Date of Hearing: April 13, 2021

ASSEMBLY COMMITTEE ON HEALTH
Jim Wood, Chair
AB 114 (Maienschein) – As Amended April 5, 2021

SUBJECT: Medi-Cal benefits: Rapid Whole Genome Sequencing.

SUMMARY: Requires Rapid Whole Genome Sequencing (RWGS), including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, to be a Medi-Cal covered benefit for any Medi-Cal beneficiary who is one year of age or younger and is receiving inpatient hospital services in an intensive care unit (ICU). Specifically, **this bill**:

1) Requires RWGS, including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, to be a Medi-Cal covered benefit for any Medi-Cal beneficiary who is one year of age or younger and is receiving inpatient hospital services in an ICU.

2) Prohibits diagnosis-related group-based (DRG) payments (to hospitals) from applying to claims for RWGS.

3) Requires RWGS to be reimbursed in addition to, and separate from, a DRG-based payment for any other qualifying claim for other services provided to the same individual.

4) Requires the Department of Health Care Services (DHCS), without taking any further regulatory action, to implement, interpret, or make specific this bill by means of all-county letters, plan letters, plan or provider bulletins, or similar instructions until the time regulations are adopted.

EXISTING LAW:

1) Establishes the Medi-Cal program, administered by DHCS, under which qualified low-income individuals receive health care services pursuant to a schedule of benefits.

2) Requires, pursuant to budget bill language from the Budget Act of 2018, $2 million in funds appropriated in the Medi-Cal Local Assistance line item, to be available for the Whole Genome Sequencing Pilot Project, as follows:

    a) Requires DHCS to provide this grant to a state nonprofit organization for the execution of a one-time Clinical Whole Genome Sequencing Pilot Project, to investigate the potential clinical and programmatic value of utilizing clinical Whole Genome Sequencing in the Medi-Cal program.

    b) Requires the grantee to complete whole genome sequencings of Medi-Cal neonatal and pediatric intensive care patients from identified Medi-Cal sites statewide with a goal of completing a minimum of 100 sequencings.

    c) Requires the grantee to report semi-annual updates to DHCS, and to the fiscal and policy committees of the Legislature through July 1, 2020, or until the funds are fully expended, whichever is sooner.

d) Requires, within 120 days of the final expenditure of all funds appropriated for this purpose, the grantee to report to DHCS and to the fiscal and policy committees of the Legislature the results of the pilot project including:
   i) The number of Medi-Cal genomically-informed pediatric cases; and,
   ii) A cost analysis of comparative effectiveness on patient diagnostics and treatment.

3) Requires DHCS to develop and implement a payment methodology based on DRGs, subject to federal approval, that reflects the costs and staffing levels associated with quality of care for patients in all general acute care hospitals in state and out of state, including Medicare critical access hospitals, but excluding public hospitals, psychiatric hospitals, and rehabilitation hospitals, which include alcohol and drug rehabilitation hospitals.

4) Requires the DRG-based payments to apply to all claims, except claims for psychiatric inpatient days, rehabilitation inpatient days, managed care inpatient days, and swing bed stays for long-term care services, provided, however, that psychiatric and rehabilitation inpatient days shall be excluded regardless of whether the stay was in a distinct-part unit.

5) Permits DHCS to exclude or include other claims and services as may be determined during the development of the payment methodology.

FISCAL EFFECT: Unknown. This bill has not been analyzed by a fiscal committee.

COMMENTS:

1) **PURPOSE OF THIS BILL.** According to the author, Project Baby Bear demonstrated that RWGS has the potential to provide parents and doctors with vital information to determine the course of treatment for critically ill infants. The benefits that this testing can provide to so many families of infants with rare diseases are extraordinary. The author concludes that, by ensuring that testing is a covered Medi-Cal benefit, California can achieve significant health care cost savings and families can shorten their search for answers in how to optimally care for their children.

2) **BACKGROUND.** The Budget Act of 2018 (SB 840 (Mitchell), Chapter 29, Statutes of 2018) appropriated $2 million for the Whole Genome Sequencing Pilot Project, and required DHCS, through budget bill language, to provide a grant to a state nonprofit organization for a one-time pilot project to investigate the potential clinical and programmatic value of utilizing RWGS in the Medi-Cal program. Whole genome sequencing is a method used to evaluate a person's entire genome to identify mutations that may be responsible for a health condition. Rapid refers to the length of time to receive test results. This pilot was known as Project Baby Bear and ended in June 2020. Project Baby Bear enrolled 178 infants who were hospitalized and in ICUs at one of five pilot sites with unexplained critical illnesses. All 178 infants received RWGS and of those, 76 (43%) resulted in a diagnosis. The median time to receive provisional results was reported to be three days, with 31.5% of the cases analyzed using ultra-rapid whole genome sequencing. The diagnoses led to a change in care for 55 infants (31% of overall sample; 72% of those with a diagnosis), including changes to medication, treatments, and procedures, as well as discontinuing futile care. To model reductions in health care utilization, a retrospective analysis was performed on a sample of 29 infants from this program for whom RWGS resulted in significant clinical benefit. This analysis estimated that use of RWGS in

this sample of 29 infants resulted in 16 fewer invasive diagnostic tests, 11 fewer major surgeries, and 454 to 573 fewer hospitalization days in total.

