Evaluation of HF 3330 – Coverage for Rapid Whole Genome Sequencing

Report to the Minnesota Legislature Pursuant to Minn. Stat. § 62J.26

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Executive Summary

House File 3330 would require a health carrier to provide health insurance coverage for rapid whole genome sequencing (rWGS) for enrollees 21 years of age or younger with a complex or acute illness without known cause in an intensive care unit (ICU) or a neonatal or high-acuity pediatric care unit. Required coverage would be based on medical necessity, which may be determined by the following criteria: The diagnosis would require multiple genetic tests in lieu of rWGS, timely identification of a diagnosis is needed to assist in clinical decision-making, or the illness has unknown origin and includes at least one clinical sign or symptom identified in the bill's language.

Clinical symptoms for coverage include but are not limited to

- abnormalities present since birth that involve at least two organ systems or complex or multiple anomalies present since birth that occur in one organ system;
- specific organ malformations that are highly suggestive of a genetic cause; and
- abnormal laboratory tests or chemistry profiles that suggest the presence of a genetic disease, complex metabolic disorder, or genetic disorder that affects the body's ability to process nutrients.

There are no federal laws relating to rWGS; however, Minnesota Health Care Programs cover rWGS for critically ill infants and children in an ICU with no unifying diagnosis when the clinical circumstances and specifications in the regulation are met. Several other states have proposed similar health benefit mandates for their Medicaid programs and/or individual health plans.

RFI respondents indicated that the proposed mandate would increase access but may not address other barriers to receiving rWGS. Responses indicated that the proposed mandate language does not align with clinical guidelines, does not specify the medical professionals qualified to order the testing, and does not include limitations on the frequency of use. Several stakeholders noted that the coverage criteria in this proposed mandate would impact a small proportion of the Minnesota population.

Literature indicates that rWGS identified rare genetic diseases in between 30% and 40% of cases and changed the course of medical treatment in approximately 30% of infants and children that underwent genome sequencing. While rWGS costs more than other diagnostic tests, it has been shown to be cost-effective for young infants with difficult-to-diagnose rare diseases.

The mandate is projected to increase health care premiums by $0.02 to $0.55 per member per month (PMPM) for the total non-public insured population in the first year and by $0.04 to $1.27 PMPM by Year 10.

The potential state fiscal impact of this mandate is as follows:

- Minnesota Management and Budget estimates the cost of this legislation for the state plan to be $46,440 for partial Fiscal Year 2025 (FY 2025) and $97,524 for FY 2026.
- Commerce has determined that this proposed mandate would likely require full defrayal under the Affordable Care Act, with an estimated cost between $20,000 and $800,000 in the first year.
- There is no estimated cost for public programs.

Introduction

In accordance with Minn. Stat. § 62J.26, the Minnesota Department of Commerce (Commerce), in consultation with the Minnesota Department of Health (MDH) and Minnesota Management and Budget (MMB), performs a detailed evaluation of all relevant benefit mandate proposals. For evaluation criteria and required evaluation components, please review the Evaluation Report Methodology, available at https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Bill Requirements

House File (HF) 3330 is sponsored by Rep. Hemmingsen-Jaeger and was introduced in the 93rd Legislature (2023–24) on May 18, 2023.

If enacted, this bill would require a health carrier to provide health insurance coverage for rapid whole genome sequencing (rWGS) for enrollees 21 years of age or younger with a complex or acute illness confirmed not to have been caused by environmental exposure, toxic ingestion, an infection with a normal response to therapy, or trauma. Coverage is specific to those receiving inpatient hospital services in an intensive care unit or neonatal or high-acuity pediatric care unit. Required coverage would be based on medical necessity, which may be determined by the following criteria: A diagnosis would require multiple genetic tests in lieu of rWGS, timely identification of a diagnosis is needed to assist in clinical decision-making, or the illness is of unknown origin and includes at least one clinical sign or symptom identified in the bill's language (see Appendix A).

For the purpose of this bill and its evaluation, "rapid whole genome sequencing" means mapping the entire human genome to identify disease-causing genetic changes. This includes whole genome sequencing of a patient and their biological parent(s) and provides preliminary positive results within 5 days and final results in 14 days.

This proposed mandate would apply to fully insured small and large group commercial health plans, individual market plans, and the State Employee Group Insurance Program (SEGIP). This would not apply to self-insured employer plans, grandfathered plans, Medicare and Medicare supplemental policies, and Minnesota public health insurance programs.

Related Health Conditions and Associated Services

Clinical symptoms for coverage include but are not limited to

- abnormalities present since birth that involve at least two organ systems or complex or multiple anomalies present since birth that occur in one organ system;
- specific organ malformations that are highly suggestive of a genetic cause; and
- abnormal laboratory tests or chemistry profiles suggesting the presence of a genetic disease, complex metabolic disorder, or genetic disorder that affects the body's ability to process nutrients.

An expanded list of clinical symptoms specified in the proposed health benefit mandate can be found in Appendix A.

Related State and Federal Laws

This section provides an overview of state and federal laws related to the proposed mandate and any external factors that provide context for current policy trends related to this topic.

