 131st Maine Legislature

Review and Evaluation of LD 1577
An Act to Require Health Insurance Coverage for Biomarker Testing

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I. Executive Summary

The Joint Standing Committee on Health Coverage, Insurance and Financial Services (Committee) of the 131st Maine Legislature directed the Bureau of Insurance (Bureau) to review LD 1577 An Act to Require Health Insurance Coverage for Biomarker Testing. The review was conducted as required by 24-A M.R.S.A § 2752 to answer prescribed questions about the bill including the estimated cost. This document and review are a collaborative effort of NovaRest, Inc. and the Bureau of Insurance, and are intended to respond to the Committee's request.

LD 1577 proposes coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition when the test is supported by medical and scientific evidence. LD 1577 applies to the MaineCare program, individual and group nonprofit hospital and medical services plans, individual and group insurance policies, and individual and group health maintenance organization policies. This would not apply to policies designed to cover only specific diseases, accidental injury, or dental procedures. LD 1577 would not apply to self-insured plans.

Current language in LD 1577 could require plans to cover a large and diverse number of tests that are supported by varying levels of evidence and may lead to patient harm through unnecessary testing, treatment, and other unintended consequences. If the committee does not intend to include asymptomatic screening, we recommend adding language to specifically exclude it.

This report includes information from several sources to provide more than one perspective on the proposed mandate with the intention of providing an unbiased report. As a result, there may be some conflicting information within the contents. Although we only used sources that we considered credible, we do not offer any opinions regarding whether one source is more credible than another, leaving it to the reader to develop his/her own conclusions.

States are required to pay for ("defray") the costs of all health insurance benefit mandates that are included in individual Qualified Health Plans (QHPs) unless the mandate was in effect prior to December 31, 2011 and part of the state's defined essential benefit package (EHB). The state must pay to defray the cost of the mandate's premium impact on those individual exchange/QHP plans. Defrayal only represents the impact of a mandate on Maine's individual exchange plans and does not consider the mandate's impact on the small or large group market.

The Affordable Care Act (ACA) describes a broad set of benefits that must be included in a state's EHB package.[1] Federal regulators consider state mandated health benefits that were in effect *prior to December 31, 2011* part of a state's EHB. Generally, mandates adopted by a state *after December 31, 2011* are subject to defrayal. The ACA permits certain narrow exceptions to the defrayal requirements for mandates that are: an expansion of an existing mandate, required by federal law, a cost-sharing requirement, or a provider mandate.

[1] The 10 categories of benefits in an EHB package are: 1) ambulatory patient services, 2) emergency services, 3) hospitalization, 4) maternity and newborn care, 5) mental health and substance use disorder services, 6) prescription drugs, 7) rehabilitative and habilitative services and devices, 8) lab services, 9) preventive and wellness services and chronic disease management, and 10) pediatric services, including oral and vision care.

Maine determined its current EHB benchmark plan based on guidance from the Federal Department of Health and Human Services (HHS)[2]. Maine chose the small group Anthem PPO Off Exchange Blue Choice, $2,500 Deductible as its benchmark plan.

The Maine EHB benchmark plan currently covers many tests which could be classified as biomarker tests. LD 1577 does not list all tests that are required to be covered. If it was considered a new mandate subject to defrayal based on approximately 63,000 qualified health plan (QHP) members with coverage through the exchange in Maine,[3] the expected total annual defrayal cost would be approximately $25,000 to $340,000. Kentucky has a similar mandate and the state in consultation with CMS determined it required defrayal.[4] In contrast, Arizona determined their biomarker mandate does not require defrayal because the diagnostic testing benefit in Arizona's benchmark already included biomarker testing due to its broad language in the plan.[5]

CMS recently proposed that any mandated benefits included in a state's benchmark plan as of 2025 would not require defrayal.[6] States also have the opportunity to redesign their EHBs to include new benefits under CMS guidelines for 2027 plans. However, it is important to note that the redesign process is complicated and any new EHB benchmark plan must meet typicality, generosity and other requirements. It could mean that a redesigned benchmark plan would need to eliminate some existing EHB benefits to achieve the generosity test.

This is not a legal interpretation, nor should it be considered legal advice.

NovaRest anticipates this bill will result in increases in health insurance premiums of less than 0.1% of premiums. Please note we expect that this premium impact will vary among carriers and products depending on each plan's cost sharing, population, whether it is currently covered, prior authorization, and current reimbursement levels. Also note, LD 1577 does not prohibit individual or group health insurers from applying cost sharing.

We had to make several assumptions to develop our cost estimate, which will be described in the following sections. Our estimate did not vary significantly between the individual, small group, or large group markets.

To develop this estimate, NovaRest relied upon publicly available information, the National Association of Insurance Commissioner's 2022 Maine Supplemental Health Care Exhibits, and a carrier survey facilitated by the Maine Bureau of Insurance.

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[2] https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/essential-health-benefits12162011a accessed January 8, 2024.
[3] https://www.maine.gov/dhhs/blog/maine-people-can-now-preview-2024-health-plans-covermegov-2023-10-16
[4] https://apps.legislature.ky.gov/recorddocuments/bill/23RS/hb180/bill.pdf
[5] https://www.azleg.gov/legtext/55leg/2R/summary/S.2144FIN_ASPASSEDCOMMITTEE.DOCX.htm
[6] Notice of Benefit and Payment Parameters (NBPP) for 2025 https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2025-proposed-rule.

II. Background

LD 1577 proposes coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition when the test is supported by medical and scientific evidence, as defined by LD 1577.

A biomarker means any characteristic that is objectively measured and evaluated as an indicator of a normal biological process, pathogenic process or pharmacologic response to a specific therapeutic intervention, including a known gene-drug interaction for a medication being considered for use or already being administrated.[7] This would include everything from pulse and blood pressure through basic chemistries to more complex laboratory tests of blood and other tissues.[8]

Biomarker testing is an important part of personalized medicine.[9] People with different biomarkers may respond differently to certain treatments. Results from biomarker tests allow medical providers to select targeted treatments more likely to be effective for a patient and to avoid treatments which are more likely to cause damaging effects. Biomarker testing is already recommended at least in the treatment of cancer, amyotrophic lateral sclerosis (ALS), lupus, kidney disease and arthritis, per the public testimony provided on LD 1577 from provider organizations. We expect applications of biomarker testing to expand into many other conditions and diseases in the future.

Currently, some biomarker tests are covered by the carriers impacted by LD 1577. However, carriers make the determination about which tests have sufficient medical or scientific evidence, i.e. FDA approval. LD 1577 would require carriers to consider a uniform definition of sufficient medical or scientific evidence for coverage of biomarker tests, which we believe would expand the tests currently covered. The criteria LD 1577 uses to consider sufficient medical or scientific evidence include the following:

A. A labeled indication for a test approved or cleared by the federal FDA;
B. An indicated test for a drug approved by the federal FDA;
C. A warning or precaution on a label of a drug approved by the federal FDA;
D. A federal Department of Health and Human Services, Centers for Medicare and Medicaid Services national coverage determination or Medicare administrative contractor local coverage determination; or
E. A nationally recognized clinical practice guideline or consensus statement.

Not all carriers agree with this definition of sufficient medical or scientific evidence. Specifically, some carriers believe Medicare Local Coverage Determinations (Medicare LCDs), some clinical practice guidelines, and consensus statements would require plans to cover a large

[7] Per LD 1577, the full definitions in LD 1577 are provided in Appendix B.
[8] Strimbu K, Tavel JA. What are biomarkers? Curr Opin HIV AIDS. 2010 Nov;5(6):463-6. doi: 10.1097/COH.0b013e32833ed177. PMID: 20978388; PMCID: PMC3078627.
[9] "Biomarker Testing for Cancer Treatment." National Cancer Institute. December 14, 2021. https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment. Accessed October 1, 2023.

and diverse number of tests not supported by enough evidence and may lead to patient harm through unnecessary testing, treatment, and other unintended consequences. Additionally, the carriers have concerns that this definition of sufficient medical or scientific evidence does not consider "clinical utility," which is the key evaluation of the scientific evidence performed by payers (including CMS) to determine whether a test should be covered and evaluates whether that test is "reasonable and necessary". The carrier comments instead included suggestions that the definition refer to biomarker testing that is based on peer-reviewed medical literature and be proven to materially improve net health outcomes.

Similar legislation regarding biomarker testing has been passed in at least 14 states and introduced in another 7 states. Some states include "clinical utility," meaning the test result provides information that is used in the formulation of a treatment or monitoring strategy that informs a patient's outcome and impacts the clinical decision.

The extent to which the bill expands coverage beyond the State's essential health benefits package and, if so, the estimated costs to the State to defray the costs of including coverage in qualified health plans.

States are required to pay for ("defray") the costs of all health insurance benefit mandates that are included in individual Qualified Health Plans (QHPs) unless the mandate was in effect prior to December 31, 2011 and part of the state's defined essential benefit package (EHB). The state must pay to defray the cost of the mandate's premium impact on those individual exchange/QHP plans. Defrayal only represents the impact of a mandate on Maine's individual exchange plans and does not consider the mandate's impact on the small or large group market.

The Affordable Care Act (ACA) describes a broad set of benefits that must be included in a state's EHB package.[10] Federal regulators consider state mandated health benefits that were in effect *prior to December 31, 2011* part of a state's EHB. Generally, mandates adopted by a state *after December 31, 2011* are subject to defrayal. The ACA permits certain narrow exceptions to the defrayal requirements for mandates that are: an expansion of an existing mandate, required by federal law, a cost-sharing requirement, or a provider mandate.

Maine determined its current EHB benchmark plan based on guidance from the Federal Department of Health and Human Services (HHS)[11]. Maine chose the small group Anthem PPO Off Exchange Blue Choice, $2,500 Deductible as its benchmark plan. The EHB benchmark plan currently covers many tests which would be classified as biomarker tests, although the plan documents do not discuss all covered tests.[12] Additionally, LD 1577 does not specifically mention that all tests are required to be covered, so we are unable to verify if each qualifying test

[10] The 10 categories of benefits in an EHB package are: 1) ambulatory patient services, 2) emergency services, 3) hospitalization, 4) maternity and newborn care, 5) mental health and substance use disorder services, 6) prescription drugs, 7) rehabilitative and habilitative services and devices, 8) lab services, 9) preventive and wellness services and chronic disease management, and 10) pediatric services, including oral and vision care.

