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Analysis of California Assembly Bill 2258 Doula Care: Medi-Cal Pilot Program

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Analysis of California Assembly Bill 2258 Doula Care: Medi-Cal Pilot Program

A Report to the 2019–2020 California State Legislature

April 14, 2020



Key Findings Analysis of California Assembly Bill 2258 Doula Care: Medi-Cal Pilot Program

Summary to the 2019–2020 California State Legislature, April 14, 2020



AT A GLANCE

The version of California Assembly Bill (AB) 2258 analyzed by CHBRP would establish a three-year pilot program in Medi-Cal for coverage of doula care across 14 specified counties.

- 1. CHBRP estimates that, in the first year postmandate, 10.2 million Medi-Cal enrollees within the 14 specified counties would have insurance subject to AB 2258.
- 2. **Benefit coverage.** Benefit coverage of doula care would increase from 0% at baseline to 100% postmandate.
- Utilization. Approximately 20% of the almost 204,000 eligible pregnant women¹ who experienced live birth, abortion, miscarriage, or stillbirth would use the doula services offered by the pilot.
- 4. **Expenditures.** Total net annual Medi-Cal expenditures in the 14 pilot counties would increase by \$32,495,448, or 0.08%.
- 5. **Medical effectiveness.** The medical effectiveness review examined the impact of doulas on a multitude of maternal and neonatal and infant outcomes. Findings across outcomes varied.
- 6. **Public health.** AB 2258 would produce an unknown but positive impact on birth experiences, including improved agency for pregnant Medi-Cal enrollees, especially among the racial and ethnic minority populations that access community-based doula care in the first year, postmandate.
- 7. Long-Term Impacts. The reduction in cesarean deliveries among Medi-Cal managed care enrollees is unlikely to be reflected in prospectively set payments in the short-term. After 2 to 3 years when rates are recalculated, reductions in caesarian deliveries could be reflected in the payments made to plans, which may result in savings to the Medi-Cal program.

CONTEXT

Full spectrum doulas are trained to provide *nonclinical emotional, physical, and educational support* to help women manage pain, fear, fatigue, and uncertainty throughout their pregnancy and postpartum; *doulas do not provide medical care.*² In addition to supporting pregnant people, doulas also may support their partners and families.

Because insurance does not commonly cover doula services, *traditional* doulas typically serve higher-income women due to the associated out-of-pocket costs. Traditional doulas are trained to provide unconditional, nonjudgmental support; however, some may lack cultural and historical understanding of how race, institutional bias, and social determinants influence birth outcomes.

In contrast, *community-based doulas* practice full spectrum care, but focus on women of color and underserved pregnant women who face disparities in care and in maternal and infant outcomes. The community-based doula practice extends beyond most traditional doula practices to encompass culturally congruent, trauma-informed care, which provides intensive support throughout the perinatal period, including extensive postpartum visits. Their training covers ways that social determinants of health affect pregnancy and birth outcomes. Many community doulas have shared experience and reside in the communities they serve.

BILL SUMMARY

Assembly Bill (AB) 2258 would establish a 3-year pilot program in Medi-Cal for coverage of full-spectrum doula care. For a pregnancy carried to term, enrollees are eligible for at least four prenatal appointments, continuous support during labor and delivery, and at least eight postpartum appointments during the first year postpartum. Beginning July 1, 2021, the Department of Health Care Services (DHCS) shall establish a "fullspectrum" doula care pilot program for all pregnant and postpartum Medi-Cal enrollees residing in 14 counties, as specified. Full-spectrum doula care is defined as

¹ CHBRP notes that persons who do not identify as "women" may also experience pregnancy.

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



including prenatal and postpartum doula care, continuous presence during labor and delivery, and doula support during miscarriage, stillbirth, or abortion.

AB 2258 provides multiple definitions related to doula care, specifies how reimbursements for doula care are provided and determined, establishes a state-wide doula registry, requires notification of availability of doula care to eligible enrollees, establishes a set of "core competencies" doulas must possess, and requires a program evaluation.

CHBRP is unable to determine how many doulas currently exist in California, how many provide care, and how many would meet the core competency requirements specified within AB 2258. CHBRP assumes the supply of doulas in California would meet the needs of Medi-Cal enrollees in the 14 specified counties for the purposes of this analysis.

IMPACTS

Benefit Coverage, Utilization, and Cost

CHBRP estimates that approximately 204,000 female Medi-Cal beneficiaries aged 15 to 44 years (childbearing age) who reside in the 14 counties identified by AB 2258 would be eligible for the doula pilot program due to pregnancy or postpartum status.

Benefit Coverage

Currently, no enrollees in Medi-Cal that would be subject to AB 2258 have coverage for full-spectrum doula services as proposed in AB 2258. Postmandate, 100% of enrollees in the 14 counties would have coverage for doula care through the pilot program.

Utilization

Due to the lack of benefit coverage, CHBRP concludes that Medi-Cal is providing no doula services to their enrollees in the 14 pilot counties, and if any Medi-Cal enrollees are using doula services they are paying outof-pocket for the service or relying on other community or hospital programs that are not covered by Medi-Cal. While CHBRP is aware of some existing doula care pilot programs, these programs are not available to all pregnant enrollees and may not be available as of July 1, 2021.

Postmandate, CHBRP estimates approximately 20% of the almost 204,000 eligible pregnant women who experience live birth, abortion, miscarriage, or stillbirth

would use the doula services offered by the pilot. As a result, vaginal deliveries would increase by 3,441 (2.44%), while cesarean deliveries would decrease by the same number (which represents a 5.84% decrease because the number of vaginal deliveries exceeds the number of cesarean deliveries in Medi-Cal).

Expenditures

The prices CHBRP used to calculate the costs associated with the doula pilot program are based on external benchmarks and relative costs of equivalent programs. The rates used by Medi-Cal in each pilot county could differ substantially, and therefore the costs of the program estimated by CHBRP may not be supported by final reimbursement rates and methods used by DHCS in estimating the expenditures for the pilot or the long-term actual costs of the pilot program.

CHBRP estimates that each pilot participant would use, based on the language in AB 2258, four prenatal doula visits (\$120), one labor/delivery attendance or equivalent service (\$360), and eight postpartum doula visits (\$240), for a total all-inclusive rate of \$720 on average for each pilot program participant. Despite the predicted reduction in cesarean deliveries due to the pilot program, the blended Medicaid maternity supplemental (kick) payments used to compensate health plans for labor and delivery costs will not reduce Medicaid expenditures enough to offset the costs of administering the program.

AB 2258 would increase total net annual Medi-Cal expenditures in the 14 pilot counties by \$32,495,448, or 0.08%.

Number of Uninsured in California

Because the change in expenditures is limited to the Medi-Cal program and does not cause increases in private insurance premiums, CHBRP expects no measurable change in the number of uninsured persons due to the enactment of AB 2258.

Medical Effectiveness

The medical effectiveness review summarizes findings from evidence on the effectiveness of doula care for pregnant and postpartum persons, including prenatal and postpartum doula care, continuous presence during labor and delivery, and doula support during miscarriage, stillbirth, and abortion. Specifically, this review assesses the incremental impact of adding doula care to the standard perinatal care that pregnant women receive as compared with standard perinatal care alone.



There is evidence that adjunctive doula care interventions are *more effective* than standard perinatal care alone for decreasing the use of pain medication (including epidurals) during labor, and increasing the incidence of spontaneous vaginal delivery.

There is evidence that adjunctive doula care interventions are *not more effective* than standard perinatal care alone for managing severe labor pain, reducing the use of synthetic oxytocin for labor augmentation, reducing the incidence of perineal trauma, managing postpartum depression, promoting sustained breastfeeding after hospital discharge, managing pain during surgical abortions or miscarriages, reducing NICU admissions, and reducing the duration of hospital stays for infants.

There is *inconclusive evidence* regarding the effectiveness of adjunctive doula care interventions as compared with standard labor care alone for duration of labor, rates of cesarean delivery, rates of operative vaginal delivery, breastfeeding initiation, preterm birth, and low neonatal birth weight.

There is *insufficient evidence* to assess the effectiveness of doula care interventions as compared with standard labor care alone for attendance at childbirth classes, infant mortality, maternal mortality, and prenatal depression or anxiety. Please note that absence of evidence is not evidence of no effect. Maternal and infant mortality are rare outcomes, and no studies to date have been of sufficient size to assess the effect of doula care interventions on mortality.

Finally, there is insufficient evidence to determine whether adjunctive doula care — delivered at any stage of pregnancy or postpartum, during labor and delivery, or for abortion, miscarriage, or stillbirth — is associated with harms.

CHBRP notes the lack of studies using certified doulas, and, more specifically, the community doula model, in the U.S. Medicaid population. The above outcomes with inconclusive or insufficient evidence outcomes are due to this lack of studies. The limited and preponderance of evidence conclusions are based on more studies with the limitations as noted in the main body of the analysis.

Public Health

In the first year postmandate, CHBRP estimates AB 2258 would:

 Decrease disparities in access to doula services between Medi-Cal (low income) and higher income pregnant women;

- Increase spontaneous vaginal births by about 3,400 cases (with a commensurate decrease in cesarean births);
 - Likely reduce disparities between Medi-Cal beneficiaries' and privately insured enrollees' cesarean birth rates and may decrease disparities within the Medi-Cal population among racial/ethnic groups, specifically for Latina and black Medi-Cal beneficiaries, who experience the highest rates of cesarean deliveries in California;
- Decrease unwanted/unnecessary pain medication use during labor by an unknown quantity; and
- *Increase* maternal satisfaction with the birth experience.

Due to evidence of no effectiveness of doula services, CHBRP projects that AB 2258 would *not change* rates of severe labor pain, utilization of synthetic oxytocin, breastfeeding, NICU admission, or prolonged infant hospital stay.

CHBRP is unable to project a change in rates of maternal mortality, infant mortality, preterm birth and low birth weight due to insufficient or inconclusive evidence of doula services.

The projected decrease in cesarean deliveries would likely result in some decreased rate of complications from wound infections, organ damage during surgery, prolonged healing, and increased risk for future cesarean deliveries. Infant rates of negative health outcomes (e.g., asthma, decreased intestinal microbiome diversity) could also be reduced. CHBRP also anticipates an unquantified decrease in the use of pain medication, including epidurals, based on the evidence reviewed.

Long-Term Impacts

The 14-county pilot program proposed in AB 2258 is limited to three years without further legislative or administrative action. If the program is successful based upon the required evaluation, DHCS would have the option of expanding the pilot to additional counties and also continuing to operate the pilot in the existing counties. If the pilot results in additional doulas obtaining training, obtaining a National Provider Identification number, and being added to the registry, additional supply would be available to provide services to pregnant women in the state if doula services became more popular and readily accessible. That could result in additional women participating (above the estimated 20% participation rate) and additional utilization of services.



Despite the cost offsets created by fewer cesarean births in fee-for-service Medi-Cal, the long-term costs would increase if utilization increased over time. In the case of this pilot, the reduction in cesarean deliveries among Medi-Cal managed care enrollees is unlikely to be reflected in the prospectively set maternity supplemental (kick) payments made to plans in the short term. However, after 2 to 3 years when rates are recalculated, if the mix of cesarean and vaginal delivery changes due to the program, it could be reflected in the maternity supplemental (kick) payments made to plans, which may result in savings to the Medi-Cal program.

To the extent that (1) the doula supply expands according to the bill's criteria, and (2) pregnant Medi-Cal beneficiaries learn about and engage doula support, CHBRP projects an unknown, positive public health impact on some physical and emotional perinatal outcomes in years 2 and 3 of the pilot program due to physical, educational, and social supports provided by community-based doulas. These improvements include continued reductions in potentially preventable cesarean deliveries and use of pain medication, including epidurals. Qualitative evidence also supports the conclusion that doulas would improve pregnant Medi-Cal beneficiaries' birth experiences as well as access to community and social supports.

In the long term, because Medi-Cal covers approximately 50% of births in California, the pilot program established by AB 2258 could begin to reduce statewide racial/ethnic and income disparities in spontaneous vaginal delivery rates and birth experiences (e.g., undesired pain medication use); however, the extent of the changes is unknown.

Essential Health Benefits and the Affordable Care Act

Medi-Cal plans are not subject to the same set of Essential Health Benefits (EHBs) as nongrandfathered small group and individual market plans and policies and are not subject to the requirement to defray costs, should a benefit exceed EHBs.

At the time of this CHBRP analysis, there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Because the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamics.

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April 14, 2020

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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 <u>www.chbrp.org.</u>

TABLE OF CONTENTS

Policy Context		1
Bill-Specific	Analysis of AB 2258, Doula Care: Medi-Cal Pilot Program	1
Interaction V	/ith Existing Requirements	4
Analytic App	roach and Key Assumptions	6
Background on	Doula Care	8
Doula Care a	and Training	8
	e of Doulas	
Disparities a	nd Social Determinants of Health in Use of Doulas and Birth Outcomes	11
Societal Imp	act of Poor Perinatal Outcomes in California	13
Medical Effection	veness	15
	pproach and Methods	
-	cal Considerations	
Outcomes A	ssessed	16
	gs	
•	Findings	
	ge, Utilization, and Cost Impacts	
	d Postmandate Benefit Coverage	
	Postmandate Utilization	
	d Postmandate Per-Unit Cost	
	d Postmandate Expenditures	
	derations for Policymakers	
Public Health I	mpacts	
	ublic Health Outcomes	
	minants of Health (SDoH)	
• •	pacts	
-	Jtilization and Cost Impacts	
0	Public Health Impacts	
Appendix A	Text of Bill Analyzed	
Appendix B	Literature Review Methods	
Appendix C	Cost Impact Analysis: Data Sources, Caveats, and Assumptions	
Appendix D	Information Submitted by Outside Parties	D-1

References

California Health Benefits Review Program Committees and Staff Acknowledgments

LIST OF TABLES AND FIGURES

Table 1. AB 2258 Impacts on Benefit Coverage, Utilization, and Cost, First Year	ix
Table 2. Description of Services Provided by Doulas*	9
Table 3. Preference for Actual and Future Doula Use by California Women Surveyed in Listening to Mothers in California, 2017 (n=1433)	10
Table 4. Disparities Among Key Maternal and Infant Health Outcomes in California	14
Table 5. Summary of Evidence of Medical Effectiveness of Doula Care	33
Figure 1. Maternal Outcomes — Increase Attendance at Childbirth Classes	18
Figure 2. Maternal Outcomes — Decrease Prenatal Depression or Anxiety	18
Figure 3. Maternal Outcomes — Decrease Length of Labor	19
Figure 4. Maternal Outcomes — Reducing Labor Pain	20
Figure 5. Maternal Outcomes — Reduce Use of Pain Medication (including epidurals) During Labor	21
Figure 6. Maternal Outcomes — Reducing Use of Synthetic Oxytocin for Labor Augmentation	22
Figure 7. Maternal Outcomes — Increase the Rate of Spontaneous Vaginal Delivery	22
Figure 8. Maternal Outcomes — Decrease the Rate of Cesarean Delivery	23
Figure 9. Maternal Outcomes — Decrease the Rate of Operative Vaginal Delivery	24
Figure 10. Maternal Outcomes — Reduce Perineal Trauma	25
Figure 11. Maternal Outcomes — Reduce Maternal Mortality	25
Figure 12. Maternal Outcomes — Decrease Postpartum Depression	26
Figure 13. Maternal Outcomes — Increase Breastfeeding Initiation	26
Figure 14. Maternal Outcomes — Increase Sustained Breastfeeding	27
Figure 15. Maternal Outcomes — Reduce Procedural Pain During Abortion or Miscarriage	28
Figure 16. Infant Outcomes — Reduce Neonatal and Infant Mortality and Stillbirth	28
Figure 17. Infant Outcomes — Reducing Preterm Birth	29
Figure 18. Infant Outcomes — Reducing the incidence of Low Birth Weight	
Figure 19. Infant Outcomes — Reducing Admissions to Neonatal Intensive Care Units	31
Figure 20. Infant Outcomes — Reducing Prolonged Hospital Stays	31
Figure 21. Harms of Doula Care	32

	Baseline	Postmandate	Increase/ Decrease	Change Postmandate
Benefit Coverage				
Total enrollees with health insurance subject to AB 2258 (a)	10,206,442	10,206,442	0	0.00%
Total percentage of enrollees with coverage (b)	0%	100%	100%	N/A
Utilization and Cost				
Medi-Cal population who are women aged 15–44	2,646,939	2,646,939	-	0.00%
Potential users (pregnant and postpartum women in Medi-Cal)	0	203,991	203,991	N/A
Estimated number of pregnant or postpartum women using doula services (c)	0	40,798	40,798	N/A
Distribution of Pregnancy	0	40,790	40,790	N/A
Outcomes (d)				
Deliveries	199,882	199,882	-	0.00%
Vaginal delivery	140,968	144,409	3,441	2.44%
Cesarean delivery	58,914	55,473	(3,441)	-5.84%
Nondeliveries (e)	4,109	4,109	-	0.00%
Average Visits Per User	· · ·	·		
Prenatal – doula visits	0	4	4	N/A
Labor/delivery – doula				
attendance	0	1	1	N/A
Postpartum – doula visits	0	8	8	N/A
Per-Unit Costs (f)				
Prenatal – doula visits	\$0	\$30	\$30	0.00%
Labor/delivery – doula	ድር	¢260	¢260	0.00%
attendance	\$0	\$360	\$360	0.00%
Postpartum – doula visits	\$0	\$30	\$30	0.00%
Per-user doula care cost	\$0	\$720	\$720	N/A
Per-enrollee doula care cost	\$0	\$3	\$3	N/A
Average Cost per Live Vaginal and Cesarean Delivery	\$5,149	\$5,128	-\$21	-0.41%
Expenditures	· · · · ·		*	
Total Medi-Cal Expenditures for 14 Pilot Counties (g)	\$40,636,797,354	\$43,240,939,784	\$32,583,938	0.08%

Table 1. AB 2258 Impacts on Benefit Coverage, Utilization, and Cost, First Year

Source: California Health Benefits Review Program, 2020.

Notes: (a) Enrollees in the 14 counties subject to AB 2258. This includes enrollees in a Medi-Cal managed care plan, County-Organized Health System, and Medi-Cal fee-for-service, aged 0 to 64. Dually eligible enrollees are excluded.

(b) Some Medi-Cal managed care plans may offer a pilot program to cover doula services in certain counties but these are not available to all enrollees. Based on the current coverage survey, enrollment in pilot programs are capped. Therefore, CHBRP has assumed current coverage rates to be 0%.

(c) 20% of potential users (pregnant and postpartum women in Medi-Cal) are estimated to utilize doula care.

(d) Stillbirths are included in vaginal or cesarean deliveries based on claims data. Stillbirths categories as "other" are categorized as nondeliveries.

(e) Nondeliveries include miscarriage, abortion, and stillbirths, which are not categorized as a vaginal or cesarean delivery in this table.

(f) Costs are based on the assumption that each prenatal and postpartum doula visit would average one hour in duration at a rate of \$30 per hour.

(g) Medi-Cal Expenditures in the 14 counties included in AB 2258 are based upon Medi-Cal managed care capitation rates paid to plans for managed care enrollees, plus spending on acute care through Medi-Cal fee-for-service reported by Kaiser Family

Foundation State Health Facts (https://www.kff.org/medicaid/state-indicator/spending-on-acute-care/). The total acute care fee-for-service spending was prorated by approximately 80% to represent the portion of fee-for-service spend associated with enrollees in the 14 pilot counties.

POLICY CONTEXT

The California Assembly Committee on Health has requested that the California Health Benefits Review Program (CHBRP)³ conduct an evidence-based assessment of the medical, financial, and public health impacts of Assembly Bill (AB) 2258, which would establish a three-year pilot program in Medi-Cal for coverage of doula services across 14 specified counties.

Bill-Specific Analysis of AB 2258, Doula Care: Medi-Cal Pilot Program

Bill Language

AB 2258 would establish a three-year pilot program in Medi-Cal for coverage of full-spectrum doula care. For a pregnancy carried to term, enrollees are eligible for at least four prenatal appointments, continuous support during labor and delivery, and at least eight postpartum appointments during the first year postpartum. The full text of AB 2258 can be found in Appendix A.