Relevant Federal Laws

There are no federal laws specific to this mandate. In 2019, Congress proposed the Ending the Diagnostic Odyssey Act (H.R. 4144), which would have allowed states to provide rWGS clinical services to certain children covered by Medicaid.[1] The services would have been available to Medicaid-enrolled children under age 21 who had been referred or admitted to an intensive care unit, had been seen by at least one medical specialist for a suspected genetic or undiagnosed disease, or had a neonatal or pediatric-onset genetic disease. This bill was not enacted.

Relevant Minnesota Laws

In April 2022,[2] Minnesota Health Care Programs began covering rWGS for critically ill infants and children in an ICU with no unifying diagnosis when the clinical circumstances require rapid testing and when other clinical specifications in the regulation are met.[3]

State Comparison

Several states have included rWGS in their Medicaid programs or mandated it for individual health plans.

- In 2023, Connecticut and Washington proposed coverage of rWGS for a critically ill child when ordered by their provider and other clinical criteria are met for individual health plans.[4,5]
- California Anthem Blue Cross Blue Shield, along with 10 regional plans, began reimbursing for coverage of rWGS in March 2020.[6]
- Several other states either provide or have proposed rWGS for children covered by Medicaid:
  - Three states, Massachusetts, Arizona, and Florida, have proposed including rWGS in their Medicaid program.[7–9]
  - Four states, California, Maryland, Michigan, and Oregon, provide coverage as a part of their Medicaid programs.[2] Michigan was the first state to reimburse for rWGS in critically ill Medicaid-covered infants in neonatal intensive care units (NICUs) and pediatric intensive care units (PICUs). California passed a law in 2022 to provide $6 million to reimburse for rWGS in Medicaid-covered infants in the state.[2]

Public Comments Summary

Commerce solicited public input on the potential health benefit mandate through a request for information (RFI) posted to Commerce's website and the Minnesota State Register. The summary below represents only the opinions and input of the individuals and/or organizations who responded to the RFI.

Key Stakeholder Comment Themes

For this proposed mandate, Commerce received comments from one medical organization that expressed support for the proposed mandate and four commercial health carriers that provided information related to insurance coverage.

One RFI respondent indicated that, on average, it takes rare disease patients 4.8 years and 7.3 different specialists to be properly diagnosed.[a,b] When used in an inpatient setting for critically ill infants without a clear diagnosis, rWGS can help provide quick and definitive answers for families, allow physicians to provide timely and targeted treatment, and prevent costly expenses associated with a delayed rare disease diagnosis.[c]

Responses indicated that the proposed mandate would increase access but not address barriers such as lack of patient knowledge of testing benefits and risks and provider apprehension. Hesitation by providers to use rWGS has been seen in states that have implemented similar legislation. However, among patients that used rWGS under similar coverage policies in California and Michigan, 43% and 39%, respectively, received diagnoses that resulted in overall health care cost savings due to avoided unnecessary procedures and days in the NICU.[d,e] One organization noted that some of the cost savings can be attributed to cessation of treatment after a provider determines through rWGS that an infant has a terminal condition.

Some respondents indicated that the proposed mandate language does not align with clinical guidelines, the mandate may lead to unnecessary testing, and the outcomes literature on this testing is limited. It was also noted that the mandate does not specify the medical professionals qualified to order the testing or include any limitations on the frequency of use. Additionally, one respondent stated that rWGS may not be appropriate for some of the conditions listed in the proposed mandate and therefore had concerns about the medical necessity criteria. Several stakeholders noted that the coverage criteria in this proposed mandate would impact only a small proportion of the Minnesota population.

Cost Estimates Provided in Stakeholder Comments

Stakeholders and MMB provided the following cost estimates for the proposed benefit mandate:

- MMB's health plan administrators estimated the average state fiscal impact of the proposed mandate to be $0.06 per member per month (PMPM).
- rWGS is not typically covered by most insurers for critically ill infants admitted to an intensive care unit. RFI respondents reported that, if enacted, this proposed mandate may result in an estimated cost increase of up to $0.50 PMPM.

Cost estimates shared in RFI responses may reflect different methodologies, data sources, and assumptions than those used in the actuarial analysis for this evaluation. Stakeholders' results may or may not reflect generalizable estimates for the mandate.

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[a] Nguengang Wakap S, Lambert DM, Olry A, et al. Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database. *Eur J Hum Genet*. 2020;28(2):165-173. doi:10.1038/s41431-019-0508-00

[b] RARE Disease Facts. Global Genes. Accessed November 29, 2023. https://globalgenes.org/rare-disease-facts/

[c] Delayed Diagnosis Study. EveryLife Foundation for Rare Diseases. Accessed November 29, 2023. https://everylifefoundation.org/delayed-diagnosis-study/

[d] California: Project Baby Bear. RCIGM. Accessed November 29, 2023. https://radygenomics.org/case-studies/project-baby-bear/

[e] Bupp CP, Ames EG, Arenchild MK, et al. Breaking Barriers to Rapid Whole Genome Sequencing in Pediatrics: Michigan's Project Baby Deer. *Child Basel Switz*. 2023;10(1):106. doi:10.3390/children10010106

Evaluation of Proposed Health Benefit Mandate

Methodology

The following section includes an overview of the literature review and actuarial analysis performed to examine the potential public health and economic impact of the mandate. The literature review includes moderate- to high-quality relevant peer-reviewed literature and/or independently conducted domestic research that was published within the last 10 years and is related to the public health, economic, or legal impact of the proposed health benefit mandate. For further information on the literature review methodology, please reference https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