[11] https://www.cms.gov/cciio/resources/fact-sheets-and-faqs/essential-health-benefits12162011a

[12] Information on Essential Health Benefits (EHB) Benchmark Plans. Centers for Medicare & Medicaid Services. September 19, 2023. https://www.cms.gov/marketplace/resources/data/essential-health-benefits#Maine. Accessed October 1, 2023.

is covered by the EHB Benchmark Plan.

Bureau staff met with Centers for Medicare & Medicaid Services (CMS) staff in November 2023 and they indicated that because LD 1577 requires a specific type of testing and if not required by federal law, the mandate, if enacted, would likely require the state to defray the cost. If it was considered a new mandate subject to defrayal based on approximately 63,000 qualified health plan (QHP) members in Maine,[13] the expected total defrayal cost would be approximately $25,000 to $340,000.

CMS recently proposed effective for 2025 that any mandated benefits included in a state's benchmark plan would not require defrayal.[14] States also have the opportunity to redesign their EHBs to include new benefits into their EHBs under CMS guidelines. However, it is important to note that the redesign process is complicated and any new EHB benchmark plan must meet typicality, generosity and other requirements. It could mean that a redesigned benchmark plan would need to eliminate some existing EHB benefits to achieve the generosity test.

This is not a legal interpretation, nor should it be considered legal advice.

Carriers were unable to estimate or did not believe there would be cost to be defrayed by the state except Anthem, which indicated "This would be a new mandated benefit enacted after December 31, 2011. The expansion of coverage for biomarker testing under the bill as drafted would exceed the current scope of essential health benefits and, therefore, would be subject to defrayal by the State. We estimate the defrayal cost to the individual market to be $0.24 PMPM."

III. Social Impact

A. Social Impact of Mandating the Benefit

1. The extent to which the treatment or service is utilized by a significant portion of the population.

The Maine Health Data Organization (MHDO) All-Payer Claims Database (APCD) reported the total number of biomarker tests[15] annually for 2017-2022 for commercial, MaineCare, Medicare FFS, and Medicare Advantage as shown below.

[13] https://www.maine.gov/dhhs/blog/maine-people-can-now-preview-2024-health-plans-covermegov-2023-10-16
[14] Notice of Benefit and Payment Parameters (NBPP) for 2025 https://www.cms.gov/newsroom/fact-sheets/hhs-notice-benefit-and-payment-parameters-2025-proposed-rule.
[15] As defined by CPT codes 80321, 80322, 81490, 82373, and 86352 consistent with the Evaluation of HF 4899: Requirement for Health Plans to Provide Coverage for Biomarker Testing Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26. Minnesota Commerce Department. January 2023.

Year	Commercial	MaineCare	Medicare FFS	Medicare Advantage	Total
2022	254	526	*	449	1,229*
2021	255	401	449	355	1,460
2020	300	249	386	265	1,200
2019	379	63	186	63	691
2018	177	32	133	43	385
2017	175	39	96	22	332

* Medicare FFS data for 2022 was not available at the time of the data pull.

We expect the usage of biomarker testing will increase significantly with increases in treatment options, insurance coverage, and medical provider awareness.

2. The extent to which the service or treatment is available to the population.

The availability of biomarker tests will vary significantly. Many biomarker tests such as blood pressure, glucose, and many others have been used routinely for years and are available to the population. We expect more advanced biomarker tests to have limited availability to the population.

Much of the testimony in support of LD 1577 referred to lack of access to biomarker testing specifically for marginalized communities. Our understanding after discussing with advocates for biomarker testing is that more advanced biomarker testing is being done in academic environments. This may be due to a lack of medical provider knowledge about all biomarker tests or access to tests.

3. The extent to which insurance coverage for this treatment is already available.

Carrier responses indicated that carriers currently cover some biomarker tests. Some examples of biomarker tests could include tests such as blood pressure, which are required to be covered under the EHB Benchmark Plan and MaineCare. However, the definition of biomarker in LD 1577 is broad, and, based on carrier responses, we do not believe all biomarker tests with sufficient medical or scientific evidence per LD 1577 are currently covered.

Aetna: "We currently cover biomarkers when medically necessary and ordered by a physician." "We project the mandate to increase claims by $0.15 to $0.50 PMPM."

Anthem: "Anthem provides coverage for certain evidence-based biomarker tests consistent with our medical necessity guidelines. L.D. 1577 would require coverage of all biomarker tests, regardless of whether the tests actually serve to improve health outcomes. This can lead to unnecessary testing, which in turn leads to higher costs and higher premiums without a corresponding positive impact on health outcomes."

"Many biomarker tests are considered investigational and not medically necessary while others are covered when medically necessary. For example, gene mutation testing for cancer susceptibility and management is covered when certain criteria are met. If a biomarker testing

mandate is implemented, we anticipate that some laboratories and/or providers will:

• add unnecessary tests to a test panel;

• order biomarker tests that are more expensive than the current biomarker tests; or

• order experimental tests that currently are not covered.

As noted in response to Question 1, this will [lead] to unnecessary testing, which in turn results in higher costs and higher premiums without a corresponding positive impact on health outcomes."

Cigna: "There is no coverage policy specific to biomarker testing. This proposal as it written is overly vague and will potentially allow unnecessary and scientifically disproven biomarker testing not in line with evidenced-based guidelines, resulting in overutilization that will add costs, not always benefit patients and potentially cause patient harm. Coding is not currently available for some of the services mentioned in the mandate which makes it difficult to ascertain costs of services yet to be delivered. Without more specific information such as service codes, diagnosis codes, conditions, or diseases, we are unable to fully respond to this survey as answers would be dependent upon the specific biomarker testing codes included in the proposed coverage."

Community Health Options: "Biomarker testing is currently [covered] when clinical guidelines support such testing and when labs are either CLIA or FDA approved to provide such testing and subject to Member cost sharing. We do not anticipate a significant change to our current process."

Harvard Pilgrim: "Harvard Pilgrim provides coverage for biomarker testing in accordance with this mandate. WES is covered per Carelon "Clinical Appropriateness Guidelines for Whole Exome Sequencing and Whole Genome Sequencing". WGS is covered for members under the age of 18 in the outpatient setting when whole exome sequencing criteria outlined in the Carelon "Clinical Appropriateness Guidelines for WES and WGS" are met."

"Harvard Pilgrim currently covers biomarker testing that is of proven clinical validity/utility to predict member response to or identify contraindications or exclusions related to FDA planned targeted therapy and FDA approved companion diagnostic tests in support of planned targeted FDA approved therapy of which individual is a candidate."

Taro Health: "We currently do not cover biomarker testing. We do not provide Benefits for genetic testing or genetic counseling to diagnose a condition. Genetic testing and counseling performed on a previously diagnosed patient is covered only if the genetic testing and counseling is required to plan treatment of the diagnosed condition."

"As stated above, we will cover genetic testing and counseling performed on a previously diagnosed patient only if the genetic testing and counseling is required to plan treatment of the diagnosed condition. Therefore, expanding the coverage would require additional costs on our end depending on the utilization."

UnitedHealthcare: "We do not cover biomarker testing at this time."

4. If coverage is not generally available, the extent to which the lack of coverage results in a person being unable to obtain the necessary health care treatment.

Many of the public hearing testimonies submitted stated that coverage of this benefit would result in equitable access to biomarker testing. According to these testimonies, without coverage many patients who are older, live in rural communities, those who get their care in a community setting vs. academic medical centers, etc. are less likely to be tested for certain biomarkers. In addition, many patients may be unable to obtain biomarker testing because of insurance coverage restrictions or high out of pocket costs. Per the public hearing testimonies, coverage for biomarker testing is key to reducing health disparities.

5. If coverage is not generally available, the extent to which the lack of coverage involves unreasonable financial hardship.

The cost of biomarker testing varies significantly, ranging up to $1,800.[16] With new innovations it is not unreasonable to assume that even more expensive tests could be developed in the future. Additionally, multiple biomarker tests may be performed whether looking for different biomarkers or for impact on a biomarker as treatment progresses. One public testimony mentioned more than $20,000 in expenses for biomarker testing.[17] This could prevent patients from pursuing medically necessary testing, as determined by their medical provider.

6. The level of public demand and the level of demand from providers for this treatment or service.

The definition of biomarker testing is broad and includes many tests such as critical tests that are already commonly used by providers, as well as tests that may be considered experimental. We do not know the level of demand for each biomarker test, although it is likely that biomarker tests that are shown to materially improve net health outcomes in peer-reviewed medical literature are in higher demand. Not all biomarker tests meet this criteria, and therefore would likely have varying degrees of demand based on medical and scientific evidence.

7. The level of public demand and the level of demand from the providers for individual or group coverage of this treatment.

The public hearing on LD 1577 received 27 comments, with 24 comments in support, 1 against, and 2 neither for or against.[18] Thirteen of these comments appeared to be from medical providers or medical provider groups in support of LD 1577, including the ALS Association, Lupus and Allied Diseases Association, American Lung Association, American Kidney Fund, Arthritis Foundation, American Cancer Society, American Academy of Pediatrics Maine Chapter, Oncology Nursing Society and National Alliance on Mental Illness.

[16] Evaluation of HF 4899: Requirement for Health Plans to Provide Coverage for Biomarker Testing Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26. Minnesota Commerce Department. January 2023.
[17] https://legislature.maine.gov/legis/bills/getTestimonyDoc.asp?id=10021413
[18] https://legislature.maine.gov/legis/bills/display_ps.asp?LD=1577&snum=131#

8. The level of interest in and the extent to which collective bargaining organizations are negotiating privately for the inclusion of this coverage by group plans.

No information is available.

9. The likelihood of meeting a consumer need as evidenced by the experience in other states.

Legislation regarding biomarker testing has been passed in 14 states and introduced in another 7 states.[19] Among other New England states, similar legislation has been enacted in Rhode Island and New York as well as introduced in Massachusetts and Connecticut.

In early May 2023, Georgia passed a bill that requires "health benefit policy coverage for biomarker testing if supported by medical and scientific evidence."

