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California Health Benefits Review Program

Analysis of California Senate Bill 613
Maternal Health: Neonate Medical Wrap

A Report to the 2021–2022 California State Legislature

April 20, 2021

CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Key Findings

Analysis of California Senate Bill 613
Maternal Health: Neonate Medical Wrap

Summary to the 2021–2022 California State Legislature, April 20, 2021

CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM

SUMMARY

The version of California Senate Bill 613 analyzed by CHBRP would require plans and policies with maternity benefits to cover neonate medical wraps following a cesarean delivery and, if the mother requests, after a natural birth.

In 2022, of the 21.9 million Californians enrolled in state-regulated health insurance, all of them would have insurance subject to SB 613.

Benefit Coverage: Postmandate, 100% of enrollees would have coverage for neonate medical wraps. SB 613 is unlikely to be considered to exceed EHBs.

Medical Effectiveness: There is insufficient evidence to determine whether use of wraps is associated with increased rates of skin-to-skin contact between mother and child while in the hospital, or whether the use of wraps results in a reduction in newborn falls.

Cost and Health Impacts[1]: Due to the lack of claims or utilization data and the uncertainty regarding how these wraps would be reimbursed, CHBRP has provided two illustrative examples of potential impacts: the first demonstrates impacts if the wraps are included in the global payment for maternity services; the second demonstrates potential impacts if the wraps are classified as durable medical equipment (DME) and eligible for separate reimbursement.

To illustrate potential impacts of SB 613, CHBRP discusses impacts if 100% of women who have a cesarean delivery (67,835 women) and 50% of women who deliver vaginally (74,765 women) use the wraps while in the hospital.

1. Should the wraps be included in the global payment for maternity services, CHBRP would not expect an increase in expenditures due to SB 613 in the first year postmandate. In the future, hospitals could negotiate for higher global payment rates for deliveries to include the cost of providing wraps to eligible enrollees.
2. Should the wraps be classified as DME and subject to a separate charge, SB 613 would increase total net annual expenditures by $10,463,000 or 0.01% for enrollees with DMHC-regulated plans and CDI-regulated policies.

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions in SB 613. While it is possible that use of the neonate medical wraps improves rates of skin-to-skin contact or decreases the number of newborn falls, CHBRP is unable to quantify the fiscal impacts of these changes due to lack of evidence about the effectiveness of these wraps. Newborn falls result in serious injury 8.5% of the time. For the cases that are averted, CHBRP would expect to see a reduction in expenditures related to evaluating and treating the injuries caused by a fall.

In the first year postmandate, the public health impact of SB 613 is unknown, due to insufficient evidence regarding the use of neonate medical wraps. However, it stands to reason that should a neonate medical wrap help prevent a newborn fall, the newborn would avoid potentially suffering adverse health outcomes and parents would not experience anxiety related to the fall. Similarly, should use of the wrap encourage earlier skin-to-skin contact between mother and newborn, improved outcomes could include earlier maternal-child bonding, earlier thermoregulation, decreased maternal and newborn stress reactivity, and reduction in newborn pain response during painful procedures. The degree to which improvements in these outcomes would occur is unknown.

[1] 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 over time.

CONTEXT

There is one product called a "neonate medical wrap" on the direct-to-consumer market. This AEGIS Neonate Medical Wrap is manufactured and sold by Saplacor, is available in five sizes, and holds an infant that weighs up to 14 pounds.[2] The wrap enables hands-free baby-wearing through use of compression fabric that securely holds the baby to an adult's chest. The wrap also features X-Static® Silver Technology, which provides the AEGIS wrap with antimicrobial/anti-odor properties to protect the fabric from odor-causing bacteria.

There are many other baby-wearing wraps on the market that perform similar functions, although they may or may not use compression fabric and may have other ways of attaching to the adult and baby (for example, the cross-back Baby K'tan wrap). Slings and other baby carriers also perform similar functions, although they may not encourage chest-to-chest contact.

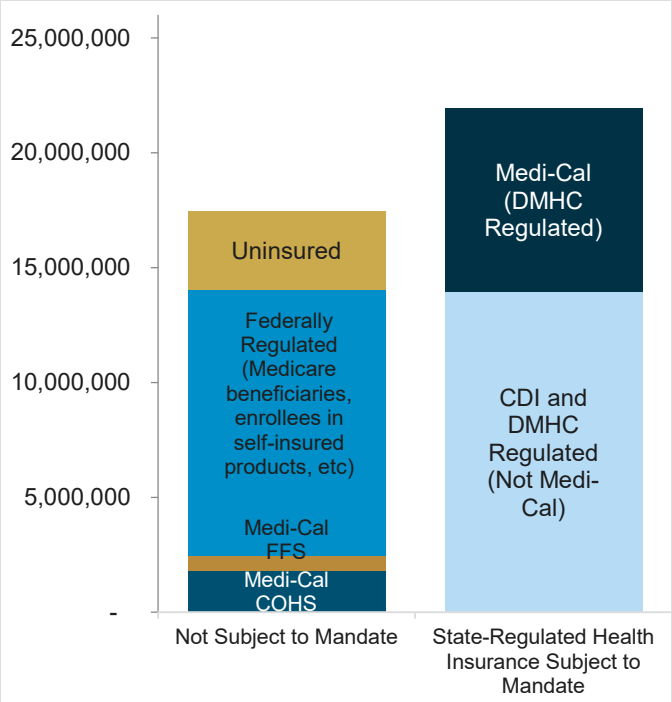
Wraps may be used for a variety of reasons, including parental preference or convenience. The analysis of SB 613 focuses on two reasons wraps may be used in a hospital setting: (1) to facilitate skin-to-skin contact; and (2) to help prevent newborn falls. Skin-to-skin is recommended for all mothers and newborns, regardless of delivery method, immediately after birth and to continue for at least one hour. The wrap could help facilitate this by allowing hands free contact between mother and newborn. Falls among newborns in hospitals (sometimes called "drop events" or accidental/unintentional falls) are a relatively rare but sometimes serious event. No California-specific estimates are available. However, applying the estimates developed by Helsley et al. (2010) that indicate rates of newborn falls are between 1.6 per 10,000 births and 4.1 per 10,000 births nationally, between 71 and 183 newborn falls could occur annually among the 446,479 births in California. Newborn falls within the first month of life are more likely to occur on the second or third day of a hospital stay and when the mother is feeding the newborn and falls asleep. To prevent newborn falls, the wrap would be worn by the mother in the hospital.

BILL SUMMARY

SB 613 would require plans and policies with maternity benefits to cover neonate medical wraps following a cesarean delivery and, if the mother requests, after a natural birth.

Figure A shows how many Californians have health insurance that would be subject to SB 613.

Figure A. Health Insurance in CA and SB 613



Source: California Health Benefits Review Program, 2021.

CHBRP made the following assumptions for this analysis:

There are a variety of "wraps" intended for use with newborns that can help encourage skin-to-skin contact or that can be used when transporting a newborn from one location to another, such as from the emergency department to the neonatal intensive care unit or within an ambulance. Because the bill language specifically mentions "wraps", CHBRP does not discuss slings or other types of carriers, although some reasons for use may also apply to these other products.

"Natural birth" is assumed to mean vaginal delivery, given the context and structure of the sentence. "Natural birth" is a term used in describing children in the definition of "family member" as either being a child "by natural birth or adoption" in the Health and Safety Code. "Natural birth" is also used to refer to vaginal deliveries without pain medications, such as epidural anesthesia, or births that are not induced. It is unclear why the wraps would be covered for women who deliver vaginally without medication, but not for those who deliver vaginally with medication. CHBRP assumes SB 613

[2] Refer to CHBRP's full report for full citations and references.

requires coverage of neonate medical wraps for all vaginal deliveries, if the mother requests a wrap.

Because the bill does not provide a definition of "neonate medical wraps", there are many potential interpretations of the location where these wraps would be used. The bill authors indicated the wraps are intended to be used in the hospital during, and immediately following, delivery. CHBRP's analysis focuses on use of wraps during hospital stays, although interpretation could also include use of wraps for home use.

IMPACTS

Benefit Coverage, Utilization, and Cost

Due to the lack of claims or utilization data and the uncertainty regarding how these wraps would be reimbursed, CHBRP has provided two illustrative examples of potential impacts: the first demonstrates impacts if the wraps are included in the global payment for maternity services; the second demonstrates potential impacts if the wraps are classified as durable medical equipment (DME) and eligible for separate reimbursement.

Benefit Coverage

It is possible that some hospitals are already providing these wraps to women who deliver in their hospitals; however, CHBRP is unable to determine the frequency at which this occurs. CHBRP assumes that 100% of enrollees would have benefit coverage for the neonate medical wraps postmandate.

Utilization

It is important to note that benefit coverage does not equate to utilization. Although these wraps may be newly covered postmandate, hospitals would still need to purchase the wraps, train hospital staff on their use, and actively provide them to patients. Patients would also need to initiate use of the wraps if they are in their hospital room without a medical provider; rates of use would likely be dependent upon ease of use and patient satisfaction.

To illustrate potential impacts of SB 613, CHBRP discusses impacts if 100% of women who have a cesarean delivery (67,835 women) and 50% of women who deliver vaginally (74,765 women) use the wraps while in the hospital.

Among women with coverage through DMHC-regulated plans and CDI-regulated policies, including Medi-Cal managed care beneficiaries, there are approximately 217,364 deliveries. Approximately 31% of births are cesarean deliveries and almost 40% of births are covered by Medi-Cal managed care plans.