Public Health Impact

Prevalence of Genetic Disease. It is estimated that 350 million people worldwide have rare diseases, and of these diseases, 80% are genetic. Children account for about half of those with genetic diseases, and 30% do not survive past 5 years.[10] Genetic diseases are the most frequent cause of infant deaths in the United States, accounting for 20.6% of infant deaths in 2019.[11]

Genetic testing has been demonstrated to be an effective approach for diagnosing those with genetic diseases, especially children. Whole genome sequencing (WGS) can analyze approximately 90% of the human genome, and it has been shown to be more effective at identifying genetic abnormalities than other methods, such as exome sequencing. Additionally, WGS provides the opportunity to identify diseases and genetic anomalies not related to the illness motivating the test.

Benefits of rWGS. While WGS can take days or weeks to complete, rWGS can deliver results in a matter of hours. Rapid diagnosis is especially important for rare pediatric diseases, as disease progression is rapid and many cases present in the first month of life.[10] Due to its fast delivery of results, rWGS may allow more patients to receive life-saving measures. One study reports that rWGS is considered a first-tier diagnostic test.[10]

Over the last 10 years, the speed, cost, and diagnostic yield of rWGS have improved iteratively. Sensitivity and specificity have continued to improve and now both exceed 99.5% for single-nucleotide variants.[f] Additionally, parents of infants undergoing rWGS can be notified of incidental findings, such as the presence of genomic variants that are not related to the infant's current illness but could have significant consequences for future health.[10]

Efficacy of rWGS. rWGS has been demonstrated to identify rare genetic diseases in 30% to 40% of cases and led to a change in the course of medical treatment in approximately 30% of infants and children that underwent genome sequencing. Recent studies have evaluated the clinical efficacy and cost-effectiveness of rWGS. Many of these studies have been funded by states, such as California, to investigate how to incorporate rWGS into their payment policies. One study focused on 184 acutely ill infants under a year old who did not respond to standard therapy.[12] rWGS revealed rare genetic diseases in 40% of cases and led to a change in medical care in 35% of cases. For 30 infants, their length of stay in the hospital was less than predicted, and between 457 and 592 days of hospitalization were avoided across all cases. For the 30 affected infants, this meant an average of 17 fewer days in the hospital.

[f] A single-nucleotide variant is a substitution of a single nucleotide at a single position in the genome, which can increase susceptibility to a wide range of diseases across the population.

Several other studies also found that using rWGS in infants results in shorter treatment time and a change in medical care after diagnosis.[13–15] A review article[11] on the diagnostic yield in 31 clinical studies from 2012 to 2021 found that

- the weighted average rate of genetic disease diagnosis was 36%,
- the weighted average rate of change in management was 27%, and
- the weighted average rate of change in outcome was 18%.

Economic Impact

Cost-Effectiveness of rWGS. Recent studies have shown that rWGS is cost-effective for young infants with difficult-to-diagnose rare diseases. Whether cost savings result from using rWGS with older children and young adults is less clear. The cost of rWGS is significantly greater than the cost of other diagnostic tests, and one study found the average cost to be $7,400.[16] Recent literature indicates that there are both financial and quality-of-life benefits associated with pediatric use of rWGS. One study of 38 children[16] found a total reduction in cost of nearly $185,000 and a total gain of 12.1 quality-adjusted life years (QALYs). The savings included $156,575 in hospital cost savings (shorter length of stay and avoided procedures) and $28,271 in avoided professional fees. Recent literature indicates that there are both financial and quality-of-life benefits associated with pediatric use of rWGS.

A study in Michigan on rWGS estimated a net savings per patient of $4,155.[14] This analysis found that rWGS is cost-effective for infants and also found that it could be cost-effective for all children given optimistic assumptions about rWGS accuracy.

Limitations

Recent literature on the effectiveness of rWGS identified several limitations that should be noted. First, it is challenging to accurately calculate costs and savings of rWGS, as variation in provider care and billing practices for rare disease treatment makes comparing lengths of stay and costs difficult.[13]

There is also limited research into the long-term benefits to children and their families in scenarios where rWGS has been successfully administered. This is complicated by the fact that there is little research on the lifetime outcomes for many of the rare diseases identified by rWGS.[17] This prevents an accurate calculation of QALYs, which is one of the key measures used to calculate the benefits of rWGS.

Due to the nature of rare diseases, there is a large amount of variation in the conditions, populations, and clinical presentations of cases for which rWGS may be appropriate. This presents challenges in determining the effectiveness of these tests and for whom they may be most beneficial.

Finally, the speed at which families decide whether to accept the use of rWGS differs, and the results may not be generalizable across cultural settings.[17] Due to the time-sensitive nature of diagnosing these rare diseases, some outcomes may be affected by a delay in carrying out the test.

Actuarial Analysis[g]

Objective

This actuarial analysis includes an assessment of current prevalence of rWGS diagnoses, current levels of utilization, and potential effects of increased utilization with expanded coverage on cost-sharing, premiums, and overall expenditures.