Below is a brief summary of the implementation status of the six state laws requiring health insurance coverage of comprehensive biomarker testing:[20]

- Effective in January 2022, Louisiana Senate Bill 84 requires broad health insurance coverage for genetic and molecular testing for cancer only.
- Effective in January 2022, Illinois House Bill 1779 requires insurance to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.
- Effective in January 2023, Arizona House Bill 2144 requires health insurance coverage for biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.
- Effective in January 2024, Rhode Island Senate Bill 2201 requires individual and group health insurance plans to cover biomarker testing for the purposes of diagnosis, treatment, management, or monitoring of any medical condition.
- Effective for January 2025, Minnesota requires insurance and Medicaid coverage of biomarker tests to diagnose, treat, manage, and monitor illness or disease when the testing is supported by medical evidence and includes a definition for clinical utility.
- Effective for April 2024 , New York Legislation S.1196-A/A.1673-A requires insurance plans, including Medicaid, to cover biomarker testing for diagnosis, treatment, appropriate management, or ongoing monitoring of a patient's disease or condition when the test is supported by medical and scientific evidence and meets clinical utility.
- Passed by the California State Legislature in August 2022, California Senate Bill 912 would require state-regulated insurance plans and Medi-Cal managed care plans to cover

[19] "Access to Biomarker Testing." American Cancer Society Cancer Action Network. https://www.fightcancer.org/what-we-do/access-biomarker-testing. Accessed October 10, 2023.
[20] https://www.accc-cancer.org/acccbuzz/blog-post-template/accc-buzz/2022/09/30/state-legislation-requiring-coverage-of-biomarker-testing-gains-momentum Accessed on January 12, 2024.

biomarker testing, including whole genome sequencing, for any medical condition effective in July 2023. On September 29, 2022, California Governor Gavin Newsom announced his decision to veto the bill, despite its passage with unanimous, bipartisan support.

Similar pieces of legislation have been introduced in Ohio and Washington, and efforts to pass these bills are likely to continue in the upcoming year, as well as renewed efforts in California.

10. The relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

In Acting Superintendent of Insurance Timothy Schott's testimony he indicated "In nonemergency cases where prior authorization is required, the entity must approve or deny the request within 72 hours for nonurgent cases or within 24 hours for urgent cases.

The Committee may want to consider including specific effective date language that provides adequate time for approval of revised contract forms."[21]

11. The alternatives to meeting the identified need.

We do not know of any alternatives. If not covered, members would pay out-of-pocket or would use other tests which are covered but may be less effective.

12. Whether the benefit is a medical or a broader social need and whether it is inconsistent with the role of insurance and the concept of managed care.

The benefit is a medical need and coverage required by LD 1577 is not inconsistent with the role of insurance to provide medically necessary services. However, the language in the bill is broad and could require the coverage of many biomarker tests with varying levels of medical and scientific evidence.

13. The impact of any social stigma attached to the benefit upon the market.

We do not know of any social stigma attached to biomarker testing.

14. The impact of this benefit upon the other benefits currently offered.

Biomarker testing can be used to select treatments most likely to help, and to avoid treatments that are unlikely to help.[22] Some biomarker tests are considered a companion diagnostic which is required to pursue a certain treatment.[23] It is unclear whether more effective or less effective treatment options are currently covered. We would need to perform a data call regarding specific biomarker tests to verify.

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[21] https://legislature.maine.gov/legis/bills/getTestimonyDoc.asp?id=10022276

[22] "Biomarker Testing for Cancer Treatment." National Cancer Institute. December 14, 2021. https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment. Accessed Oct 1, 2023.

[23] Taylor CR. Predictive biomarkers and companion diagnostics. The future of immunohistochemistry: "in situ proteomics," or just a "stain"? Appl Immunohistochem Mol Morphol. 2014 Sep;22(8):555-61. doi: 10.1097/PAI.0000000000000126. PMID: 25203298; PMCID: PMC4215952.

15. The impact of the benefit as it relates to employers shifting to self-insurance and the extent to which the benefit is currently being offered by employers with self-insured plans.

As premiums increase, employers look to have more control over the benefits they provide to employees to control the costs. While this mandate, considered individually, is expected to have a minimal impact on premiums, it does add to the cumulative impact of mandates on overall rates. The cumulative impact of mandates is likely a consideration for employers when considering moving out of the fully insured market or shifting a higher cost-sharing responsibility to their covered employees.

16. The impact of making the benefit applicable to the state employee health insurance program.

Anthem estimated the impact to the state employee plan to be $0.14 PMPM.[24]

IV. Financial Impact

B. Financial Impact of Mandating Benefits

1. The extent to which the proposed insurance coverage would increase or decrease the cost of the service or treatment over the next five years.

There may be a potential impact on the cost of biomarker tests that are not currently covered, especially those that may be currently reserved for academic environments. We are unable to estimate the impact on the cost of each biomarker test, although we expect the impact would be small considering the size of the Maine market impacted. We do not believe there would be an impact to biomarker tests that are already covered.

2. The extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years.

The Maine Health Data Organization (MHDO) All-Payer Claims Database (APCD) reported biomarker test[25] annual utilization as 0.1 to 2.2 tests per 1,000 depending on the market (commercial, MaineCare, Medicare) and year (2017-2022). We expect LD 1577 would increase the usage of biomarker tests, although we are unclear how much utilization would increase. A Minnesota actuarial report on similar legislation estimated 1.3 tests per 1,000, while a Milliman report estimated between 1.0 to 39.4 tests per 1,000.

[24] NovaRest, Inc. does not have information on how Anthem developed their cost estimate and cannot comment on the magnitude.

[25] As defined by CPT codes 80321, 80322, 81490, 82373, and 86352 consistent with the Evaluation of HF 4899: Requirement for Health Plans to Provide Coverage for Biomarker Testing Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26. Minnesota Commerce Department. January 2023.

LD 1577 requires coverage for biomarker tests for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition when the test is supported by medical and scientific evidence, as defined by LD 1577. Additionally, LD 1577 provides for prior authorization for commercial individual and group policies within 24 hours for urgent requests and 72 hours for non-urgent requests. The length of time requirement appears consistent with the EHB Benchmark Plan and our understanding of individual and group policy practices.

For MaineCare, LD 1577 does not specifically discuss prior authorization. Currently, biomarker testing requires prior authorization and MaineCare indicated they would prefer to continue this practice.[26] If prior authorization is not allowed, there is potential for the inappropriate use of services.

Public testimony and carriers indicated concern that the bill would be used for asymptomatic screening. We interviewed Hilary Gee Goeckner and Hilary Schneider of the American Cancer Network who indicated asymptomatic screening is not the intent of LD 1577. If the committee does not intend to include asymptomatic screening, we recommend adding language to specifically exclude it.

The excerpts below discuss the carrier parameters to be considered in the bill language:

Aetna: "Coverage should be subject to existing UR/UM[27] standards and not have its own special or unique UR/UM standards. We recommend the standard for coverage to be when medically necessary and ordered by a physician."

Anthem: "Anthem strongly believes that this mandate is unnecessary, will increase costs, and should not be enacted. Health plans have processes for determining medical necessity, under which plans consider biomarker tests "medically necessary" when there is reasonable, unbiased evidence to support the test's clinical utility. Plans should be permitted to use medical necessity to determine the clinical utility of biomarker testing.

However, if this legislation were to move forward, we would suggest that the mandate apply only to coverage of biomarker testing that is based on peer-reviewed medical literature and be proven to materially improve net health outcomes.

The criteria for the tests that must be covered under the proposed mandate are extremely broad and would require the coverage of essentially any biomarker test, regardless of its medical efficacy. Not all "evidence" is appropriate to serve as the basis for determining medical necessity of biomarker testing. Our concerns with the criteria include:

- Medicare Local Coverage Determinations (Medicare LCDs), some clinical practice guidelines, and consensus statements would require plans to cover an incredibly large and diverse number of tests that are not supported by evidence and may lead to patient harm through unnecessary testing, treatment, and other unintended consequences;

[26] https://legislature.maine.gov/legis/bills/getTestimonyDoc.asp?id=10022091
[27] We believe the acronym is for Utilization Review/Utilization Management

- Medicare LCDs vary widely across regions, and many are inconsistent with one another. The variation in Medicare LCDs is such a problem that the U.S. Dept. of Health and Human Services, Office of Inspector General issued a report in 2014, Local Coverage Determinations Create Inconsistency in Medicare Coverage. That report showed:
    - There is no correlation between the number of states with LCDs for an item or service and the unit cost or utilization rate of the item or service.
    - 59 percent of Medicare procedure codes are subject to two or more different coverage policies.
    - In some states, LCDs affect as few as 5 percent of Part B items and services while they affect over 50 percent in others.
    - Procedure and diagnostic codes to describe Medicare's coverage of a given therapy often vary across LCDs.
    - Nearly 1/3 of LCDs that explicitly prohibit coverage are for new technologies.
- Conflicts of interest are a potential source of bias in the development of clinical practice guidelines. Physician-industry relationships and industry funding of research are cited as frequent and increasingly prevalent. See Conflicts of Interests, Authors, and Journals New Challenges for a Persistent Problem; Conflict of Interest Disclosures for Clinical Practice Guidelines in the National Guideline Clearinghouse.
- Many specialty societies have close ties to patient advocacy groups, which are heavily funded by the biopharmaceutical industry. Examples include:
    - Clinical Practice Guidelines: The Good, the Bad, and the Ugly. Science Direct, February 1, 2022
    - Financial conflicts of interest among oncologist authors of reports of clinical drug trials. JAMA Oncol. 2018;4(10):1426-1428.
    - Evaluation of industry relationships among authors of otolaryngology clinical practice guidelines. JAMA Otolaryngol Head Neck Surg. 2018;144(3):194-201.
    - Top cancer researcher fails to disclose corporate financial ties in major research journals. New York Times, Sept. 8, 2018."

Cigna: "This proposal as it written is overly vague and will potentially allow unnecessary and scientifically disproven biomarker testing not in line with evidenced-based guidelines, resulting in overutilization that will add costs, not always benefit patients and potentially cause patient harm." Suggested changes:

- Add or amend current language to include "clinical utility," defined as: the effect of testing on the balance on the benefits and harms associated with the use of the test in practice, including improvement in measurable and clinical outcomes and the usefulness or added value in decision-making compared with not using the test.

- Add "an FDA reviewed biomarker" at the end of the first sentence in the "biomarker testing" definition.

RATONALE: Limiting biomarker testing to biomarkers relevant to FDA-cleared or approved therapies or devices helps align the coverage scope with the original intent of the "biomarker" coverage. Mandated coverage of lab testing beyond FDA-regulated cleared or approved therapies may harm patients by promoting the use of tests that are unproven to improve health and medical management.

- Page 4, line 12: Note the FDA can only ensure clinical utility for companion and complimentary diagnostics. FDA clearance or approval is insufficient for any other lab tests.