Scenario 1: Reimbursement for Wraps is Included in Global Payments for Maternity Services

Should the wraps be included in the global payment for maternity services, CHBRP would not expect an increase in expenditures due to SB 613 in the first year postmandate. Moving forward, hospitals could negotiate for higher global payment rates for deliveries to include the cost of providing wraps to eligible enrollees.

Scenario 2: Wraps are Classified as Durable Medical Equipment and Billed Separately

Expenditures

Should the wraps be classified as DME and subject to a separate charge, SB 613 would increase total net annual expenditures by $10,463,000 or 0.01% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $9,539,000 increase in total health insurance premiums paid by employers, CalPERS, and Medi-Cal, and enrollees for newly covered benefits, plus an increase of $924,000 in enrollee expenses for covered benefits. Total premiums for commercial and CalPERS payers and enrollees would increase by $6,981,000 and total premiums for Medi-Cal managed care plans would increase by $2,558,000.

Potential Offsets During the First 12 Months Postmandate

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions in SB 613. While it is possible that use of the neonate medical wraps improves rates of skin-to-skin contact or decreases the number of newborn falls, CHBRP is unable to quantify the fiscal impacts of these changes, due to lack of evidence about the effectiveness of these wraps. For the cases that are averted, CHBRP would expect to see a reduction in expenditures related to evaluating and treating the injuries caused by a fall.

Medical Effectiveness

There is *insufficient evidence*[3] that use of customized baby wraps is associated with more hours of skin-to-skin contact between newborns and mothers while hospitalized. However, the generalizability of this finding to the AEGIS Neonate Medical Wrap is unknown, because it assessed a different customized baby wrap and was conducted in a developing country. There is *inconclusive evidence* regarding the impact of customized baby wraps on hours of skin-to-skin contact after the mother and newborn are discharged from a hospital. As with the finding regarding effects on hours of skin-to-skin contact during hospitalization, findings regarding skin-to-skin contact after hospital discharge may not be generalizable to use of the AEGIS Neonate Medical Wrap in the United States.

There is *insufficient evidence* to determine whether use of baby wraps prevents newborn falls, whether other interventions to prevent newborn falls do reduce falls, or whether there are any harms associated with baby wraps.

Public Health

In the first year postmandate, the public health impact of SB 613 is unknown, due to insufficient evidence regarding the use of neonate medical wraps. It is important to note that the absence of evidence is not "evidence of no effect." It is possible that an impact — desirable or undesirable — could result, but current evidence is insufficient to inform an estimate.

However, it stands to reason that should a neonate medical wrap help prevent a newborn fall, the newborn would avoid potentially suffering adverse health outcomes, and parents would not experience anxiety related to the fall. Similarly, should use of the wrap encourage earlier skin-to-skin contact between mother and newborn, improved outcomes could include earlier maternal-child bonding, earlier thermoregulation, decreased maternal and newborn stress reactivity, and reduction in newborn pain response during painful procedures. The degree to which improvements in these outcomes would occur is unknown.

Long-Term Impacts

Utilization of neonate medical wraps and related cost impacts are expected to be similar in the long term as to utilization in the first 12 months postmandate. However, should knowledge of coverage of neonate medical wraps increase, more women who deliver vaginally may request a wrap while in the hospital, thereby increasing overall utilization and cost. Similarly, patient satisfaction and ease of use of the wraps may influence utilization of the wraps after the first experience.

Essential Health Benefits and the Affordable Care Act

If the wraps are designated within the maternity and newborn care category, SB 613 would likely not exceed EHBs. If the wraps are classified as DME, SB 613 *could* be interpreted to exceed EHBs. However, DME is a currently covered category within California's benchmark plan and does not place restrictions on which DME are included in coverage.

[3] *Insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

A Report to the California State Legislature

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Maternal Health: Neonate Medical Wrap

April 20, 2021

California Health Benefits Review Program
MC 3116; Berkeley, CA 94720-3116
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The California Health Benefits Review Program (CHBRP) was established in 2002. As per its authorizing statute, CHBRP provides the California Legislature with independent analysis of the medical, financial, and public health impacts of proposed health insurance benefit-related legislation. The state funds CHBRP through an annual assessment on health plans and insurers in California.

An analytic staff based at the University of California, Berkeley, supports a task force of faculty and research staff from multiple University of California campuses to complete each CHBRP analysis. A strict conflict-of-interest policy ensures that the analyses are undertaken without bias. A certified, independent actuary helps to estimate the financial impact. Content experts with comprehensive subject-matter expertise are consulted to provide essential background and input on the analytic approach for each report.

More detailed information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

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POLICY CONTEXT

The California Senate Committee on Health has requested that the California Health Benefits Review Program (CHBRP)[4] conduct an evidence-based assessment of the medical, financial, and public health impacts of SB 613, which would require coverage of neonate medical wraps.

Bill-Specific Analysis of SB 613, Maternal Health: Neonate Medical Wraps

Bill Language

SB 613 would require plans and policies with maternity benefits to cover neonate medical wraps following a cesarean delivery and, if the mother requests, after a natural birth.

The full text of SB 613 can be found in Appendix A.

Relevant Populations

If enacted, SB 613 would apply to the health insurance of approximately 21.9 million enrollees (55.7% of all Californians). This represents 100% of the 21.9 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law, which includes health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would apply to the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies, including beneficiaries enrolled in DMHC-regulated Medi-Cal managed care plans.

Analytic Approach and Key Assumptions

The bill language of SB 613 is very broad. CHBRP has noted the bill author's intent compared with how the bill language may be interpreted.

- "Neonate medical wraps" are not defined by the bill, nor do they have a claim code associated with them. There are a variety of "wraps" intended for use with newborns that can help encourage skin-to-skin contact or that can be used when transporting a newborn from one location to another, such as from the emergency department to the neonatal intensive care unit or within an ambulance. More information about "wraps" on the market is included in the *Background* section. Because the bill language specifically mentions "wraps", CHBRP does not discuss slings or other types of carriers, although some reasons for use may also apply to these other products.
- "Natural birth" is assumed to mean vaginal delivery, given the context and structure of the sentence. "Natural birth" is a term used in describing children in the definition of "family member" as either being a child "by natural birth or adoption" in the Health and Safety Code.[5] "Natural birth" is also used to refer to vaginal deliveries without pain medications, such as epidural anesthesia, or births that are not induced. It is unclear why the wraps would be covered for women who deliver vaginally without medication and not for those who deliver vaginally with medication. CHBRP assumes SB 613 requires coverage of neonate medical wraps for all vaginal deliveries, if the mother requests a wrap.
- The bill language does not include a time period during which these wraps would be covered. However, the "neonate" period is defined as the 28 days of the child's life. CHBRP assumes the wraps are covered for any period within this neonate period.

[4] CHBRP's authorizing statute is available at www.chbrp.org/about_chbrp/faqs/index.php.
[5] Personal communication with CDI on March 16, 2021.

- Because the bill does not provide a definition of "neonate medical wraps" and there are no official codes[6] associated with these products, there are many potential interpretations of the location where these wraps would be used. The bill authors indicated the wraps are intended to be used in the hospital during and immediately following delivery. CHBRP's analysis focuses on use of wraps during hospital stays, although interpretation could also include use of wraps for home use.
- Reimbursement for wraps could be included in the global payments hospitals receive for maternity services, or reimbursement could be a separate charge if the wrap is determined to be durable medical equipment (DME). More information about the potential impacts depending on how the wraps are billed is included in the *Benefit Coverage, Utilization, and Cost Impacts* section.
- CHBRP uses the term "pregnant women," but recognizes that some individuals may identify as male or nonbinary, and may also have female reproductive organs.
- Because the language of SB 613 states "mother", fathers with a child within the neonate period would be excluded from receiving coverage of these neonate medical wraps.

Interaction with Existing State and Federal Requirements

Health benefit mandates may interact and align with the following state and federal mandates or provisions.

California Policy Landscape

California law and regulations

CDI-regulated individual and group policies are required to cover maternity services, including prenatal care, ambulatory care maternity services, involuntary complications of pregnancy, neonatal care, and inpatient hospital maternity care, including labor and delivery and postpartum care.[7]

DMHC-regulated plans are required to cover "basic health care services", which include medically necessary physician and hospital services, as well as preventive services. To the extent maternity care falls under these categories, maternity care is a covered benefit.

Similar requirements in other states

CHBRP is unaware of other state laws or introduced legislation requiring coverage of neonate medical wraps.

Federal Policy Landscape

Affordable Care Act

A number of Affordable Care Act (ACA) provisions have the potential to or do interact with state benefit mandates. Below is an analysis of how SB 613 may interact with requirements of the ACA as presently

[6] The bill sponsors suggested to CHBRP that neonate medical wraps could be covered under medical device code L0621. See more information in Appendix C about this code.
[7] IC 10123.865 & 10123.866.

exist in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).[8,9]

Any changes at the federal level may impact the analysis or implementation of this bill, were it to pass into law. However, CHBRP analyzes bills in the current environment given current law and regulations.

Essential Health Benefits

Nongrandfathered plans and policies sold in the individual and small-group markets are required to meet a minimum standard of benefits as defined by the ACA as essential health benefits (EHBs). In California, EHBs are related to the benefit coverage available in the Kaiser Foundation Health Plan Small Group Health Maintenance Organization (HMO) 30 plan, the state's benchmark plan for federal EHBs.[10,11] CHBRP estimates that approximately 4.2 million Californians (11%) have insurance coverage subject to EHBs in 2022.[12] Maternity and newborn care is an explicit EHB category.