Beginning July 1, 2021, the Department of Health Care Services (DHCS) shall establish a "full-spectrum" doula care pilot program for all pregnant and postpartum Medi-Cal enrollees residing in 14 counties, as specified. The bill language states these 14 counties were chosen because these communities experience the highest burden of birth disparities in California. The 14 counties are Alameda, Contra Costa, Fresno, Kern, Los Angeles, Orange, Riverside, Sacramento, San Bernardino, San Diego, San Francisco, San Joaquin, Santa Clara, and Solano.

Doula care should be provided to any eligible Medi-Cal enrollee without prior authorization or cost sharing.

Definitions

AB 2258 provides a few important definitions related to doula care:

- Community-based doula group: A group or collective of doulas working together that prioritizes doula access for underserved populations.
- Doula: A birth worker who provides health education, advocacy, and physical, emotional, and nonmedical support for pregnant and postpartum persons before, during, and after childbirth.
- Full-spectrum doula care: Includes prenatal and postpartum doula care, continuous presence during labor and delivery, and doula support during miscarriage, stillbirth, or abortion.
- Perinatal period: The period including pregnancy, labor, delivery, and the postpartum period.
- Postpartum: The one-year period following the end of a pregnancy.

Reimbursement

AB 2258 specifies how reimbursements for doula care are provided and determined. The bill states DHCS should develop multiple payment and billing options for doula care, by ensuring all of the following:

- Any doula and community-based doula group participating in the pilot program shall be guaranteed payment within 30 days of submitting a claim for reimbursement;
- An individual doula shall be able to obtain a National Provider Identifier (NPI) number and be directly reimbursed by DHCS; and

³ CHBRP's authorizing statute is available at <u>www.chbrp.org/faqs.php</u>.

• A community-based doula group shall be able to obtain reimbursement for any doula working as part of their group. If a community-based doula group employs doulas on a salaried basis, DHCS shall determine appropriate rates based on the salaries provided and not on a per-client or per-service basis.

In setting reimbursement rates for doula services, DHCS and Medi-Cal managed care plans are directed to take into consideration the following:

- The current rate for any existing, paid, community-based doula pilot programs that are already serving the Medi-Cal population;
- The cost of living in the pilot program counties; and
- The sustainable living wage, as calculated in the pilot program counties.

AB 2258 also provides direction for which services doulas should receive reimbursement:

- Presence at a stillbirth shall be reimbursed at the same rate as presence at a labor and delivery resulting in a live birth. Postpartum services should also be covered for a stillbirth.
- A separate reimbursement would be provided for presence during a miscarriage or abortion.
- Doulas should be reimbursed separately for each appointment. There would also be a separate reimbursement for administrative costs, including travel costs.

Other provisions

Registry: AB 2258 directs DHCS to develop a registry listing any doula who is available to take on new clients in each of the 14 counties participating in the pilot program. The registry should be searchable by a variety of characteristics and should align with existing Medi-Cal directory requirements.

Notice to enrollees: Medi-Cal managed care plans would be required to provide information about the availability of doula care in their materials and notices on reproductive and sexual health, family planning, pregnancy, and prenatal care. All pregnant and postpartum enrollees should also be informed at each prenatal and postpartum visit about the availability of doula care, the benefits of doula care, and how to obtain a doula.

Core competencies: Doulas providing services are required to have a set of "core competencies," defined as the foundational and essential knowledge, skills, and abilities required for doulas serving the Medi-Cal population. AB 2258 directs DHCS to convene an advisory board to determine the list of core competencies required for doulas who are authorized to be reimbursed under the Medi-Cal program. The core competencies should include, at a minimum, a demonstration of competency, through training or attestation of equivalency or lived experience, in all of the following areas:

- Understanding basic anatomy and physiology as related to pregnancy, the childbearing process, the postpartum period, breast milk feeding, and breastfeeding or chestfeeding;
- Capacity to employ different strategies for providing emotional support, education, and resources during the perinatal period;
- Knowledge of an ability to assist families with utilizing a wide variety of nonclinical labor coping strategies;
- Strategies to foster effective communication between clients, their families, support services, and health care providers;
- Awareness of integrative health care systems and various specialties of care that a doula can provide information for in order to address client needs beyond the scope of the doula;
- Knowledge of community-based, state-funded and federal funded, and clinical resources available to the client for any need outside of the doula's scope of practice; and

• Knowledge of strategies for supporting breastfeeding or chestfeeding, breast milk feeding, and lactation.

Evaluation: DHCS is directed to allocate funding and resources for data collection, reporting, and analysis for the purposes of conducting an evaluation of this pilot program. Specifically, the evaluation should examine the impact of the pilot program on a range of outcomes, including those focused on client and client family experience, prenatal and postnatal care engagement, doula workforce retention, cost savings, and clinical outcomes.

Relevant Populations

If enacted, AB 2258 would affect the health insurance of approximately 10.2 million Medi-Cal enrollees within the 14 specified counties. This is approximately 26% of all Californians and 80% of Medi-Cal enrollees ages 0 to 64 statewide. If enacted, the law would affect the health insurance of enrollees in Department of Managed Health Care (DMHC)–regulated Medi-Cal managed care plans, County Organized Health Systems (COHS), and the fee-for-service (FFS) program within the 14 counties specified by AB 2258.

Medi-Cal Eligibility for Pregnant Women⁴

Pregnant or postpartum women can be eligible for and access Medi-Cal through a few routes, including traditional Medi-Cal eligibility, eligibility through Medi-Cal expansion, and pregnancy-specific eligibility and coverage.^{5,6}

- Pregnant women with incomes between 0% up to 138% of the federal poverty level (FPL) are eligible for full-scope benefit coverage through Medi-Cal managed care plans or FFS.
- Pregnant women with incomes above 138% up to 213% of the FPL:
 - Are eligible for pregnancy-related Medi-Cal coverage. Pregnancy-related services are services required to assure the health of the pregnant woman and the fetus. These include but are not limited to prenatal care, services for other conditions that might complicate the pregnancy, labor, delivery, postpartum care, and family planning services. Pregnancy-related services may be provided prenatally from the day that pregnancy is medically established and postnatally to the end of the month in which the 60th day following delivery occurs.
 - Pregnant women whose incomes are above 138% up to 213% of the FPL can also choose to enroll in a Qualified Health Plan (QHP) through Covered California and receive advanced premium tax credit (APTC) to reduce their monthly premiums. Pregnant women who are enrolled in a QHP prior to becoming pregnant and are eligible for Medicaid may enroll in Medi-Cal or stay enrolled in their QHP and continue to receive APTC and cost-share reductions. Pregnant women in this income range may not, however, be enrolled in Medi-Cal and a QHP at the same time.
- Pregnant women who have income over 213% up to 322% of the FPL may be eligible for the Medi-Cal Access Program (MCAP). Pregnant women who are not eligible for full-scope or pregnancy-related Medi-Cal may qualify for the MCAP, regardless of citizenship and immigration status. MCAP offers low-cost comprehensive coverage, with no copayments, deductibles, or coinsurance. However, there is a fee equal to 1.5% of the yearly family income. The fee can be paid in monthly installments over 12 months. Pregnant women may qualify for both Covered California and the MCAP, but cannot enroll in both programs and must choose one program.

 ⁴ CHBRP notes that persons who do not identify as "women" may also experience pregnancy. This report uses the terminology from the source material cited, which uses the term "women" to describe the eligible populations.
 ⁵ Department of Health Care Services (DHCS). Full-scope Medi-Cal Coverage and Affordability and Benefit Program for Low-Income Pregnant Women and Newly Qualified Immigrants. 2019. Available at: https://www.dhcs.ca.gov/services/medi-cal/Pages/Affordability-and-Benefit-Program.aspx
 ⁶ Covered California. Health Coverage Options for Pregnant Women. Available at: https://www.coveredca.com/individuals-and-families/getting-covered/pregnant-women/

• **Undocumented pregnant women** through age 26 who meet the income eligibility thresholds may be eligible for full-scope Medi-Cal coverage or may be eligible for partial-scope pregnancy-related Medi-Cal or MCAP if their income exceeds 138% FPL. Undocumented women over age 26 may be eligible for partial-scope pregnancy-related Medi-Cal coverage or MCAP.

Interaction With Existing Requirements

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

California Policy Landscape

California law and regulations

There are no existing laws in California that require coverage of doula care, either within Medi-Cal or commercial and CalPERS DMHC-regulated plans.

Doula care pilot programs

CHBRP is aware of existing and terminated insurance-based doula care pilot programs in California, as well as programs provided through partnerships not specific to insurance plans. The details of many of these programs, however, are not publicly available. Pilot programs tend to provide services for a predetermined number of enrollees, and therefore all eligible enrollees would not be guaranteed access to doula services through the pilot programs. Below is a brief summary of existing programs:

- SisterWeb⁷, San Francisco Community Doula Network. SisterWeb provides prenatal, birth, and postpartum care to low-income women of color in San Francisco in need of doula support. This program began providing services in 2019 and is a partnership between the San Francisco Department of Public Health and SisterWeb.⁸
- HealthNet Community Doula Pilot Program (terminated).⁹ In 2019, the Association for Wholistic Maternal and Newborn Health partnered with HealthNet, in a pilot program to help improve birth outcomes for African American/black women and infants in Los Angeles County. This pilot program's goal was to provide 150 African American/black women enrolled in HealthNet Medi-Cal with 10 mostly African American/black doulas in order to lower cesarean rates for their African American clients. The program provided services to 30 women during a 6-month period.
- Perinatal Equity Initiative grants.¹⁰ Planning Grants were awarded to 13 county health departments currently operating Black Infant Health programs for the purpose of improving black infant birth outcomes and reducing infant mortality. Counties are allowed to use this funding to establish doula care programs.

Similar requirements in other states

A few other states passed laws or enacted budget measures to provide doula care for enrollees in state Medicaid programs: Indiana (2019)¹¹; Minnesota (2013); New Jersey (2019); Oregon (2011); and

 ⁷ SisterWeb, San Francisco Community Doula Network. Available at: <u>https://www.sisterweb.org/</u>
 ⁸ California Preterm Birth Initiative. Doula Program Announced in San Francisco. 2018. Available at: <u>https://pretermbirthca.ucsf.edu/news/doula-program-announced-san-francisco</u>

⁹ Happy Mama Healthy Baby Alliance. Health Net Community Doula Pilot Program. Available at:

https://motherbabysupport.net/projects-programs/health-net-community-doula-program/ ¹⁰ California Department of Public Health. Perinatal Equity Initiative. Available at:

https://www.cdph.ca.gov/Programs/CFH/DMCAH/Pages/Perinatal-Equity-Initiative.aspx

¹¹ No funding was allotted for Indiana's doula care program, so implementation of this program is uncertain as of April 2020.

Washington (2019 budget)¹². Minnesota and Oregon have the most established programs in operation. Key characteristics of these state programs include:

- Minnesota (Minnesota Department of Human Services, 2016):
 - Covered services include childbirth education and support services provided before childbirth, during labor and delivery, and postpartum. Up to seven sessions are covered, one of which must be for labor and delivery. Reimbursement for services provided totals up to \$411.
 - Doulas must register with the Minnesota Department of Health and be certified by one of eight specific organizations. Doulas must bill for services under a supervising professional's NPI.
- Oregon (Oregon Health Authority, 2018):
 - The standard doula benefit includes two visits before delivery, two visits after delivery, and support during labor and delivery. Reimbursement for services provided totals up to \$350.
 - Doulas must be certified and registered as a Traditional Health Worker to be eligible for reimbursement. Once doulas are certified, they can apply for an NPI and enroll as an Oregon Medicaid provider.

Reimbursement for doula care in states with newer programs (Indiana, New Jersey, and Washington) have not yet been established.

Ten states have introduced legislation during the 2020 session relating to coverage of doula care under Medicaid (NHeLP, 2020). Twelve states and Washington DC introduced legislation in 2019, but the legislation failed to move forward. The majority of these bills either require coverage of doula care, determine reimbursement rates, or establish doula training requirements.

Doula care pilot programs in other states

CHBRP is aware of a doula care pilot program provided through New York's Medicaid program, beginning in 2019.

- New York (New York State Department of Health, 2019):
 - Open to Medicaid enrollees in Erie (includes city of Buffalo) and King Counties (includes residents of Brooklyn¹³).
 - Covered services include up to four prenatal visits, care during labor and delivery, and up to four postnatal visits. Reimbursement for all services can total \$600.
 - Doulas must apply for an NPI number, provide proof of specified training and competencies, and be added to a registry.

Federal Policy Landscape

Federal legislation has been introduced recently that aims to improve maternal health and pregnancy outcomes, and some of the strategies included would encourage coverage or provision of grants for doula care.¹⁴ However, these pieces of legislation have not moved forward as of April 2020.

¹³ Excludes residents currently eligible for another doula program provided to women eligible for Medicaid. Growing Up NYC. Free Childbirth Support in Central Brooklyn. Available at:

https://growingupnyc.cityofnewyork.us/programs/by-my-side-birth-support/

¹² Funding for a doula program in Medicaid was included in the final budget, but more information about the program has not been released.

¹⁴ S 3494 MOMMIES Act, 2017-2018; S 3363 Maternal CARE Act, 2017-2018; S 3568 Rural MOMS Act, 2017-2018.

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 AB 2258 may interact with requirements of the ACA as presently exists in federal law, including the requirement for certain health insurance to cover essential health benefits (EHBs).^{15,16}

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

Medi-Cal plans are not subject to the same set of EHBs as nongrandfathered small-group and individual market plans and policies and are not subject to the requirement to defray costs, should a benefit exceed EHBs.¹⁷

Analytic Approach and Key Assumptions

- Doulas are not medical providers and are not a substitute for seeing a trained physician, nurse practitioner, or nurse midwife. Although doulas may be able to help convey medical information and options to women, full-spectrum doulas are not usually part of the official medical care team. More information about the training doulas complete and the services they provide are included in the *Background on Doula Care* section.
- CHBRP acknowledges that persons who do not identify as "women" may also experience pregnancy. This analysis uses the terminology from the source material cited, which frequently uses the term "women" to describe the study populations.
- Although the bill language defines the postpartum period as one year following the end of the
 pregnancy, coverage terminates the end of the month in which the 60th day following delivery
 occurs for those enrollees who gain Medi-Cal specifically due to pregnancy. For this population,
 CHBRP assumes that coverage for doula services also would terminate the end of the month in
 which the 60th day following delivery occurs. Therefore, enrollees may not receive the eight
 postnatal visits they are eligible for under AB 2258.
- CHBRP is unable to determine how many doulas currently exist in California, how many provide care, and how many would meet the core competency requirements specified within AB 2258. CHBRP assumes the supply of doulas in California would meet the needs of Medi-Cal enrollees in the 14 specified counties for the purposes of this analysis.
 - Should the supply of doulas be insufficient to provide care as assumed by this analysis, utilization may be overestimated.
 - It is also important to note that there may be substantial barriers to accessing doula care, particularly for enrollees in rural areas of the state or those who do not speak English, as many doulas practice in urban areas and areas with higher levels of income and may be English-only speakers.
- CHBRP assumes eligible doulas would be able to obtain an NPI number, would be added to the registry, and would be eligible for reimbursement as of July 1, 2021.

¹⁵ 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.

 ¹⁶ 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.
 ¹⁷ Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website:

¹⁷ Policy and issue briefs on EHBs and other ACA impacts are available on the CHBRP website: <u>www.chbrp.org/other_publications/index.php</u>.

At the time of this CHBRP analysis, there is substantial uncertainty regarding the impact of the COVID-19 pandemic on premium rates and health plan enrollment, including how the pandemic will impact healthcare costs in 2021. Because the variance of potential outcomes is significant, CHBRP does not take these effects into account as any projections at this point would be speculative, subject to federal and state decisions and guidance currently being developed and released. In addition, insurers', providers', and consumers' responses are uncertain and rapidly evolving to the public health emergency and market dynamics.

BACKGROUND ON DOULA CARE

Doula Care and Training

Full-spectrum doulas are trained to provide *nonclinical emotional, physical, and educational support* to help women¹⁸ manage pain, fear, fatigue, and uncertainty throughout their pregnancy and postpartum; *doulas do not provide medical care* (Stuebe and Barbieri, 2019). In addition to supporting pregnant women, doulas also may support their partners and families.

Type of Practice and Location

There is wide variation in the type of practice or specialization among doulas. They may practice prenatalonly, birth-only, postpartum-only, miscarriage/abortion-only care, or a combination of these types of practices. Doulas who practice *full-spectrum care* (as specified in AB 2258) provide educational and emotional support throughout the perinatal period (pregnancy through one year postpartum). Fullspectrum and birth doulas are also trained to provide stillbirth and miscarriage support services. Doulas may practice part time or full time; independently, with a group, or through a hospital-based program; and may volunteer or require reimbursement for services (Stuebe and Barbieri, 2019). See below for discussion of differences between *traditional* and *community-based* doulas.

Doula Training and Services

There are at least eight national or international organizations that offer doula training and certification online, in person, or a combination thereof, as well as local nonprofits across the United States. Average cost of training among the larger organizations is \$860 (CBI, 2020). Although the program syllabi may differ, the basic components required for certification include: required reading, attending a multi-day training program, auditing a childbirth education class, attending several births, and receiving positive evaluations from laboring persons and health care practitioners (CBI, 2020; Stuebe and Barbieri, 2019). Length of training varies depending on organization requirements; but, in general, full-spectrum doula training can take 2 to 6 months inclusive of 2 to 3 days of classroom training, required independent reading, and attendance at two to three births (CBI, 2020).

Because insurance does not commonly cover doula

Full-Spectrum Doula Training Includes topics such as:

- Communication skills:
- Physiology of pregnancy, labor, and postpartum periods;
- Physical support techniques for labor;
- Strategies for managing events such as analgesia, cesarean delivery, placing baby for adoption;
- Postpartum depression;
- Breastfeeding;
- Creating local area resource list (for clients); and
- Skills in building a business.

services, *traditional* doulas typically serve higher-income women due to the associated out-of-pocket costs (Bey et al., 2019; Gebel et al., 2020; Lanz et al., 2005). Traditional doulas are trained to provide unconditional, nonjudgmental support; however, some may lack cultural and historical understanding of how race, institutional bias, and social determinants influence birth outcomes (Bey et al., 2019; Kozhimannil et al., 2015).

In contrast, *community-based doulas* focus on women of color and underserved pregnant women who face disparities in care and in maternal and infant outcomes. The community-based doula practice extends beyond most traditional doula practices to encompass culturally congruent, trauma-informed care, which provides intensive support throughout the perinatal period, including extensive postpartum visits (Bey et al., 2019). Their training covers ways that social determinants of health affect pregnancy and birth outcomes. In addition to birth planning and labor support, they create resource toolkits that

¹⁸ CHBRP notes that persons who do not identify as "women" may also experience pregnancy. This report uses the terminology from the source material cited, which uses the term "women" to describe the study populations.

include resources for clients such as transportation assistance, financial support, mental health resources, substance abuse counseling, incarceration advocacy, housing assistance environmental justice (i.e., toxic lead), and immigration assistance. They learn strategies to help clients navigate structural and institutional racism and implicit bias throughout pregnancy. They also receive training in concepts like birth justice and reproductive justice, and exercise cultural humility (Bey et al., 2019). Some community doula programs focus on subpopulations within their community such as teens, tribal nations, non-English speaking immigrants and women undergoing treatment for substance use disorder (HHS, 2015) (Table 2). Many community doulas have shared experience and reside in the communities they serve.