- P.1, line 29. Consider adding language stating required coverage must demonstrate clinical utility.

RATIONALE: Biomarker testing must demonstrate that clinical utility be required to ensure a test is "reasonable and necessary" for patients. (Explanation: Clinical Validity, which is where the FDA evaluation stops, ensures a test or drug is "safe and effective". Clinical Utility, which is the key evaluation of the scientific evidence performed by payers (including CMS) to determine whether a test should be covered, evaluates whether that test is "reasonable and necessary")

P.1, line 29. Consider adding language that excludes "asymptomatic screening"

RATIONALE: Precision medicine applied to those with known or suspected disease, not general population screening tests and this should be made clear."

Community Health Options: "Ensure that biomarker testing is available when a Member meets clinical guidelines and the labs used must be either CLIA or FDA approved."

Harvard Pilgrim: "Harvard Pilgrim provides coverage for biomarker testing in accordance with this mandate. WES is covered per Carelon "Clinical Appropriateness Guidelines for Whole Exome Sequencing and Whole Genome Sequencing". WGS is covered for members under the age of 18 in the outpatient setting when whole exome sequencing criteria outlined in the Carelon "Clinical Appropriateness Guidelines for WES and WGS" are met.

Harvard Pilgrim currently covers biomarker testing that is of proven clinical validity/utility to predict member response to or identify contraindications or exclusions related to FDA planned targeted therapy and FDA approved companion diagnostic tests in support of planned targeted FDA approved therapy of which individual is a candidate."

3. The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.

Biomarker testing is a significant part of personalized medicine which attempts to use the most effective treatment options and avoid less effective treatment options. Whether an effective treatment option is more or less expensive will depend on a case-by-case basis. There is potential for less overall usage of treatments to be used.

Three (Community Health Options, Harvard Pilgrim, and Taro Health) of the seven carriers included in the data call indicated they believe there may be potential savings. The following excerpts are from the carrier data call regarding potential benefit savings.

Aetna: "Because this mandate is new, we do not have this information at this time."

Anthem: "We do not believe there are potential benefits or savings as a result of the proposed mandate. Legislation mandating coverage of biomarker testing is duplicative of plans' processes for determining medical necessity under which plans determine biomarker tests are medically necessary when reasonable evidence supports their clinical utility. Plans should be permitted to use medical necessity to determine the clinical utility of biomarkers."

Cigna: "This bill is likely to increase costs related to paying for tests with no demonstrated clinical utility (i.e., that they inform treatment decisions and improve health outcomes for the patient). The current proposal would have the unintended consequence of increasing testing at great costs to payers and consumers without the benefit of making sure the proposed test would actually improve the care for those it is intended to help—the patient. There are examples of how following the mandates in this bill, without subjecting these tests establish clinical utility through evidenced-based scientific studies, would cause patient harm. Without further refining the scope of this bill, as suggested, we do not expect patients to benefit from biomarker coverage beyond what they already receive today. Overutilization, with resulting increases in costs and premiums, will occur without providing substantial benefit to patients through improved outcomes."

Community Health Options: "Genetic testing in metastatic or advanced cancer prevents use of medications targeted to specific mutations if the Member does not test positive for the mutation."

Harvard Pilgrim: "Companion diagnostic biomarker testing can assist in efficiently targeting appropriate therapies thereby maximizing treatment efficiencies and potentially also maximizing treatment response. Some links to studies:

Biomarker Testing and Cost Savings | American Cancer Society Cancer Action Network (fightcancer.org) bmjopen-2020-048141.pdf (nih.gov)"

Taro Health: "We believe that there are potential cost savings from avoiding ineffective treatments."

United Healthcare: "We are not aware of any benefits and do not expect any health cost savings from covering this mandate at this time."

4. The methods which will be instituted to manage the utilization and costs of the proposed mandate.

For individual and group policies if treatment is not having an impact, the medical management would be able to discontinue treatment. MaineCare does not include Utilization Review language similar to that included for the individual and group policies, which will likely impact MaineCare's ability to manage the utilization and cost.

5. The extent to which insurance coverage may affect the number and types of providers over the next five years.

We do not anticipate a change in the number or type of providers over the next five years. Our understanding after discussing the issue with Hilary Gee Goeckner and Hilary Schneider of the American Cancer Network is that there are sufficient providers to administer and read tests.

6. The extent to which the insurance coverage of the health care service or providers may be reasonably expected to increase or decrease the insurance premium or administrative expenses of policyholders.

Carrier Estimate:

Aetna: "Current spend is roughly $1.00 PMPM. We project the mandate to increase claims by $0.15 to $0.50 PMPM. We estimate the mandate would have a $0.12 to $0.40 PMPM increase to premium (same across all lines of business). No impact on administrative or indirect costs."

Anthem:

	2022 Actual Experience PMPM	Assuming full coverage with $0 cost share: Premium Impact
Individual	$0.26	$0.24
Small Group	$0.27	$0.13
Large Group	$0.22	$0.11
State of Maine Employee Plan	$0.35	$0.14

Cigna: "Coding is not currently available for some of the services mentioned in the mandate which makes it difficult to ascertain costs of services yet to be delivered. Without more specific information such as service codes, diagnosis codes, conditions, or diseases, we are unable to fully respond to this survey as answers would be dependent upon the specific biomarker testing codes included in the proposed coverage."

Community Health Options: "As of now we receive minimal requests for these services therefore we do not anticipate an increase in cost.

We do not anticipate a change in premium as we already cover this in appropriate circumstances and if there are no changes to cost sharing. A study in the Journal of Medical Economics that found the median per patient total payer lifetime costs of all biomarker testing was $394/$462 (lung cancer/metastatic lung cancer) and $148/$232 (thyroid cancer/metastatic thyroid cancer)."

Harvard Pilgrim: "The average cost for covered biomarker testing in 2022 was $0.91 PMPM. We do not expect the mandate to increase the cost beyond what is already covered."

Taro Health: "While we do cover genetic testing and counseling as stated above, we do not yet have any claims experience.

Because we have no claims experience on this issue yet, it is difficult to estimate the cost implications. However, according to a 2022 analysis of biomarker testing coverage by Milliman, the average allowed unit cost to insurers per biomarker test ranges from $78.71 (Medicaid) to $224.40 (large group self-insured). This study also projected the impact of legislation requiring robust coverage of biomarker testing, projecting an impact of $0.08-$0.51 per member per month."

UnitedHealthcare: "To the best of our knowledge, we do not have any biomarker testing claim costs in our 2022 claim experience.

We expect very little additional cost if the mandate is covered."

Other State Estimates:

A Minnesota actuarial analysis on a similar bill estimated the average monthly expenditures are projected to increase between $0.09 and $0.22 per member in Year 1 and between $0.14 and $0.32 per member in Year 10. Minnesota also determined that this proposed mandate would likely require partial defrayal under the Affordable Care Act up to $2,594,000 in the first year. [28]

A Massachusetts actuarial analysis of the bill found that impacts on insurance premiums would be 14 to 51 cents per member, per month in the private market.[29]

[28] "Evaluation of HF 4899: Requirement for Health Plans to Provide Coverage for Biomarker Testing." American Institutes for Research (AIR), with actuarial analysis by Actuarial Research Corporation (ARC), at the request of the Minnesota Department of Commerce. January 2023. https://www.senate.mn/committees/2023-2024/3118_Committee_on_Commerce_and_Consumer_Protection/Evaluation%20of%20HF%204899%20Requirement%20for%20Health%20Plans%20to%20Provide%20Coverage%20for%20Biomarker%20Testing.pdf . Accessed September 17, 2023.

[29] Drysdale, Sam. "Biomarker testing bill may run into mandates debate." March 22, 2023. https://www.wwlp.com/news/state-politics/biomarker-testing-bill-may-run-into-mandates-debate/ . Accessed September 19, 2023.

NovaRest Estimate:

The Maine Health Data Organization (MHDO) All-Payer Claims Database (APCD) reported biomarker test[30] annual utilization as 0.1 to 2.2 tests per 1,000 depending on the market (commercial, MaineCare, Medicare) and year (2017-2022). Additionally, the allowed cost per biomarker test varied from $4 to $408. Using the 2022 National Association of Insurance Commissioner Supplemental Health Care Exhibit, a 75% cost-sharing estimate and an 80% loss ratio for individual and small group (85% for large group), we estimate the current cost of biomarker testing to be $0.07 PMPM. The carriers provided a current cost of $0.00 to $1.00 PMPM. This may imply some carriers had higher utilization, higher test cost, or potentially considered other codes as biomarker tests.

We expect LD 1577 would increase the usage of biomarker tests, although we are unclear how much utilization would increase. A Minnesota actuarial report on similar legislation estimated 1.3 tests per 1,000, while a Milliman report estimated between 1.0 to 39.4 tests per 1,000. To develop our estimate, we used a utilization range of 2.2 (the high end of current usage in Maine by market) to 14.4 (the 25th percentage of the Milliman report) tests per 1,000. Regarding the cost per test, a Minnesota actuarial report indicated a cost range of $200 - $1,800 while the Milliman report indicated $225 per test for commercial market. Considering the APCD allowed cost, we used a cost per test ranging from $200 to $400. This results in a $0.03 to $0.44 PMPM or 0.01% to 0.08% increase to premiums.

7. The impact of indirect costs, which are costs other than premiums and administrative costs, on the question of the cost and benefits of coverage.

We do not believe there will be any additional cost effect beyond benefit and administrative costs.

8. The impact on the total cost of health care, including potential benefits and savings to insurers and employers because the proposed mandated treatment or service prevents disease or illness or leads to the early detection and treatment of disease or illness that is less costly than treatment or service for later stages of a disease or illness.

Biomarker testing is a significant part of personalized medicine which attempts to use the most effective treatment options and avoid less effective treatment options. Whether a more effective or less effective treatment option is more or less expensive will depend on a case-by-case basis. There is potential for less overall usage of treatments to be used.

The following excerpts are from the carrier data call regarding potential benefit savings.

[30] As defined by CPT codes 80321, 80322, 81490, 82373, and 86352 consistent with the Evaluation of HF 4899: Requirement for Health Plans to Provide Coverage for Biomarker Testing Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26. Minnesota Commerce Department. January 2023.

Aetna: "Because this mandate is new, we do not have this information at this time."