Assumptions and Approach

While the data were ultimately too limited to use in the actuarial analysis, the Minnesota Department of Health (MDH) provided the Actuarial Research Corporation (ARC) with tabulations from the Minnesota All Payer Claims Database (MN APCD) for all applicable enrollees with 12 months of continuous commercial coverage from 2019 to 2022.[18] Per MDH, the MN APCD includes approximately 40% of the total commercial market in Minnesota.[19] The mandate requires coverage for enrollees 21 and younger with an illness of unknown etiology specifically when they are in an intensive care unit (ICU). To identify applicable enrollees and procedures, MDH was provided with International Classification of Diseases (ICD-10) codes targeting the mandate criteria.

MDH tabulated claims for ICD-10 diagnosis codes for conditions diagnosed by rWGS, as well as conditions that could lead to rWGS under the mandate, if accompanied by an ICU stay (indicated by an 020X revenue code). Diagnosis codes can be found in Appendix C.

Among the set of conditions diagnosed by rWGS, only E169 (disorder of pancreatic internal secretion, unspecified) was present and was redacted due to small cell size (<11). For the conditions leading to rWGS with an ICU stay, there were only 35 ICU stays across 17 enrollees for 2019–2022. Due to small cell size, MDH provided the prevalence for these conditions independently of any ICU stay.

MDH then tabulated claims for the Common Procedure Terminology (CPT®) codes for rWGS found in Appendix C. Only code 81479 (unlisted molecular pathology procedure) was found in claims, and the cell size was too small to report even after aggregating across all codes for 2019–2022. MDH noted that when inpatient stays are reimbursed via diagnosis-related group, rWGS testing is not noted separately, which could lead to underreporting. None of the 35 ICU stays with the relevant diagnoses mentioned above were associated with an rWGS procedure.

Given the limitations of the data, only population and prevalence levels were available for this analysis. The 2019–2022 population of enrollees aged 21 and younger varied only slightly (the rate fell between 26.7% and 26.9%).

Prevalence of codes leading to rWGS ranged from 0.16% to 0.18%, with no apparent directional trend. Assuming a uniform distribution across 2019–2022 of the 35 ICU stays, prevalence of ICU stays among applicable enrollees ranged from 1.8% to 2%. Together, this yielded a "rWGS-eligible" rate of 0.0031% among all enrollees aged 21 and younger. Based on information from the literature, this observed prevalence is far too low. For infants alone, minimum numbers from the literature are approximately 0.0118%, nearly 4 times the observed level. As a result, this prevalence data were deemed incomplete as a snapshot and were not relied upon for the actuarial

[g] Michael Sandler and Anthony Simms are actuaries for Actuarial Research Corporation (ARC). They are members of the American Academy of Actuaries and meet the qualification standards of the American Academy of Actuaries to render the actuarial opinions contained herein.

analysis. Additionally, any impact based on these prevalence rates would be immaterial. Just over 30 enrollees per year would qualify for rWGS. If all 30 of those individuals were not covered under current law and all of them used the benefit fully every year, the projected PMPM effect on the total non-public insured population would be just over $0.01 after 10 years.

Given the limitations of the data, the analysis relied on a review of the literature for the construction of scenarios representing low-, medium-, and high-impact mandate levels. Scenarios were constructed based on these five factors:

1. **ICU Stay Prevalence.** Dimmock et al. cited an annual prevalence rate of 7% to 10% among infants,[12] and Kingsmore and Cole noted that NICU admissions account for up to 50% of nationwide pediatric expenses.[11] The analysis leveraged a 2021 statistic from March of Dimes about live births in Minnesota to estimate the annual population level of infants in Minnesota. The total ICU prevalence was calculated as twice the infant levels, yielding prevalence rates of 0.59%, 0.72%, and 0.84% under low-, medium-, and high-impact scenarios, respectively.[20]
2. **rWGS Eligibility.** Dimmock et al. observed that 4% of infants who had criteria similar to the mandate were eligible to receive rWGS,[12] and the authors also stated that 15% of infants admitted to ICUs appear to have a genetic disorder, while Kingsmore and Cole cited a range of 10% to 25%.[11] Kingsmore et al. observed an rWGS-eligibility rate of 46% among infants using criteria similar to those in the mandate.[21] Infant prevalence levels were assumed for the entire demographic, yielding eligibility rates of 4%, 20%, and 46% under low-, medium-, and high-impact scenarios, respectively.
3. **Induced Utilization.** Dimmock et al. found that 97% of families agreed to testing for their infants during an 18-month multi-site project,[12] and Kobayashi et al. cited that same percentage as the percentage of parents who considered genomic testing useful.[16] Kingsmore et al. found that around 34.1% of eligible infants were not enrolled due to a lack of consent, denial of eligibility, or other non-specified reasons.[21] Based on this, 66%, 87%, and 97% maximum utilization rates were assumed for low-, medium-, and high-impact scenarios, respectively. A test-ordering guide from Mayo Clinic labs recommends waiting a year to reanalyze WGS, and Costain et al. recommend reanalysis every 1 to 2 years until diagnosis, with both noting shorter timelines for phenotype changes.[22] Based on this and the young demographic to which this mandate pertains, it was assumed that 60%, 70%, and 80% of induced utilization would be realized in Years 1–3 and that the percentage would increase steadily up to 90% by Year 8, where it would remain level.
4. **Insurance Coverage.** Phillips et al. offer two estimates for coverage for rWGS, ranging from 8% of enrollees in private insurance (February 2021) to 12% of insured individuals (November 2021).[23] Based on this, coverage levels were assumed to be 12%, 10%, and 8% in low-, medium-, and high-impact scenarios, respectively, utilized at 90% of the induced utilization rates.
5. **rWGS Costs.** In 2020, Dimmock et al. noted a $9,492 cost of both rWGS and precision medicine per child.[13] In 2022, Bupp et al. cited an average cost of $7,564 based on a 2022 Michigan Medicaid fee schedule.[14] Kingsmore and Cole cited a range of $8,000 to $10,000 from 2022.[11] Dollars were assumed to be from the citation years, and 7.5% cost-sharing was assumed based on Physician and Clinical Expenditures from National Health Expenditure (NHE) data.[24] Based on this, 2022 costs of rWGS were assumed to be $7,564 with $610 cost-sharing, $9,035 with $728 cost-sharing, and $10,578 with $850 cost-sharing for low-, medium-, and high-impact scenarios, respectively.