Table 2. Description of Services Provided by Doulas*

Stage	Description of Services
Prenatal care (a) Traditional: Two 1-hour visits Community-based: Up to six 1- to 2-hour visits	Educate pregnant persons about nutrition, exercise, managing stress, fetal development, labor coping skills, ways to avoid unnecessary cesarean deliveries; and create a birth plan that addresses preferences for labor assistance and pain management.
Labor and Delivery (b) Both: Continuous presence during labor and delivery lasting between a few hours and a few days (average 18 hours)	Provide physical support (e.g., massage, breathing techniques, position changes during different labor stages); advocate/educate (e.g., support client expressing her desire to medical team, explain medical decisions, demonstrate respect for client's cultural traditions and religious beliefs, encourage informed decision-making [consent and refusal], provide language interpretation); provide emotional support (encouragement, reassurance, compassion); and inform family members of labor progress.
Postpartum Care (a)(b) Traditional : Two 1-hour visits Community-based : Up to eight 1- to 2-hour visits	Encourage and support breastfeeding with referral if necessary; instruct parent(s) about necessary postpartum physical care; provide emotional support to parent and partners; teach newborn care such as diapering, bathing, swaddling and soothing; screen (and refer) for postpartum depression; educate about risks and benefits about newborn procedures (i.e., screenings, circumcision, etc.); foster positive parent-child interactions; provide information on infant development, care, and safety; and refer mothers to community resources to address other health, social, or environmental concerns.
Miscarriage/Abortion (c) Length of procedure	Provide emotional and physical comfort and education to women about miscarriage (spontaneous abortion) and abortion; and educate clients about options, procedures, and what to expect in terms of outcomes during and after. The doula can dispel misinformation and negative stigma for abortion procedures. The doula retains active communication and empathy and can also offer spiritual or religious support, and referrals to community resources and professionals for additional emotional support, if needed.
Community-based doulas pro	vide the services listed above, but focus on serving low-income, underserved

Community-based doulas provide the services listed above, but focus on serving low-income, underserved populations. They are usually from the community they serve and share similar background, culture, and/or language with their clients. They are trained in trauma-informed care. Additional training includes understanding effects of social determinants of health on pregnancy outcomes. Community-based doulas support clients through referral to and assistance with comprehensive social support services such as housing, transportation, immigration, insurance, mental health and substance abuse services, incarceration advocacy, environmental justice, and access to health services. They commonly support families up to a year postpartum (i.e., infant soothing techniques, foster positive parent-child interaction and coping skills) and help clients build community (Bey et al., 2019).

Source: California Health Benefits Review, 2020

Notes: *Full-spectrum doulas provide all services.

(a) HHS, 2015.

(b) Bey et al., 2019

(c) Austin, 2017; Chor et al., 2016.

Reported Use of Doulas

The *Listening to Mothers in California* study presents survey results about the hospital experiences, outcomes, and views from California women who recently gave birth in a California hospital. The researchers found that 4% of respondents speaking English at home (n=1,433) reported having full-spectrum doula support; 2% had prenatal and birth support; 2% had birth support only; and <1% had birth and postpartum support only. Table 3 shows that more Medi-Cal enrollees reported using doula support (11%) than women with private insurance (8%) (Sakala et al., 2018). The researchers acknowledge this unexpected difference by insurance status may be due to one or more reasons: the presence of hospital-provided doulas at the time of labor and delivery (usually hospital staff or volunteers familiar with hospital protocol and procedures, and have established relationships with the medical practitioners [Stuebe and Barbieri, 2019]); or some survey respondents' misunderstanding of the doula definition (Sakala et al., 2018).

Demand for Doula for Future Support

Labor and Delivery Support

In the same survey, when asked, "If you have a future pregnancy, how open would you be to having the support of a doula (trained labor companion) while you are giving birth?", 57% of respondents would consider or definitely want doula support in the future (Table 3). Sakala et al. (2018) note that, overall, definite interest in future use is twice that of actual use; however, differences in definite want of doula support varies across racial/ethnic groups. For example, although a higher percentage of black women reported having doula support than other races/ethnicities, they also were less likely to report definitely wanting future support than their counterparts. Fifty-five percent of women covered by Medi-Cal would definitely want or consider future doula support.

Table 3. Preference for Actual and Future Doula Use by California Women Surveyed in *Listening to Mothers in California*, 2017 (n=1433)

	Current Use	Interest in Future Use				
	Had doula support	Would definitely want doula support	Would consider doula support			
Respondents Overall	9%	18%	39%			
Black	15%	27%	39%			
Latina	10%	19%	37%			
White	8%	16%	40%			
Asian/Pacific Islander	3%	16%	39%			
Private insurance	8%	17%	41%			
Medi-Cal	11%	20%	35%			

Source: California Health Benefits Review Program, 2020 (based on Sakala et al., 2018).

Note: Difference among race/ethnicity categories and payer categories are statistically significant at p<.01.

Analysis limited to women who spoke English at home to correct for suspected misinterpretation of the doula definition among those who do not speak English at home.¹⁹

Miscarriage and Abortion Support

CHBRP found a dearth of literature studying doula support for women experiencing miscarriage or abortion. Wilson et al. (2017) conducted a randomized controlled trial about the impact of doula support

¹⁹ Personal communication, C Sakala, March 27, 2020.

for women with failed or undesired pregnancies who underwent an office-based uterine aspiration (n=70). No statistical difference in satisfaction, emotional response, or perceived ability to cope was found between the control and intervention groups; however, the authors noted that 74% of all participants said they would want a doula if they underwent that procedure again. Of those who received doula support, 94% reported that such support helped them during the procedure, and 97% would recommend a doula to a friend undergoing this procedure (Wilson et al., 2017). In another small qualitative study of women undergoing an abortion (n=30), Chor et al. (2016) reported that 33% of participants heard of a doula before the procedure, and, after learning about doulas, 70% requested doula support during the procedure. Respondents found the support valuable and suggested that doula practices also integrate pre- and post-abortion information and emotional support.

Disparities²⁰ and Social Determinants of Health²¹ in Use of Doulas and Birth Outcomes

Per statute, CHBRP includes discussion of disparities and social determinants of health (see the *Public Health* section for detailed discussion about social determinants). CHBRP found literature identifying disparities (differences between groups that are modifiable) in perinatal outcomes by race/ethnicity and insurance status (Medi-Cal vs. private insurance). Social determinants of health can lead to disparities in perinatal outcomes (Koz, 2016).

AB 2258 would make full-spectrum doula care accessible to Medi-Cal enrollees in 14 counties to help reduce poor maternal and infant health outcomes disproportionately experienced by racial/ethnic minority populations. CHBRP estimates that approximately 204,000 pregnant and postpartum female Medi-Cal enrollees aged 15 to 44 years (childbearing age) who reside in the 14 counties identified by AB 2258 would be eligible for the doula pilot program; this represents approximately 80% of the childbearing Medi-Cal population (see the *Benefit Coverage, Utilization, and Cost Impacts* section for details).

Racial/ethnic minorities are disproportionately represented in Medi-Cal, with Latinos (46%) and whites (21%) comprising the majority of the Medi-Cal managed care population, followed by Asian/Pacific Islanders (14%), blacks (8%) and other/unknown (12%) (Gaines, 2020).

Disparities in Perinatal Outcomes in California

Disparities among key maternal and infant health outcomes exist within California. Notably, among all racial/ethnic groups, black mothers and their infants experience the highest rates of negative health outcomes including preterm birth, low infant birth weight, cesarean deliveries, infant mortality, maternal mortality, perinatal depression, as well as the lowest rates of two health process outcomes that are associated with longer-term health outcomes: postpartum care and exclusive breast feeding (Table 4) (Gaines, 2019).

Maternal and infant mortality

The California maternal mortality rate is 17.6 deaths per 100,000 live births in 2013 (5-year average, 2013–2017). This is above the Healthy People 2020 goal of 11.4 deaths per 100,000 live births (UnitedHealth Foundation, 2020). Hispanic and Asian/Pacific Islander women experience the lowest maternal mortality rates (14.6 and 14.1 deaths per 100,000 live births, respectively), followed by white women (17.0). Maternal mortality for black women is almost four times greater than for white women (63.9/100,000 live births).

²⁰ Several competing definitions of "health disparities" exist. CHBRP relies on the following definition: Health disparity is defined as the differences, whether unjust or not, in health status or outcomes within a population (Wyatt et al., 2016).

²¹ CHBRP defines social determinants of health as conditions in which people are born, grow, live, work, learn, and age. These social determinants of health (economic factors, social factors, education, physical environment) are shaped by the distribution of money, power, and resources and impacted by policy (adapted from: CDC, 2014; Healthy People 2020, 2019). See CHBRP's SDoH white paper for further information: <u>http://chbrp.com/analysis_methodology/public_health_impact_analysis.php</u>.

The infant mortality rate in California is higher than the maternal mortality rates, averaging 4.3/1,000 live births. Racial/ethnic differences also extend to infant mortality rates, with black infants experiencing the highest rate of infant mortality in California (8.2/1,000 live births) — more than twice the rate of white infants (3.5/1,000) (Table 4). Moreover, the infant mortality rate is also higher for those with Medi-Cal (5.5/1,000 live births) as compared with private insurance (3.5/1,000 live births) (Let's Get Healthy, 2020).

Preterm and low weight births

Preterm infants and infants with low birth weight are more likely to experience serious physical and developmental disabilities such as chronic lung disease, growth reduction, hearing impairment, cardiopulmonary conditions, necrotizing enterocolitis, cerebral palsy, and even death (Ward and Beachy, 2003). In California, the rate of preterm births among black and Native American mothers (12.6% and 10.9%, respectively) was above the national Healthy People 2020 target of 9.4%, and 40% higher than preterm births for Asian (7.9%) and white (7.5%) mothers. Similar disparities exist for black and Native American infants whose low birth weight rates (12.2% and 8.4%, respectively) are above the Healthy People 2020 target of 7.8% (Table 4) (Gaines, 2019).

Cesarean deliveries

Cesarean deliveries can be a life-saving intervention for the mother and infant; however, they have risks for the mother and infant and should be avoided if possible. Risks of cesarean deliveries include damage to other organs during surgery, prolonged maternal healing after birth, maternal infection, and risks to future pregnancies and births (uterine rupture, abnormal placentation, ectopic pregnancy, preterm birth, higher risk labor and vaginal delivery, or need for repeat cesarean delivery). Infants born through cesarean delivery are at higher risk of acquiring asthma and reduced intestinal microbiome diversity (Keag et al., 2018; Sandall et al., 2018).

Disparities for cesarean delivery rates by race and by insurance status are marked. One source shows California rates of cesarean deliveries among first births to low-risk women are highest among black mothers (29.8%) as compared with whites and Latinas (23.8%), and above the Healthy People target of 23.9% (Table 4) (Gaines, 2019). In the *Listening to Mothers in California* study, women covered by Medi-Cal were more likely to have a cesarean delivery (34%) than women with private insurance (28%) (Sakala et al., 2018). Among those with Medi-Cal coverage, Asian/Pacific Islander women had the highest rate of cesarean delivery (45%) (more than twice that of their privately insured counterparts) followed by black, white, and Latina enrollees (43%, 33%, and 32%, respectively). Sakala et al. (2018) also report that among all respondents who spoke English, fewer with labor doula support reported a cesarean delivery (22%) as compared with those with no labor doula support (31%).

Perinatal depression and anxiety

Screening for and addressing perinatal depression and anxiety is important to maternal and infant health. Evidence indicates prenatal depression is associated with preterm birth, low birth weight, and behavioral problems, while postpartum depression is associated with interruptions in bonding and attachment, breastfeeding success, and infant cognitive and social development (Freeman, 2019). Risks to the mother range from lethargy to increased maternal disengagement and hostile, coercive behaviors and, less commonly, suicide ideation. California black and Latina pregnant women were about two times more likely to experience symptoms of prenatal depression than their white and Asian counterparts and 50% more likely to experience postpartum depressive symptoms (Table 4) (Gaines, 2019). Women covered by Medi-Cal experienced a statistically higher screening rate for prenatal anxiety than those with private insurance (23% and 19%, respectively), but similar postpartum screening rates (9% and 10%, respectively) (Sakala et al., 2018).

Postpartum care visits

Practitioners recommend at least one postpartum care visit within four to six weeks of delivery to conduct a full assessment of physical, social, and psychological well-being. Check-ups can prevent complications and death from infection, stroke, or heart disease, which are primary causes of maternal mortality (March

of Dimes, 2020). Visits should include screening for postpartum depression; postpartum complications such as urinary incontinence; follow up for gestational diabetes, gestational hypertension, and preeclampsia; and discussion about breastfeeding and reproductive planning (ACOG, 2018).

Disparities in postpartum visits were present according to insurance status: postpartum women with Medi-Cal coverage were less likely than those with private insurance to have a postpartum visit. Black women were the most likely to have four or more postpartum visits regardless of coverage by Medi-Cal or private insurance. Sakala et al. (2018) postulate that this may be due to greater number of postpartum health challenges in this population. Medi-Cal enrollee respondents who had a postpartum visit were consistently about 8 percentage points less likely than those with private insurance to report having discussed the aforementioned topics with their provider (Sakala et al., 2018).

Breastfeeding

The benefits of any breastfeeding, but especially exclusive breastfeeding up to six months, are widely recognized by health care providers and public health experts. Evidence shows that breast milk provides antibodies important for the development of a strong infant immune system, and reduces infants' risk of gastrointestinal diseases, diabetes, allergies, and sudden infant death syndrome. These protective effects appear to carry through adulthood. Mothers who breastfeed also benefit through the stimulation of uterine contractions that stop bleeding and return the uterus to pre-pregnancy size, faster weight loss, reduced risk of depression, and lower rates of disease such as breast and ovarian cancers (Bjarnadottir, 2017).

About 90% of California postpartum women, including those insured by Medi-Cal, reported "ever breastfeeding" (Backman et al., 2015). However, rates for *exclusive breastfeeding at 3 months postpartum* declined significantly for all women, but most especially for black and Latino postpartum women insured by Medi-Cal, whose rates dropped to just over 10%. Rates of breastfeeding by their white and Asian counterparts were two and three times greater (Table 4) (Backman et al., 2015). A different study by Sakala et al. (2018) showed that postpartum women with private insurance (67%) reported higher breastfeeding rates than postpartum women covered by Medi-Cal (59%) at one week; at six months, the rates dropped to 34% and 24%, respectively. The authors observed that postpartum women covered by Medi-Cal returned to or started paid jobs more quickly than those with private insurance. Return to work can be disruptive to continued or exclusive breastfeeding.

Disparities in Birth Care Experience

The *Listening to Mothers in California* survey by Sakala et al. (2018) compares the experiences of mothers by race/ethnicity and insurance status. The study reported no significant differences in rates of attempts to induce labor when comparing racial/ethnic groups. However, privately insured pregnant women were more likely than those with Medi-Cal to experience such an attempt (43% and 36%, respectively).

Additionally, most women reported that they had been granted autonomy in decisions about how their birth would proceed, had been well supported and had experienced good communication during the hospital stay for giving birth. However, Sakala et al. (2018) observed that women covered by Medi-Cal were more likely to identify concerns in all three areas than women with private insurance.

Finally, Medi-Cal enrollees overall were less likely to have access to both emotional and practical support than women with private insurance (40% vs. 25%) (Sakala et al., 2018).

Societal Impact of Poor Perinatal Outcomes in California

CHBRP found no summary estimates of societal costs related to avoidable, negative health outcomes for pregnant women and infants.

	Infant Mortality ^(a)	Low Birth Weight Infants ^(a)	Preterm Births ^(a) (2017)	Cesarean Birth Rate ^(a) (2017)	Maternal Mortality Rates ^(a) (2011-13)	Postpartum Care Rates ^(b) (2016)	Prenatal Depression ^(a) (2013-2015)	Postpartum Depression ^(a) (2013-2015)	Exclusive Breast Feeding 3 Months Postpartum ^(c) (2011)
	(per 1,000 live births)	(%)	(%)	(%)	(per 100,000 live births)	(per 100,000 live births)	(%)	(%)	(%)
California Average	4.2	6.9%	8.7%	24.5%			14.1%	13.5%	
Black	8.2	12.2%	12.6%	29.8%	26.4	49.8%	19.9%	15.6%	~11%
Native American	*	8.4%	10.9%		5.3**	53.2%			
Latina	4.3	6.6%	9.0%	23.8%	4.9	65.6%	17.1%	15.4%	~13%
White	3.5	5.7%	7.5%	23.8%	7.0	63.2%	9.5%	10.9%	20%
Asian/Pacific Islander	3.1	7.5%	7.9%	25.6%	7.8	74.1%	10.3%	11.7%	30%

Table 4. Disparities Among Key Maternal and Infant Health Outcomes in California

Source: California Health Benefits Review Program, 2020.

Notes: * Estimated Native American infant mortality rate (5.3%) is unstable due to fewer than 20 (numerator) deaths. **Nationally, Native Americans experience the second highest rate of pregnancy-related mortality. Non-Hispanic black (black) and non-Hispanic American Indian/Alaska Native (Al/AN) women experienced the highest pregnancy-related mortality (40.8/100,000 births and 29.7/100,000 births respectively) as compared with the national average of 16.7/100,000 births (Peterson et al., 2019).

(a) Gaines, 2019.

(b) Gaines, 2019. Reflects Medi-Cal managed care only. At least one postpartum visit on or between 21 and 56 days following delivery

(c) Backman et al., 2013.

MEDICAL EFFECTIVENESS

As discussed in the *Policy Context* section, AB 2258 would establish a 3-year pilot program in 14 California counties mandating coverage of full-spectrum doula care for pregnant and postpartum persons enrolled in Medi-Cal. Additional information on doula services is included in the *Background on Doula Care* section. The medical effectiveness review summarizes findings from evidence²² on the effectiveness of doula care for pregnant and postpartum persons, including prenatal and postpartum²³ doula care, continuous presence during labor and delivery, and doula support during miscarriage, stillbirth, and abortion.

Research Approach and Methods

As described in the *Background on Doula Care* section, doulas are persons who are not medical professionals, but have training and experience focused on childbirth and, as such, provide nonmedical supportive care to pregnant, laboring, and postpartum women²⁴ as an adjunct to standard medical pregnancy and childbirth care. This medical effectiveness review assesses the incremental impact of adding doula care to the standard perinatal care that pregnant women receive as compared with standard perinatal care alone.

Studies of doula care were identified through searches of PubMed, the Cochrane Library, Web of Science, the Cumulative Index of Nursing and Allied Health Literature, and PsycINFO. 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 International Network of Agencies for Health Technology Assessment (INAHTA), the National Health Service (NHS) Centre for Reviews and Dissemination, the National Institute for Health and Clinical Excellence (NICE), and the Scottish Intercollegiate Guideline Network.

The search was limited to abstracts of studies published in English and from 2000 to the present.

Of the 326 articles found in the literature review, 102 were reviewed for potential inclusion in this report on AB 2258, and a total of 13 studies were included in the medical effectiveness review for this report. The other articles were eliminated because they did not focus on doula care, were of poor quality, were not conducted in settings generalizable to U.S. populations 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.

The conclusions below are based on the best available evidence from peer-reviewed and grey literature.²⁵ 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.

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.

²³ Defined by AB 2258 as "the one-year period following the end of pregnancy."

²⁴ CHBRP recognizes that persons who do not identify as women, but are of female sex, may become pregnant. Pregnant women is the most common terminology used in the literature and thus is used throughout this report.
²⁵ 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.

Key Questions

- 1. What is the medical effectiveness of doula care during pregnancy, delivery, and up to one year postpartum with respect to maternal outcomes?
- 2. What is the medical effectiveness of doula care for abortion, miscarriage, and stillbirth with respect to maternal outcomes?
- 3. What is the medical effectiveness of doula care during pregnancy, delivery, and up to one year postpartum with respect to neonatal and infant outcomes?
- 4. What are the harms of doula care?

Methodological Considerations

A 2017 Cochrane review of continuous labor support²⁶ (Bohren et al., 2017) has been widely referenced in the doula care community and provides the largest base of evidence for many outcomes of interest to the medical effectiveness analysis in this report; however, this review is limited in its applicability to the model of doula care proposed in this bill for the following reasons:

- This review included several studies where the labor support was provided by non-doula companions with minimal or no training in doula techniques;
- The period of doula support varied across studies, with some interventions including prenatal or
 postpartum support in addition to labor support, whereas others were limited to labor support
 only; and
- Trials from both high- and middle-income countries were included, many of which have different health care systems and birth practices from the United States; when possible, CHBRP reported results stratified by country income (high-income only), but differences in health care practices are still present between high-income countries.

Given these limitations, CHBRP only reported outcomes from the Cochrane review when country income-stratified results were available and relied more heavily on findings from individual good- and fairquality comparative studies conducted among pregnant women in the United States in making its final determinations on the state of the evidence for each outcome. As a result, many of CHBRPs findings regarding the effectiveness of doula care are contrary to findings from the 2017 Cochrane review.

Although most of the individual studies included in this analysis evaluated the effectiveness of doula care provided by certified doulas, two trials evaluated doula-type care provided by volunteer nurses (Hodnett et al., 2002) and female birth partners (Campbell et al., 2006) with training in doula support techniques in the role of the doula support. Many of the included studies evaluated doula care interventions that included elements of the community doula model, such as prenatal and postpartum care in addition to labor support; however, no trial specifically engaged community doulas or evaluated the community doula model systematically.