Anthem: "We do not believe there are potential benefits or savings as a result of the proposed mandate. Legislation mandating coverage of biomarker testing is duplicative of plans' processes for determining medical necessity under which plans determine biomarker tests are medically necessary when reasonable evidence supports their clinical utility. Plans should be permitted to use medical necessity to determine the clinical utility of biomarkers."

Cigna: "This bill is likely to increase costs related to paying for tests with no demonstrated clinical utility (i.e., that they inform treatment decisions and improve health outcomes for the patient). The current proposal would have the unintended consequence of increasing testing at great costs to payers and consumers without the benefit of making sure the proposed test would actually improve the care for those it is intended to help—the patient. There are examples of how following the mandates in this bill, without subjecting these tests establish clinical utility through evidenced-based scientific studies, would cause patient harm. Without further refining the scope of this bill, as suggested, we do not expect patients to benefit from biomarker coverage beyond what they already receive today. Overutilization, with resulting increases in costs and premiums, will occur without providing substantial benefit to patients through improved outcomes."

Community Health Options: "Genetic testing in metastatic or advanced cancer prevents use of medications targeted to specific mutations if the Member does not test positive for the mutation."

Harvard Pilgrim: "Companion diagnostic biomarker testing can assist in efficiently targeting appropriate therapies thereby maximizing treatment efficiencies and potentially also maximizing treatment response. Some links to studies:

Biomarker Testing and Cost Savings | American Cancer Society Cancer Action Network (fightcancer.org) bmjopen-2020-048141.pdf (nih.gov)"

Taro Health: "We believe that there are potential cost savings from avoiding ineffective treatments."

UnitedHealthcare: "We are not aware of any benefits and do not expect any health cost savings from covering this mandate at this time."

9. The effects of mandating the benefit on the cost of health care, particularly the premium and administrative expenses and indirect costs, to employers and employees, including the financial impact on small employers, medium-sized employers and large employers.

The carriers' responses indicate a cost impact of anywhere from $0 to $0.51 PMPM on employer group premiums.

10. The effect of the proposed mandates on cost-shifting between private and public payers of health care coverage and on the overall cost of the health care delivery system in this State.

No material impact expected. This coverage is required for both commercial and MaineCare.

V. Medical Efficacy

C. The Medical Efficacy of Mandating the Benefit

1. *The contribution of the benefit to the quality of patient care and the health status of the population, including any research demonstrating the medical efficacy of the treatment or service compared to the alternative of not providing the treatment or service.*

The definition of biomarker testing is broad and includes many tests including critical tests that are already commonly used by providers, as well as tests that may be considered experimental.

The carriers currently select which biomarker tests to cover based on their own determination, which appears to consider peer-reviewed medical literature where biomarker tests are proven to materially improve the net health outcome. LD 1577 requires carriers to consider other requirements such as whether a biomarker is considered a warning or precaution on an FDA approved drug, a nationally recognized clinical practice guideline or consensus statement, or a CMS national coverage determination or Medicare administrative contractor local coverage determination.

Our understanding is that the requirements in LD 1577 ensure the biomarker tests required to be covered demonstrate medical efficacy. Relying solely on biomarker improvement does not necessarily imply improved quality of patient care,[31] although studies are being done to review the consistency between quality of patient care and treatments guided by biomarker testing.[32]

2. If the legislation seeks to mandate coverage of an additional class of practitioners:

The bill will not apply to an additional class of practitioners.

[31] Medeiros FA. Biomarkers and Surrogate Endpoints: Lessons Learned From Glaucoma. Invest Ophthalmol Vis Sci. 2017 May 1;58(6):BIO20-BIO26. doi: 10.1167/iovs.17-21987. PMID: 28475699; PMCID: PMC5455347.
[32] D Avó Luís AB, Seo MK. Has the development of cancer biomarkers to guide treatment improved health outcomes? Eur J Health Econ. 2021 Jul;22(5):789-810. doi: 10.1007/s10198-021-01290-4. Epub 2021 Mar 30. PMID: 33783662; PMCID: PMC8214594.

VI. Balancing the Effects

D. The Effects of Balancing the Social, Economic, and Medical Efficacy Considerations

1. The extent to which the need for coverage outweighs the cost of mandating the benefit for all policyholders.

Biomarker testing is an important part of personalized medicine[33] that has applications in many diseases and conditions. LD 1577 ensures coverage for biomarker tests which have sufficient medical and scientific evidence, as defined by LD 1577, although as carriers noted may not necessarily demonstrate clinical utility. In the commercial market carriers are able to use prior authorization to ensure medical necessity, although this is not discussed in the section regarding MaineCare.

2. The extent to which the problem of coverage can be resolved by mandating the availability of coverage as an option for policyholders.

It is likely that only those who would benefit from the services would purchase the optional coverage. This would result in an alternative coverage that would be very expensive. This cost would be reduced if the option were only available when the coverage was initially purchased, but it would then be less effective because many individuals would not anticipate needing the coverage and therefore would not purchase it. In addition, separate riders for ACA plans are prohibited.

3. The cumulative impact of mandating this benefit in combination with existing mandates on costs and availability of coverage.

We estimate an increase in cost of $0.03 to $0.44 PMPM for LD 1577, less than 0.10% of premiums.

The estimated cost of current Maine mandates is detailed in Appendix A. For most of these mandates, our estimate is based on the net impact on premiums as estimated at the time the mandate was enacted. Four of the mandates – mental health, substance abuse, chiropractic, and screening mammograms – require carriers to report annually the number of claims paid for these benefits and the estimates are based on that data. The true cost for the Maine mandates is impacted by the fact that:

1. Some services would be provided and reimbursed in the absence of a mandate.
2. Certain services or providers will reduce claims in other areas.

[33] "Biomarker Testing for Cancer Treatment." National Cancer Institute. December 14, 2021. https://www.cancer.gov/about-cancer/treatment/types/biomarker-testing-cancer-treatment. Accessed October 1, 2023.

3. Some mandates are required by Federal law.

Cumulative % of Premium Impact of Current Maine Mandates			
	Current Impact of Maine Mandates	**Low End Estimate of LD 1577**	**High End Estimate of LD 1577**
Total cost for groups larger than 20:	**10.41%**	**10.42%**	**10.49%**
Total cost for groups of 20 or fewer:	**10.46%**	**10.47%**	**10.54%**
Total cost for individual contracts:	**10.49%**	**10.50%**	**10.56%**

Limitations

NovaRest has prepared this report in conformity with its intended use by persons technically competent to evaluate our estimate of the proposed bill. Any judgments as to the data contained in the report or conclusions about the ramifications of that data should be made only after reviewing the report in its entirety, as the conclusions reached by review of a section or sections on an isolated basis by be incorrect. Appropriate staff are available to explain and/or clarify any matter presented herein. It is assumed that any user of this report will seek such explanations as to any matter in question.

NovaRest has developed projections in conformity with what we believe to be the current and proposed operating environments and are based on best estimates of future experience within such environments. It should be recognized that actual future results may vary from those projected in this report. Factors that may cause the actual results to vary from the projected include new insurance regulations, differences in implementation of the required coverage by carrier, accounting practices, changes in federal and/or local taxation, external economic factors such as inflation rates, investment yields and ratings and inherent potential for normal random fluctuations in experience.

Reliance and Qualifications

We are providing this report to you solely to communicate our findings and analysis of the bill's consideration. The reliance of parties other than the Maine Bureau of Insurance and the Joint Standing Committee on Health Coverage, Insurance and Financial Services on any aspect of our work is not authorized by us and is done at their own risk.

To arrive at our estimate, we made use of information provided by carriers included in the data call. We also made assumptions based on information gained from interviews with medical professionals. We did not perform an independent investigation or verification. If this information was in any way inaccurate, incomplete, or out of date, the findings and conclusions in this report may require revision. While we have relied on information without independent investigation or verification, the medical professionals we spoke to are fully qualified and knowledgeable in their field.

This memorandum has been prepared in conformity with the applicable Actuarial Standards of Practice

We have no conflicts of interest in performing this review and providing this report.

We are members of the American Academy of Actuaries and meet that body's Qualification Standards to render this opinion. We meet the Qualification Standards promulgated by these professional organizations to perform the analyses and opine upon the results presented in this Actuarial Report.

VII. Appendices

Appendix A: Cumulative Impact of Mandates

Bureau of Insurance
Cumulative Impact of Mandates in Maine

Report for the Year 2023

This report provides data for medical insurance coverage of mandates as required by 24-A M.R.S.A. §2752 and compiled by the Bureau of Insurance. While some data was provided through annual mandate reports by insurers, other figures were estimated as a part of the proposed mandates study. The following provides a brief description of each state mandate and the estimated claim cost as a percentage of premium. Many of these mandates are now required by the federal Affordable Care Act (ACA). In addition, the ACA requires benefits covered by the benchmark plan which includes all state mandates to be covered by all individual and small group plans effective January 1, 2014. A summary chart is provided at the end of this report.

- ***Mental Health*** (Enacted 1983)

Mental health parity for group plans in Maine became effective in 1996 and was expanded in 2003. The percentage of mental health group claims paid has been tracked since 1984 and has historically been between 3% - 4% of total group health claims. Claims jumped sharply in 2020 by 1.3% to 5.2% for groups after steadily declining by a half point per year for the previous 3 years. For 2022, group claims were 4.11% of total medical claims.

Maine mental health parity was only a mandated offer for individual plans until it was included in the essential health benefits for ACA (Affordable Care Act) individual and small group plans beginning 2014. The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) amended the PHS Act, ERISA, and the Code to provide increased parity between mental health and substance use disorder benefits and medical/surgical benefits and extended parity to all individual plans. As expected, mental health claims have stabilized back to a lower level of 2.5% in 2017 after meeting pent-up demand of 9.4% in 2015. For 2022, individual claims are 3.07% of total medical claims.

- ***Substance Abuse*** (Enacted 1983)

Maine's mandate initially only applied to group coverage. Effective in 2003, substance abuse was added to the list of mental health conditions for which parity is required. Effective in 2014 the federal Affordable Care Act requires substance abuse treatment benefits for individual and small group plans as part of the essential health benefits. The percentage of claims paid for group plans has been tracked since 1984. Substance abuse claims paid have remained flat at 1% average for the past 3 years of the total group health claims. Individual substance abuse health claims have also remained flat at 1% for the past 3 years. As expected, substance abuse claims have leveled out as pent-up demand is met and carriers manage utilization. For 2022, group claims for substance abuse were reported as 1.10% and individual claims 0.77% of total medical claims.