The analysis includes projected total plan expenditures and enrollee cost-sharing for enrollees utilizing rWGS under the low-, medium-, and high-impact scenarios outlined above. The overall Minnesota population

projections for 2025 (the base year) through 2034 are based on the figures published by the Minnesota State Demographic Center. Given historic non-public health insurance coverage levels from Minnesota Public Health Data Access, 65% of the total state population was assumed to be included in the non-public insured population.[25] Physician and clinical cost trends were derived from NHE data for use in projections. Projections were performed for each scenario under current law and under the proposed mandate, with current law numbers reflecting estimated utilization under current coverage, and mandate numbers reflecting induced utilization under mandated coverage. This isolated the impact of the mandate for the purposes of calculating the change in PMPM costs.

Results

Tables 1–3 show the total projected population of enrollees utilizing rWGS; the resulting prevalence, utilization, and expenditures; and the net projected impact of the mandate on the total non-public insured population PMPM for low-, medium-, and high-impact scenarios.

Table 1. Total Projected rWGS Prevalence, Expenditures, and Non-Public Insured PMPM Impact, Low-Impact Scenario[h]

	Population			Estimated low prevalence		Estimated low current law utilization and expenditures			Projected low utilization and expenditures under mandate			
	Total Minnesota population	Non-public insured population	Non-public insured population aged 21 and under	Non-public insured population aged 21 and under with an ICU stay	Non-public insured population aged 21 and under with an ICU stay qualifying for rWGS	Non-public insured enrollees 21 and under undergoing rWGS	Plan paid	Cost-sharing	Non-public insured enrollees 21 and under undergoing rWGS	Plan paid	Cost-sharing	Total non-public insured population PMPM change
2025	5,833,655	3,101,454	830,400	4,901	196	14	$124,388	$9,732	78	$691,044	$54,066	$0.02
2026	5,863,731	3,107,430	832,000	4,911	196	14	$129,171	$10,185	91	$837,217	$66,014	$0.02
2027	5,893,080	3,112,920	833,470	4,919	197	14	$135,263	$10,665	104	$1,001,949	$78,997	$0.02
2028	5,921,625	3,117,886	834,800	4,927	197	14	$141,717	$11,167	107	$1,075,996	$84,790	$0.02
2029	5,949,303	3,122,300	835,982	4,934	197	14	$148,259	$11,681	109	$1,153,129	$90,849	$0.03
2030	5,976,058	3,126,137	837,009	4,940	198	14	$155,341	$12,236	112	$1,236,978	$97,435	$0.03
2031	6,001,850	3,139,298	840,533	4,961	198	14	$162,797	$12,827	115	$1,326,496	$104,513	$0.03
2032	6,026,651	3,151,878	843,901	4,981	199	14	$170,641	$13,458	118	$1,422,012	$112,146	$0.03
2033	6,050,458	3,163,936	847,129	5,000	200	14	$178,831	$14,117	119	$1,490,26	$117,641	$0.03
2034	6,073,273	3,175,472	850,218	5,018	201	14	$187,380	$14,806	119	$1,561,504	$123,383	$0.04

[h] The state health benefit mandates generally only apply to fully insured individual and small group health plans regulated in Minnesota, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to individual and small group data, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 2. Total Projected rWGS Prevalence, Expenditures, and Non-Public Insured PMPM Impact, Medium Impact Scenario[i]