States may require plans and policies to offer benefits that exceed EHBs.[13] However, a state that chooses to do so must make payments to defray the cost of those additionally mandated benefits, either by paying the purchaser directly or by paying the qualified health plan.[14,15] Health plans and policies sold outside of the health insurance marketplaces are not subject to this requirement to defray the costs. State rules related to provider types, cost sharing, or reimbursement methods would not meet the definition of state benefit mandates that could exceed EHBs.[16]

If the wraps are determined to fall with the maternity and newborn care category, SB 613 would likely not exceed EHBs. If the wraps are classified as DME, SB 613 *could*[17] be interpreted to exceed the EHBs. However, DME is a currently covered category within California's benchmark plan and does not place restrictions on which DME are included in coverage.

Should the regulators determine that SB 613 exceeds EHBs, this would trigger the ACA requirement that the state defray the cost of additional benefit coverage for enrollees in QHPs.

[8] The ACA requires nongrandfathered small-group and individual market health insurance — including but not limited to QHPs sold in Covered California — to cover 10 specified categories of EHBs. Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: www.chbrp.org/other_publications/index.php.
[9] Although many provisions of the ACA have been codified in California law, the ACA was established by the federal government, and therefore, CHBRP generally discusses the ACA as a federal law.
[10] CCIIO, Information on Essential Health Benefits (EHB) Benchmark Plans. Available at: https://www.cms.gov/cciio/resources/data-resources/ehb.html.
[11] H&SC Section 1367.005; IC Section 10112.27.
[12] CHBRP, *Estimates of Sources of Health Insurance in California in 2021*. Available at: www.chbrp.org/other_publications/index.php.
[13] ACA Section 1311(d)(3).
[14] State benefit mandates enacted on or before December 31, 2011, may be included in a state's EHBs, according to the U.S. Department of Health and Human Services (HHS). Patient Protection and Affordable Care Act: Standards Related to Essential Health Benefits, Actuarial Value, and Accreditation. Final Rule. Federal Register, Vol. 78, No. 37. February 25, 2013. Available at: https://www.gpo.gov/fdsys/pkg/FR-2013-02-25/pdf/2013-04084.pdf.
[15] However, as laid out in the Final Rule on EHBs HHS released in February 2013, state benefit mandates enacted on or before December 31, 2011, would be included in the state's EHBs, and there would be no requirement that the state defray the costs of those state-mandated benefits. For state benefit mandates enacted after December 31, 2011, that are identified as exceeding EHBs, the state would be required to defray the cost.
[16] Essential Health Benefits. Final Rule. A state's health insurance marketplace would be responsible for determining when a state benefit mandate exceeds EHBs, and QHP issuers would be responsible for calculating the cost that must be defrayed.
[17] Personal communication with DMHC on March 24, 2021.

BACKGROUND ON NEONATE MEDICAL WRAPS AND POTENTIAL USES

This section provides information about neonate medical wraps, potential reasons for use, prevalence of related medical conditions and outcomes, and information about childbirth in California.

Neonate Medical Wraps



There is one product called a "neonate medical wrap" on the market (available direct-to-consumer and to hospitals and other medical providers). This AEGIS Neonate Medical Wrap is manufactured and sold by Saplacor, is available in five sizes, and holds an infant that weighs up to 14 pounds (image to the right). The wrap enables hands free baby-wearing through use of compression fabric that securely holds the baby to an adult's chest. The wrap also features X-Static® Silver Technology, which provides the AEGIS wrap with antimicrobial/anti-odor properties to protect the fabric from odor-causing bacteria.

There are many other baby-wearing wraps on the market that perform similar functions, although they may or may not use compression fabric, may or may not be specific to the neonate period, and may have other ways of attaching to the adult and baby (for example, the cross-back Baby K'tan wrap). Slings and other baby carriers also perform similar functions, although they may not encourage chest-to-chest contact, as is demonstrated in the picture.

Uses of Wraps

Wraps may be used for a variety of reasons, including parental preference or convenience. The analysis of SB 613 focuses on two reasons wraps may be used in a hospital setting: (1) to facilitate skin-to-skin contact; and (2) to help prevent newborn falls[18].

Skin-to-Skin Contact

Skin-to-skin[19] contact is the practice of placing infants in direct contact with the mother or other caregivers with the ventral skin of the infant facing and touching the ventral skin of the mother (chest-to-chest) (Feldman-Winter and Goldsmith, 2016). Skin-to-skin contact is recommended for all mothers and newborns, regardless of delivery method, immediately after birth and to continue for at least one hour (AAP & ACOG, 2017). Skin-to-skin contact is also used to describe continued holding of the infant in the manner described above beyond the immediate delivery period, lasting throughout infancy, whenever infant and caregiver have the opportunity.

A 2017 systematic review of the impacts of skin-to-skin contact for healthy, full-term newborns found evidence that skin-to-skin contact results in: greater breastfeeding initiation and exclusivity, more rapid mother-infant interaction, earlier infant thermoregulation, decreased maternal and newborn stress reactivity/salivary cortisol levels, and reduction in newborn pain response during painful procedures (e.g. heel lances and vaccinations) (Cleveland et al., 2017).

A recent study examining in-hospital practices surround skin-to-skin contact reported that all centers and hospitals in their survey sample reported practicing skin-to-skin contact and 95% had policies in place

[18] Newborn falls refer to when an infant is dropped by another person or falls from a basinet, bed, or other surface. These are usually unintentional or accidental events.
[19] "Kangaroo care" is sometimes used to refer to skin-to-skin contact, but is clinically used when referring to preterm newborns or infants cared for in the NICU or other high-risk settings (WHO, 2003).

(Tyrala et al., 2021). All hospital locations with policies applied these practices in the delivery area following vaginal delivery, but only 55% of locations applied these policies immediately after a cesarean delivery, and 73% of locations applied these policies in the mother's room. More than two-thirds of the centers and hospitals reported over 80% of mothers experienced skin-to-skin contact immediately post-delivery. A delivery room nurse was given the responsibility to monitor the mother and infant immediately post-delivery almost all of the time (94%). Other health care providers or family members were also called upon to monitor the skin-to-skin contact. All centers that practiced skin-to-skin contact on the maternity floor reported providing mothers with strategies to help minimize the risk of falling asleep with the baby during skin-to-skin contact.

Newborn Falls

Falls among newborns in hospitals (sometimes called "drop events" or accidental/unintentional falls) are relatively rare, but sometimes serious, events. Falls are reported through hospitals' adverse event reporting systems and are not displayed in claims data through diagnosis codes. Studies have estimated that the number of newborn falls annually is between 160 and 1600 events throughout the United States (Helsley et al., 2010; Monson et al., 2008; Wallace, 2015). No California-specific estimates are available. However, applying the estimates developed by Helsley et al. (2010) that indicate rates of newborn falls are between 1.6 per 10,000 births and 4.1 per 10,000 births nationally, between 71 and 183 newborn falls could occur annually among the 446,479 births in California.[20] The number of reported falls is likely an undercount due to parental or practitioner hesitance to report falls and voluntary hospital reporting systems (Helsley et al., 2010).

Newborn falls in hospitals are more likely to occur between the hours of 12am and 7am, when the mother is feeding the newborn and falls asleep, as well as on the second or third night of a hospital stay (Ainsworth et al., 2013; Hughes Driscoll et al., 2019; Galuska, 2011; Helsley et al., 2010; Kahn et al., 2017; Monson et al., 2008; Ruddick et al., 2010; Wallace, 2015). Some studies report instances of newborn falls are also higher among women who delivered via cesarean (Galuska, 2011; Janiszweski, 2015), although this finding is not consistent (Loyal et al. 2018). Case reports from newborn falls indicate the outcomes of falls vary from no injuries to superficial injuries to skull fractures with potential adverse impacts such as related seizures (Helsley et al., 2010; Hughes Driscoll et al., 2019). Wallace (2015) determined falls occurring within the first 30 days of life result in serious harm 8.5% of the time using data from the Pennsylvania Patient Safety Reporting System. Wallace also found most falls (85.3%) occurred within the first four days of life. As mentioned above, studies and case reviews have found most newborn falls occur when the mother is feeding the newborn and falls asleep; other less common instances of newborn falls include when a family member holding the newborn falls asleep, during transport from basinets, incubators, or arms, or from the hands of a provider at birth (Carr et al., 2019)

One contributing factor to newborn falls is the hospital practice of rooming-in after a baby is born. Hospitals have moved away from housing newborns in nurseries away from the mother and instead place the newborn in a basinet in the mother's room, in part to encourage breastfeeding initiation (Carr et al., 2019). However, this practice potentially contributes to maternal fatigue and encourages breastfeeding on demand.

More information about fall-prevention strategies in hospitals is included in the *Medical Effectiveness* section.