- ***Chiropractic*** (Enacted 1986)

This mandate requires coverage for the services of chiropractors to the extent that the same services would be covered if performed by a physician. Using annual experience reports from the carriers, the percentage of claims paid has been tracked since 1986 and, in 2022, was 0.52% of total health claims. Individual claims at 0.32% (group at 0.58%) in 2022 have continued a trend of lower than group claims since 2017 when they were equivalent.

- ***Screening Mammography*** (Enacted 1990)

This mandate requires that benefits be provided for screening mammography at no cost to the insured. We estimate the current 2022 levels of 0.66% for group and 1.2% for individual going forward. Coverage is required by ACA for preventive services.

- ***Dentists*** (Enacted 1975)

This mandate requires coverage for dentists' services to the extent that the same services would be covered if performed by a physician. A 1992 study done by Milliman and Robertson for the Mandated Benefits Advisory Commission estimated that these claims represent 0.5% of total health claims and that the actual impact on premiums is "slight." It is unlikely that this coverage would be excluded in the absence of a mandate. We include 0.1% as an estimate.

- ***Breast Reconstruction*** (Enacted 1998)

This mandate requires coverage for reconstruction of both breasts to produce a symmetrical appearance after a mastectomy. At the time this mandate was being considered in 1995, one carrier estimated the cost at $0.20 per month per individual. We do not have a more recent estimate. We include 0.02% in our estimate of the maximum cumulative impact of mandates.

- ***Errors of Metabolism*** (Enacted 1995)

This mandate requires coverage for metabolic formula and prescribed modified low-protein food products. At the time this mandate was being considered in 1995, Blue Cross estimated the cost at $0.10 per month per individual. We do not have a more recent estimate. We include 0.01% in our estimate.

- ***Diabetic Supplies*** (Enacted 1996)

This mandate requires that benefits be provided for medically necessary diabetic supplies and equipment. Based on data collected in 2006, most carriers reported that there would be no cost increase or an insignificant cost increase because they already provide this coverage. Based on our report we estimate 0.2%.

- ***Minimum Maternity Stay*** (Enacted 1996)

This mandate requires that if a policy provides maternity benefits, the maternity (length of stay) and newborn care benefits must be provided in accordance with "Guidelines for Prenatal Care." Based on carrier responses indicating that they did not limit maternity stays below those recommended, we estimate no impact.

- ***Pap Smear Tests*** (Enacted 1996)

This mandate requires that benefits be provided for screening Pap smear tests. We estimate a negligible impact of 0.01%. Coverage is required by ACA for preventive services.

- ***Annual GYN Exam Without Referral*** (Enacted 1996)

This mandate only affects HMO plans and similar plans, and it requires the provision of benefits for annual gynecological exams without prior approval from a primary care physician. To the extent the Primary Care Physician (PCP) would, in absence of this law, have performed the exam personally rather than referring to an OB/GYN, the cost may be somewhat higher; therefore, we include 0.1%.

- ***Breast Cancer Length of Stay*** (Enacted 1997)

This mandate requires that benefits for breast cancer treatment be provided for a medically appropriate period of time as determined by the physician in consultation with the patient. Claims for breast cancer treatment in 2022 remain level with past years at 1.7% of total medical claims.

- ***Off-label Use Prescription Drugs*** (Enacted 1998)

This mandate requires coverage of off-label prescription drugs in the treatment of cancer, HIV, and AIDS. Our 1998 report stated a "high-end cost estimate" of about $1 per member per month (0.6% of premium) if it is assumed there is currently no coverage for off-label drugs. Because the HMOs claimed to already cover off-label drugs, in which case there would be no additional cost; and providers testified that claims have been denied on this basis, we include half this amount, or 0.3%.

- ***Prostate Cancer*** (Enacted 1998)

This mandate requires prostate cancer screenings. Our report estimated additional claims cost would approximate $0.10 per member per month. With the inclusion of administrative expenses, we would expect a total cost of approximately $0.11 per member per month, or approximately 0.07% of total premiums. Coverage is required by ACA for preventive services.

- ***Nurse Practitioners and Certified Nurse Midwives*** (Enacted 1999)

This law mandates coverage for nurse practitioners and certified nurse midwives and allows nurse practitioners to serve as primary care providers. This mandate is estimated to increase premium by 0.16%.

- ***Coverage of Contraceptives*** (Enacted 1999)

This mandate requires health plans that cover prescription drugs to cover contraceptives. Our report estimated an increase in premium of 0.8%.

- ***Registered Nurse First Assistants*** (Enacted 1999)

This mandate requires health plans that cover surgical first assistants to cover registered nurse first assistants if an assisting physician would be covered. No material increase in premium is expected.

- ***Access to Clinical Trials*** (Enacted 2000)

This mandate requires that coverage be provided for an eligible enrollee to participate in approved clinical trials. Our report estimated a cost of 0.19% of premium.

- ***Access to Prescription Drugs*** (Enacted 2000)

This mandate only affects plans with closed formularies. Our report concluded that enrollment in such plans is minimal in Maine and therefore the mandate will have no material impact on premiums.

- ***Hospice Care*** (Enacted 2001)

No cost estimate was made for this mandate because the Legislature waived the requirement for a study. Because carriers generally covered hospice care prior to the mandate, we assume no additional cost.

- ***Access to Eye Care*** (Enacted 2001)

This mandate affects plans that use participating eye care professionals. Our report estimated a cost of 0.04% of premium.

- ***Dental Anesthesia*** (Enacted 2001)

This mandate requires coverage for general anesthesia and associated facility charges for dental procedures in a hospital for certain enrollees for whom general anesthesia is medically necessary. Our report estimated a cost of 0.05% of premium.

- ***Prosthetics*** (Enacted 2003)

This mandate requires coverage for prosthetic devices to replace an arm or leg. Our report estimated a cost of 0.03% of premium for groups over 20, and a cost of 0.08% of premium for small employer groups and individuals.

- ***LCPCs*** (Enacted 2003)

This mandate requires coverage of licensed clinical professional counselors. Our report on mental health parity indicated no measurable cost impact for coverage of LCPCs.

- ***Licensed Pastoral Counselors and Marriage & Family Therapists*** (Enacted 2005)

This mandate requires coverage of licensed pastoral counselors and marriage & family therapists. Our report indicated no measurable cost impact for this coverage.

- ***Hearing Aids*** (Enacted 2007 and revised 2019)

The prior mandate required coverage for a hearing aid for each ear every 36 months for children age 18 and under. The mandate was phased-in between 2008 and 2010, and our report estimated a cost of 0.1% of premium. For 1/2020 the hearing aid mandate was expanded to require adult hearing aids. Based on rate filings and a proposed mandate study we estimate 0.2% addition impact to rates to provide hearing aids to adults.

- ***Infant Formulas*** (Enacted 2008)

This mandate requires coverage for amino acid-based elemental infant formulas for children two years of age and under, regardless of delivery method. This mandate is effective January 2009, and our report estimated a cost of 0.1% of premium.

- ***Colorectal Cancer Screening*** (Enacted 2008)

This mandate requires coverage for colorectal cancer screening. This mandate is effective January 2009. No carriers stated they denied coverage prior to this mandate; therefore, our report estimated no impact on premium. Coverage is required by ACA for preventive services.

- ***Independent Dental Hygienist*** (Enacted 2009)

This mandate requires individual dental insurance or health insurance that includes coverage for dental services to provide coverage for dental services performed by an independent practice dental hygienist. This mandate applies only to policies with dental coverage; therefore, there is no estimated impact on medical plan premiums.

- ***Autism Spectrum* Disorders** (Enacted 2010)

This mandate was effective January 2011 and required all contracts to provide coverage for the diagnosis and treatment of autism spectrum disorders for individuals five years of age or under. It was expanded to age 10 for January 2014 effective dates. A recent report estimated a cost of 0.3% of premium once the mandate is fully implemented if it included those under age 10. Based on that estimate and recently reported experience we are estimating this going forward.

- ***Children's Early Intervention Services*** (Enacted 2010)

This mandate requires all contracts to provide coverage for children's early intervention services from birth to 36 months for a child identified with a developmental disability or delay. This mandate was effective January 2011, and our report estimated a cost of 0.05% of premium.

- ***Chemotherapy Oral Medications*** (Enacted 2014)

Policies that provide chemotherapy treatment must provide coverage for prescribed orally administered anticancer medications equivalent to the coverage for IV or injected anticancer medication. No material increase in premium is expected.

- ***Bone Marrow Donor Testing*** (Enacted 2014)

Reimbursement for human leukocyte antigen testing to register as a bone marrow donor. Limited to $150 per lifetime. May not be applied to any deductible or other cost share. No material increase in premium is expected.

- ***Dental Hygienist*** (Enacted 2014)

Coverage for services provided by a dental hygiene therapist for policies with dental coverage. No material increase in premium is expected.

- ***Abuse-Deterrent Opioid Analgesic Drugs*** (Enacted 2015)

Coverage for abuse-deterrent opioid analgesic drugs on a basis not less favorable than that for opioid analgesic drugs that are not abuse-deterrent and are covered by the health plan. No material increase in premium is expected.

- ***Preventive Health Services*** (Enacted 2018)

Coverage for preventive health services including evidence-based items or services with a rating of A or B in the United States Preventive Services Task Force or equivalent, preventive care and screenings and immunizations supported by the federal DHHS. Currently covered and no material increase in premium is expected.

- ***Naturopathic Doctor*** (Enacted 2018)

Coverage for services provided by a naturopathic doctor when those services are covered when provided by any other health care provided and within the lawful scope of practice of the naturopathic doctor. No material increase in costs is expected and if the services are a substitute for medical doctor services, there may be a decrease in cost for some patients.

- ***Abortion Coverage*** (Enacted 2019)

This mandate requires that health insurance carriers who provide coverage for maternity services also provide coverage for abortion services except for employers granted a religious exclusion.

- ***Coverage for certified registered nurse anesthetists (CRNA)*** (Enacted 2021)

This mandate requires insurers, health maintenance organizations and nonprofit hospitals or medical service organizations to provide coverage for the services of certified registered nurse anesthetists provided to individuals.

- ***Coverage for certified midwives*** (Enacted 2021)

This mandate requires insurers, health maintenance organizations and nonprofit hospitals or medical service organizations to provide coverage under those contracts for services performed by a certified nurse midwife to a patient who is referred to the certified nurse midwife by a primary care provider when those services are within the lawful scope of practice of the certified nurse midwife.

