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.

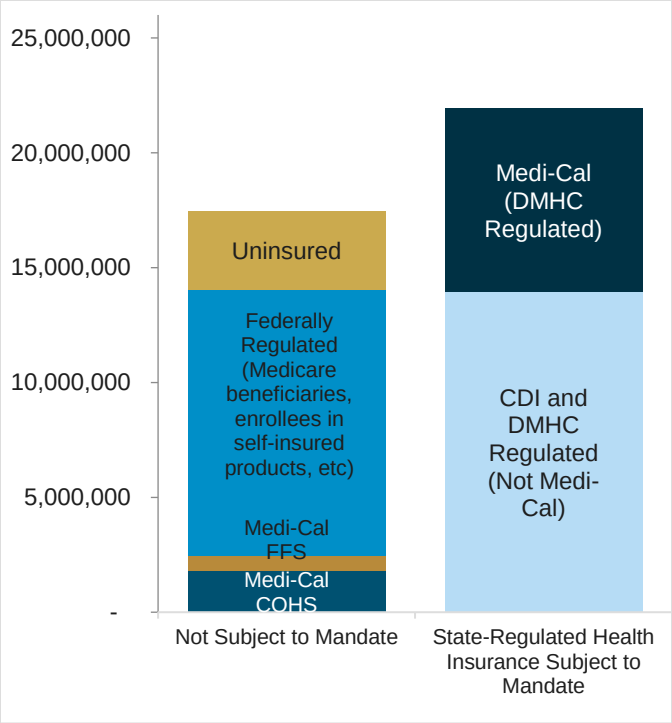
Wraps may be used for a variety of reasons, including parental preference or convenience. The analysis of SB 613 focuses on two reasons wraps may be used in a hospital setting: (1) to facilitate skin-to-skin contact; and (2) to help prevent newborn falls. Skin-to-skin is recommended for all mothers and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