Outcomes Assessed

Studies of doula care have examined a wide range of maternal outcomes related to the prenatal and postpartum periods, labor and delivery, and for abortion or miscarriage. Maternal outcomes assessed include attendance at prenatal appointments, birth-related anxiety, pain during surgical evacuation (for abortion or miscarriage), length of labor, severity of labor pain, labor augmentation with synthetic

²⁶ Definitions as to what constitutes continuous labor support varies across studies but is generally agreed to mean the presence of a nonclinical companion whose sole responsibility is to provide a combination of comfort measures, information, and advocacy for a pregnant woman from the beginning of labor (often upon hospital admission) through birth.

oxytocin, use of pain medication during labor (e.g., epidural), modes of delivery (i.e., spontaneous vaginal, cesarean, operative vaginal), perineal trauma, maternal mortality, postpartum depression, breastfeeding, and harms of doula care.

Studies of doula care have typically examined infant outcomes associated with the effects of delivery and in-hospital measures; fewer studies have evaluated infant outcomes after discharge from the hospital. Neonatal and infant outcomes assessed include infant mortality, preterm birth, low birth weight, admission to a neonatal intensive care unit, skin-to-skin contact, and length of hospital stay.

As described in the *Background on Doula Care* section, maternal and infant mortality are disproportionately experienced by black women in California and doula care is a potential mediator of this outcome. Studies of doula care either did not assess or were not powered to evaluate maternal and infant mortality outcomes. When data were available, raw numbers were reported and the causes of death were described, but the literature was deemed insufficient and no conclusions regarding the impact of doula care on these outcomes should be drawn.

Outcomes regarding patient satisfaction, perception, and quality of life are reported in the *Public Health Impacts* section.

Study Findings

This following section summarizes CHBRP's findings regarding the strength of evidence for the effectiveness of full-spectrum doula care, including prenatal support, continuous labor support, postpartum support, and support for stillbirth or abortion. Each outcome 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.

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.

As defined by AB 2258, a full-spectrum doula provides prenatal and postpartum care, continuous support during labor and delivery, support during stillbirth, and support during miscarriage and abortion; however,

CHBRP's literature review did not identify any studies or evaluations of doula care programs that were inclusive of all elements of this model.

Effectiveness of Doula Care: Maternal Outcomes

Prenatal outcomes

Attendance at childbirth preparation classes

Pregnant women are encouraged to attend childbirth preparation classes.

CHBRP's literature review identified one recent randomized control trial (RCT) (Hans et al., 2018) that assessed the impact of doula care on prenatal class attendance. In this study, 312 low-income pregnant women recruited from predominately African American and Latina communities were randomized during the second trimester to either a low-intensity case management control group for the duration of pregnancy or a doula home-visiting intervention that included weekly prenatal visits, labor support, and six postpartum visits during the first 3 months postpartum from a community doula. At the onset of labor, women who received doula care were significantly more likely to have attended at least one childbirth preparation class as compared with women in the control group (odds ratio 9.82 [95% CI: 4.84 to 19.89]; p<0.0001). Although Hans et al. (2018) determined that almost all participants were informed of and had the opportunity to attend childbirth preparation classes through prenatal clinics and hospitals, about one-tenth of women in the control group (9.5%) attended one of these classes compared with half of the women in the doula care group (50.0%).

Summary of findings regarding doula care on attendance at prenatal classes and appointments: CHBRP found insufficient evidence from one high-quality RCT conducted among low-income pregnant women in the United States on the effectiveness of doulas on attendance at prenatal childbirth preparation classes.

Figure 1. Maternal Outcomes — Increase Attendance at Childbirth Classes



Prenatal depression and/or anxiety

Some women experience depression or anxiety during a pregnancy, which can make it difficult for a woman to care for herself or her pregnancy. Unaddressed prenatal depression is associated with a range of adverse birth and infant outcomes and places a woman at higher risk for developing postpartum depression (Chan et al., 2014).

CHBRP did not find any studies that assessed the role of doulas on prenatal depression and/or anxiety.

Figure 2. Maternal Outcomes — Decrease Prenatal Depression or Anxiety

NOT EFFECTIVE	FFECTIVE INSUFFICIENT EVIDENCE						
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing	

Labor and delivery outcomes

Length of labor

Longer labors are not inherently dangerous but may be exhausting to the mother and are associated with increased risk of fetal distress and cesarean delivery (ACOG, 2019).

CHBRP identified two RCTs (Campbell et al., 2006; Hodnett et al., 2002) and one prospective cohort study (Nommsen-Rivers et al., 2009) of doula care interventions that assessed the length of labor. It should be noted that both RCTs relied on non-doula volunteers with limited labor support training to provide the doula care component. Campbell et al. (2006) asked women randomized to doula care to identify a female friend or relative to be their labor partner after which both participant and her elected birth partner attended two 2-hour classes on continuous labor support techniques provided by a certified doula. Comparatively, Hodnett et al. (2002) designated nurse volunteers recruited from labor and delivery units who attended a 2-day training in labor support to act in the role of doulas; during labor, nurse volunteers were instructed to only provide doula support and additional nurses provided standard nursing care for labor.

Two of these studies did not observe any significant differences in labor length between doula care and standard care groups. In a trial of doula care conducted among 6,915 women from 13 hospitals in the United States and Canada, Hodnett et al. (2002) did not observe any significant differences in mean labor lengths — whether measured from time of admission, assignment of a doula, start of active labor, or from the administration of an epidural — for women randomized to doula care as compared to women who experienced standard labor care (p=0.89). Similarly, a cohort study of 141 low-income women presenting to a labor unit at a hospital in northern California (Nommsen-Rivers et al., 2009) did not observe any differences in the proportion of women with an overall labor length (measured as admission to delivery) below the 14-hour median between women who received continuous labor support from an on-call certified doula versus women who had standard labor care, regardless of whether a women was induced or in spontaneous labor. However, excluding women with a cesarean delivery, women who had doula support were significantly more likely to experience shorter Stage II labor durations as compared with their standard care counterparts (adjusted OR 3.07 [95% CI: 1.19 to 7.90]).

Conversely, in a trial of 600 primarily low-income women conducted at a tertiary care center in New Jersey, Campbell et al. (2006) observed that women with vaginal deliveries who were randomized to labor support from lay doulas had significantly shorter labors as compared with women delivering vaginally with standard labor care (10.4 hours vs. 11.7 hours, p=0.004).

Summary of findings regarding the impact doula care on length of labor: There is inconclusive evidence from two RCTs and one cohort study regarding the effect of doula care on the length of labor as compared with standard labor care alone. Both RCTs assessed the impact of lay support person with minimal training in place of a certified doula.

Figure 3. Maternal Outcomes — Decrease Length of Labor

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Clear and Convincing	Preponderance	Limited		Limited	Preponderance	Clear and Convincing		

Labor pain severity

Pain during labor is a common experience, but for some the pain may be severe and impede the progress of labor.

CHBRP identified one prospective cohort study that assessed the impact of doula care on labor pain (Nommsen-Rivers et al., 2009). In this study, conducted among 141 low-income women presenting to a labor unit at a hospital in Northern California, women who received continuous labor support from an oncall certified doula did not experience any differences in reported severity of labor pain as compared with women who had standard labor care (adjusted OR 0.51 [95% CI: 0.22 to 1.19]).

In addition to the cohort study, a meta-analysis of four non-U.S. RCTs (2,456 women) from high- and middle-income countries performed as part of a 2017 Cochrane systematic review (Bohren et al., 2017) found no difference in postpartum report of severe labor pain among women who were randomized to receive continuous support (by a doula, nurse, or friend/family member) during labor as compared with women who received usual labor care (RR 1.00 [95% CI: 0.83 to 1.21]). Given that none of the studies included in this meta-analysis were conducted in the United States and two were from middle-income countries, the strength of this finding is of limited applicability to pregnant women in the United States.

Summary of findings regarding the effect of doula care on labor pain: CHBRP found limited evidence from one U.S.-based cohort study and one meta-analysis of four non-U.S. RCTs indicating that doula support during labor is not effective in mediating the experience or intensity of labor pain.

Figure 4. Maternal Outcomes — Reducing Labor Pain



Use of pain medication during labor

There are several types of medications for managing pain during labor that may be administered locally (e.g., injection of a numbing agent to a painful area), regionally (e.g., epidurals), or systemically (e.g., nitrous oxide, opioid medications). Side effects are typically minor but use of these medications may result in restricted movement and increase the duration of labor overall (ACOG, 2017). Some women prefer to not use pharmacologic pain interventions during labor.

CHBRP's literature review identified four RCTs and one cohort study that evaluated the impact of doula support during labor on the use of pain medication during labor. Three RCTs (Hans et al., 2018; Hodnett et al., 2002; McGrath and Kennell, 2008) found significant reductions in the likelihood of women utilizing epidurals or other regional anesthesia during labor among women who were randomized to receive doula-type support during labor as compared with women who were randomized to standard labor care. In the fourth trial, conducted among women with low-risk pregnancies at a hospital in New Jersey, Campbell et al. (2006) observed no difference in the use of epidurals between the study groups, although slightly fewer women with doula-type support during labor received epidurals (85%) as compared with women who had standard labor care (88%). Whereas doula care in the three trials with significant findings was provided by certified doulas or nurse volunteers from labor and delivery units, labor support in the trial with nonsignificant findings was provided by a female friend or relative of the participant who received minimal training from a certified doula.

In addition to the four RCTs, one cohort study of 141 low-income women presenting to a labor unit at a hospital in Northern California, Nommsen-Rivers et al. (2009) found that women who received continuous labor support from an on-call certified doula were about as likely as women who had standard labor care to utilize any form of pain medication during labor; however, if pain medication was used, women who received labor support from a doula were significantly more likely to utilize pain medication for a shorter duration (adjusted OR 2.96 [95% CI: 1.16 to 7.53]).

A meta-analysis of eight RCTs (10,145 women) from high-income countries performed as part of a 2017 Cochrane systematic review (Bohren et al., 2017) found that women who were randomized to receive continuous labor support were significantly less likely to utilize any intrapartum anesthesia for labor pain, including epidurals, as compared with women who received standard labor care (RR 0.89 [95% CI: 0.81 to 0.97]).

Summary of findings regarding the effect of doula care on the use of pain medication during labor: CHBRP found a preponderance of evidence from four RCTs, one cohort study conducted among U.S. women, and one systematic review of limited applicability to U.S. populations, that doula support during labor is effective in decreasing the utilization of epidurals and other regional anesthesia as well as the duration of any pain medication use.

Figure 5. Maternal Outcomes — Reduce Use of Pain Medication (including epidurals) During Labor

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Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	PREPONDERANCE	Clear and Convincing

Synthetic oxytocin

Synthetic oxytocin (i.e., Pitocin[®]) stimulates uterine muscles and is widely used in the United States to induce or augment labor; it is estimated that oxytocin is used in up to 57% of U.S. births (Bell et al., 2014). The use of synthetic oxytocin in U.S. clinical practice requires continuous intravenous infusion and continuous external fetal monitoring, limiting the laboring woman's ability to move around during labor (ACOG, 2019).

Three RCTs published since 2000 (Campbell et al., 2006; Hodnett et al., 2002; McGrath and Kennell, 2008) have evaluated the impact of doula care compared to routine labor care on the use of synthetic oxytocin for labor augmentation among U.S. populations. Whereas two single-center trials accounting for 1,286 women found no differences in rates of labor augmentation with synthetic oxytocin between the study groups (Campbell et al., 2006; McGrath and Kennell, 2008), the largest trial (Hodnett et al., 2002) including 6,915 women from 13 hospitals in the United States and Canada observed a significantly greater rate of labor augmentation among women randomized to doula care as compared women who experienced standard labor care (RR 1.11 [95% CI: 1.03 to 1.19]; p=0.008). Although all three trials included a doula care intervention, it should be noted that two of these studies relied on non-doula volunteers with limited labor support training to provide the doula care component. Campbell et al. (2006) asked women randomized to doula care to identify a female friend or relative to be their labor partner after which both participant and her elected birth partner attended two 2-hour classes on continuous labor support techniques provided by a certified doula. Comparatively, Hodnett et al. (2002) designated nurse volunteers who attended a 2-day training in labor support to act in the role of doulas.

Two recent systematic reviews of doula-supported labor (Bohren et al., 2017; Fortier and Godwin, 2015) found no differences in rates of labor augmentation with synthetic oxytocin between doula-supported groups and standard care controls; however, both reviews have limited applicability to U.S. populations (see Methodologic Considerations for a description of these two reviews).

Summary of findings regarding the effect of doula care on labor augmentation with synthetic oxytocin: CHBRP found a preponderance of evidence from three RCTs conducted among U.S. women and two systematic reviews of limited applicability to U.S. populations that doula support during labor is not effective in decreasing the rate of labor augmentation with synthetic oxytocin. It should be noted that labor support was provided by lay doulas (i.e., friends and nurse volunteers) in at least two of the trials contributing to this evidence base.

Figure 6. Maternal Outcomes — Reducing Use of Synthetic Oxytocin for Labor Augmentation

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Convincing	PREPONDERANCE	Limited	Inconclusive	Limited	Preponderance	Convincing

Spontaneous vaginal delivery

A spontaneous vaginal delivery occurs when a woman goes into labor without being induced and delivers without the use of forceps, vacuum extraction, or cesarean delivery (ACOG, 2016a).

One RCT (Hodnett et al., 2002) including 6,915 women from 13 hospitals in the United States and Canada observed no difference in the rate of spontaneous vaginal delivery among women randomized to doula-type labor support provided by nurse volunteers as compared women who experienced standard labor care (RR 1.01 [95% CI: 0.98 to 1.04]; p=0.54).

In contrast, among a cohort of 141 low-income women presenting to a labor unit at a hospital in Northern California, Nommsen-Rivers et al. (2009) found that women who received continuous labor support from an on-call certified doula had over four times the odds of a spontaneous vaginal delivery as compared with women who had standard labor care, after adjustment for clinical presentation and baseline characteristics (adjusted OR 4.68 [95% CI: 1.14 to 19.28]).

A meta-analysis analysis of 10 RCTs (11,284 women) performed as part of a 2017 Cochrane systematic review (Bohren et al., 2017) found that women from high-income countries who were randomized to receive continuous support during labor in hospital settings were significantly more likely to have a spontaneous vaginal birth as compared with women in high-income countries who received standard labor care (RR 1.07 [95% CI: 1.02 to 1.12]). It should be noted that only three of the included trials included U.S. women (including Hodnett et al., 2002) thereby limiting the applicability of these findings to U.S. populations.

Summary of findings regarding the impact of doula care on spontaneous vaginal delivery: CHBRP found limited evidence from one RCT, one cohort study conducted among U.S. women, and one systematic review of limited applicability to U.S. populations indicating that doula or doula-type support during labor is an effective intervention for increasing the rate of spontaneous vaginal deliveries.

Figure 7. Maternal Outcomes — Increase the Rate of Spontaneous Vaginal Delivery

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Clear and Convincing	Preponderance	Limited	Inconclusive	Preponderance	Clear and Convincing

Cesarean delivery

A cesarean delivery is the surgical delivery of a baby through an incision in the mother's abdomen and uterus. As a surgical procedure, cesarean delivery is not without risk and increases the length of maternal recovery time after birth, and is therefore usually reserved for circumstances when vaginal delivery poses serious risks to the mother or infant. In most cases, cesarean deliveries are medically necessary procedures that could not be prevented; however, a small portion of cesarean deliveries are potentially preventable and occur among women who may be able to deliver vaginally (ACOG, 2014).

CHBRP identified three RCTs (Campbell et al., 2006; Hans et al., 2018; Hodnett et al., 2002), one cohort study (Thomas et al., 2017), and one systematic review and meta-analysis (Bohren et al., 2017) indicating that doula care is not effective in reducing the rate of cesarean deliveries among women in the United States. Whereas two studies assessed rates of cesarean deliveries among women who received prenatal and postpartum care in addition to labor support from a certified doula (Hans et al., 2018; Thomas et al., 2017), two studies assessed labor support provided by female friends or nurse volunteers with training from a certified doula (Campbell et al., 2006; Hodnett et al., 2002); the meta-analysis was nested in a review that included only studies of continuous labor support partners from high-income countries.

In contrast, CHBRP also identified one RCT (McGrath and Kennell, 2008), one cohort study (Kozhimannil et al., 2013a), and one systematic review and meta-analysis (Fortier and Godwin, 2015) suggesting that U.S. women who receive doula care are significantly less likely to experience a cesarean delivery as compared with women who received standard pregnancy care. Whereas doulas in the RCT only provided labor support, doulas in the cohort provided both prenatal and postnatal care in addition to labor support, and doula support models in the five U.S. and Canadian trials included in the meta-analysis were mixed.

Across this body of literature, three studies evaluated certified doula care interventions that included prenatal and labor support among low-income and minority women and, therefore, provide the most relevant evidence of the potential impact of doula care on the rate of cesarean deliveries among populations who would be affected by the pilot program proposed in AB 2258.

- In a prospective cohort study of 1,079 pregnant Medicaid recipients in Minneapolis, Kozhimannil et al. (2013a) observed that women who received prenatal education and childbirth support from certified doulas were about 40% less likely to have a cesarean birth as compared with all Medicaid-funded births nationally when adjusted for clinical and sociodemographic factors (adjusted odds ratio 0.59 [95% CI: 0.51 to 0.68]). A subsequent analysis of this program that included two additional years of data found that this reduction in cesarean deliveries was only present among women with full-term births (adjusted odds ratio 0.44 [95% CI 0.39-0.49]) (Kozhimannil et al., 2016). The two groups were medically and demographically dissimilar, and it is unknown if any women in the comparison group had doula support.
- In a prospective cohort study of 489 pregnant women who participated in a doula care program offered in four lower-income New York City neighborhoods between 2010 and 2015, Thomas et al. (2017) found that the rate of cesarean deliveries was not significantly different between those receiving doula support vs. those receiving standard care (33.5% vs. 36.9%, p=0.122).
- In a recent RCT (Hans et al., 2018), 312 low-income pregnant women recruited from
 predominately African American and Latinx communities in Illinois were randomized to either a
 low-intensity case management control group for the duration of pregnancy or a doula homevisiting intervention that included weekly prenatal visits and labor support. The rate of cesarean
 deliveries did not differ significantly between the two study groups (21.5% vs. 23.2%, OR 1.04
 [95% CI: 0.59 to 1.84]).

Summary of findings regarding the impact doula care on cesarean delivery rate: There is inconclusive evidence from five RCTs, two cohort studies, and two meta-analyses regarding the effect of doula care on the rate of cesarean deliveries. Three studies with populations and interventions most relevant to the program proposed in AB 2258 exhibited different cesarean delivery outcomes in three different low-income areas in the United States.

Figure 8. Maternal Outcomes — Decrease the Rate of Cesarean Delivery

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Clear and Convincing	Preponderance	Limited	INCONCLUSIVE	Limited	Preponderance	Clear and Convincing

Operative vaginal delivery

Sometimes referred to as *assisted vaginal delivery*, operative vaginal birth is the vaginal delivery of a baby with the assistance of forceps or a vacuum device (ACOG, 2016a).

One RCT (Hodnett et al., 2002) including 6,915 women from 13 hospitals in the United States and Canada observed no difference in the rate of operative vaginal deliveries among women randomized to labor support provided by nurse volunteers as compared women who experienced standard labor care (RR 0.97 [95% CI: 0.87 to 1.08]; p=0.54).

Conversely, results of a meta-analysis including four U.S. and Canadian trials accounting for 1,587 pregnant women performed for a 2015 systematic review of doula support during labor (Fortier and Godwin, 2015) showed a significant reduction in the rate of operative vaginal deliveries with doula support during labor as compared with standard labor care (OR 0.56 [95% CI: 0.35 to 0.92]).

Summary of findings regarding the impact of doula care on spontaneous vaginal delivery: There is inconclusive evidence from one RCT and one systematic review and meta-analysis of limited applicability regarding the effect of doula care on the rate of operative vaginal deliveries among U.S. women.

Figure 9. Maternal Outcomes — Decrease the Rate of Operative Vaginal Delivery

NOT EFFECTIVE						
Clear and Convincing	Preponderance	Limited		Limited	Preponderance	Clear and Convincing

Perineal trauma

Lacerations and tearing of the perineum during vaginal delivery are common. Most obstetrical lacerations do not result in adverse outcomes or result in minimal adverse outcomes (first or second degree); however, a small portion of women may experience lacerations that extend into the anal sphincter complex (third or fourth degree), increasing the likelihood of pain and urinary and/or fecal incontinence (ACOG, 2016b).