- ***Coverage for HIV prevention drugs*** (Enacted Federal 2021)

This mandate requires health insurance carriers to provide coverage for an enrollee for HIV prevention drugs that have been determined to be medically necessary by a health care provider.

- ***Mental health parity for individuals 21 years of age or younger*** (Enacted 2022)

This mandate requires health insurance carriers to provide coverage for mental health services that use evidence-based practices and are determined to be medically necessary health care for individuals 21 years of age or younger. No material premium impact expected.

- ***Expanded coverage for contraceptives without cost-sharing*** (Enacted 2022)

This mandate requires health insurance carriers to provide coverage for all prescription contraceptives without cost-sharing.

- ***Expanded coverage for postpartum care*** (Enacted 2022)

Health insurance carriers must provide coverage to include recommendations in the "Optimizing Postpartum Care" opinion published May 2018 by the American College of Obstetricians and Gynecologists including pelvic floor surgery. Our report estimated a cost of 0.15% of premium.

- ***Fertility care*** (Enacted 2022)

This mandate effective 1/1/2024 requires health insurance carriers to provide coverage for fertility diagnostic care, fertility treatment if the enrollee is a fertility patient and for fertility preservation services. Our report along with limits in the proposed regulation estimated a cost of 0.56% of premium.

- ***Prosthetic needs of children for recreational purposes*** (Enacted 2022)

This mandate requires health insurance carriers to provide coverage for prosthetic devices of those under 18 years of age to meet the recreational needs of an enrollee in addition to their medical needs. No material premium impact expected. Our report estimated a cost of 0.01% of premium.

- ***Medically necessary dental procedures for cancer patients*** (Enacted 2022)

This mandate requires health insurance carriers to provide coverage for dental procedures that are medically necessary to reduce the risk of infection, eliminate infection, or to treat tooth loss or decay in an enrollee prior to beginning cancer treatment or that are the direct or indirect result of cancer treatment. Our report estimated a cost of 0.2% of premium.

- ***Donor breast milk for infants (***Enacted 2023)

This mandate requires health insurance carriers to provide coverage for donor breast milk for infants when medically necessary. No material increase in premium is expected.

- ***First dollar coverage for diagnostic breast exams*** (Enacted 2023)

Health insurance carriers are prohibited from imposing cost-sharing on diagnostic breast examinations, including mammography, MRI, or ultrasound. No material premium impact expected.

COST OF EXISTING MANDATED HEALTH INSURANCE BENEFITS

Year Enacted	Benefit	Type of Contract Affected	Est. Maximum Cost as % of Premium
1975	Must include benefits for **dentists'** services to the extent that the same services would be covered if performed by a physician.	All Contracts	0.10%
1983	Benefits must be included for treatment of **alcoholism and drug dependency**.	Groups	1.10%
		Individual	0.77%
1975 1983 1995 2003	Benefits must be included for **Mental Health Services**, including psychologists and social workers.	Groups	4.11%
		Individual	3.07%
1986 1994 1995 1997	Benefits must be included for the services of **chiropractors** to the extent that the same services would be covered by a physician. Benefits must be included for therapeutic, adjustive and manipulative services.	Group	0.58%
		Individual	0.32%
1990 1997	Benefits must be made available for screening **mammography**.	Group	0.66%
		Individual	1.20%
1995	Must provide coverage for **reconstruction of both breasts** to produce symmetrical appearance according to patient and physician wishes.	All Contracts	0.02%
1995	Must provide coverage for **metabolic formula** and up to $3,000 per year for prescribed modified low-protein food products.	All Contracts	0.01%
1996	If policies provide maternity benefits, the **maternity (length of stay)** and newborn care benefits must be provided in accordance with "Guidelines for Prenatal Care."	All Contracts	0
1996	Benefits must be provided for medically necessary equipment and supplies used to treat **diabetes** and approved self-management and education training.	All Contracts	0.20%
1996	Benefits must be provided for **screening Pap tests**.	All	0.01%
1996	Benefits must be provided for **annual gynecological exam** without prior approval of primary care physician.	Group managed care	0
1997	Benefits provided for **breast cancer treatment** for a medically appropriate period of time determined by the physician in consultation with the patient.	All Contracts	1.71%
1998	Coverage required for **off-label use of prescription drugs** for treatment of cancer, HIV, or AIDS.	All Contracts	0.30%
1998	Coverage required for **prostate cancer screening**.	All Contracts	0.07%
1999	Coverage of nurse **practitioners and nurse midwives** and allows nurse practitioners to serves as primary care providers.	All Managed Care Contracts	0
1999	Prescription drug must include **contraceptives**.	All Contracts	0.80%

1999	Coverage for **registered nurse first assistants**.	All Contracts	0
2000	Access to **clinical trials**.	All Contracts	0.19%
2000	Access to **prescription drugs**.	All Managed Care Contracts	0
2001	Coverage of **hospice care services** for terminally ill.	All Contracts	0
2001	Access to **eye care**.	Plans with participating eye care professionals	0
2001	Coverage of **anesthesia** and facility charges for certain **dental** procedures.	All Contracts	0.05%
2003	Coverage for **prosthetic devices** to replace an arm or leg	Groups >20	0.03%
		All other	0.08%
2003	Coverage of licensed clinical professional counselors	All Contracts	0
2005	Coverage of licensed pastoral counselors and marriage & family therapists	All Contracts	0
2007	Coverage of hearing aids for children	All Contracts	0.1%
2008	Coverage for amino acid-based elemental **infant formulas**	All Contracts	0.1%
2008	Coverage for **colorectal cancer screening**	All Contracts	0
2009	Coverage for **independent dental hygienist**	All Contracts	0
2010	Coverage for **autism spectrum**	All Contracts	0.3%
2010	Coverage for **children's early intervention services**	All Contracts	0.05%
2014	Coverage for **chemotherapy oral medications**	All Contracts	0
2014	Coverage for **human leukocyte antigen testing**	All Contracts	0
2014	Coverage for **dental hygienist**	All Contracts	0
2015	Coverage for **abuse-deterrent opioid analgesic medications**	All Contracts	0
2018	Coverage for **naturopath**	All Contracts	0
2018	Coverage for **preventive services**	All Contracts	0
2019	Coverage for **adult hearing aids**	All Contracts	0.20%
2019	Coverage for **abortion services**	Individual	0.14%
		Group	0.19%
2021	Coverage for **certified registered nurse anesthetists**	All Contracts	0
2021	Coverage for **certified midwives**	All Contracts	0
2021	Coverage for **HIV prevention drugs**	All Contracts	0
2022	Mental health parity for those 21 and younger	All Contracts	0
2022	Expanded coverage for contraceptives without cost-sharing	All Contracts	0
2022	Expanded coverage for postpartum care	All Contracts	0.15%
2022	Coverage for fertility care	All Contracts	0.56%
2022	Prosthetics for the recreational needs of children	All Contracts	0.01%
2022	Medically necessary dental procedures for cancer patients	All Contracts	0.02%
2023	Coverage for donor breast milk for infants	All Contracts	0
2023	First dollar coverage for diagnostic breast exams	All Contracts	0
	Total cost for groups larger than 20:		**10.41%**
	Total cost for groups of 20 or fewer:		**10.46%**
	Total cost for individual contracts:		**10.49%**

Appendix B: Letter from the Committee on Health Coverage, Insurance and Financial Services with Proposed Legislation

STATE OF MAINE
ONE HUNDRED AND THIRTY-FIRST LEGISLATURE
COMMITTEE ON HEALTH COVERAGE, INSURANCE AND FINANCIAL SERVICES

June 7, 2023

Timothy A. Schott
Acting Superintendent
Bureau of Insurance
34 State House Station
Augusta, Maine 04333

Dear Acting Superintendent Schott,

Title 24-A Maine Revised Statutes Annotated, Section 2752 requires the Joint Standing Committee on Health Coverage, Insurance and Financial Services to submit legislation proposing health insurance mandates to the Bureau of Insurance for review and evaluation if there is substantial support for the mandate among the committee after a public hearing on the proposed legislation. Pursuant to that statute, we request that the Bureau of Insurance prepare a review and evaluation of **LD 1577, An Act to Require Health Insurance Coverage for Biomarker Testing.**

A copy of the bill is enclosed. Please prepare the evaluation using the guidelines set out in Title 24-A § 2752. In addition, we ask that the Bureau provide an analysis of the extent to which the bill expands coverage beyond the State's essential benefits package and, if so, the estimated costs to the State to defray the costs of including the coverage in qualified health plans.

Please submit the report to the committee no later than January 15, 2024 so the committee can take final action on LD 1577 before the end of the Second Regular Session. If you have any questions, please do not hesitate to contact us or our legislative analyst, Colleen McCarthy Reid.

Sincerely,

Sen. Donna A. Bailey
Senate Chair

Rep. Anne C. Perry
House Chair

Appendix C: LD 1577

131st MAINE LEGISLATURE

FIRST SPECIAL SESSION-2023

Legislative Document **No. 1577**

H.P. 1022 House of Representatives, April 11, 2023

An Act to Require Health Insurance Coverage for Biomarker Testing

Reference to the Committee on Health Coverage, Insurance and Financial Services suggested and ordered printed.

ROBERT B. HUNT
Clerk

Presented by Representative ZAGER of Portland.
Cosponsored by Senator BENNETT of Oxford and
Representatives: ARATA of New Gloucester, CYRWAY of Albion, JAVNER of Chester, PERRY of Calais, SWALLOW of Houlton, Senators: BAILEY of York, RENY of Lincoln.

Be it enacted by the People of the State of Maine as follows:

Sec. 1. 22 MRSA §3174-KKK is enacted to read:

§3174-KKK. Biomarker testing coverage

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of a normal biological process, pathogenic process or pharmacologic response to a specific therapeutic intervention, including a known gene-drug interaction for a medication being considered for use or already being administered. "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or protein expression.

B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological specimen for the presence of a biomarker. "Biomarker testing" includes but is not limited to a single analyte test, multiplex panel test, protein expression and whole exome, whole genome and whole transcriptome sequencing.