Childbirth in California

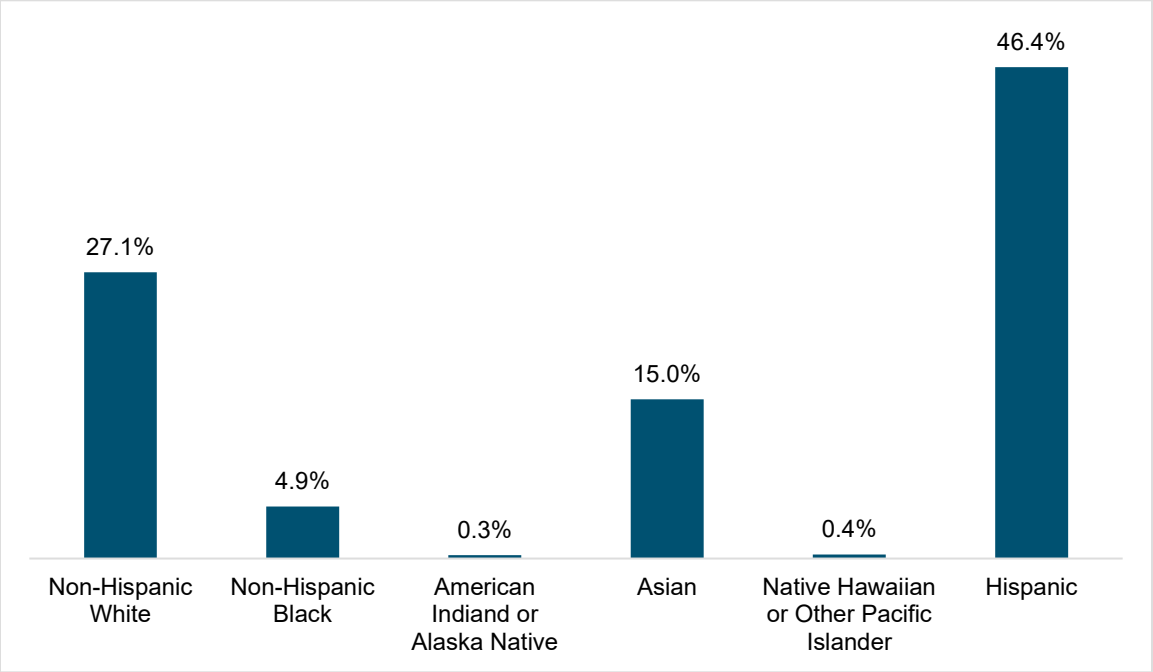
In 2019, there were 446,479 births in California (CDC, 2020). Medi-Cal pays for almost half of all births in California (45% in 2017) (Joynt, 2019). In 2017, there was a larger share of births among women with

[20] The number of newborn falls in California were estimated using the CDC reported number of births (446,479) in California in 2019 (CDC, 2020).

incomes below 200% of the federal poverty level (FPL) relative to the size of the population they represent (57% of births vs 42% of female population) (Joynt, 2019).

Almost half of births in California are among women of Hispanic origin (46.4), followed by non-Hispanic White women (27.1%) and Asian women (15%) (Martin et al., 2018).

Figure 1. Births in California by Race/Ethnicity, 2018



Source: California Health Benefits Review Program, 2021. Adapted from Martin et al., 2018.
Note: Race and Hispanic origin are reported separately on birth certificates; persons of Hispanic origin may be of any race.

Approximately 30.8% of deliveries in California in 2019 were cesarean deliveries (Hamilton et al., 2020). Rates of cesarean delivery differ by race/ethnicity. Among low-risk, first-birth cesarean deliveries in 2017, Black women were more likely (29.8%) to deliver via cesarean compared to Asian (25.6%), Latina (23.8%) or White (23.8%) women (Joynt, 2019).

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, SB 613 would require plans and policies with maternity benefits to cover neonate medical wraps following a cesarean delivery and, if a mother requests, after a natural birth.[21] Additional information about baby-wearing wraps is included in the *Background* section. The medical effectiveness review summarizes findings from evidence[22] on the impact of baby-wearing wraps on skin-to-skin contact and newborn falls. The review also summarizes literature on other interventions to prevent newborn falls.

As discussed in the *Background* section, a neonate medical wrap enables hands-free baby-wearing through use of compression fabric that securely holds the baby to an adult's chest. Other baby-wearing wraps perform similar functions but may use different fabric and may have different ways of attaching the adult and baby.

Baby-wearing wraps could increase the duration of skin-to-skin contact between newborns and parents because a wrap holds a newborn securely to a parent's chest, enabling the parent to rest their arms or use them for other purposes. As described in the *Background* section, a systematic review of studies of full-term newborns found that skin-to-skin contact increases breastfeeding initiation and exclusivity, which is associated with a variety of health benefits for children and mothers (CDC, 2021). The systematic review also found that skin-to-skin contact is associated with more rapid mother-infant interaction, earlier infant thermoregulation, decreased maternal and newborn stress reactivity, and reduction in newborn pain response during painful procedures (Cleveland et al., 2017).

Baby-wearing wraps could prevent newborn falls by holding the newborn securely to a mother's chest. This secure holding is especially important if a mother falls asleep while breastfeeding or holding the newborn.

Research Approach and Methods

Studies of relevant disease/condition were identified through searches of PubMed, the Cochrane Library, Web of Science, EMBASE, Scopus, and the Cumulative Index of Nursing and Allied Health Literature. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), the Scottish Intercollegiate Guideline Network, and the World Health Organization.

The search was limited to abstracts of studies published in English.

The search was limited to studies published from 2015 to present. Of the 69 articles found in the literature review, six were reviewed for potential inclusion in the medical effectiveness review for this report, and all of these were included. Two additional articles were identified through review of references cited in articles found in the literature search. The other articles were eliminated because they did not focus on baby-wearing wraps or prevention of newborn falls, were of poor quality, or did not report findings from clinical research studies. A more thorough description of the methods used to conduct the medical effectiveness review and the process used to grade the evidence for each outcome measure is presented in Appendix B.

[21] As mentioned in the Policy Context section, CHBRP assumes "natural birth" means vaginal delivery.
[22] Much of the discussion in this section is focused on reviews of available literature. However, as noted in the section on Implementing the Hierarchy of Evidence on page 11 of the *Medical Effectiveness Analysis and Research Approach* document (posted at http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php), in the absence of fully applicable to the analysis peer-reviewed literature on well-designed randomized controlled trials (RCTs), CHBRP's hierarchy of evidence allows for the inclusion of other evidence.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.[23] Unpublished studies are not reviewed because the results of such studies, if they exist, cannot be obtained within the 60-day timeframe for CHBRP reports.

Key Questions

1. Do baby-wearing wraps increase skin-to-skin contact between newborns and parents?
2. Do baby-wearing wraps prevent newborn falls?
3. Is there evidence that other alternatives for preventing newborn falls are effective?

Methodological Considerations

The literature review did not identify any studies of the AEGIS Neonate Medical Wrap or of similar wraps. Only a few studies of other baby wraps were identified.

Studies of other interventions to prevent newborn falls did not compare these interventions to use of baby wraps.

Outcomes Assessed

The Medical Effectiveness review examined the impact of baby wraps on two outcomes that could be affected by their use.

- The amount of skin-to-skin contact between newborns and parents
- The prevalence of newborn falls

The Medical Effectiveness review also assessed whether there is any evidence of harms associated with baby wraps.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of baby-wearing wraps. Each section is accompanied by a corresponding figure. The title of the figure indicates the test, treatment, or service for which evidence is summarized. The statement in the box above the figure presents CHBRP's conclusion regarding the strength of evidence about the effect of a particular test, treatment, or service based on a specific relevant outcome and the number of studies on which CHBRP's conclusion is based. Definitions of CHBRP's grading scale terms is included in the box below, and more information is included in Appendix B.

The following terms are used to characterize the body of evidence regarding an outcome:

Clear and convincing evidence indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

[23] Grey literature consists of material that is not published commercially or indexed systematically in bibliographic databases. For more information on CHBRP's use of grey literature, visit http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

Preponderance of evidence indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

Limited evidence indicates that the studies have limited generalizability to the population of interest and/or the studies have a fatal flaw in research design or implementation.

Inconclusive evidence indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

Insufficient evidence indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

More information is available in Appendix B.

Impact of Baby Wraps on Skin-to-Skin

CHBRP did not identify any studies of the AEGIS Neonate Medical Wrap or of similar wraps.

CHBRP identified three studies of other customized baby wraps (Amaliya et al., 2017; Chavula et al., 2020; Thapa et al., 2018). All three studies were conducted in developing countries (Indonesia, Malawi, and Nepal), and they compared baby wraps that were designed specifically for skin-to-skin contact with traditional wraps that mothers in these countries use to hold infants.

The study conducted in Indonesia compared three types of baby wraps (i.e. pouch, customized wrap, and traditional wrap). The authors found no statistically significant differences in mothers' level of comfort when using the three types of wraps to while providing their newborns with skin-to-skin contact. (Amaliya et al., 2017).

Two of the studies assessed the impact of baby wraps on the duration of skin-to-skin contact (Chavula et al., 2020; Thapa et al., 2018). The study conducted in Nepal enrolled 96 mothers and low birthweight infants who were delivered vaginally. The mothers tested a traditional wrap and a customized wrap, designed specifically for skin-to-skin contact, for six hours each. The traditional wrap was a three-meter-long, thick, flannel cloth that at least one person other than the wearer had to help tie and untie. The customized wrap, known as CarePlus,[24] was designed so that the wearer could tie it on himself or herself. Mother-and-infant dyads were sequentially assigned to try either the traditional or ergonomic wrap first, to reduce the risk that findings would be affected by the order in which the wraps were tested. At the end of the trial period, mothers selected one of the two wraps and were encouraged to use it to care for their newborns at home. Families' use of the wraps was tracked for four weeks post-discharge. The authors found that mothers who selected the customized wrap provided skin-to-skin contact for more hours than mothers who selected the traditional wrap (429.1 vs. 351.7 hours), but the difference was not statistically significant. The number of hours of skin-to-skin contact per day decreased over time in both groups, but decreased less rapidly among mothers using the customized wrap – although this difference was also not statistically significant (Thapa et al., 2018).