CHBRP identified two studies of U.S. women published since 2000 that assessed the impact of doula support during labor on the incidence of perineal trauma. One study, an RCT including 6,915 women from 13 hospitals in the United States and Canada (Hodnett et al., 2002), observed no difference in the incidence of episiotomies or perineal lacerations requiring sutures among women randomized to labor support provided by doula-trained nurse volunteers as compared women who experienced standard labor care (RR 0.98 [95% CI: 0.84 to 1.03]; p=0.50). Similarly, among a cohort of 141 low-income women presenting to a labor unit at a hospital in Northern California, Nommsen-Rivers et al. (2009) found that women who received continuous labor support from an on-call certified doula were equally likely as women who had standard labor care to not have an episiotomy or experience greater than a second-degree perineal tear even after adjustment for clinical presentation and baseline characteristics (adjusted OR 1.76 [95% CI: 0.67 to 4.64]).

Summary of findings regarding the effect of doula care on perineal trauma: There is limited evidence from one RCT and one geographically limited cohort study that doula care does not decrease the incidence of perineal trauma, such as episiotomies or perineal tears requiring intervention, as compared with standard labor practices.

Figure 10. Maternal Outcomes — Reduce Perineal Trauma



Maternal mortality

Maternal mortality is defined as the death of a woman during pregnancy, childbirth, or immediately after delivery as a result of birth-related complications (CDC, 2019a). As described in the *Background on Doula Care* section, there are significant disparities in maternal mortality in the United States.

CHBRP's literature review did not identify any studies that assessed the impact of doula care, delivered at any stage of pregnancy or postpartum, on maternal mortality. In typical U.S. settings, maternal mortality is a very rare outcome²⁷; therefore, a randomized controlled trial with the power to assess the effect of doulas on maternal mortality would need to include a great number of women and/or a number of years.

Figure 11. Maternal Outcomes — Reduce Maternal Mortality

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Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Postpartum outcomes

Postpartum depression

Postpartum depression is depression that occurs within the first year after giving birth. Postpartum depression is more intense and lasts longer than the worry and sadness that are commonly known as the "baby blues," and may impact a mother's ability to care for herself or her child (CDC, 2019b).

Two RCTs have evaluated the impact of doula care on postpartum depression among U.S. women. In Hodnett et al. (2002), women recruited from 13 U.S. and Canadian tertiary hospitals who were randomized to labor support by doula-trained nurse volunteers were about as likely to report depressive symptoms indicative of postpartum depression as compared with women who received standard care (RR 0.86 [95% CI: 0.73 to 1.02]; p=0.08). In another RCT (Hans et al., 2018), women in the doula intervention group had access to at-home certified doulas in the first six weeks postpartum (in addition to labor support in the hospital), and were equally as likely as women in the control group to report a high burden of depressive symptoms at the 3-week and 3-month follow-up assessments.

Summary of findings regarding the effect of doula care on postpartum depression: There is limited evidence from two RCTs that doula care is not effective in decreasing the occurrence of postpartum depression or depressive symptoms after childbirth. Findings from one of the trials may be limited in its generalizability to the program proposed in AB 2285 as the doula intervention was provided by a nurse volunteer and did not include a postpartum home visit component.

²⁷ About 700 women in the United States die each year as result of a pregnancy- or birth-related complication (CDC, 2019a).

Figure 12. Maternal Outcomes — Decrease Postpartum Depression



Breastfeeding initiation

Breastfeeding is the recommended standard of infant feeding by the American Academy of Pediatrics and is associated with a range of positive infant and maternal outcomes (AAP, 2012). Breastfeeding initiation is an important measure of potential future breastfeeding and typically occurs in hospital settings shortly after birth.

CHBRP identified three RCTs (Campbell et al., 2006; Edwards et al., 2013; Hans et al., 2018) and two comparative cohort studies (Kozhimannil et al., 2013b; Nommsen-Rivers et al., 2009) that assessed differences in breastfeeding initiation between doula care and standard care groups; all five studies were conducted among low-income women. Four studies assessed rates of breastfeeding initiation among women who received labor support and postpartum visits from a certified doula, whereas doula-type support in Campbell et al. (2006) was labor support only provided by female friends or family members with minimal training.

Two studies — one RCT of pregnant women in Illinois (Hans et al., 2018) and one prospective comparative cohort study of low-income women in northern California (Nommsen-Rivers et al., 2009) — did not observe any significant differences in breastfeeding initiation between women who received prenatal and postpartum doula support in addition to labor support and women who received standard labor care.

In contrast, three studies — two RCTs (Campbell et al., 2006, Edwards 2013) and one comparative cohort study (Kozhimannil et al., 2013b) — found that that low-income women who received doula or doula-type care were significantly more likely to initiate breastfeeding in the hospital setting as compared with women who received standard labor care. Specifically, the Edwards study evaluating labor support and postpartum doula care, conducted entirely among low-income African American mothers, found that significantly more women who received doula care attempted breastfeeding at least once as compared with women in the standard care control group (63.9% vs. 49.6%, p=0.02).

Summary of findings regarding the impact of doula care on breastfeeding: There is inconclusive evidence from three RCTs and two comparative cohort studies regarding the effectiveness of doula care on breastfeeding initiation among low-income women as compared with standard care.

Figure 13. Maternal Outcomes — Increase Breastfeeding Initiation



Sustained breastfeeding after hospital discharge

Not all women who initiate breastfeeding after birth will continue to breastfeed throughout the first year of the infant's life as recommended by the American Academy of Pediatrics. Although there are many reasons why some women cannot breastfeed, studies indicate that disparities in breastfeeding may be attributable to differences in healthcare access and education.

Three studies — two RCTs (Edwards et al., 2013; Hans et al., 2018) and one cohort study (Nommsen-Rivers et al., 2009) — evaluated long-term breastfeeding after discharge from the hospital; all three studies were conducted among low-income women and included postpartum doula care.

Two studies reported breastfeeding outcomes at 6 weeks postpartum. Whereas the cohort study (Nommsen-Rivers et al. (2009)) did not observe a significant difference in 6-week breastfeeding rates between mothers who had access to two visits from a doula in the first 10 days postpartum and mothers who received standard postpartum care (67.6% vs. 53.8%, p=0.06), one RCT (Edwards et al., 2013) observed that mothers who were randomized to receive up to 12 visits from a doula in the first three months postpartum were significantly more likely to be breastfeeding at 6 weeks as compared with mothers in the usual care group (64% vs. 50%, p=0.04).

The two trials reported breastfeeding outcomes at 3 months postpartum or longer. In their study of doula care for low-income women in Illinois, Hans et al. (2018) observed no differences in breastfeeding at the 3-month follow-up between mothers who were randomized to receive weekly postpartum visits from a doula versus women who had standard postpartum care. Similarly, in a randomized trial of 248 low-income African American mothers, Edwards et al. (2013) did not observe a significant difference in breastfeeding rates at 4 months postpartum between mothers who were randomized to receive up to 12 postpartum visits from a doula as compared with mothers in the usual care group.

Summary of findings regarding the impact of doula care on sustained breastfeeding after hospital discharge: There is limited evidence from two RCTs and one comparative cohort study that doula care is not an effective intervention for increasing post-hospital breastfeeding rates as compared with standard postpartum care. Although mothers in one trial demonstrated greater rates of breastfeeding in the doula intervention group in the short-term (6 weeks), the difference was no longer significant at 4 months postpartum. All studies were conducted among low-income women and included multiple postpartum visits from a doula.

Figure 14. Maternal Outcomes — Increase Sustained Breastfeeding



Abortion and miscarriage outcomes

Procedural pain and length of procedure

Surgical management of abortion or miscarriage is associated with some discomfort that may be attributed to both physical and psychological factors. Doulas provide physical soothing and relaxation techniques during these procedures that may have an impact on the patient experience of discomfort.

CHBRP's literature review identified two RCTs (Chor et al., 2015; Wilson et al., 2017) that assessed the effectiveness of doula support in the context of surgical miscarriage management²⁸ and/or abortion. Both studies found no differences in recalled procedural pain between women who received doula support compared with women who experienced routine care, even after controlling for baseline characteristics. Additionally, Chor et al. (2015) found that the intervention and control groups did not experience significant differences in pain at the time of speculum insertion or differ with respect to procedure duration. Despite the lack of differences in procedural outcomes, almost all women in both doula support groups (97% and 96.2%) said that they would recommend doula support in instances of abortion or miscarriage.

²⁸ Defined as fetal loss at less than 20 weeks of pregnancy (<u>CDC</u>, 2019c).

Summary of findings regarding the impact of doula care on procedural pain or length during abortion or miscarriage: There is limited evidence from two recent RCTs that doula care is not effective in reducing in reducing pain at the time of speculum insertion, procedural pain, or length of procedure for women receiving surgically managed abortions or miscarriages.

Figure 15. Maternal Outcomes — Reduce Procedural Pain During Abortion or Miscarriage

EFFECTIVE						EFFEC
		∧				
Clear and Convincing	Preponderance	LIMITED	Inconclusive	Limited	Preponderance	Clear and Convincing

Effectiveness of Doula Care: Neonatal and Infant Outcomes

Neonatal and infant mortality and stillbirth

Infant mortality is defined as the death of a child after birth and at less than one year of age and is an important marker of the overall health of society (CDC, 2019d). As described in the *Background on Doula Care* section, there are significant disparities in infant mortality in the United States. Stillbirth is fetal death after 20 weeks of pregnancy and before birth.

Two U.S.-based randomized controlled trials of doula care have reported on infant mortality. Among a sample of 6,915 predominantly white Canadian and U.S. women, Hodnett et al. (2002) observed two infant deaths in the control group (one due to a heart defect and one to birth complications) and one death in the intervention group (potentially due to sudden infant death syndrome) with labor supported by doula-trained nurse volunteers. In a more recent trial conducted among 312 mostly Hispanic and African American low-income women in Illinois who were randomized to case-management and standard labor care or prenatal visits and labor support from a certified doula, Hans et al. (2018) recorded three infant deaths in the control group (two in the hospital and one before four months of age, causes of death not described) and no deaths in the doula care group.

Although both trials observed a greater number of infant deaths in the control groups compared with the groups who received doula care interventions, neither trial was powered to assess infant mortality and significance testing was not performed; therefore, CHBRP has insufficient evidence to determine an effect.

Additionally, CHBRP did not identify any studies of doula support in the context of stillbirth.²⁹

Figure 16. Infant Outcomes — Reduce Neonatal and Infant Mortality and Stillbirth

NOT EFFECTIVE		INSUFFICIENT EVIDENCE					
Clear and						Clear and	
Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Convincing	

Preterm birth

A preterm birth is one that occurs more than three weeks before a baby's due date (i.e., before 37 weeks of gestation). Babies born too early are at higher risk of death or disability (CDC, 2019e).

²⁹ Defined as fetal loss after 20 weeks of pregnancy (CDC, 2019c)

CHBRP identified one RCT and three U.S.-based cohort studies comparing preterm birth rates among women who had access to doula care with women who received routine prenatal and labor care.

In a randomized trial of doula care conducted among 312 mostly Hispanic and African American lowincome women in Illinois, Hans et al. (2018) did not observe a significant difference in the incidence of preterm birth between women who were randomized to case-management and standard labor care as compared with women randomized to a doula care intervention that included prenatal visits and labor support from a certified doula (p=0.18).

In contrast, Thomas et al. (2017) found that the rate of preterm births was significantly lower among the 489 women who participated in a full-spectrum doula program offered in four lower-income New York City neighborhoods from 2010 to 2015 (6.3%) as compared with the overall rate in these four communities over the same time period (12.4% [34,912 women]; p=0.001).

In an earlier retrospective cohort study, Kozhimannil et al. (2013a) observed that Medicaid recipients who received prenatal education and childbirth support from trained doulas from 2010 to 2012 in Minneapolis, Minnesota, had a lower rate of preterm birth (6.1%) as compared with all Medicaid-funded births nationally in 2009 (7.3%) but, when adjusted for clinical and sociodemographic factors, this difference was not significant (adjusted odds ratio 0.81 [95% CI: 0.63 to 1.04]). However, a subsequent analysis of this program cohort from Minneapolis including two additional years of data (2010 to 2014) compared with a sample of women on Medicaid from the East North Central and West North Central regions of the Nationwide Inpatient Sample³⁰ observed a significantly lower rate of preterm births among women with doula care after adjustment for maternal age, race-ethnicity, and clinical complications (adjusted OR 0.77 [95% CI: 0.61 to 0.96]). Although Kozhimannil et al. (2016) detected a positive outcome after adjustment, it should be noted that, before adjustment, the control group had significantly higher rates of gestational diabetes, gestational hypertension, and incidence of cesarean delivery, which are all associated with preterm birth. The comparison group was also younger and whiter than the doula group. Additionally, although the preterm birth findings were adjusted for differences in age and race-ethnicity, the control group included women from many highly rural states who may have differed significantly in access to prenatal and birth support as compared with the women in the intervention group who were all residents in the greater Minneapolis area. The authors were unable to control for doula use in the comparator aroup.

Summary of findings regarding the impact of doula care on preterm birth: There is inconclusive evidence from three studies of doula care interventions for low-income U.S. women (one RCT and two large cohort studies) regarding the effectiveness of doula care interventions for reducing the incidence of preterm birth.

Figure 17. Infant Outcomes — Reducing Preterm Birth



Low birth weight

Low birth weight, as defined by the World Health Organization, is a birth weight of less than 2500 grams and is an important predictor of infant health and survival (Cutland et al., 2017).

³⁰ An all-payer inpatient claims database; East North Central region includes Wisconsin, Michigan, Illinois, Indiana, and Ohio; West North Central region includes Minnesota, North Dakota, South Dakota, Iowa, Missouri, Nebraska, and Kansas.

One recent trial conducted among 312 mostly Hispanic and African American low-income women in Illinois observed a 2.6% higher incidence of low-birth-weight babies born to women who were randomized to case-management and standard labor care as compared with women randomized to a doula care intervention that included prenatal visits and labor support from a certified doula (9% vs. 6.4%, respectively); however, the difference between these groups was not statistically significant (p=0.17) (Hans et al., 2018).

In contrast, one comparative cohort study (35,401 women) among women who participated in a fullspectrum doula program offered in four lower-income New York City neighborhoods from 2010 to 2015, found a significantly reduced rate of low-birth-weight infants as compared with the overall rate in these four communities over the same time period (6.5% vs. 11.1%; p=0.001) (Thomas et al., 2017).

Summary of findings regarding the impact of doula care on low birth weight: There is inconclusive evidence from two studies of doula programs for U.S. women (one RCT and one large cohort study) regarding the effect of doula care on the incidence of babies with low birth weight. Although both studies included prenatal and labor support from doulas and were conducted among low-income women, the results yielded contrasting findings, which may be due in part to regional variations between the geographically limited study areas.

Figure 18. Infant Outcomes — Reducing the incidence of Low Birth Weight

NOT EFFECTIVE					EFFECTIVE
Clear and Convincing	Preponderance	Limited	Limited	Preponderance	Clear and Convincing

Admission to neonatal intensive care unit

NICU admission occurs when an infant has significant medical needs, including those due to congenital health issues, birth or pregnancy complications, low birth weight, or prematurity (Harrison and Goodman, 2015).

A meta-analysis of three RCTs (7,740 infants) from high-income countries — specifically, Canada and the United States — performed as part of a 2017 Cochrane review (Bohren et al., 2017) found no difference in the risk of admission to special care nurseries (e.g., neonatal intensive care units) among infants of women who were randomized to receive doula support during labor as compared with infants of women who received standard labor care (RR 0.97 [95% CI: 0.84 to 1.11]).

In addition to the Cochrane review, a recent trial conducted among 312 mostly Hispanic and African American low-income women in Illinois (Hans et al., 2018) found no difference in the risk of NICU admissions among infants born to women who were randomized to standard labor care as compared with women randomized to a doula care intervention that included prenatal visits and labor support from a certified doula (OR 0.87 [95% CI: 0.45 to 1.68], p=0.34).

Summary of findings regarding the effect of doula care on infant admissions to neonatal intensive care units: CHBRP found a preponderance of evidence from a 2017 meta-analysis of three U.S. and Canadian RCTs and one recent U.S.-based RCT indicating that doula support during labor is not effective in reducing the proportion of infants admitted to neonatal intensive care units as compared with standard care.

Figure 19. Infant Outcomes — Reducing Admissions to Neonatal Intensive Care Units

NOT EFFECTIVE					EFFECTIVE
Clear and Convincing	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Prolonged hospital stay

The prolonged hospital stay after birth is a marker of maternal or infant health, as complications or illness could necessitate more time in the hospital. Healthy mothers and infants who experienced an uncomplicated birth stay 1 to 2 days for a vaginal delivery and 3 to 4 days for a cesarean delivery.

A meta-analysis of two U.S.-based RCTs (1,098 infants) performed as part of a 2017 Cochrane systematic review (Bohren et al., 2017) found no difference in the proportion of infants with prolonged neonatal hospital stays among women who were randomized to receive continuous support during labor as compared with women who received standard labor care (RR 0.83 [95% CI: 0.42 to 1.65]).

In addition to the Cochrane review, a recent trial conducted among 312 mostly Hispanic and African American low-income women in Illinois (Hans et al., 2018) found no difference in the risk of a neonatal hospital stay of four days or longer among infants born to women who were randomized to a doula care intervention that included prenatal visits and labor support from a certified doula as compared with as compared with women randomized to standard labor care (OR 0.89 [95% CI: 0.48 to 1.63], p=0.35).

Summary of findings regarding the effect of doula care on prolonged neonatal hospital stays: CHBRP found a preponderance of evidence from a 2017 meta-analysis of two U.S.-based RCTs and one recent U.S.-based RCT indicating that doula support during labor is not effective in reducing the proportion of infants with prolonged hospital stays as compared with standard labor care.

Figure 20. Infant Outcomes — Reducing Prolonged Hospital Stays

NOT EFFECTIVE					EFFECTIVE
Clear and Convincing	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing

Harms of Doula Care

A 2017 Cochrane systematic review of continuous support for women during childbirth including 27 RCTs accounting for 15,858 women in high- and middle-income countries found no evidence of maternal or infant harms attributed to labor support companions (i.e., doulas) (Bohren et al., 2017). It is, however, unclear whether harms were systematically assessed in the included studies.

None of the13 individual studies (seven trials and five cohort studies) of doula care included in CHBRP's medical effectiveness analysis evaluated the harms of doula care. However, as described in the *Public Health Impacts* section, women who receive doula care report high rates of satisfaction and positive birth experience perceptions.

Summary of findings regarding the harms of doula care: There is insufficient evidence from one systematic review and 13 individual studies to determine whether adjunctive doula care — delivered at any stage of pregnancy or postpartum; during labor and delivery; or for abortion, miscarriage, or stillbirth — is associated with harms.

Figure 21. Harms of Doula Care

NOT EFFECTIVE		INSU	INSUFFICIENT EVIDENCE			EFFECTIVI		
Clear and Convincing	Preponderance	Limited	Inconclusive	Limited	Preponderance	Clear and Convincing		

Summary of Findings

Table 5 summarizes evidence of the effectiveness of doula care interventions provided in conjunction with standard perinatal care versus standard perinatal care alone with respect to maternal and neonatal/infant outcomes. Evidence is reported separately by outcome and level of outcome effectiveness.

There is evidence that adjunctive doula care interventions are *more effective* than standard perinatal care alone for: decreasing the use of pain medication (including epidurals) during labor and increasing the incidence of spontaneous vaginal delivery.

There is evidence that adjunctive doula care interventions are *not more effective* than standard perinatal care alone for reducing severe labor pain, reducing the use of synthetic oxytocin for labor augmentation, reducing the incidence of perineal trauma, reducing postpartum depression, increasing sustained breastfeeding after hospital discharge, reducing pain during surgical abortions or miscarriages, reducing NICU admissions, and reducing prolonged hospital stays for infants.

There is *inconclusive evidence* regarding the effectiveness of adjunctive doula care interventions as compared with standard labor care alone for: duration of labor, rates of cesarean delivery, rates of operative vaginal delivery, breastfeeding initiation, preterm birth, and low neonatal birth weight.

There is *insufficient evidence* to assess the effectiveness of doula care interventions as compared with standard labor care alone for: attendance at childbirth classes, infant mortality, maternal mortality, prenatal depression or anxiety, and harms. Please note that absence of evidence is not evidence of no effect. Maternal and infant mortality are rare outcomes, and no studies to date have been of sufficient size to assess the effect of doula care interventions on mortality.