C. "Consensus statement" means a statement:

(1) Developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy;

(2) Aimed at specific clinical circumstances; and

(3) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

D. "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or medical professional society using a transparent methodology and reporting structure and with a conflict of interest policy that establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

2. Required coverage. The department shall provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition of a MaineCare member when the test is supported by medical and scientific evidence, including, but not limited to:

A. A labeled indication for a test approved or cleared by the federal Food and Drug Administration;

B. An indicated test for a drug approved by the federal Food and Drug Administration;

C. A warning or precaution on a label of a drug approved by the federal Food and Drug Administration;

D. A federal Department of Health and Human Services, Centers for Medicare and Medicaid Services national coverage determination or Medicare administrative contractor local coverage determination; or

E. A nationally recognized clinical practice guideline or consensus statement.

Coverage described in this subsection must provide for the delivery of biomarker testing services in a manner that limits disruptions in care, including the need for multiple biopsies or biological specimen samples.

Sec. 2. 24 MRSA §2320-H is enacted to read:

§2320-H. Biomarker testing insurance coverage

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of a normal biological process, pathogenic process or pharmacologic response to a specific therapeutic intervention, including a known gene-drug interaction for a medication being considered for use or already being administered. "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or protein expression.

B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological specimen for the presence of a biomarker. "Biomarker testing" includes but is not limited to a single analyte test, multiplex panel test, protein expression and whole exome, whole genome and whole transcriptome sequencing.

C. "Consensus statement" means a statement:

(1) Developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy;

(2) Aimed at specific clinical circumstances; and

(3) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

D. "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or medical professional society using a transparent methodology and reporting structure and with a conflict of interest policy that establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

2. Required coverage. An individual and group nonprofit hospital and medical services plan contract must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition of a subscriber or member when the test is supported by medical and scientific evidence, including, but not limited to:

A. A labeled indication for a test approved or cleared by the federal Food and Drug Administration;

B. An indicated test for a drug approved by the federal Food and Drug Administration;

C. A warning or precaution on a label of a drug approved by the federal Food and Drug Administration;

D. A federal Department of Health and Human Services, Centers for Medicare and Medicaid Services national coverage determination or Medicare administrative contractor local coverage determination; or

E. A nationally recognized clinical practice guideline or consensus statement.

A contract described in this subsection must provide for coverage in a manner that limits disruptions in care, including the need for multiple biopsies or biological specimen samples.

3. Utilization review. If an individual and group nonprofit hospital and medical services plan contract contains a provision whereby in nonemergency cases the insured is required to be prospectively evaluated through a prehospital admission certification, a preinpatient service eligibility program or any similar preutilization review or screening procedure prior to biomarker testing, the utilization review entity or any 3rd party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the subscriber or member, the subscriber's or member's health care provider and any entity requesting authorization of the service within 72 hours for nonurgent requests or within 24 hours for urgent requests.

4. Application. This section applies to a policy, contract and certificate, except those designed to cover only specific diseases, accidental injury or dental procedures, executed, delivered, issued for delivery, continued or renewed in this State. For purposes of this section, a contract is deemed to be renewed no later than the next yearly anniversary of the contract date.

Sec. 3. 24-A MRSA §2745-H is enacted to read:

§2745-H. Biomarker testing insurance coverage

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of a normal biological process, pathogenic process or pharmacologic response to a specific therapeutic intervention, including a known gene-drug interaction for a medication being considered for use or already being administered. "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or protein expression.

B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological specimen for the presence of a biomarker. "Biomarker testing" includes but is not limited to a single analyte test, multiplex panel test, protein expression and whole exome, whole genome and whole transcriptome sequencing.

C. "Consensus statement" means a statement:

(1) Developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy;

(2) Aimed at specific clinical circumstances; and

(3) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

D. "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or medical professional society using a transparent methodology and reporting structure and with a conflict of interest policy that establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

2. Required coverage. An individual insurance policy, except those designed to cover only specific diseases, accidental injury or dental procedures, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition of a person covered by the policy when the test is supported by medical and scientific evidence, including, but not limited to:

A. A labeled indication for a test approved or cleared by the federal Food and Drug Administration;

B. An indicated test for a drug approved by the federal Food and Drug Administration;

C. A warning or precaution on a label of a drug approved by the federal Food and Drug Administration;

D. A federal Department of Health and Human Services, Centers for Medicare and Medicaid Services national coverage determination or Medicare administrative contractor local coverage determination; or

E. A nationally recognized clinical practice guideline or consensus statement.

A policy described in this subsection must provide for coverage in a manner that limits disruptions in care, including the need for multiple biopsies or biological specimen samples.

3. Utilization review. If an individual insurance policy contains a provision whereby in nonemergency cases the insured is required to be prospectively evaluated through a prehospital admission certification, a preinpatient service eligibility program or any similar preutilization review or screening procedure prior to biomarker testing, the utilization review entity or any 3rd party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the person covered by the policy, the person's health care provider and any entity requesting authorization of the service within 72 hours for nonurgent requests or within 24 hours for urgent requests.

4. Application. This section applies to a policy, contract and certificate executed, delivered, issued for delivery, continued or renewed in this State. For purposes of this section, a contract is deemed to be renewed no later than the next yearly anniversary of the contract date.

Sec. 4. 24-A MRSA §2837-I is enacted to read:

§2837-I. Biomarker testing insurance coverage

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of a normal biological process, pathogenic process or pharmacologic response to a specific therapeutic intervention, including a known gene-drug

interaction for a medication being considered for use or already being administered. "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or protein expression.

B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological specimen for the presence of a biomarker. "Biomarker testing" includes but is not limited to a single analyte test, multiplex panel test, protein expression and whole exome, whole genome and whole transcriptome sequencing.

C. "Consensus statement" means a statement:

(1) Developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy;

(2) Aimed at specific clinical circumstances; and

(3) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

D. "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or medical professional society using a transparent methodology and reporting structure and with a conflict of interest policy that establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

2. Required coverage. A group insurance policy, except those designed to cover only specific diseases, accidental injury or dental procedures, must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition of an insured person or subscriber covered by that policy when the test is supported by medical and scientific evidence, including, but not limited to:

A. A labeled indication for a test approved or cleared by the federal Food and Drug Administration;

B. An indicated test for a drug approved by the federal Food and Drug Administration;

C. A warning or precaution on a label of a drug approved by the federal Food and Drug Administration;

D. A federal Department of Health and Human Services, Centers for Medicare and Medicaid Services national coverage determination or Medicare administrative contractor local coverage determination; or

E. A nationally recognized clinical practice guideline or consensus statement.

A policy described in this subsection must provide for coverage in a manner that limits disruptions in care, including the need for multiple biopsies or biological specimen samples.

3. Utilization review. If a group insurance policy contains a provision whereby in nonemergency cases the insured is required to be prospectively evaluated through a prehospital admission certification, a preinpatient service eligibility program or any similar preutilization review or screening procedure prior to biomarker testing, the utilization

review entity or any 3rd party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the insured person or subscriber covered by that policy, the insured person's or subscriber's health care provider and any entity requesting authorization of the service within 72 hours for nonurgent requests or within 24 hours for urgent requests.

4. Application. This section applies to a policy, contract and certificate executed, delivered, issued for delivery, continued or renewed in this State. For purposes of this section, a contract is deemed to be renewed no later than the next yearly anniversary of the contract date.

Sec. 5. 24-A MRSA §4237-B is enacted to read:

§4237-B. Biomarker testing insurance coverage

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings.

A. "Biomarker" means a characteristic that is objectively measured and evaluated as an indicator of a normal biological process, pathogenic process or pharmacologic response to a specific therapeutic intervention, including a known gene-drug interaction for a medication being considered for use or already being administered. "Biomarker" includes but is not limited to a gene mutation, characteristic of a gene or protein expression.

B. "Biomarker testing" means the analysis of a patient's tissue, blood or other biological specimen for the presence of a biomarker. "Biomarker testing" includes but is not limited to a single analyte test, multiplex panel test, protein expression and whole exome, whole genome and whole transcriptome sequencing.

C. "Consensus statement" means a statement:

(1) Developed by an independent, multidisciplinary panel of experts using a transparent methodology and reporting structure and with a conflict of interest policy;

(2) Aimed at specific clinical circumstances; and

(3) Based on the best available evidence for the purpose of optimizing the outcomes of clinical care.

D. "Nationally recognized clinical practice guideline" means an evidence-based clinical practice guideline developed by an independent organization or medical professional society using a transparent methodology and reporting structure and with a conflict of interest policy that establishes a standard of care informed by a systematic review of evidence and an assessment of the benefits and risks of alternative care options and includes recommendations intended to optimize patient care.

2. Required coverage. Individual or group coverage subject to this chapter must provide coverage for biomarker testing for the purposes of diagnosis, treatment, appropriate management or ongoing monitoring of a disease or condition of an insured person, member or subscriber covered by that policy when the test is supported by medical and scientific evidence, including, but not limited to:

A. A labeled indication for a test approved or cleared by the federal Food and Drug Administration;

B. An indicated test for a drug approved by the federal Food and Drug Administration;

C. A warning or precaution on a label of a drug approved by the federal Food and Drug Administration;

D. A federal Department of Health and Human Services, Centers for Medicare and Medicaid Services national coverage determination or Medicare administrative contractor local coverage determination; or

E. A nationally recognized clinical practice guideline or consensus statement.

A policy described in this subsection must provide for coverage in a manner that limits disruptions in care, including the need for multiple biopsies or biological specimen samples.

3. Utilization review. If a group insurance policy contains a provision whereby in nonemergency cases the insured is required to be prospectively evaluated through a prehospital admission certification, a preinpatient service eligibility program or any similar preutilization review or screening procedure prior to biomarker testing, the utilization review entity or any 3rd party acting on behalf of an organization or entity subject to this section must approve or deny a prior authorization request and notify the insured person or subscriber covered by that policy, the insured person's, member's or subscriber's health care provider and any entity requesting authorization of the service within 72 hours for nonurgent requests or within 24 hours for urgent requests.

4. Application. This section applies to a policy, contract and certificate, except those designed to cover only specific diseases, accidental injury or dental procedures, executed, delivered, issued for delivery, continued or renewed in this State. For purposes of this section, a contract is deemed to be renewed no later than the next yearly anniversary of the contract date.

Sec. 6. Application. The requirements of the Maine Revised Statutes, Title 22, section 3174-KKK, Title 24, section 2320-H and Title 24-A, sections 2745-H, 2837-I and 4237-B apply to a policy, contract, certificate or other instrument of insurance coverage that takes effect or is renewed on or after the effective date of this Act.

SUMMARY

This bill requires insurance coverage, including coverage in the MaineCare program, for biomarker testing.