The study conducted in Malawi randomized 301 mothers and low birthweight infants to receive either the CarePlus customized wrap or a traditional *chitenje* wrap made of a long piece of cotton cloth. Mother-infant dyads were followed for up to 15 days post-discharge. Mothers who received the customized wrap were more likely to report providing skin-to-skin contact for 20 or more hours per day while hospitalized; this is a statistically significant difference to mothers who received the traditional wrap (i.e. 44% vs. 33%). Following hospital discharge, there were no differences in daily duration of skin-to-skin contact between

[24] A description of the CarePlus wrap can be found on the website of the organization that developed it. https://laerdalglobalhealth.com/products/careplus/

the two groups. Rates of breastfeeding initiation also did not differ between the two groups (Chavula et al., 2020).

Summary of findings regarding the impact of baby wraps on skin-to-skin contact: There is insufficient evidence from one randomized controlled trial (RCT) that enrolled 301 mother-infant dyads that use of customized baby wraps is associated with more hours of skin-to-skin contact between newborns and mothers while hospitalized. Although this study was an RCT, the generalizability of this finding to the AEGIS Neonate Medical Wrap is unknown because it assessed a different customized baby wrap and was conducted in a developing country. There is inconclusive evidence from two studies that enrolled 397 mother-infant dyads regarding the impact of customized baby wraps on hours of skin-to-skin contact after the mother and newborn are discharged from a hospital. One study found that using a customized wrap was associated with more hours of skin-to-skin contact post-discharge but the difference was not statistically significant; the other study found no difference. As with the finding regarding effects on hours of skin-to-skin contact during hospitalization, findings regarding skin-to-skin contact after hospital discharge may not be generalizable to use of the AEGIS Neonate Medical Wrap or to similar wraps in the United States.

Figure 2. Impact of Baby Wraps on Skin-to-Skin Contact in Hospitals



Figure 3. Impact of Baby Wraps on Skin-to-Skin Contact Following Hospital Discharge



Impact of Baby Wraps on Newborn Falls

None of the three studies of baby wraps that CHBRP identified examined the impact of baby wraps on newborn falls.

Summary of findings regarding the impact of baby wraps on newborn falls: There is insufficient evidence to determine whether use of baby wraps prevents newborn falls. Insufficient evidence indicates that there is not enough evidence available to know whether baby wraps prevent newborn falls. It does not indicate that baby wraps are not effective for preventing newborn falls.

Figure 4. Impact of Baby Wraps on Newborn Falls



Harms of Baby Wraps

CHBRP did not identify any studies that examined whether there are any harms associated with baby wraps.

A potential harm of the AEGIS Neonate Medical Wrap is the use of X-Static® Silver Technology in the fabric. Use of this technology is intended to protect from bacteria and fungus that can lead to odor and stains. While protecting newborns from microbes on health professionals who care for them is important, use of this technology could limit newborns' ability to colonize helpful bacteria from their mothers. Reduced exposure to mother's microbes is of particular concern for children delivered by cesarean section because, unlike children delivered vaginally, they are not exposed to microbes in the birth canal. A meta-analysis has found that children delivered by cesarean section are at elevated risk for developing allergic rhinitis and asthma (Bager et al. , 2008).

Summary of findings regarding harms associated with baby wraps: There is insufficient evidence to determine whether there are any harms associated with baby wraps. Insufficient evidence indicates that there is not enough evidence available to know whether or not there are any harms associated with baby wraps. It does not indicate that there are no harms associated with baby wraps.

Figure 5. Harms Associated with Baby Wraps



Impacts of Other Interventions to Prevent Newborn Falls

CHBRP identified five articles that describe other interventions that three hospitals (Ainsworth et al., 2016; Galuska, 2011; Lipke et al., 2018) and two multi-hospital systems (Carr et al., 2019; Helsley et al., 2010) have implemented to prevent newborn falls. These interventions encompass educating health professionals, parents, and family members about fall prevention; safety contracts; monitoring mothers more closely; moving newborns to bassinets if mother falls asleep; lowering mothers' beds; and lifting side rails during feeding. Four of these studies reported that newborn falls decreased after the interventions were implemented (Ainsworth et al. 2018; Carr et al., 2019). However, the numbers of falls that occurred before and after implementation were so small that no statistically significant differences could be detected. In addition, the interventions were implemented for all mothers giving birth in the hospitals, which prevented the authors from ruling out the possibility that the decreases were due to other factors that changed over time.

Summary of findings regarding other interventions to prevent newborn falls: There is insufficient evidence to determine whether other interventions to prevent newborn falls, such as patient safety contracts and more frequent monitoring of mothers, reduce falls. Insufficient evidence indicates that there is not enough evidence available to know whether or not other interventions to prevent newborn falls are effective, either because there are too few studies of the screening, or because the available studies are not of high quality. It does not indicate that these interventions are not effective.

Summary of Findings

CHBRP did not identify any studies of the efficacy of AEGIS Neonate Medical Wrap or of similar wraps. One study of another customized baby wrap suggest that use of these wraps is associated with longer duration of skin-to-skin contact between mothers and newborns while in the hospital but the findings may not be generalizable to AEGIS Neonate Medical Wrap or to other similar wraps because the study assessed a different customized baby wrap and was conducted in a developing country. CHBRP did not identify any studies of the impact of customized baby wraps on newborn falls.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, SB 613 would require health plans and health policies regulated by the Department of Managed Health Care (DMHC) or the California Department of insurance (CDI) to cover neonate medical wraps following a cesarean delivery and, if the mother requests, after a natural birth.[25]

In addition to commercial enrollees, more than 50% of enrollees associated with the California Public Enrollees' Retirement System (CalPERS) and more than 70% of Medi-Cal beneficiaries are enrolled in DMHC-regulated plans.[26] As noted in the *Policy Context* section, AB 613 would impact these CalPERS enrollees' and Medi-Cal beneficiaries' benefit coverage.

This section reports the potential incremental impacts of AB 613 on estimated baseline benefit coverage, utilization, and overall cost. SB 613 does not provide a definition of "neonate medical wraps", which creates uncertainty as to how the regulators (DMHC and CDI) would interpret coverage requirements related to this bill. Due to the lack of claims or utilization data and the uncertainty regarding how these wraps would be reimbursed, CHBRP has provided two illustrative examples of potential impacts: the first demonstrates impacts if the wraps are included in the global payment for maternity services; the second demonstrates potential impacts if the wraps are classified as durable medical equipment (DME) and eligible for separate reimbursement.

For further details on the underlying data sources and methods used in this analysis, please see Appendix C.

It is possible some hospitals are already providing these wraps to women who deliver in their hospitals; however, CHBRP is unable to determine the frequency at which this occurs. CHBRP assumes that 100% of enrollees would have benefit coverage for the neonate medical wraps postmandate.

Baseline and Postmandate Per-Unit Cost

The AEGIS Neonate Medical Wrap is sold directly through their website for $98.[27] CHBRP assumes hospitals would negotiate a discounted purchase price of $80 for commercial and CalPERS enrollees.[28] The unit cost would not change postmandate.

If the wraps are billed as DME and therefore eligible for a separate reimbursement, CHBRP assumes the reimbursement rate for wraps provided to Medi-Cal managed care beneficiaries would be $40 (see Table 1).[29]

Baseline and Postmandate Utilization

It is important to note that benefit coverage does not equate to utilization. Although these wraps may be newly covered postmandate, hospitals would still need to purchase the wraps, train hospital staff, and

[25] As mentioned in the Policy Context section, CHBRP assumes "natural birth" means vaginal delivery.
[26] For more detail, see CHBRP's *Estimates of Sources of Health Insurance in California for 2021*, a resource available at: http://chbrp.org/other_publications/index.php.
[27] According to information at: https://saplacor.com/products/aegis-neonate-medical-wrap
[28] This assumption is supported by a 2019 news article that stated Saplacor sells the neonate medical wrap to hospitals for $79. The article is available at: https://verticalmag.com/news/neonate-medical-wrap-finding-uses-in-patient-transport/.
[29] This assumption is in line with the reimbursement ratio for health care services between Medicare and Medicaid rates. Kaiser Family Foundation, Medicaid to Medicare Fee Index. Available at: https://www.kff.org/medicaid/state-indicator/medicaid-to-medicare-fee-index/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

actively provide them to patients. Patients would also need to initiate use of the wraps if they are in their hospital room without a medical provider. Rates of use would likely be dependent upon ease of use and patient satisfaction.

Due to the lack of literature surrounding neonate medical wraps, CHBRP is unable to make an assumption regarding utilization postmandate. However, to illustrate potential impacts of SB 613, CHBRP discusses impacts if 100% of women who have a cesarean delivery (67,835 women) and 50% of women who deliver vaginally (74,765 women) use the wraps while in the hospital (see Table 1). CHBRP presents estimates of 50% of women who deliver vaginally using the wrap postmandate, because the bill language states these women would receive coverage of the wrap if they request one.

Among women with coverage through DMHC-regulated plans and CDI-regulated policies, including Medi-Cal managed care beneficiaries, there are approximately 217,364 deliveries (see Table 1). Approximately 31% of births are cesarean deliveries and almost 40% of births are covered by Medi-Cal managed care plans. CHBRP calculated average utilization for vaginal and caesarian section deliveries from 2019 Milliman Consolidated Health Cost Guidelines Source Database Plus (CHSD+).

Scenario 1: Reimbursement for Wraps is Included in Global Payments for Maternity Services

Should the wraps be included in the global payment for maternity services, CHBRP would not expect an increase in expenditures due to SB 613 in the first year postmandate. In the future, hospitals could negotiate for higher global payment rates for deliveries to include the cost of providing wraps to eligible enrollees.