3) **CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM (CHBRP) ANALYSIS.** AB 1996 (Thomson), Chapter 795, Statutes of 2002, requests the University of California to assess legislation proposing a mandated benefit or service and prepare a written analysis with relevant data on the medical, economic, and public health impacts of proposed health plan and health insurance benefit mandate legislation. CHBRP was created in response to AB 1996. SB 125 (Hernandez), Chapter 9, Statutes of 2015, added an impact assessment on health benefits (EHBs), and legislation that impacts health insurance benefit designs, cost sharing, premiums, and other health insurance topics. This bill would expand the Medi-Cal schedule of benefits to include RWGS including individual sequencing, trio sequencing for a parent or parents and their baby, and ultra-rapid sequencing, for any Medi-Cal beneficiary who is 1 year of age or younger receiving inpatient hospital services in an ICU. This bill would be relevant to the benefit coverage of the subset of Medi-Cal beneficiaries who are 1 year of age or younger receiving care in an ICU. CHBRP states in its analysis of this bill the following:

   a) **Benefit Coverage**: DHCS considers genetic testing a lab test that is already a covered benefit for Medi-Cal beneficiaries. RWGS used to diagnose children one year of age or younger in an ICU is already included in the existing all-inclusive inpatient DRG or per diem payment hospitals receive from Medi-Cal managed care plans, Medi-Cal fee-for-service (FFS), or California Children's Services (CCS). This bill would not result in new benefit coverage that exceeds the definition of EHBs in California. Per the CHBRP report, according to DHCS, there are 209,885 children enrolled in Medi-Cal under one year of age; of whom approximately 250 would be born with a genetic condition of which a subset would potentially have RWGS used in their care.

   b) **Medical Effectiveness**: Though the Project Baby Bear findings did not meet CHBRP's requirements for inclusion in the medical effectiveness grading, CHBRP found a preponderance of evidence shows that RWGS is effective at providing diagnoses for ill infants with diseases of unknown cause, resulting in a higher diagnostic rate than other standard genetic tests and a faster turnaround time to diagnosis. CHBRP states there is limited evidence showing that RWGS improved clinical utility in the treatment of ill infants in an ICU who received a diagnosis, including more precise care management and reduced hospitalization.

   c) **Cost and Health Impacts**: At baseline, 100% of beneficiaries with Medi-Cal coverage that would be subject to this bill have coverage for RWGS delivered in an ICU setting. CHBRP's analysis found no claims. Similar cost and health impacts could be expected for the following year, though possible changes in medical science and other aspects of health make stability of impacts less certain as time goes by or encounters paid during 2019 for RWGS or other genetic tests delivered to Medi-Cal beneficiaries in an ICU, suggesting that DHCS is not paying separately for RWGS, whole exome sequencing, other gene sequencing, or other genetic tests. This bill would have no impact on Medi-Cal expenditures because it is already a covered benefit under current law for 100% of Medi-Cal beneficiaries one year of age or younger who would be in an ICU bed. CHBRP estimates this bill would produce no measurable public health impact due to no projected change in coverage. CHBRP did not find evidence to suggest that this bill would impact

utilization of RWGS differentially by race/ethnicity, gender, income, or geography and so projects no impact on these disparities related to genetic disorders and clinical outcomes. It is expected that this bill would result in no long-term utilization impacts, cost impacts, or public health impacts.

4) **SUPPORT.** This bill is sponsored by Rady Children's Hospital – San Diego (Rady Children's), which writes that RWGS is a single, comprehensive tool historically employed as a last resort test. More recently, it has become a front-line test physicians utilize to provide rapid diagnoses to their sickest patients. The purpose of RWGS is to find genetic changes that are causing a child's symptoms. RWGS quickly reads through the entire human genome (roughly 22,000 genes or "instructions") and looks for changes that are causing the child's illness. With this information, physicians are able to provide medical care based on the molecular diagnosis, allowing for more precise medications and treatments to be directed to the patient. Project Baby Bear was a California demonstration project that utilized RWGS in the intensive care setting for patients under one year of age. The project demonstrated that using RWGS as a first-line test for critically ill Medi-Cal babies improved clinical outcomes, improved the experience of care for families and clinicians, and reduced net healthcare expenditures. Of the 178 patients that received sequencing, 76 patients (43%) received a diagnosis that explained the cause of their hospitalization. In addition, 55 patients (31%) had a change in management that led to fewer hospital days, fewer procedures, or more appropriate therapies and medications. Rady Children's concludes that adding RWGS to the list of Medi-Cal covered benefits will not only save the lives of many babies and change how they are able to live the rest of their lives, but will make the test available to all babies who need it by adding it to the list of Medi-Cal covered benefits.

5) **FISCAL ISSUE:** Based on input from DHCS, CHBRP's analysis of this bill states that DHCS' payment policy for inpatient services delivered through MCMC plans, FFS Medi-Cal or CCS indicates RWGS is already through the DRG or per diem payment for inpatient stays. The amendments adopted after the CHBRP analysis was completed prohibit DRG payments from applying to claims for RWGS, and require RWGS to be reimbursed in addition to, and separate from, a DRG-based payment for any other qualifying claim for other services provided to the same individual. This would affect the CHBRP cost estimate but also the likelihood of the RWGS being utilized as the current cost of RWGS ranges from $8,500 to $12,500, depending upon how quickly the results are furnished and whether the infant's parents are tested.

REGISTERED SUPPORT / OPPOSITION:

Support
Rady Children's Hospital – San Diego (sponsor)
California Chronic Care Coalition
Children's Specialty Care Coalition
California Children's Hospital Association
Valley Children's Healthcare

Opposition
None on file.

Analysis Prepared by: Scott Bain / HEALTH / (916) 319-2097