CHBRP notes the lack of studies using certified doulas, and, more specifically, the community doula model, in the U.S. Medicaid population. The above outcomes with inconclusive or insufficient evidence outcomes are due to this lack of studies. The limited and preponderance of evidence conclusions are based on more studies with the limitations as noted. Additionally, few studies conducted analyses stratified by racial or ethnic groups with known disparities in maternal and infant outcomes thereby limiting the ability of this review to assess the potential effect of doula care interventions on disparities in birth outcomes in California.

	Not Effective	Not Effective	Not Effective		Effective	Effective	Effective	
Outcome	Clear and Convincing	Preponderance of evidence	Limited evidence	Inconclusive	Limited evidence	Preponderance of evidence	Clear and Convincing	Insufficient
Maternal Outcome	es							
Attendance at childbirth class classes								Х
Prenatal Depression and/or Anxiety								х
Length of Labor				Х				
Severe Labor Pain		Х						
Use of Pain Medication						Х		
Use of Synthetic Oxytocin		Х						
Spontaneous Vaginal Delivery					Х			
Cesarean Delivery				Χ*				
Operative Vaginal Delivery				х				
Perineal Trauma			Х					
Maternal Mortality								Х
Postpartum Depression			Х					
Breastfeeding Initiation				Х				

Table 5. Summary of Evidence of Medical Effectiveness of Doula Care

Outcome	Not Effective Clear and Convincing	Not Effective Preponderance of evidence	Not Effective Limited evidence	Inconclusive	Effective Limited evidence	Effective Preponderance of evidence	Effective Clear and Convincing	Insufficient
Sustained Breastfeeding after Hospital Discharge			Х					
Pain During Abortion and Miscarriage Surgical Procedure			х					
Neonatal and Infa	nt Outcomes							
Neonatal and Infant Mortality, Stillbirth								х
Preterm Birth				Х				
Low Birth Weight				Х				
Admission to NICU		Х						
Prolonged Infant Hospital Stay		Х						

Source: California Health Benefits Review Program, 2020. *The medical effectiveness review conclusion is based on conflicting evidence from five RCTs, two cohort studies, and two meta-analyses regarding the effect of doula care on the rate of cesarean deliveries; the Cost section uses evidence from a single cohort study showing a reduction in cesarean deliveries in a similar Medicaid pilot program for their cost estimates (see *Benefit Coverage, Utilization and Cost Impacts section* for details). *Key:* NICU = Neonatal Intensive Care Unit.

BENEFIT COVERAGE, UTILIZATION, AND COST IMPACTS

As discussed in the *Policy Context* section, AB 2258 would establish a three-year pilot program in Medi-Cal for coverage of full-spectrum doula services by DMHC-regulated Medi-Cal managed care plans, County Organized Health Systems (COHS), and the Medi-Cal fee-for-service (FFS) program in 14 counties (see *Policy Context* section for list of counties). Beginning July 1, 2021, the Department of Health Care Services (DHCS) would implement the pilot such that enrollees are eligible for at least four prenatal appointments, continuous support during labor and delivery, and at least eight postpartum appointments (within 12 months of delivery) without prior authorization or cost sharing. The doula services would be available for pregnant women in the event of a live birth, abortion, stillbirth, or miscarriage. CHBRP estimates that approximately 204,000 female Medi-Cal beneficiaries aged 15 to 44 years (childbearing age) who reside in the 14 counties identified by AB 2258 would be eligible for the newly developed doula pilot program.

The full text of AB 2258 can be found in Appendix A.

This section reports the potential incremental impacts of AB 2258 on estimated baseline benefit coverage, utilization, and overall cost. The analysis presented here is based upon the following:

Assumptions

- The first year of the pilot is set to launch by July 1, 2021, based upon the state fiscal year. The CHBRP cost model is based upon a calendar year estimate due to the focus on insurance benefit mandates that typically go into effect by January 1, 2021. CHBRP assumes that the time period, enrollment trends, claims experiences, and program implementation from July 1, 2021, to June 30, 2022 (Year 1 of the pilot), would be equivalent to the time period from January 1, 2021, to December 31, 2021 (Year 1 from CHBRP's cost model), such that the calendar year estimates of benefit coverage, utilization, and cost impacts would be similar to modeling the state fiscal year impacts.
- Implementation of the pilot program would occur on-time (by July 1, 2021) and that DHCS and the affiliated Medi-Cal managed care plans would be able to enroll eligible pregnant women and provide the full-spectrum of doula services to support enrollees in all 14 pilot counties by July 1, 2021. Therefore, CHBRP's First Year estimate (Table 1) is based on "full implementation" of the program, including the necessary competency training, billing, registry, contracting, rate setting, and other steps required by the program.
- The size and proportion of the eligible Medi-Cal population aged 15 to 44 (based on 2020 administrative enrollment data and demographic data from the 2018 California Health Interview Survey), and the underlying rate of pregnancy, abortion, miscarriage, and stillbirth would not substantially change by 2021 when the program is scheduled to be fully implemented.
- Pregnant women in Medi-Cal would continue to receive services through FFS or Medi-Cal managed care plans based on their aid code and eligibility for partial- or full-scope benefits. The new doula services required in the 14 pilot counties would be paid at the same rates determined by the state for each pilot county, regardless of whether a Medi-Cal managed care plan or Medi-Cal FFS is paying for the service.
- The prices CHBRP used to calculate the costs associated with the doula pilot program are based on external benchmarks and relative costs of equivalent programs. The rates used by Medi-Cal in each pilot county could differ substantially, and therefore the costs of the program estimated by CHBRP may not be supported by final reimbursement rates and methods used by DHCS in estimating the expenditures for the pilot or the long-term actual costs of the pilot program.
- It is assumed that 18% of non-elderly, non-disabled enrollees in California have FFS coverage (Kaiser Family Foundation, 2019).

 Locally run or health plan–operated doula pilots are not equivalent in terms of benefit coverage or scope of program to the pilot program proposed by AB 2258. CHBRP is aware of two different doula pilots that may have enrolled Medi-Cal enrollees in the past two years, but both are small in size (150 or fewer people) and therefore are not counted as a covered benefit in Medi-Cal. Additionally, no paid claims or encounters are available in the 2017 Milliman Consolidated Health Cost Guidelines Sources Database (CHSD) to estimate their availability, use or cost.

Considerations

- According to administrative enrollment data from Medi-Cal, there are 10,206,442 non-elderly beneficiaries who are not dually eligible in Medicare in the 14 pilot counties in 2020. Based upon 2018 California Health Interview Survey (CHIS) data, 26% (2.65 million) of the Medi-Cal enrollees in those 14 counties are women aged 15 to 44. Using actuarial analysis of the 2017 Milliman Consolidated Health Cost Guidelines Sources Database (CHSD), which includes Medi-Cal claims and encounter data and information on the number of births paid for by Medi-Cal managed care plans each year, CHBRP was able to estimate that 203,991 pregnant women in the first year postmandate would be eligible for doula services through the pilot. Pregnancy events within the claims data are as follows:
 - o Live births: 97.2%
 - Abortion or miscarriage: 1.9%
 - Stillbirth: 0.9%
- Approximately 20% of the almost 204,000 eligible pregnant women who experienced live birth, abortion, miscarriage, or stillbirth would use the doula services offered by the pilot. This estimate is based on the participation rate of a previous evaluation of a program offered by the YWCA, (Mottl-Santiago et al., 2008) and preferences from the *Listening to Mothers in California* survey, which found that 20% of Medi-Cal enrollees reported definitely wanting doula services and that 11% of respondents in Medi-Cal reported using doula services in the past (Sakala et al., 2018).
 - The participation rate for the doula program is in part based on the assumption that the program would be implemented by DHCS per the requirements of the bill (including the requirements to establish a doula registry and certification program, establish payment rates, issue NPIs, and ensure Medi-Cal managed care plans provide information to pregnant Medi-Cal enrollees about the doula program). However, the participation in the program may be lower if there are delays or challenges to implementation or if there are not enough trained doulas available to provide the services.
- Although AB 2258 states that reimbursement rates for doula services would be based on the underlying cost of living and sustainable living wage in the pilot region, CHBRP calculated an average per-visit fee based inclusive of travel reimbursement, benefits, administration, and overhead. The range of fees could differ depending on the pilot county's underlying wages, travel distances, and cost of living. However, CHBRP is not estimating a county-level benefit coverage, utilization, or cost impact and therefore the average price per visit should not be used to estimate the cost for each county pilot due to differences in underlying pregnancy rates, population age, Medi-Cal reimbursement rates, doula capacity, and other related factors.
 - AB 2258 requires each county's reimbursement rate to be based upon underlying wages, benefits, and transportation needs in the area. CHBRP calculated an average rate for use in this analysis that represents a \$30/hour living wage (inclusive of transportation, overhead, and benefits) that should be broadly applicable whether services are delivered by a community-based doula or individual doula. However, CHBRP acknowledges that actual rates paid by Medi-Cal could be higher in higher-cost urban counties and lower in lower-cost rural or suburban counties. CHBRP has also assumed each prenatal and postpartum visit would on average be one hour in duration. It is possible that doula visits may be shorter or longer depending on the expecting mother's needs and the doula's practice.

Existing doula programs in Oregon (\$350) and Minnesota (\$411) have lower total 0 reimbursement rates than used in CHBRP's calculations (Kozhimannil & Hardeman, 2015: Oregon Health Authority, 2018). CHBRP assumed that the underlying sustainable living wages and cost of living were higher in the 14 pilot counties than those in Oregon and Minnesota. In addition, the Oregon and Minnesota programs covered a lower number of prenatal and postpartum visits than proposed in AB 2258. CHBRP also examined the rates paid to doulas in New York's pilot program (which covers Erie [Buffalo] and Kings [Brooklyn] counties. New York's pilot pays \$30 per visit (for up to four prenatal and four postpartum) and \$360 for labor and delivery attendance, for a total of \$600. The \$30 per visit (\$720 inclusive of all 12 visits plus labor and delivery attendance) reimbursement rate for doula services calculated by CHBRP is based partially on data from the three other states with existing doula programs or pilot programs, as well as a collection of private doulas who have publicly available rates online.³¹ Historically, Medi-Cal reimbursement rates are 40% lower than those available in the commercial insurance market or Medicare for a range of services (Zuckerman et al., 2017).

CHBRP estimated that each pilot participant would use, based on the language in AB 2258: four prenatal doula visits (\$120), one labor/delivery attendance or equivalent service (\$360), and eight postpartum doula visits (\$240), for a total all-inclusive rate of \$720 on average for each pilot participant. Although AB 2258 states that at least eight doula visits would be covered during the postpartum period, some populations (e.g., those with only 60 days of postpartum eligibility, partial-scope enrollees) may use fewer visits overall due to short-term Medi-Cal enrollment but are not prohibited from using all eight visits in the 60-day period following delivery. The population who have full-scope Medi-Cal has postpartum coverage for up to a year following the end of the pregnancy. This population may use more than eight visits postpartum. For simplicity and to model utilization and cost impacts, CHBRP assumes that women enrolled in a doula program would use an average of eight visits postpartum.

It is also possible that women who experience stillbirth, miscarriage, or abortion may not use the same number of prenatal or attendance services as enrollees experiencing live births.

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

Baseline and Postmandate Benefit Coverage

Currently, no enrollees with health insurance that would be subject to AB 2258 have coverage for fullspectrum doula services as proposed in AB 2258.

Current coverage of full-spectrum doula services for live births, abortion, miscarriage, and stillbirth was determined by a CHBRP survey of the largest (by enrollment) providers of Medi-Cal managed care in California. Responses to this survey represent 43% of enrollees with Medi-Cal health insurance that would be subject to this 14-county pilot program.

AB 2258 would result in new benefit coverage for all 203,991 pregnant women in the 14 pilot counties who are enrolled in Medi-Cal (see estimates in Table 1). As discussed in the *Policy Context* section, and above, Medi-Cal managed care plans may offer a pilot program to cover doula services in certain counties but these are not available to all enrollees. Based on the current coverage survey, enrollment in pilot programs are capped. In addition, while the Listening to Mothers survey indicated that 11% of Medi-Cal enrollees reported using a doula in the past, it is unlikely that it was delivered through Medi-Cal

³¹ International Doula Institute. Doula Salary. Available at: <u>https://internationaldoulainstitute.com/doula-salary/;</u> University of Washington Center for Health Innovation & Policy Science. The Doula Option, an Opportunity to Improve Birth Outcomes in Washington State. Available at: <u>https://depts.washington.edu/uwchips/docs/brief-doula-option.pdf;</u> Office of the Secretary of State, Oregon. Permanent Administrative Order DMAP 19-2018. Available at: <u>https://www.oregon.gov/oha/HSD/OHP/Policies/130-0015-04022018.pdf</u>.

directly and may have been delivered via separate community or hospital programs, paid for out-ofpocket, or delivered via a health plan pilot program that was not explicitly part of Medi-Cal benefits (Sakala et al. 2018). Therefore, CHBRP has assumed current coverage rates to be 0%.

Baseline and Postmandate Utilization

Currently, CHBRP does not have estimates of baseline utilization of doula services by pregnant women in Medi-Cal managed care plans or in FFS Medi-Cal because the services are not covered and there is no mechanism to bill Medi-Cal for doula services. Due to the lack of benefit coverage, CHBRP concludes that Medi-Cal is providing no doula services to their enrollees in the 14 pilot counties, and if any Medi-Cal enrollees are using doula services they are paying out of pocket for the service or receiving the services through separate community or hospital programs, or through a separate health plan pilot program.

Postmandate, CHBRP estimates that 40,798 (20%) of the 203,991 pregnant women would use doula services. On average, they would use four prenatal visits, one attendance visit for labor/delivery, and eight postpartum visits. Although the *Medical Effectiveness* section reported mixed findings on doula services impact on cesarean delivery rates, CHBRP used one study on Medicaid coverage for doula services in Minnesota (Kozhimannil et al., 2013) which is most applicable to this specific pilot program and design to predict a 29% reduction in cesarean delivery rates among doula pilot participants in the 14 counties. CHBRP estimates that vaginal deliveries would increase by 3,441 (2.44%), while cesarean deliveries would decrease by the same number (which represents a 5.84% decrease because the number of vaginal deliveries exceeds the number of cesarean deliveries in Medi-Cal) (Table 1).

See Potential Cost Offsets or Savings in the First 12 Months After Enactment section below for summary of the rationale for these estimates, and Appendix C for more detailed information on the methods and data sources used in this analysis.

Baseline and Postmandate Per-Unit Cost

Due to the lack of baseline benefit coverage and payment mechanisms in Medi-Cal to deliver doula services, CHBRP estimated the per-unit cost of each visit to be \$30 for doula services. CHBRP estimated that each doula visit (prenatal or postpartum) would last approximately one hour and the rate would include the cost of travel/mileage. CHBRP estimated the labor/delivery attendance per-unit cost to be \$360 (the equivalent of a 12-hour-long visit on average). The total average cost of doula services per pregnant woman is estimated to be \$720 per year.

Baseline and Postmandate Expenditures

AB 2258 would increase total net annual Medi-Cal expenditures in the 14 pilot counties by \$32,495,448, or 0.08%. AB 2258 prohibits cost sharing for enrollees using doula services, meaning the entire increase would be borne by Medi-Cal, and none by enrollees.

Enrollee Expenses

AB 2258–related changes in enrollee expenses for covered benefits (deductibles, copays, etc.) and enrollee expenses for noncovered benefits would be zero due to the prohibition on cost sharing in AB 2258 for enrollees in the 14-county pilot.

Out-of-pocket spending for covered and noncovered expenses

CHBRP concludes that there would be an unknown reduction in out-of-pocket spending on doula services for pregnant women who are able to obtain coverage for doula services through Medi-Cal in the 14 pilot

counties. It is unknown how many Medi-Cal enrollees currently use doula services and pay out-of-pocket at commercial rates. If residing in the 14 pilot counties, those enrollees would benefit from no cost doula services to replace their current out-of-pocket spending on doula services.

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

As described in the *Medical Effectiveness* section, the evidence is inconclusive regarding reduction in cesarean delivery rates due to doula care. Findings vary from interventions with no effect to others with significant positive associations between doula services and higher rates of spontaneous vaginal delivery. Two randomized controlled trials and one cohort study (Hodnett et al., 2002; Hans et al., 2018; Thomas et al., 2017) found slight, not statistically significant reductions in cesarean deliveries when compared to spontaneous vaginal deliveries for participants in three different doula models. However, another study that relied on an on-call certified doula model found that women who received doula support were four times more likely to deliver vaginally. The meta-analyses reviewed in the *Medical Effectiveness* section also showed variation in overall findings, with several showing nonsignificant effects and others suggesting a 25% reduction in cesarean births (Bohren et al., 2017).

Another study analyzed national hospital discharge data to estimate the cost-effectiveness of doula care (Kozhimmanil et al. 2016). This study found a 40.4% difference in cesarean deliveries experienced by women who used doula care when compared to births that occurred without a doula. Multivariate results suggested a 22% lower odds of delivering via cesarean when using doula services. CHBRP did not rely on this study for the cost estimates for several reasons. First, the study relied on the 20% National Inpatient Sample (NIS) of hospital discharges for 12 central states (including Minnesota) for control group data. The NIS does not support state-level estimates and is only considered representative of the universe of inpatient hospital discharges at the regional or national-level. Because of this, the authors could not remove discharges that occurred in Minnesota from the control group, or determine whether women in the other 11 states included in the region had received doula services that may have influenced their birth outcomes. Secondly, the data for those using doula services in Minnesota came from a separate community-based organization that provided doula services in the state. It is unclear if the organization had access to actual Medicaid claims or enrollment data, and whether all 1,935 women participating in the program were Medicaid enrollees, although many of their clients came via referral from Medicaid managed care plans. The authors report that all 1.935 participants were at or below the Medicaid eligibility threshold in terms of income, but it is unclear if that data is comparable to the Medicaid variables used in the 20% NIS sample or if the participants were continuously enrolled in Medicaid throughout the program. Thirdly, as mentioned in the Medical Effectiveness section, CHBRP had concerns about the make-up of the control group from the 12 states and their underlying health issues that could have been associated with preterm births or cesarean delivery use at baseline. Lastly, the 2016 study provides data on the impact of the doula program in Minnesota over a longer period of time. The earlier Kozhimannil et al. (2013) study may better reflect the likely impact of AB 2258's proposed Medicaid pilot program during the first year, as reported in Table 1.

CHBRP relied on one recent study (Kozhimannil et al., 2013) for the cost modeling, because it provides evidence from a Medicaid program in Minnesota that is very similar to the doula pilot proposed by AB 2258. This study found that Medicaid enrollees who participated in the full-spectrum doula program experienced a 29% reduction in cesarean delivery compared to nonparticipating Medicaid enrollees. Because CHBRP estimates that only 20% of eligible women would participate in the first year of the program (Mottl-Santiago et al., 2008, Sakala et al., 2018), the 29% reduction in cesarean delivery use is only applied to that subset of participating women. Because this predicted reduction is based upon a cohort study (Kozhimannil et al., 2013) rather than a randomized clinical trial (RCT) or meta-analysis, it could be subject to a selection effect such that women who participated in the Minnesota Medicaid doula program may have had a predisposition to seek vaginal delivery over cesarean. While that is a concern, the 20% of women CHBRP predicts would participate in the Medi-Cal doula pilot proposed by AB 2258 may also have a predisposition to seek vaginal delivery regardless of their decision to seek doula services. CHBRP is not suggesting that all eligible women would participate in the program or that they would all experience a lower likelihood of delivering via cesarean. CHBRP predicts that of the 11,783

deliveries that would have been performed via cesarean among women using doula care, 3,441 (29%) would be replaced by vaginal delivery due to the presence of the doula program. CHBRP determined that the results from Minnesota's Medicaid doula program are most consistent with the design and approach of the doula pilot proposed by AB 2258.