Scenario 2: Wraps are Classified as Durable Medical Equipment and Billed Separately

Should the wraps be classified as DME and subject to a separate charge, hospitals would be able to bill plans and policies for $80 or $40, depending on whether the patient is enrolled in a commercial or CalPERS plan or policy or a Medi-Cal managed care plan. In order for an item to be classified as DME, hospitals would need to indicate the wrap is intended primarily for home use and not hospital use.

Baseline and Postmandate Expenditures

Should the wraps be classified as DME and subject to a separate charge, SB 613 would increase total net annual expenditures by $10,463,000 or 0.01% for enrollees with DMHC-regulated plans and CDI-regulated policies. This is due to a $9,539,000 increase in total health insurance premiums paid by employers, CalPERS, and Medi-Cal, and enrollees for newly covered benefits, plus an increase of $924,000 in enrollee expenses for covered benefits. Total premiums for commercial and CalPERS payers and enrollees would increase by $6,981,000 and total premiums for Medi-Cal managed care plans would increase by $2,558,000 (see Table 1).

Enrollee Expenses

Due to new coverage, CHBRP estimates that cost sharing for enrollees who use the neonate medical wrap would increase by $924,000 (see Table 1). Enrollees with coverage through commercial and CalPERS plans and policies would have an average cost share of $10.95 per wrap, if wraps are considered DME. Some enrollees may hit their out-of-pocket maximum due to other medical services, including vaginal or cesarean deliveries, and therefore would not be responsible for the cost share associated with the neonate medical wrap. These enrollees are more likely to have high deductibles and have coinsurance (versus copayment) requirements.

Enrollees with coverage through Medi-Cal managed care plans would not have associated cost sharing for the wraps due to existing plan designs.

Potential Cost Offsets or Savings in the First 12 Months After Enactment

CHBRP does not project any cost offsets or savings in health care that would result because of the enactment of provisions in SB 613. While it is possible that use of the neonate medical wraps improves rates of skin-to-skin contact or decreases the number of newborn falls, CHBRP is unable to quantify the fiscal impacts of these changes due to lack of evidence about the effectiveness of these wraps. As discussed in the *Background* section, newborn falls result in serious injury 8.5% of the time. For the cases that are averted, CHBRP would expect to see a reduction in expenditures related to evaluating and treating the injuries caused by a fall.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of DMHC-regulated plans and/or CDI-regulated policies will remain proportional to the increase in premiums. CHBRP assumes that if health care costs increase as a result of increased utilization or changes in unit costs, there is a corresponding proportional increase in administrative costs. CHBRP assumes that the administrative cost portion of premiums is unchanged. All health plans and insurers include a component for administration and profit in their premiums.

Other Considerations for Policymakers

In addition to the impacts a bill may have on benefit coverage, utilization, and cost, related considerations for policymakers are discussed below.

Potential Cost of Exceeding Essential Health Benefits

As explained in the *Policy Context* section, neonate medical wraps are not included in California's EHB package. The state is required to defray the additional cost incurred by enrollees in qualified health plans (QHPs) for any state benefit mandate that exceeds the state's definition of essential health benefits (EHBs). Coverage for neonate medical wraps, as would be required if SB 613 were enacted, *could* trigger this requirement and so require the state to defray related costs.

Postmandate Changes in the Number of Uninsured Persons

Because the change in average premiums does not exceed 1% for any market segment (see Table 1), CHBRP would expect no measurable change in the number of uninsured persons due to the enactment of SB 613.

Changes in Public Program Enrollment

CHBRP estimates that the mandate would produce no measurable impact on enrollment in publicly funded insurance programs due to the enactment of SB 613.

How Lack of Benefit Coverage Results in Cost Shifts to Other Payers

Baby wearing is common for many women with newborns. Many women in the United States purchase special baby-wearing wraps or carriers for personal use. It is unknown how many of these women bring wraps with them to the hospital for use during the inpatient stay. If women are allowed to take home the neonate medical wraps, it is possible women who may not have purchased or been able to afford to

purchase a wrap for use during the neonate period would now have access to free (or low-cost) wraps.

Table 1. SB 613 Impacts on Benefit Coverage, Utilization, and Cost, 2022 (Assuming Neonate Medical Wraps are Billed as DME)

	Baseline (2022)	Postmandate Year 1 (2022)	Increase/ Decrease	Change Postmandate
Utilization and Cost				
Number of deliveries				
C-Section	67,835	67,835	0	0.00%
Vaginal	149,529	149,529	0	0.00%
Total number of deliveries	217,364	217,364	0	0.00%
Number of enrollees using neonate medical wrap in the hospital, by delivery method				
C-Section	-	67,835	67,835	100.00%
Vaginal	-	74,765	74,765	100.00%
Total number of enrollees using neonate medical wraps	-	142,600	142,600	100.00%
Average cost of neonate medical wrap per enrollee (f)				
Commercial, CalPERS enrollees (g)	$80.00	$80.00	$0.00	0.00%
Medi-Cal enrollees	$40.00	$40.00	$0.00	0.00%
Average neonate medical wrap cost share per enrollee (f)				
Commercial, CalPERS enrollees (g)	-	$10.95	$10.95	100.00%
Medi-Cal enrollees	-	$0.00	$0.00	0.00%
Expenditures				
Enrollee / Payer premium (expenditures)				
Commercial, CalPERS Premiums for enrollees and payers (b) (c)	$97,398,773,000	$97,405,754,000	$6,981,000	0.01%
Medi-Cal Managed Care Plan expenditures	$24,150,529,000	$24,153,087,000	$2,558,000	0.01%
Enrollee out-of-pocket expenses				
Cost sharing for covered benefits (deductibles, copayments, etc.)	$13,168,032,000	$13,168,956,000	$924,000	0.01%
Expenses for noncovered benefits (d) (e)	$0	$0	$0	0.00%
Total Expenditures	$134,717,334,000	$134,727,797,000	$10,463,000	0.01%

Source: California Health Benefits Review Program, 2021.
Notes: (a) Enrollees in plans and policies regulated by DMHC or CDI aged 0 to 64 years as well as enrollees 65 years or older in employer-sponsored health insurance. This group includes commercial enrollees (including those associated with Covered California or CalPERS) and Medi-Cal beneficiaries enrolled in DMHC-regulated plans.

(b) Of the increase in CalPERS employer expenditures, about 54.1% or $205,000 would be state expenditures for CalPERS members who are state employees or their dependents.

(c) Enrollee premium expenditures include contributions by employees to employer-sponsored health insurance, health insurance purchased through Covered California, and contributions to Medi-Cal Managed Care

(d) Includes only expenses paid directly by enrollees (or other sources) to providers for services related to the mandated benefit that are not covered by insurance at baseline. This only includes those expenses that will be newly covered postmandate. Other components of expenditures in this table include all health care services covered by insurance.

(e) Although enrollees with newly compliant benefit coverage may have paid for some neonate medical wraps before SB 613, CHBRP cannot estimate the frequency with which such situations may have occurred and therefore cannot estimate the related expense. Postmandate, such expenses would be eliminated, though enrollees with newly compliant benefit coverage might, postmandate, pay for some neonate wraps for which coverage is denied (through utilization management review), as some enrollees who always had compliant benefit coverage may have done and may continue to do, postmandate.

(f) The costs impact illustrated here assumes the neonatal wrap is billed separately from the inpatient bundle as DME.

(g) The cost sharing for neonatal wrap is estimated by applying the effective coinsurance by line of business. Some enrollees may have reached their out-of-pocket maximum, resulting in $0 cost sharing.

Key: CalPERS HMOs = California Public Employees' Retirement System Health Maintenance Organizations; CDI = California Department of Insurance; DME = durable medical equipment; DMHC = Department of Managed Health

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, SB 613 would mandate coverage of neonate medical wraps following a cesarean delivery and, at the mother's request, following a vaginal delivery.

The public health impact analysis includes estimated impacts in the short term (within 12 months of implementation) and in the long term (beyond the first 12 months postmandate). This section estimates the short-term impact[30] of SB 613 on rates of skin-to-skin contact and newborn falls. See *Long-Term Impacts* for discussion of impacts beyond the first 12 months.

Estimated Public Health Outcomes

Measurable health outcomes relevant to SB 613 include rates of skin-to-skin contact and number of newborn falls.

As presented in *Medical Effectiveness,* there is:

- Insufficient evidence that use of customized baby wraps is associated with more hours of skin-to-skin contact between newborns and mothers while hospitalized; and
- Insufficient evidence to determine whether neonate medical wraps contribute to a reduction in newborn falls.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, depending on how the wraps are billed by hospitals, the wraps could be included in the global payment for hospital deliveries, or they could be billed as durable medical equipment (DME) for at home use. If the wraps are billed as part of the global payment, there are no immediate cost expenditure impacts. However, the hospitals could negotiate for a higher global payment in the future. If the wraps are billed as part of DME, expenditures could increase by as much as $10,463,000, assuming the wraps are used during 100% of cesarean deliveries and 50% of vaginal deliveries.

Barriers to Skin-to-Skin Contact After Cesarean Delivery

As mentioned in the *Background* section, rates of skin-to-skin contact are lower immediately following cesarean delivery compared to vaginal delivery. Reasons for this difference may be due to challenges surrounding safety of the newborn (e.g. fall prevention and thermoregulation), nurse staffing, and logistics (e.g. ability to safely monitor skin-to-skin contact with unobstructed views) (Balatero et al., 2019). It is unknown whether providing neonate medical wraps to all women who have cesarean deliveries would increase rates of skin-to-skin contact immediately following delivery.