	Population			Estimated medium prevalence		Estimated medium current law utilization and expenditures			Projected medium utilization and expenditures under mandate			
	Total Minnesota population	Non-public insured population	Non-public insured population aged 21 and under	Non-public insured population aged 21 and under with an ICU stay	Non-public insured population aged 21 and under with an ICU stay qualifying for rWGS	Non-public insured enrollees 21 and under undergoing rWGS	Plan paid	Cost-sharing	Non-public insured enrollees 21 and under undergoing rWGS	Plan paid	Cost-sharing	Total non-public insured popula-tion PMPM change
2025	5,833,655	3,101,454	830,400	5,952	1,190	93	$988,309	$77,234	619	$6,588,729	$514,892	$0.15
2026	5,863,731	3,107,430	832,000	5,963	1,193	93	$1,026,310	$80,830	723	$7,982,407	$628,675	$0.19
2027	5,893,080	3,112,920	833,470	5,974	1,195	93	$1,074,716	$84,636	828	$9,553,035	$752,321	$0.23
2028	5,921,625	3,117,886	834,800	5,983	1,197	93	$1,125,991	$88,626	850	$10,259,033	$807,483	$0.24
2029	5,949,303	3,122,300	835,982	5,992	1,198	93	$1,177,977	$92,699	872	$10,994,448	$865,187	$0.26
2030	5,976,058	3,126,137	837,009	5,999	1,200	94	$1,234,246	$97,107	894	$11,793,903	$927,911	$0.28
2031	6,001,850	3,139,298	840,533	6,024	1,205	94	$1,293,485	$101,794	919	$12,647,413	$995,315	$0.30
2032	6,026,651	3,151,878	843,901	6,048	1,210	94	$1,355,810	$106,801	943	$13,558,104	$1,068,006	$0.32
2033	6,050,458	3,163,936	847,129	6,071	1,214	95	$1,420,881	$112,034	947	$14,208,810	$1,120,336	$0.34
2034	6,073,273	3,175,472	850,218	6,094	1,219	95	$1,488,808	$117,502	950	$14,888,082	$1,175,019	$0.35

[i] The state health benefit mandates generally only apply to fully insured individual and small group health plans regulated in Minnesota, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to individual and small group data, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

Table 3. Total Projected rWGS Prevalence, Expenditures, and Non-public Insured PMPM Impact – High Impact Scenario[j]

	Population			Estimated high prevalence		Estimated high current law utilization and expenditures			Projected high utilization and expenditures under mandate			
	Total Minnesota population	Non-public insured population	Non-public insured population aged 21 and under	Non-public insured population aged 21 and under with an ICU stay	Non-public insured population aged 21 and under with an ICU stay qualifying for rWGS	Non-public insured enrollees 21 and under undergoing rWGS	Plan paid	Cost-sharing	Non-public insured enrollees 21 and under undergoing rWGS	Plan paid	Cost-sharing	Total non-public insured population PMPM change
2025	5,833,655	3,101,454	830,400	7,002	3,221	225	$2,804,316	$218,534	1,875	$23,369,304	$1,821,113	$0.55
2026	5,863,731	3,107,430	832,000	7,015	3,227	225	$2,912,141	$228,708	2,191	$28,312,486	$2,223,549	$0.68
2027	5,893,080	3,112,920	833,470	7,028	3,233	226	$3,049,495	$239,478	2,509	$33,883,283	$2,660,871	$0.83
2028	5,921,625	3,117,886	834,800	7,039	3,238	226	$3,194,988	$250,769	2,575	$36,387,359	$2,855,975	$0.89
2029	5,949,303	3,122,300	835,982	7,049	3,242	226	$3,342,495	$262,291	2,642	$38,995,776	$3,060,065	$0.95
2030	5,976,058	3,126,137	837,009	7,058	3,246	227	$3,502,158	$274,765	2,708	$41,831,331	$3,281,913	$1.02
2031	6,001,850	3,139,298	840,533	7,087	3,260	228	$3,670,250	$288,026	2,783	$44,858,611	$3,520,314	$1.09
2032	6,026,651	3,151,878	843,901	7,116	3,273	229	$3,847,096	$302,193	2,858	$48,088,706	$3,777,413	$1.17
2033	6,050,458	3,163,936	847,129	7,143	3,286	229	$4,031,733	$317,000	2,868	$50,396,667	$3,962,497	$1.22
2034	6,073,273	3,175,472	850,218	7,169	3,298	230	$4,224,476	$332,473	2,879	$52,805,952	$4,155,907	$1.27

[j] The state health benefit mandates generally only apply to fully insured individual and small group health plans regulated in Minnesota, except where explicitly indicated. However, the actuarial analysis is based on gross expenditures for all non-public insurance in Minnesota. Although the analysis was not limited to individual and small group data, this does not affect the accuracy of the PMPM estimates. Using all non-public claims improves the robustness and accuracy of the PMPM estimates because the analyses rely on a larger, more representative set of data.

The total statewide non-public insured population expenditures for rWGS in Year 1 are projected to range from $745,110 (with $691,044 to be paid by plans) under the low-impact scenario to $25.2 million (with $23.4 million to be paid by plans) under the high-impact scenario. By the 10th and final year of the projection period, the expenditures are projected to rise to $1.7 (with $1.6 million to be paid by plans) under the low-impact scenario and to $57 million (with $52.8 million to be paid by plans) under the high-impact scenario.

Overall, the mandate is projected to result in a net increase of $0.02 PMPM (low impact) to $0.55 PMPM (high impact) for the total non-public insured population in the first year and a net increase of $0.04 PMPM (low impact) to $1.27 PMPM (high impact) by Year 10. Overall, PMPM delta (change) varied widely across scenarios. A sensitivity analysis was also conducted using the medium-impact scenario as a base case, testing the change in PMPM across the range of each factor. The PMPM change was most sensitive to rWGS eligibility and equaled $0.32 and $0.74 in Years 1 and 10, respectively. This factor is understandably pivotal, given its role in determining the utilizing population under the mandate and the broad spread of eligibility rates found in the literature. ICU stay prevalence, rWGS cost, and induced utilization were more moderately sensitive, each with an individual PMPM effect roughly between the range of $0.05 and $0.13 in Years 1 and 10, respectively. Insurance coverage was least sensitive, and the PMPM change equaled $0.01 and $0.02 in Years 1 and 10, respectively.