In the 12 counties that participate partially in FFS Medi-Cal (representing 16% of the county Medi-Cal enrollees), the lower relative price for vaginal delivery when compared to cesarean delivery would result in a reduction in expenditures for births in the 12 counties participating in the pilot program. However, due to fixed maternity supplemental (kick) payments made by Medi-Cal to the Medi-Cal managed care plans, there would be no difference in Medi-Cal expenditures between cesarean and vaginal births.³² The current maternity supplemental (kick) payments are triggered by a live-birth event and are a blended rate based on both cesarean and vaginal live births (DHCS, 2012). Therefore, the cost savings in Year 1 (see Table 1) of the program would only be realized in the FFS portion of the Medi-Cal births, and there would be no savings to the Medi-Cal program for Medi-Cal managed care plan enrollees because the existing maternity supplemental (kick) payment are set prospectively and would not differ based on type of delivery. Unless the pilot program explicitly sets new maternity supplemental (kick) payments for the participating counties, cost savings would not be realized by Medi-Cal even if the Medi-Cal managed care plans are experiencing a shift in cesarean deliveries due to the pilot program. Please see the *Long-Term Impacts* section for additional discussion.

Although the *Medical Effectiveness* section states that doula care is likely to decrease use of epidural anesthesia, CHBRP does not incorporate that into the cost offsets because of the manner in which claims/encounters are paid for in Medi-Cal managed care, and the way in which labor/delivery is paid for via maternity supplemental (kick) payments. Because DHCS calculates a blended payment rate for all births in a county, immediate changes in epidural use would not result in direct cost savings or offsets. Further discussion of this issue is included in Appendix C and the *Long-Term Impacts* section.

CHBRP concluded that there are no savings due to a reduction in preterm births because there is mixed evidence that doula care results in reductions in preterm births, with a nonstatistically significant reduction in a recent systematic review (Bohren et al., 2017). As mentioned in the *Medical Effectiveness* section, there are no differences in perineal trauma, postpartum depression, oxytocin use, need for Neonatal Intensive Care (NICU), or length of hospital stay associated with doula care when compared to standard care.

Overall, despite savings to FFS Medi-Cal for avoided cesarean deliveries, the overall spending in Medi-Cal would increase due to the payments to doulas for providing care to 20% of pregnant women in the pilot counties.

Postmandate Administrative Expenses and Other Expenses

CHBRP estimates that the increase in administrative costs of Medi-Cal managed care plans would remain proportional to the increase in expenditures. 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 and to comply with the requirements of participating in the pilot, Medi-Cal managed care plans would develop methods to inform pregnant women and their providers about access to doula services as described in AB 2258 (i.e., notifications at each visit). All health plans and insurers include a component for administration and profit in their premiums. In the case of Medi-Cal managed care plans, CHBRP estimates a 12% administrative/overhead rate.

³² The Department of Health Care Services publishes the range of capitated rates and maternity supplemental (kick) payments for Geographic Managed Care

⁽https://www.dhcs.ca.gov/Documents/CRDD%20Files/GMC%20Classic%20Rates%20SFY%202017-18.xls) and Two-Plan Model (https://www.dhcs.ca.gov/Documents/CRDD%20Files/Two-Plan_Classic_Rates_SFY_2017-18.xls) counties.

In administering the pilot, DHCS would incur costs related to creating and maintaining the registry of doulas, negotiating and contracting with the managed care plans in the 14 counties, and overseeing the pilot. However, these expenditures by the program are typically absorbed by changes in staff assignments, division resources, and other methods that may not result in new administrative costs. The actual costs of those tasks are unknown, because they are likely to be delivered using current resources and staffing allocations as many other DHCS demonstrations and pilot programs have been. States receive 50% Federal Financial Participation for spending related to administration of Medicaid programs, therefore any added cost would be partially paid for with federal funds.

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.

Postmandate Changes in the Number of Uninsured Persons

Because the change in expenditures is limited to the Medi-Cal program and does not cause increases in private insurance premiums, CHBRP expects no measurable change in the number of uninsured persons due to the enactment of AB 2258.

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 AB 2258.

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

Despite the lack of benefit coverage for doula services in the commercial insurance market, the creation of the 14-county pilot in Medi-Cal to provide doula services is unlikely to result in new take-up of Medi-Cal coverage by eligible women. Technically, women with commercial insurance coverage could sign up for Medi-Cal to cover benefits related to their pregnancy, either because they are already low income (below 138% FPL) and currently have commercial, employer-based insurance; or because they earn between 150% FPL to 213% FPL and are eligible for Medi-Cal for pregnant women; or can buy in to the pregnancy benefit by paying 1.5% of their annual household income through the Medi-Cal Access Program (MCAP) if they earn between 213% FPL to 322% FPL. However, the network of providers, appointment availability, other benefit differences, share of cost (especially for those eligible for MCAP who must pay 1.5% of their family income), and other factors are likely to prevent any measurable shift.

PUBLIC HEALTH IMPACTS

As discussed in the *Policy Context* section, AB 2258 would mandate coverage of full-spectrum doula care through a 3-year Medi-Cal pilot program across 14 counties, which cover about 80% of Medi-Cal enrollees. This bill seeks to improve maternal and infant health outcomes for groups at excess risk of poor pregnancy and birth outcomes.

This section estimates the short-term impact (within first 12 months of implementation of AB 2258) on process measures and health outcomes for which there is evidence of positive effects for pregnant women using doula services (see *Medical Effectiveness* section). This section also presents the impact of AB 2258 on disparities and social determinants of health. See *Long-Term Impacts* for additional discussion of social determinants of health beyond the first 12 months postmandate.

Estimated Public Health Outcomes

See the *Medical Effectiveness* section (Table 5) for detailed evidence regarding the impact of doula care for multiple maternal and neonatal/infant outcomes. In brief, CHBRP found evidence that doulas may help to increase spontaneous vaginal deliveries and reduce use of pain medications during labor. However, CHBRP found no evidence that these nonclinical support persons reduce maternal or infant mortality, preterm birth, or low-birth-weight babies.

As presented in *Benefit Coverage, Utilization, and Cost Impacts*, CHBRP projects a 20 percentage point increase in the use of doulas by Medi-Cal beneficiaries in the 14 specified counties. This would result in approximately 3,400 fewer cesarean births (5.84% decrease from 58,914 cesarean births) and a commensurate increase in spontaneous vaginal births (2.44% increase). Based on the evidence, this projected decrease in cesarean deliveries would likely result in some decreased rate of complications from wound infections, organ damage during surgery, prolonged healing, and increased risk for future cesarean deliveries. Infant rates of negative health outcomes (e.g., asthma, decreased intestinal microbiome diversity) could also be reduced. CHBRP also anticipates an unquantified decrease in the use of pain medication, including epidurals, based on the evidence reviewed.

Birth experience and disparities

Although CHBRP's medical effectiveness review found no effect on diminishing postpartum depression or labor pain, there is evidence of maternal satisfaction with doulas improving the overall birth experience. Sakala et al. (2018) reported that more than 50% of Medi-Cal beneficiaries who recently gave birth were definitely interested or would consider doula support for future pregnancies. Among racial/ethnic groups, 27% of black women reported future desire for doula support, followed by Asians and whites (16% each). The requirement in AB 2258 for at least eight postpartum visits could be well matched with the needs of black California mothers, who report more postpartum visits than their white counterparts, perhaps indicating a need for more postpartum care (Sakala et al., 2018).

The body of literature around full-spectrum doulas, especially those who practice a community-based model, is under development and opportunities for more rigorous evaluations of such interventions remain (see Table 2 for doula descriptions). Based on current evidence, there is an association with full-spectrum/community-based doula support in helping low-income pregnant women exercise agency, assert informed labor decisions, and improve pregnant women's overall birth experience including better provider communication and adherence to birth plan (Bey et al., 2019; Kozhimannil et al., 2016; Thomas et al., 2017; Wilson et al., 2017). The shared experience, trauma-informed training, and well-developed referral sources for clients are unique traits that inform culturally concordant care provided by community-based doulas in particular (Bey et al, 2019; CBI, 2020). Uptake of doula support, especially community-based doulas for low income women, could reduce some disparities among racial/ethnic groups' birth experiences and birth outcomes (i.e., potentially preventable cesarean births and undesired epidural use).

Evidence indicates that disparities in access to doula care in the general population exist. Furthermore, racial/ethnic and income disparities in birth outcomes exist in California.

Due to evidence of effectiveness of doula services and a projected increased use of doulas, CHBRP anticipates that AB 2258 would:

- Decrease disparities in access to doula services between Medi-Cal (low income) and higher income pregnant women.
- *Increase* spontaneous vaginal births by about 3,400 cases (with a commensurate decrease in cesarean births).
 - Likely reduce disparities between Medi-Cal beneficiaries' and privately insured enrollees' cesarean birth rates and may decrease disparities within the Medi-Cal population among racial/ethnic groups, specifically for Latina and black Medi-Cal beneficiaries, who experience the highest rates of cesarean deliveries in California.
- Decrease unwanted/unnecessary pain medication use during labor by an unknown quantity.
- Increase maternal satisfaction with the birth experience.

Due to evidence of no effectiveness of doula services, CHBRP projects that AB 2258 would:

• Not change rates of severe labor pain, utilization of synthetic oxytocin, breastfeeding, NICU admission, or prolonged infant hospital stay.

CHBRP is unable to project a change in rates of maternal mortality, infant mortality, preterm birth and low birth weight due to insufficient or inconclusive evidence of doula services.

Social Determinants of Health (SDoH)

SDoH include factors outside of the traditional medical care system that influence health status and health outcomes (e.g., education, housing, income, racism/implicit bias, income).

Potential Impact of Doula Support on the Intersection of Discrimination, Racism, and Poverty in Poor Perinatal Outcomes

Disparities in maternal and infant birth outcomes by race/ethnicity and income are prevalent in California. As described in the *Background on Doula Care* section, blacks and Native Americans are overrepresented in Medi-Cal, yet experience higher rates of infant mortality, maternal mortality, preterm labor, low-birth-weight babies, and cesarean deliveries than whites. Latinas have the second highest rate of low-birth-weight babies in the state. Excluding mortality, each of these outcomes is accompanied by short- and/or long-term complications for the infant.

AB 2258 seeks to establish full-spectrum doula care pilot programs, including community-based doulas, in those communities most affected by high rates of poor birth outcomes. In particular, community-based doulas provide well-rounded knowledge of community resources and services, which are used to help clients navigate systems and mitigate negative social determinants of health.

Discrimination and racism

There is a growing body of evidence that associates discrimination and racism (interpersonal and structural, respectively) with self-reported poor health outcomes, including poor birth outcomes (Chambers et al., 2018; Chambers et al., 2019; Williams et al., 2019) that can lead to lifelong health

disparities (Pearl et al., 2008). A systematic review by Priest et al. (2013) reported that 14 studies measured negative pregnancy outcomes (low birth weight, preterm birth, low birth weight with preterm birth, and very low birth weight) and in 11 of those studies (79%), the outcomes were "positively associated with reported racial discrimination." Furthermore, based on a systematic review of 121 studies, Paradies et al. (2014) found evidence (but no pattern) of racist beliefs, emotions, and behavior/practices among health care providers. Another study described an association between chronic worry about racial discrimination and preterm birth disparities between black and white California women (Braveman et al., 2017).

Due to a lack of evidence regarding doula services impacting social determinants of health, CHBRP is unable to estimate a change in poor perinatal outcomes associated with interpersonal or structural racism.

Poverty and poor perinatal outcomes

Medi-Cal can be considered a proxy indicator of low income. Pearl et al. (2018) describe the significant role that early-life and sustained exposure to residential poverty play in risk of preterm birth based on analysis of two generations of California births. They found that "low opportunity" (income at or below the federal poverty line) was associated with a statistically significant risk difference for preterm birth among white (7.7/100 births), black (11.0/100), and Latina (8.7/100) populations. Increased risk for preterm birth was also associated with a decline in opportunity ("downward mobility") for these populations. A smaller risk persisted for black mothers who experienced upward mobility.

Due to a lack of evidence regarding doula services impacting social determinants of health, CHBRP is unable to estimate a change in poor perinatal outcomes associated with poverty.

LONG-TERM IMPACTS

In this section, CHBRP estimates the long-term impact of AB 2258, 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

The 14-county pilot program proposed in AB 2258 is limited to three years without further legislative or administrative action. If the program is successful based upon the required evaluation, DHCS would have the option of expanding the pilot to additional counties and also continuing to operate the pilot in the existing counties. If the pilot results in additional doulas obtaining training, obtaining an NPI number, and being added to the registry, additional supply would be available to provide services to pregnant women in the state if doula services became more popular and readily accessible. That could result in additional women participating (above the 20% participation rate CHBRP calculated based upon Mottl-Santiago et al. (2008) and Sakala et al. (2018) and additional utilization of services.

Cost Impacts

Any increase in doula popularity, supply, or expansion of the pilot to more counties could result in additional utilization of doula services. Despite the cost offsets created by fewer cesarean deliveries in fee-for-service Medi-Cal, the long-term costs would increase if utilization increased over time. It is also important to note that the Medi-Cal managed care plan payments made by Medi-Cal to the health plans are calculated in advance based on previous claims experience. In the case of this pilot, the reduction in cesarean deliveries among Medi-Cal managed care enrollees is unlikely to be reflected in the prospectively set maternity supplemental (kick) payments made to plans in the short-term. However, after 2 to 3 years when rates are recalculated, if the mix of cesarean and vaginal delivery changes due to the program, it could be reflected in the maternity supplemental (kick) payments made to plans, which may result in savings to the Medi-Cal program.

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.

As noted above, CHBRP projects a potential unknown increase in utilization of doulas by Medi-Cal beneficiaries in years 2 and 3 of the pilot established by AB 2258. There are several reasons supporting a projected unquantified increase in use of doulas. First, research (discussed in the *Background on Doula Care* and *Public Health* sections) demonstrates Medi-Cal beneficiary receptivity to doula use (Mottl-Santiago et al., 2008; Sakala et al., 2018). Second, AB 2258 requires plans and policies to inform pregnant Medi-Cal beneficiaries of coverage for doula care, who are less likely to be familiar with doulas than middle- and upper-income women (Lanning and Klaman, 2019).

Third, AB 2258 directs DHCS to work with nonprofits and foundations to establish free training that meets AB 2258 criteria. In a small qualitative study by Hardeman and Kozhimannil (2016), recent doula trainees reported a key motivation for pursuing this profession was their ability to "hold space" to help transition

clients to motherhood in a culturally competent manner. Because of shared experience (plus training), these respondents felt that their cultural knowledge and commitment to social justice acted as a buffer or improved the patient-provider interaction during labor and birth. Access to free training programs would eliminate the \$300 to \$1600 training cost (CBI, 2020) that may prevent some women with shared experience in low-income communities from pursuing a community-based doula career. Thus, an increasing supply of trained doulas could occur throughout the three-year pilot program. Finally, as mentioned above, AB 2258 removes barriers to reimbursement through the "professionalization" of doula services (living wage, permission to obtain NPI, etc.).

To the extent that (1) the doula supply expands according to the bill's criteria, and (2) pregnant Medi-Cal beneficiaries learn about and engage doula support, CHBRP projects an unknown, positive public health impact on some physical and emotional perinatal outcomes in years 2 and 3 of the pilot program due to physical, educational, and social supports provided by community-based doulas. These improvements include continued reductions in potentially preventable cesarean deliveries and use of pain medication, including epidurals. Qualitative evidence also supports the conclusion that doulas would improve pregnant Medi-Cal beneficiaries' birth experiences as well as access to community and social supports.

CHBRP projects no long-term change in maternal or infant mortality rates attributable to AB 2258. This is due to a lack of evidence that doulas, who do not provide clinical care to pregnant women, can affect mortality outcomes. No studies were found that were powered to assess these outcomes.

Impacts on Disparities and the Social Determinants of Health³³

Whites are underrepresented in Medi-Cal and have better birth outcomes than those of other races or ethnicities. To the extent that doula supply keeps up with demand and uptake of doula services is equivalent among racial/ethnic beneficiaries in Medi-Cal, CHBRP projects an unknown positive change in birth disparities between white and populations of color. As discussed in *Public Health* and *Background on Doula Care* sections, doula-provided resources that link clients to community social services may also impact social determinants of health over time and help improve parent-infant bonding and interaction similar to that of evidence-based home visiting programs (Breedlove, 2005; Cawthorne and Aarons, 2010; Han et al., 2013).

In the long term, because Medi-Cal covers approximately 50% of births in California, the pilot program established by AB 2258 could begin to reduce statewide racial/ethnic and income disparities in spontaneous vaginal delivery rates and birth experiences (e.g., undesired pain medication use); however, the extent of the changes is unknown.

³³ For more information about SDoH, see CHBRP's publication Incorporating Relevant Social Determinants of Health Into CHBRP Benefit Mandate Analyses at <u>http://chbrp.com/analysis_methodology/public_health_impact_analysis.php</u>.

APPENDIX A TEXT OF BILL ANALYZED

On February 14, 2020, the California Assembly Committee on Health requested that CHBRP analyze AB 2258.

ASSEMBLY BILL

NO. 2258

Introduced by Assembly Members Reyes, Bonta, Limón, and McCarty

(Coauthor: Assembly Member Bauer-Kahan)

February 13, 2020

An act to add and repeal Section 14132.24 of the Welfare and Institutions Code, relating to Medi-Cal.

LEGISLATIVE COUNSEL'S DIGEST

AB 2258, as introduced, Reyes. Doula care: Medi-Cal pilot program.

Existing law provides for the Medi-Cal program, which is administered by the State Department of Health Care Services and under which qualified low-income persons receive health care benefits. The Medi-Cal program is, in part, governed and funded by federal Medicaid program provisions. Existing federal law authorizes, at the option of the state, preventive services, as defined, to be provided by practitioners other than physicians or other licensed practitioners.

This bill would require the department to establish, commencing July 1, 2021, a full-spectrum doula care pilot program to operate for 3 years for pregnant and postpartum Medi-Cal beneficiaries residing in 14 counties, including the Counties of Alameda, Sacramento, San Diego, and Solano, that experience the highest burden of birth disparities in the state, and would provide that any Medi-Cal beneficiary who is pregnant as of July 1, 2021, and residing in a pilot program county, is entitled to doula care. The bill would require the department to develop multiple payment and billing options for doula care, and to ensure specified payment and billing practices, including that any doula and community-based doula group participating in the pilot program be guaranteed payment within 30 days of submitting any claim for reimbursement. The bill would require the department to establish a centralized registry listing any doula who is available to take on new clients in each county participating in the pilot program, and would provide several requirements for the registry, such as the information on the registry being accessible by various means, including the internet website. The bill would require each Medi-Cal managed care health plan in any county participating in the pilot program to provide information in its materials, and specified notices, on identified topics related to doula care, including reproductive and sexual health, and to inform pregnant and postpartum enrollees at prenatal and postpartum appointments about doula care, such as the availability of doula care and how to obtain a doula.

The bill would require the department to convene a doula advisory board that would be responsible for deciding on a list of core competencies, such as the capacity to employ different strategies for providing emotional support, education, and resources during the perinatal period, required for doulas who are authorized by the department to be reimbursed under the Medi-Cal program. The bill would require a doula to provide documentation that they have met the core competencies specified by the board as a prerequisite to be reimbursed under the Medi-Cal program. The bill would require the department to work

with outside entities, such as foundations, to make trainings available at no cost that meet the core competencies to people who are from communities experiencing the highest burden of birth disparities in the state.

The bill would require the department to allocate funding and resources for data collection, reporting, and analysis for purposes of conducting an evaluation of the pilot program, to ensure that an evaluation of the pilot program begins no later than July 1, 2023, and that it be completed by January 1, 2024, to submit a report to the appropriate policy and fiscal committees of the Legislature, and to include the board and relevant stakeholders, including practicing doulas, in the department's evaluation design. The bill would authorize the department to consider the feasibility of a statewide doula benefit for Medi-Cal beneficiaries during the perinatal period if, after the first 3 years of the pilot program, the pilot program is achieving improved birth outcomes for people using doulas and their babies, and to terminate the pilot program if the pilot program is not achieving those outcomes during that period.

The bill would repeal these provisions on January 1, 2026.

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

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

SECTION 1. Section 14132.24 is added to the Welfare and Institutions Code, immediately following Section 14132.23, to read:

14132.24. (a) The Legislature hereby finds and declares all of the following:

(1) Racism and racial basis in health care contribute to the national maternal mortality and morbidity crisis, in particular for pregnant and postpartum people who are Black and Native American or indigenous.

(2) Pregnant and postpartum people who are Black are three to four times more likely than pregnant and postpartum people who are non-Hispanic White to die during pregnancy or shortly after birth. Babies of people who are Black are two and one-half times more likely to be born prematurely or to die within the first year of life than the babies of people who are non-Hispanic White. Notably, the racial disparities in maternal mortality rates exist across all levels of income, age, and education.