Newborn Fall Prevention in Hospital Settings

As described in the *Medical Effectiveness* section, strategies to reduce newborn falls in hospitals include safety contracts, educating health professionals, parents and family members about fall prevention, monitoring mothers more closely, moving newborns to bassinets if mother falls asleep, lowering mothers' beds, and lifting side rails during feeding.

It is unknown whether wraps used in a hospital setting would lead to fewer numbers of newborn falls.

[30] CHBRP defines short-term impacts as changes occurring within 12 months of bill implementation.

In the first year postmandate, the public health impact of SB 613 is unknown due to insufficient evidence regarding the use of neonate medical wraps. Please note that the absence of evidence is not "evidence of no effect." It is possible that an impact — desirable or undesirable — could result, but current evidence is insufficient to inform an estimate.

However, it stands to reason that should a neonate medical wrap help prevent a newborn fall, the newborn would avoid potentially suffering adverse health outcomes and parents would not experience anxiety related to the fall. Similarly, should use of the wrap encourage earlier skin-to-skin contact between mother and newborn, improved outcomes could include earlier maternal-child bonding, earlier thermoregulation, decreased maternal and newborn stress reactivity, and reduction in newborn pain response during painful procedures. The degree to which improvements in these outcomes would occur is unknown.

Impact on Disparities[31]

Insurance benefit mandates that bring more state-regulated plans and policies to parity may change an existing disparity. As described in the *Background* section, disparities in childbirth rates and rates of cesarean delivery exist by race/ethnicity and income. Rates of newborn falls by race/ethnicity or income are unknown. CHBRP estimates SB 613 would not change these disparities in the first 12 months postmandate. (For a discussion of potential impacts beyond the first 12 months of implementation [including SDOH], see *Long-Term Impacts*.)

However, for women who may be unable to afford a similar baby-wearing wrap for home use who now receive coverage of a wrap, use of wraps and corresponding rates of baby wearing (whether used for skin-to-skin contact or other reasons) may increase.

[31] For details about CHBRP's methodological approach to analyzing disparities, see the *Benefit Mandate Structure and Unequal Racial/Ethnic Health Impacts* document here: http://chbrp.com/analysis_methodology/public_health_impact_analysis.php.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of SB 613, which CHBRP defines as impacts occurring beyond the first 12 months after implementation. These estimates are qualitative and based on the existing evidence available in the literature. CHBRP does not provide quantitative estimates of long-term impacts because of unknown improvements in clinical care, changes in prices, implementation of other complementary or conflicting policies, and other unexpected factors.

Long-Term Utilization and Cost Impacts

Utilization Impacts

Utilization of neonate medical wraps is expected to be similar in the long term as to utilization in the first 12 months postmandate. However, should knowledge of coverage of neonate medical wraps increase, more women who deliver vaginally may request a wrap while in the hospital, thereby increasing overall utilization. Similarly, patient satisfaction and ease of use of the wraps may influence utilization of the wraps after the first experience.

Cost Impacts

Cost impacts are expected to also be similar to those projected in the first 12 months postmandate. As mentioned in the *Benefit Coverage, Utilization, and Cost Impacts* section, hospitals may be able to negotiate higher global payments for maternity services in future years in order to account for the increased cost of providing wraps to patients. Similarly, should more women who deliver vaginally request a wrap while in the hospital, expenditures would be expected to increase proportionally.

Long-Term Public Health Impacts

Some interventions in proposed mandates provide immediate measurable impacts (e.g., maternity service coverage or acute care treatments), whereas other interventions may take years to make a measurable impact (e.g., coverage for tobacco cessation or vaccinations). When possible, CHBRP estimates the long-term effects (beyond 12 months postmandate) to the public's health that would be attributable to the mandate, including impacts on social determinants of health, premature death, and economic loss.

Due to insufficient evidence of the effectiveness of neonate medical wraps, the long-term public health impact is unknown. As mentioned in the *Public Health* section, it is possible SB 613 would result in increased rates of skin-to-skin contact in hospitals and improvements in related health outcomes, as well as reductions in newborn falls. However, due to the lack of evidence, CHBRP is unable to project these changes.

APPENDIX A TEXT OF BILL ANALYZED

On February 19, 2021, the California Senate Committee on Health requested that CHBRP analyze SB 613.

SENATE BILL **NO. 613**

Introduced by Senator Limón

February 18, 2021

An act to add Section 1367.621 to the Health and Safety Code, and to add Section 10123.875 to the Insurance Code, relating to maternal health.

LEGISLATIVE COUNSEL'S DIGEST

SB 613, as introduced, Limón. Maternal health: neonate medical wrap.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law imposes certain requirements on health care service plans and health insurance policies that provide maternity coverage, including requiring those plans and policies to provide inpatient hospital care to a mother for no less than less than 48 hours following a normal vaginal delivery and no less than 96 hours following a delivery by caesarean section, except as specified.

This bill would require a health care service plan or health insurance policy issued, amended, or renewed on or after January 1, 2022, that provides maternity coverage, to include coverage for a neonate medical wrap following a cesarean section delivery, and, if requested by the mother, to include coverage for a neonate medical wrap following a natural birth.

Because a willful violation of the bill's requirement by a health care service plan would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority Appropriation: no Fiscal Committee: yes Local Program: yes

THE PEOPLE OF THE STATE OF CALIFORNIA DO ENACT AS FOLLOWS:

SECTION 1. Section 1367.621 is added to the Health and Safety Code, immediately following Section 1367.62, to read:

1367.621. A health care service plan issued, amended, or renewed on or after January 1, 2022, that provides maternity coverage, shall include coverage for a neonate medical wrap following a cesarean section delivery, and, if requested by the mother, shall include coverage for a neonate medical wrap following a natural birth.

SEC. 2. Section 10123.875 is added to the Insurance Code, immediately following Section 10123.87, to read:

10123.875. A health insurance policy issued, amended, or renewed on or after January 1, 2022, that provides maternity coverage, shall include coverage for a neonate medical wrap following a cesarean section delivery, and, if requested by the mother, shall include coverage for a neonate medical wrap following a natural birth.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

APPENDIX B LITERATURE REVIEW METHODS

This appendix describes methods used in the literature review conducted for this report. A discussion of CHBRP's system for medical effectiveness grading evidence, as well as lists of MeSH Terms, publication types, and keywords, follows.

Studies of relevant disease/condition were identified through searches of PubMed, the Cochrane Library, Web of Science, EMBASE, Scopus, and the Cumulative Index of Nursing and Allied Health Literature. Websites maintained by the following organizations that produce and/or index meta-analyses and systematic reviews were also searched: the Agency for Healthcare Research and Quality (AHRQ), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), the Scottish Intercollegiate Guideline Network, and the World Health Organization.

Medical Effectiveness Review

The search was limited to studies published from 2015 to present. Of the 69 articles found in the literature review, six were reviewed for potential inclusion in the medical effectiveness review for this report and all were included. Two additional articles were identified through review of references cited in articles found in the literature search.

Medical Effectiveness Evidence Grading System

In making a "call" for each outcome measure, the medical effectiveness lead and the content expert consider the number of studies as well the strength of the evidence. Further information about the criteria CHBRP uses to evaluate evidence of medical effectiveness can be found in CHBRP's *Medical Effectiveness Analysis Research Approach*.[32] To grade the evidence for each outcome measured, the team uses a grading system that has the following categories:

- Research design;
- Statistical significance;
- Direction of effect;
- Size of effect; and
- Generalizability of findings.

The grading system also contains an overall conclusion that encompasses findings in these five domains. The conclusion is a statement that captures the strength and consistency of the evidence of an intervention's effect on an outcome. The following terms are used to characterize the body of evidence regarding an outcome:

- *Clear and convincing evidence;*
- *Preponderance of evidence;*
- *Limited evidence;*
- *Inconclusive evidence;* and
- *Insufficient evidence.*

A grade of *clear and convincing evidence* indicates that there are multiple studies of a treatment and that the large majority of studies are of high quality and consistently find that the treatment is either effective or not effective.

[32] Available at: http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php.

A grade of *preponderance of evidence* indicates that the majority of the studies reviewed are consistent in their findings that treatment is either effective or not effective.

A grade of *limited evidence* indicates that the studies had limited generalizability to the population of interest and/or the studies had a fatal flaw in research design or implementation.

A grade of *inconclusive evidence* indicates that although some studies included in the medical effectiveness review find that a treatment is effective, a similar number of studies of equal quality suggest the treatment is not effective.

A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, either because there are too few studies of the treatment or because the available studies are not of high quality. It does not indicate that a treatment is not effective.

Search Terms (* indicates truncation of word stem)

- Accidental Falls/prevention & control
- AEGIS
- Cesarean
- Cesarean Section
- Delivery, Obstetric
- Disparities
- Disparity
- Ethnicity
- Fall Prevention
- Frog Legged
- Health Disparities
- Health Outcomes
- Healthcare Disparities
- In hospital Falls
- Incidence
- Income
- Infant Care
- Infant, Newborn
- Kangaroo Mother Care Method
- Long Term Effects
- Maternal Health
- Mental Health
- Morbidity
- Mortality
- Neonate Medical Wraps
- Newborn Drop
- Newborn Falls
- Newborn Safety Bundle
- Patient Care Bundles
- Patient Education
- Patient Positioning
- Patient Safety
- Postnatal Care
- Prevalence
- Prevention
- Proper positioning
- Quality of Health Care
- Race
- Racial and Ethic disparities
- Racial Inequities
- Rooming in Care
- Safe Sleep
- Safety Management
- Saplacor
- Skin to Skin Care
- Skin to Skin Contact
- Sleep
- Suffocation
- Vaginal Delivery

APPENDIX C COST IMPACT ANALYSIS: DATA SOURCES, CAVEATS, AND ASSUMPTIONS

With the assistance of CHBRP's contracted actuarial firm, Milliman, Inc, the cost analysis presented in this report was prepared by the faculty and researchers connected to CHBRP's Task Force with expertise in health economics.[33] Information on the generally used data sources and estimation methods, as well as caveats and assumptions generally applicable to CHBRP's cost impacts analyses are available at CHBRP's website.[34]

This appendix describes analysis-specific data sources, estimation methods, caveats, and assumptions used in preparing this cost impact analysis.