A more comprehensive actuarial analysis and modeling of all services associated with rWGS, including downstream effects, was not possible with the available data. We conducted a literature review to assess the potential long-term effects, including savings and improved health outcomes.

- Dimmock et al. found that rWGS was diagnostic in 40% of participating babies in the study's multi-site program.[12] Clinical course was changed in 32% of babies, and 52% of those babies had significantly shorter stays at facilities as a result of rWGS. The savings totaled over $2 million, which more than paid for the costs of testing the babies. Savings were possible even when rWGS failed to diagnose a condition, as the testing ruled out some diagnoses and thus assisted in making decisions about future care. Similar outcomes were observed in a similar program cited by Bupp et al.[14]
- Sanford et al. analyzed the impact of rWGS in PICUs. rWGS was diagnostic in 45% of children, and in many cases the course of treatment was modified as a result.[16] Kobayashi et al. conducted an economic analysis of this same cohort of children in cases where there was a change in treatment and found that $184,846 was saved across seven patients, mostly due to reduced stays.[16] Across all patients, there was a net loss of $54,554, but an estimated 12.1 QALYs were gained at a cost of just $4,509 per QALY.

Data Sources

- Minnesota state population projections are from the "Long-Term Population Projections for Minnesota" published by the Minnesota State Demographic Center.[26]
- Minnesota non-public health insurance coverage levels are from Minnesota Public Health Data Access.[25]
- Trends and projection factors are derived from the National Health Expenditure (NHE) data compiled by CMS.[24]
- Minnesota Department of Health (MDH) tabulations of the MN APCD from the period 2019–2022 were provided for the estimation of the prevalence of need for rWGS and associated historic utilization, expenditures, and enrollee cost-sharing. However, these data saw limited use in this analysis because of the exceptionally low numbers of claims relevant to the proposed mandate.[18]

State Fiscal Impact

The potential state fiscal impact of this legislation includes the estimated cost to SEGIP as assessed by MMB in consultation with health plan administrators, the cost of defrayal of benefit mandates as understood under the Affordable Care Act (ACA), and the estimated cost to public programs.

- MMB estimates the cost of this legislation for the state plan to be $46,440 for partial Fiscal Year 2025 (FY 2025) and $97,524 for FY 2026.
- Commerce has determined that this proposed mandate would likely require full defrayal under the ACA, with an estimated cost of up to $800,000 in the first year.
- There is no estimated cost for public programs.

Fiscal Impact Estimate for SEGIP

MMB provided SEGIP's fiscal impact analysis, which is based on the prevalence of applicable conditions in the membership of SEGIP health plans, potential changes in utilization, and the potential for future high-cost cases. The partial fiscal year impact of the proposed legislation on SEGIP will equal $46,440 for FY 2025 ($0.06 PMPM medical cost × 129,000 members × 6 months). By FY 2026, the estimated impact will equal $97,524, and it will increase by 5% for all following years to account for medical price inflation. The analysis noted that a small proportion of members were likely to be affected by this proposed mandate due to the coverage criteria.

Affordable Care Act Mandate Impact and Analysis

States may require qualified health plan issuers to cover benefits in addition to the 10 essential health benefits (EHBs) defined by the ACA but must defray the costs, either through payments to individual enrollees or directly to issuers, and can partially defray the costs of proposed mandates if some of the care, treatment, or services are already covered in the state's benchmark plan or mandated by federal law, pursuant to section 1311(d)(3)(b) of the ACA.[27,28] For further defrayal requirements and information of the methodology, please visit https://mn.gov/commerce/insurance/industry/policy-data-reports/62j-reports/.

If enacted, the state has determined that HF 3330 would likely constitute an additional benefit mandate because rWGS is not broadly covered under Minnesota's benchmark plan. The state's benchmark plan includes coverage for non-experimental genetic testing,[29] but rWGS is considered experimental genetic testing.

The cost of defrayal associated with HF 3330 is estimated to be between $20,000 and $800,000 in the first year. Commerce based this estimate on data, methods, and assumptions that are consistent with those used by the Actuarial Research Corporation in their actuarial analysis, with adjustments to reflect enrollment and enrollee cost-sharing specific to the individual qualified health plan market.

Costs associated with defrayal are estimated to increase in future years due to the expected medical cost trend as well as utilization increases resulting from the coverage requirement.

Fiscal Impact for State Public Programs

There is no estimated cost to Minnesota public health coverage programs, as the proposed health benefit mandate does not apply to these programs.

Appendix A. Bill Text

A bill for an act relating to insurance; requiring a health carrier to provide coverage for rapid wholegenome sequencing; proposing coding for new law in Minnesota Statutes, chapter 62A.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MINNESOTA:

Section 1. **[62A.3098] RAPID WHOLE GENOME SEQUENCING; COVERAGE**.