Analysis-Specific Data Sources, Caveats, and Assumptions

Assumptions for Baseline Benefit Coverage

- The population subject to the mandated offering includes individuals covered by DMHC-regulated commercial insurance plans, CDI-regulated policies, and publicly funded plans (including CalPERS and Medi-Cal) subject to the requirements of the Knox-Keene Health Care Service Plan Act.

Assumptions for Baseline Benefit Utilization and Cost

- The utilization data for the maternal deliveries are drawn primarily from multiple sources of data used in producing the Milliman Health Cost Guidelines (HCGs). The HCGs are a health care pricing tool used by actuaries in many of the major health plans in the United States. The guidelines provide a flexible but consistent basis for estimating health care costs for a wide variety of commercial health insurance plans. The HCGs are used nationwide and by several California HMOs and insurance companies, including at least five of the largest plans. Average utilization for vaginal and caesarian section deliveries are calculated from 2019 Milliman Consolidated Health Cost Guidelines Source Database Plus (CHSD+) and include the professional and facilities claims associated with each admission.
- No neonate medical wrap was assumed to be used after maternal deliveries in the baseline scenario.

Assumptions for Post-Mandate Benefit Utilization and Cost

- The cost estimates presented assumes the neonate wrap is billed separately from the inpatient bundle as a durable medical equipment.
- The bill mandates coverage for a neonate medical wrap following a cesarean section delivery and includes, if requested by the mother, coverage for a neonate wrap following a vaginal birth. CHBRP assumes 100% of cesarean section deliveries use a neonate wrap, while 50% of vaginal deliveries use a neonate wrap.
- CHBRP assumes hospitals will be reimbursed approximately $80 for commercial and CalPERS plans and $40 for Medi-Cal plans for each neonate wrap.

[33] CHBRP's authorizing statute, available at https://chbrp.org/about_chbrp/index.php, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.
[34] See method documents posted at http://chbrp.com/analysis_methodology/cost_impact_analysis.php; in particular, see *2022 Cost Analyses: Data Sources, Caveats, and Assumptions*.

- The effective cost-share was estimated by regulator and line of business. Each enrollee using neonate wrap is assumed to pay effective cost-share corresponding to their line of business.
- Baseline utilization was trended from 2019 to 2022 at an annual rate of 1.0%, which is based on the outpatient facilities trend from the Milliman Health Cost Guidelines.
- Post-mandate coverage for neonate wrap was assumed to be 100% of enrollees subject to SB 613.

Medical Device Code L0621

The bill sponsors suggested to CHBRP that neonate medical wraps would be covered under the medical device code L0621. CHBRP looked into this code and, in consultation with experts on medical devices and durable medical equipment, determined that neonate medical wraps are unlikely to fall under this code.

The long descriptor of the L0621 code is: Sacroiliac orthosis, flexible, provides pelvic-sacral support, reduces motion about the sacroiliac joint, includes straps, closures, may include pendulous abdomen design, prefabricated, off-the-shelf. This particular code describes a brace that is used to reduce motion of the sacroiliac joint, typically for people with sacroiliac joint pain on the sides of the lower back where it joins the hipbones. The image to the right is of a product described by the code.



Determining Public Demand for the Proposed Mandate

CHBRP was unable to determine whether there is public demand for coverage of neonate medical wraps.

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CALIFORNIA HEALTH BENEFITS REVIEW PROGRAM COMMITTEES AND STAFF

A group of faculty, researchers, and staff complete the analysis that informs California Health Benefits Review Program (CHBRP) reports. The CHBRP **Faculty Task Force** comprises rotating senior faculty from University of California (UC) campuses. In addition to these representatives, there are other ongoing researchers and analysts who are **Task Force Contributors** to CHBRP from UC that conduct much of the analysis. The **CHBRP staff** coordinates the efforts of the Faculty Task Force, works with Task Force members in preparing parts of the analysis, and manages all external communications, including those with the California Legislature. As required by CHBRP's authorizing legislation, UC contracts with a certified actuary, **Milliman**, to assist in assessing the financial impact of each legislative proposal mandating or repealing a health insurance benefit.

The **National Advisory Council** provides expert reviews of draft analyses and offers general guidance on the program to CHBRP staff and the Faculty Task Force. CHBRP is grateful for the valuable assistance of its National Advisory Council. CHBRP assumes full responsibility for the report and the accuracy of its contents.

Faculty Task Force

Timothy T. Brown, PhD, University of California, Berkeley
Janet Coffman, MA, MPP, PhD, Vice Chair for Medical Effectiveness, University of California, San Francisco
Sylvia Guendelman, PhD, LCSW, University of California, Berkeley
Gerald Kominski, PhD, University of California, Los Angeles
Sara McMenamin, PhD, *Vice Chair for Medical Effectiveness and Public Health*, University of California, San Diego
Joy Melnikow, MD, MPH, *Vice Chair for Public Health*, University of California, Davis
Jack Needleman, PhD, University of California, Los Angeles
Nadereh Pourat, PhD, *Vice Chair for Cost*, University of California, Los Angeles
Marilyn Stebbins, PharmD, University of California, San Francisco

Task Force Contributors

Danielle Casteel, MA, University of California, San Diego
Shana Charles, PhD, MPP, University of California, Los Angeles, and California State University, Fullerton
Margaret Fix, MPH, University of California, San Francisco
Naomi Hillery, MPH, University of California, San Diego
Jeffrey Hoch, PhD, University of California, Davis
Julia Huerta, MPH, University of California, Davis
Michelle Keller, PhD, MPH, University of California, Los Angeles
Connie Kwong, University of California, San Francisco
Elizabeth Magnan, MD, PhD, University of California, Davis
Jacqueline Miller, University of California, San Francisco
Marykate Miller, MS, University of California, Davis
Dominique Ritley, MPH, University of California, Davis
Dylan Roby, PhD, University of California, Los Angeles, and University of Maryland, College Park
Emily Shen, University of California, San Francisco
Riti Shimkhada, PhD, University of California, Los Angeles
Meghan Soulsby Weyrich, MPH, University of California, Davis
Steven Tally, PhD, University of California, San Diego
Sara Yoeun, MPH, University of California, San Diego

National Advisory Council

Lauren LeRoy, PhD, Strategic Advisor, L. LeRoy Strategies, Chair
Stuart H. Altman, PhD, Professor of National Health Policy, Brandeis University, Waltham, MA
Deborah Chollet, PhD, Senior Fellow, Mathematica Policy Research, Washington, DC
Allen D. Feezor, Former Deputy Secretary for Health Services, North Carolina Department of Health and Human Services, Raleigh, NC
Charles "Chip" Kahn, MPH, President and CEO, Federation of American Hospitals, Washington, DC
Jeffrey Lerner, PhD, President Emeritus, ECRI Institute Headquarters, Plymouth Meeting, PA; Adjunct Senior Fellow, Leonard Davis Institute of Health Economics, University of Pennsylvania
Donald E. Metz, Executive Editor, *Health Affairs,* Bethesda, MD
Dolores Mitchell, (Retired) Executive Director, Group Insurance Commission, Boston, MA
Marilyn Moon, PhD, Senior Fellow, Retired, American Institutes for Research, Washington, DC
Carolyn Pare, (Retired) President and CEO, Minnesota Health Action Group, Bloomington, MN
Richard Roberts, MD, JD, Professor Emeritus of Family Medicine, University of Wisconsin-Madison, Madison, WI
Alan Weil, JD, MPP, Editor-in-Chief, *Health Affairs,* Bethesda, MD

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Adara Citron, MPH, Principal Policy Analyst
Karen Shore, PhD, Contractor*
An-Chi Tsou, PhD, Contractor*

California Health Benefits Review Program
MC 3116
Berkeley, CA 94720-3116
info@chbrp.org
(510) 664-5306

*Karen Shore, PhD, and An-Chi Tsou, PhD, are Independent Contractors who work with CHBRP to support legislative analyses and other special projects on a contractual basis.

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Janet Coffman, MA, MPP, PhD, of the University of California, San Francisco, prepared the medical effectiveness analysis. Min-Lin Fang, MLIS, of the University of California, San Francisco, conducted the literature search. Adara Citron, MPH, of CHBRP staff prepared the cost and public health impact analysis and Policy Context section, and synthesized the individual sections into a single report. Amy Kwong, FSA, MAAA, MPH, of Milliman, provided actuarial analysis. A subcommittee of CHBRP's National Advisory Council (see previous page of this report) and a member(s) of the CHBRP Faculty Task Force, Timothy T. Brown, PhD, and Sylvia Guendelman, PhD, LCSW, all of the University of California, Berkeley, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

CHBRP assumes full responsibility for the report and the accuracy of its contents. All CHBRP bill analyses and other publications are available at www.chbrp.org.

Garen Corbett, MS
Director

Please direct any questions concerning this document to: California Health Benefits Review Program; MC 3116; Berkeley, CA 94720-3116, info@chbrp.org, or www.chbrp.org