Subdivision 1. **Definition**. For purposes of this section, "rapid whole genome sequencing" or "rWGS" means an investigation of the entire human genome, including coding and noncoding regions and mitochondrial deoxyribonucleic acid, to identify disease-causing genetic changes that returns the preliminary positive results within five days and final results in 14 days. Rapid whole genome sequencing includes patient-only whole genome sequencing and duo and trio whole genome sequencing of the patient and the patient's biological parent or parents.

Subd. 2. **Required coverage.** A health plan that provides coverage to Minnesota residents must cover rWGS testing if the enrollee:

(1) is 21 years of age or younger;

(2) has a complex or acute illness of unknown etiology that is not confirmed to have been caused by an environmental exposure, toxic ingestion, an infection with a normal response to therapy, or trauma; and

(3) is receiving inpatient hospital services in an intensive care unit or a neonatal or high acuity pediatric care unit.

Subd. 3. **Coverage criteria**. Coverage may be based on the following medical necessity criteria:

(1) the enrollee has symptoms that suggest a broad differential diagnosis that would require an evaluation by multiple genetic tests if rWGS testing is not performed;

(2) timely identification of a molecular diagnosis is necessary in order to guide clinical decision making, and the rWGS testing may aid in guiding the treatment or management of the enrollee’s condition; and

(3) the enrollee's complex or acute illness of unknown etiology includes at least one of the following conditions:

(i) congenital anomalies involving at least two organ systems, or complex or multiple congenital anomalies in one organ system;

(ii) specific organ malformations that are highly suggestive of a genetic etiology;

(iii) abnormal laboratory tests or abnormal chemistry profiles suggesting the presence of a genetic disease, complex metabolic disorder, or inborn error of metabolism;

(iv) refractory or severe hypoglycemia or hyperglycemia; (v) abnormal response to therapy related to an underlying medical condition affecting vital organs or bodily systems;

(vi) severe muscle weakness, rigidity, or spasticity; (vii) refractory seizures;

(viii) a high-risk stratification on evaluation for a brief resolved unexplained event with any of the following features:

(A) a recurrent event without respiratory infection;

(B) a recurrent seizure-like event; or

(C) a recurrent cardiopulmonary resuscitation;

(ix) abnormal cardiac diagnostic testing results that are suggestive of possible channelopathies, arrhythmias, cardiomyopathies, myocarditis, or structural heart disease;

(x) abnormal diagnostic imaging studies that are suggestive of underlying genetic condition;

(xi) abnormal physiologic function studies that are suggestive of an underlying genetic etiology; or

(xii) family genetic history related to the patient's condition.

Subd. 4. **Cost sharing**. Coverage provided in this section is subject to the enrollee's health plan cost-sharing requirements, including any deductibles, co-payments, or coinsurance requirements that apply to diagnostic testing services.

Subd. 5. **Reimbursement.** If the enrollee's health plan uses a capitated or bundled payment 25 arrangement to reimburse a provider for services provided in an inpatient setting, reimbursement for services covered under this section must be paid separately and in addition to any reimbursement otherwise payable to the provider under the capitated or bundled payment arrangement, unless the health carrier and the provider have negotiated an increased capitated or

bundled payment rate that includes the services covered under this section.

Subd. 6. **Genetic data**. Genetic data generated as a result of performing rWGS and covered under this section: (1) must be used for the primary purpose of assisting the ordering provider and treating care team to diagnose and treat the patient; (2) is protected health information as set forth under the Health Information Portability and Accountability Act (HIPAA), the Health Information Technology for Economic and Clinical Health Act, and any promulgated regulations, including but not limited to the HIPAA Privacy Rule under Code of Federal Regulations, title 45, parts 160 and 164, subparts A and E; and (3) is a protected health record under the Minnesota Health Records Act under section 144.291.

EFFECTIVE DATE. This section is effective January 1, 2024, and applies to a health plan offered, issued, or sold on or after that date.

Appendix B. Key Search Terms for Literature Scan

Bioinformatics

Biomarkers

Children

Diagnostic odyssey

Exome sequencing

Genetics

Genomic sequencing

Neonatal intensive care unit

Next-generation sequencing

Pediatric intensive care unit

Rapid whole genome sequencing

Rare disease

Undiagnosed rare disease

Variant interpretation

Whole exome sequencing

Appendix C. Associated Codes

ICD-10 Diagnosis Codes for Conditions Diagnosed by rWGS:

Name	Code
Epilepsy, unspecified, intractable, without status epilepticus	G40919
Other specified conduction disorders	I4589
Congenital hypotonia	P942
Other disorders of muscle tone of newborn	P948
Congenital malformation of heart unspecified	Q249
Congenital malformation unspecified	Q899

CPT/HCPCS Code(s):

Name	Code(s)
Disorder of pancreatic internal secretion unspec	E169
General idiopathic epilepsy & epileptic syndromes	G403
Other specified congenital malformation syndromes, not elsewhere classified	Q878

CPT Procedure Code(s):

Name	Code
Genome rapid sequence analysis	0094U
Rare disease whole genome & mitochondrial DNA sequence analysis - Proband	0212U
Rare disease whole genome & mitochondrial DNA sequence analysis - Comparator	0213U
Rare whole genome sequencing & mitochondrial DNA sequence analysis – Proprietary	0265U
Genome sequence analysis	81425
Genome sequence analysis each comparator genome	81426
Genome re-evaluation	81427
Unlisted molecular pathology procedure	81479

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