(3) Doulas can reduce the impacts of racism and racial bias in health care on pregnant people of color by providing individually tailored, culturally appropriate, and client-centered care and advocacy. Doulas are not medical providers and do not provide medical care. Doulas provide pregnant and postpartum people with social and emotional support, individualized and culturally specific education, and strategies to reduce stress and other barriers to healthy pregnancies.

(4) Pregnant and postpartum people receiving doula care have been found to have improved health outcomes for themselves and their infants, including higher breast-feeding initiation rates, fewer low birth weight babies, and lower rates of cesarean births.

(5) The benefits of doula care can also have a financial impact in helping families avoid the cost associated with low birth weight babies, cesarean births, and other pregnancy-related complications.

(6) While doula care would be a natural fit for underserved populations, including people of color, immigrants, and low-income communities, they often cannot afford to pay out-of-pocket for doula care. In

California, doula care can cost anywhere from several hundred dollars to upwards of \$2,000. Private insurance rarely covers doula care.

(7) Doulas place a high priority on their autonomy, their role as advocates for their clients, and their ability to tailor their work and practice to their unique client populations. Therefore, doulas, as a community, have not sought broader professionalization through formal licensure. Doulas are trained to abide by the relevant regulations and protocols in whatever setting in which they provide support. The Legislature honors and supports the autonomy of doulas, and seeks to be as inclusive as possible of the wide variety of birth support work that exists, including community-based, traditional, and indigenous birth support work. Consequently, the Legislature seeks to identify and mobilize an educated and prepared doula workforce to serve the Medi-Cal population by supporting the ongoing practices of doulas working with communities experiencing the highest burden of birth disparities, but without the barriers to entry that licensure would entail.

(8) A Medi-Cal pilot program on doula care shall be designed to support doulas who are already part of, or who are entering, the workforce specifically to serve the Medi-Cal population. Thus, in order for the pilot program to succeed, for both the doulas and the Medi-Cal beneficiaries that they serve, the program must provide adequate and sustainable compensation for the doulas.

(9) This pilot program acknowledges that in order to have a truly sustainable, equitable, and inclusive program for doula care as a Medi-Cal benefit, practicing doulas and community-based doula groups must be leaders and partners in this work. To the extent possible, practicing doulas and community-based doula groups shall be involved in the design, development, and implementation of the pilot program.

(b) The following definitions apply for purposes of this section:

(1) "Community-based doula group" means a group or collective of doulas working together that prioritizes doula access for underserved populations. The doula care that is provided by community-based doula groups often goes beyond basic prenatal and postpartum care, to encompass a broader and more holistic vision of support for the pregnant person and their family or supporting loved ones. Many community-based doula groups draw their membership directly from the communities that they serve. This often allows community-based doula groups to offer culturally congruent care, and not simply culturally appropriate care.

(2) "Core competencies" means the foundational and essential knowledge, skills, and abilities required for doulas serving Medi-Cal beneficiaries.

(3) "Department" means the State Department of Health Care Services.

(4) "Doula" means a birth worker who provides health education, advocacy, and physical, emotional, and nonmedical support for pregnant and postpartum persons before, during, and after childbirth, otherwise known as the perinatal period. A doula provides support during miscarriage, stillbirth, and abortion.

(5) "Full-spectrum doula care" means prenatal and postpartum doula care, continuous presence during labor and delivery, and doula support during miscarriage, stillbirth, and abortion.

(6) "Perinatal period" means the period including pregnancy, labor, delivery, and the postpartum period.

(7) "Postpartum" means the one-year period following the end of a pregnancy.

(c) (1) Commencing July 1, 2021, the department shall establish a full-spectrum doula care pilot program to operate for three years, and concluding July 1, 2024, for all pregnant and postpartum Medi-Cal beneficiaries residing in the following 14 counties that are communities that experience the highest burden of birth disparities in the state: the Counties of Alameda, Contra Costa, Fresno, Kern, Los

Angeles, Orange, Riverside, Sacramento, San Bernardino, San Diego, San Francisco, San Joaquin, Santa Clara, and Solano.

(2) Any Medi-Cal beneficiary who is pregnant as of July 1, 2021, and residing in a pilot program county shall be entitled to full-spectrum doula care. For a pregnancy that is carried to term, a pregnant person shall be eligible for at least four prenatal appointments, continuous support during labor and delivery, and at least eight postpartum appointments.

(3) Doula care shall be available to any Medi-Cal beneficiary without prior authorization or cost-sharing.

(4) (A) The department shall develop multiple payment and billing options for doula care. The department shall ensure all of the following:

(i) Any doula and community-based doula group participating in the pilot program shall be guaranteed payment within 30 days of submitting a claim for reimbursement.

(ii) An individual doula shall be able to obtain a National Provider Identifier number and be directly reimbursed by the department.

(iii) A community-based doula group shall be able to obtain reimbursement for any doula working as part of their group. If a community-based doula group employs doulas on a salaried basis, the department shall determine appropriate reimbursement rates based on the salaries provided and not on a per-client or per-service basis.

(B) (i) Payment for doulas shall include prenatal care, care during labor and delivery, postpartum care, and additional services that encompass a broader and more holistic vision of support for the pregnant person and their family or supporting loved ones.

(ii) In setting reimbursement rates for doula care, the department and Medi-Cal managed care health plans shall take into consideration all of the following:

(I) The current rate for any existing, paid, community-based doula pilot programs that are already serving the Medi-Cal population.

(II) The cost of living in the pilot program counties.

(III) The sustainable living wage, as calculated in the pilot program counties.

(C) Presence at a stillbirth shall be reimbursed at the same rate as presence at a labor and delivery resulting in a live birth. Postpartum services shall also be covered for a stillbirth.

(D) There shall be a separate reimbursement for presence during miscarriage or abortion.

(E) The department and Medi-Cal managed care health plans shall separately reimburse for each prenatal and postpartum appointment. There shall also be separate reimbursement for administrative costs, including travel costs.

(F) If the pilot program continues beyond the first three years, the department shall make efforts to revisit the reimbursement rate as necessary to account for inflation, cost of living adjustments, and other factors.

(G) Pursuant to paragraph (4) of subdivision (d), a doula shall provide documentation that they have met the core competencies specified by the board, as described in paragraphs (1) and (2), inclusive, of subdivision (d), to be authorized by the department to be reimbursed under the Medi-Cal program.

(5) The department shall establish a centralized registry listing any doula who is available to take on new clients in each of the 14 counties participating in the pilot program.

(A) The registry shall align with existing Medi-Cal provider directory requirements.

(B) The registry shall be searchable by Medi-Cal managed care health plan, geographical area, race and ethnicity of the doula, languages spoken by the doula, and any relevant specializations, including adolescents, homeless, substance use disorder, or refugee or immigrant populations.

(C) The information included on the registry shall be accessible by internet website, an application on a smartphone, paper, and telephone.

(6) Each Medi-Cal managed care health plan in each county participating in the pilot program shall provide information about the availability of doula care in their materials and notices on reproductive and sexual health, family planning, pregnancy, and prenatal care. A Medi-Cal managed care health plan shall inform all pregnant and postpartum enrollees at each prenatal and postpartum appointment about the availability of doula care, that doula care is available in addition to other prenatal and postpartum care, and how to obtain a doula.

(d) (1) The department shall convene a doula advisory board that shall decide on a list of core competencies required for doulas who are authorized by the department to be reimbursed under the Medi-Cal program. This board shall reconvene, as deemed necessary by the department, throughout the duration of the pilot program.

(2) Core competencies shall include, at a minimum, a demonstration of competency, through training or attestation of equivalency or lived experience, in all of the following areas:

(A) Understanding of basic anatomy and physiology as related to pregnancy, the childbearing process, the postpartum period, breast milk feeding, and breast-feeding or chest-feeding.

(B) Capacity to employ different strategies for providing emotional support, education, and resources during the perinatal period.

(C) Knowledge of and ability to assist families with utilizing a wide variety of nonclinical labor coping strategies.

(D) Strategies to foster effective communication between clients, their families, support services, and health care providers.

(E) Awareness of integrative health care systems and various specialties of care that a doula can provide information for in order to address client needs beyond the scope of the doula.

(F) Knowledge of community-based, state-funded and federally funded, and clinical resources available to the client for any need outside the doula's scope of practice.

(G) Knowledge of strategies for supporting breast-feeding or chest-feeding, breast milk feeding, and lactation.

(3) At least two-thirds of the membership of the board shall be composed of practicing doulas who are providing doula care to Medi-Cal beneficiaries. At least two-thirds of the practicing doulas on the board shall be from communities experiencing the highest burden of birth disparities in the state, including doulas who are low income, doulas of color, doulas from and working in rural communities, and doulas who speak a language other than English.

(4) In order to be authorized by the department to be reimbursed under the Medi-Cal program, a doula shall provide documentation that they have met the core competencies specified by the board. The board may also create alternative ways to meet the core competencies, such as by providing documentation of certification through another doula certification program that meets the required core competencies.

(5) The department shall seek to work with outside entities, such as foundations or nonprofits, to make trainings available at no cost that meet the core competencies to people who wish to become doulas who are from communities experiencing the highest burden of birth disparities in the state, including people who are low income, people of color, people from and working in rural communities, and people who speak a language other than English, who wish to become doulas. These trainings shall be available in a manner that makes them accessible to these populations.

(e) The department shall allocate funding and resources for data collection, reporting, and analysis for purposes of conducting an evaluation of the pilot program.

(1) The department shall ensure that an evaluation of the pilot program begins no later than July 1, 2023, and that it be completed by January 1, 2024. The department shall submit a report to the appropriate policy and fiscal committees of the Legislature.

(2) The department shall include the board and relevant stakeholders, including practicing doulas, community-based doula groups, and consumer advocates, in the department's evaluation design.

(3) The evaluation shall examine the impact of the pilot program on a range of outcomes, including those focused on client and client family experience, prenatal and postpartum care engagement, doula workforce retention, cost savings, and clinical outcomes.

(f) If, after the first three years of the pilot program, the pilot program is achieving improved birth outcomes for persons using doulas and their babies, the department shall consider the feasibility of a statewide doula benefit for Medi-Cal beneficiaries during the perinatal period. If the pilot program is not achieving improved birth outcomes for persons using doulas and their babies during that period, the department may terminate the pilot program.

(g) This section shall remain in effect only until January 1, 2026, and as of that date is repealed.

APPENDIX B LITERATURE REVIEW METHODS

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

Studies of the effects of doula care on maternal and neonatal/infant outcomes were identified through searches of PubMed, the Cochrane Library, Web of Science, Cumulative Index of Nursing and Allied Health Literature (CINAHL), and PsycINFO. Websites maintained by the following organizations were also searched: Agency for Healthcare Research and Quality; American Cancer Society; American College of Obstetricians and Gynecologists; Institute for Clinical Systems Improvement; International Network of Agencies for Health Technology Assessment; National Comprehensive Cancer Network, Inc.; National Guideline Clearinghouse; National Institute for Health and Care Excellence; National Institutes of Health; National Health Service Centre for Reviews and Dissemination; Oncofertility Consortium; Scottish Intercollegiate Guideline Network; and World Health Organization.

The search was limited to abstracts of studies published in English, conducted among United States populations, and studies published from 2000 to the present. The medical effectiveness search was limited to studies published from 2000 to present, because this was a novel review for CHBRP and a 20-year span of literature review was deemed sufficient to capture studies of contemporary doula care practice. A 2017 Cochrane review of continuous labor support (Bohren et al., 2017) has been widely referenced in the doula care community and provides the largest base of evidence for many outcomes of interest to the medical effectiveness analysis in this report; however, CHBRP determined that this review is limited in its applicability to the model of doula care proposed in this bill due to the inclusion of non-doula providers, a wide range of doula support definitions, and the inclusion of studies from middle-income countries whose health care practices may differ to the extent that the results are not generalizable to U.S. populations. When possible, results from a high-income country sub analysis of this systematic review were presented throughout the *Medical Effectiveness* section.

Reviewers screened the title and abstract of each citation retrieved by the literature search to determine eligibility for inclusion. The reviewers acquired the full text of articles that were deemed eligible for inclusion in the review and reapplied the initial eligibility criteria.

The literature review returned abstracts for 326 articles, of which 102 were reviewed for inclusion in this report. A total of 13 studies (7 RCTs, 5 cohort studies, and 1 systematic review) were included in the medical effectiveness review for AB 2258.

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*.³⁴ 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.

³⁴ Available at: <u>http://chbrp.com/analysis_methodology/medical_effectiveness_analysis.php</u>.

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 <u>large majority</u> of studies are of high quality and consistently find that the treatment is either effective or not effective.

A grade of *preponderance of evidence* indicates that the <u>majority</u> 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)

- Abortion
- Admission to intensive care unit (mother or infant)
- Anesthesia/pain medication during labor (e.g., epidurals)
- Antenatal
- antenatal anxiety
- Antenatal depression
- Apgar score
- Augmentation of labor
- Birth/labor companion
- Caesarean birth
- Cerebral Palsy
- Childbirth
- Classism
- Comfort measures
- Community-based doula group
- Complications
- Continuous labor support
- Cost of Caesarean birth
- Cost of Epidural use
- Cost of Induction of labor

- Cost of Natural child birth
- Cultural competence
- culturally concordant care
- Doula
- Doula attendance at labor and/or delivery
- Duration of hospital stay
- Duration of hospital stay and cost
- Eclampsia
- Economic loss
- Emotional support
- Ethnicity
- Exclusive breastfeeding
- Expectation management
- Full spectrum doula care
- Gestational diabetes
- Gestational hypertension
- Harms of doula care
- HELLP syndrome
- Home birth use
- Induction of labor
- Infant birth injury

- Infant birth injury cost
- Infant/newborn
- Information/advice about labor progress
- Institutional bias/racism
- Instrumental vaginal birth / operative vaginal birth
- Intrapartum support
- Labor
- Labor advocacy
- Length of labor
- Long term impacts (of doula care on maternal mental/physical health)
- Low birth weight
- Low birth weight cost
- Maternal satisfaction with childbirth (intrapartum or postpartum)
- Maternal self-efficacy
- Maternal/patient/client satisfaction
- Miscarriage
- Morbidity
- Mortality
- Neonatal death / infant mortality
- Number of ER visits for pregnancy or childbirth
- Number of outpatient obstetrics/gynecology visits
- Oxytocin (Pitocin) use during labor
- Perception of birth experience
- Perinatal maternal mortality
- Perineal trauma (e.g., tearing)
- Postpartum
- postpartum anxiety
- Postpartum depression
- Postpartum depression services/visits
- postpartum doula care
- postpartum OCD
- Postpartum support
- Pre-eclampsia
- Pregnancy
- Premature death
- Prenatal appointment attendance
- prenatal doula care
- Preterm birth
- Preterm birth cost (NICU, disabilityrelated, etc.)
- Productivity and cost of illness
- Race
- Racial disparities
- Restriction of mobility during labor
- Severity of labor pain
- Social / emotional support
- Social determinants of health
- Societal burden

- Spontaneous vaginal birth
- Stillbirth
- Time from birth to breastfeeding
- Time from birth to skin-to-skin contact
- Triage

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

The cost analysis in this report was prepared by the members of the cost team, which consists of CHBRP task force members and contributors from the University of California, Los Angeles, and the University of California, Davis, as well as the contracted actuarial firm, Milliman, Inc.³⁵

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.³⁶

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

Analysis-Specific Caveats and Assumptions

In the analysis of the costs of AB 2258, several simplifying assumptions were made. These assumptions are outlined below.

- Population assumptions:
 - The size and proportion of the eligible Medi-Cal population, including those who are in feefor-service (FFS) and partial-scope Medi-Cal, are based on CHBRP's analysis of 2020 administrative enrollment data and demographic data from the 2018 California Health Interview Survey.
 - While demographic (e.g., women aged 15–44) make-up may vary among the 14 pilot counties, CHBRP presents population estimates on an aggregate, 14-pilot county basis.
 - The percentage of Medi-Cal enrollees who are female and aged 15 to 44 is estimated to be 25.9%.
 - As discussed in the *Benefit Coverage, Utilization, and Cost Impacts* section, the proportion of the population enrolled in managed care are based on estimated enrollment from the Kaiser Family Foundation for the 14 pilot counties, or 82% (Kaiser Family Foundation, 2019).
 - The population enrolled in partial-scope Medi-Cal includes pregnant women who lose Medi-Cal coverage after 60 days postpartum. This population is included in the model; however, their utilization and costs are assumed to be consistent with full-scope Medi-Cal pregnant women.
- Utilization assumptions:
 - Based on Mottl-Santiago (2008), and the percentage of Medi-Cal enrolled women who reported definitely wanting doula services for current and future pregnancies in the *Listening to Mothers in California* survey (Sakala et al., 2018) the take-up rate of the doula program is estimated to be 20% of pregnant women. The take up of the program may be lower if there are delays or challenges to implementation or fewer doulas available to provide services. As noted in the cost section, CHBRP makes a simplifying assumption that the program would be implemented by DHCS per the requirements of the bill (including the requirements to establish a doula registry and certification program, establish payment rates, issue NPIs, and ensure MMCOs provide information to Medi-Cal members regarding the doula program per the requirements of AB 2258).

³⁵ CHBRP's authorizing statute, available at <u>http://chbrp.com/CHBRP authorizing statute 2018 FINAL.pdf</u>, requires that CHBRP use a certified actuary or "other person with relevant knowledge and expertise" to determine financial impact.

³⁶ See method documents posted at <u>http://chbrp.com/analysis_methodology/cost_impact_analysis.php</u>; in particular, see 2019 Cost Analyses: Data Sources, Caveats, and Assumptions.

- As noted in the *Benefit Coverage, Utilization, and Cost Impacts* section, the evidence suggests that there would be a 29% reduction in cesarean deliveries as a result of doula care (Kozhimannil, 2013). CHBRP calculates a utilization shift from cesarean to vaginal births applying a 29% reduction to the 20% of pregnant women enrolled in Medi-Cal who would use doula services.
- AB 2258 states, "For a pregnancy that is carried to term, a pregnant person shall be eligible for at least four prenatal appointments, continuous support during labor and delivery, and at least eight postpartum appointments." CHBRP assumed that there would be full participation of women who take up the doula program, or in other words they would, on average, use the four prenatal and eight postpartum visits that must at least be covered under AB 2258.
- Cost assumptions:
 - The doula visit rate is estimated to be a statewide average of \$30 (inclusive of mileage/transportation costs). CHBRP estimated the reimbursement for doula attendance to a delivery to be equivalent to 12 hours times the state-wide average hourly rate. CHBRP also assumed each prenatal and postpartum visit would take one hour and that the average labor and delivery attendance fee would be \$360 based upon an estimated 12 hours of effort. Thus, the calculated rate for the package of doula services is estimated to be \$720. The visit rate is based on data from other states with a doula pilot program, as well as a collection of private doulas who have publicly available rates online.³⁷
 - Average cost for deliveries, by pregnancy outcome are calculated from 2017 Milliman Consolidated Health Cost Guidelines Sources Database (CHSD) and include the professional and facility charges associated with each admission. CHBRP calculated the average costs for cesarean and vaginal deliveries, which was necessary to calculate cost offsets. Some doulas charge a fee for delivery attendance to cover the possibility that another doula may have to step in due to scheduling conflicts or other concerns. CHBRP assumed this is outside of the scope of the bill, and did not factor it into the cost model.
 - As mentioned, the proportion of the population enrolled in managed care in the 14 pilot counties are estimated to be 82%. CHBRP assumed the proportion of total Medi-Cal expenditures for managed care versus FFS is similar to the enrollment proportion.
 - CHBRP calculated a utilization shift from cesarean to vaginal births, but the cost offset is only applied to the FFS enrolled portion of the population. The rationale for this approach is discussed in detail in the *Benefit Coverage, Utilization, and Cost Impact* section.
 - Total Medi-Cal expenditures presented in this analysis are for the 14 pilot counties specified by AB 2258 and are based upon Medi-Cal managed care capitation rates paid to plans for managed care enrollees, including those who are enrolled in County Operated Health Plans (COHS). In addition, spending on acute care through Medi-Cal FFS is also included and are based on Kaiser Family Foundation State Health Facts.³⁸ The total acute care FFS spending was prorated by about 80% to represent the portion of FFS spend for enrollees in the 14 pilot counties.

Second-Year Impacts on Benefit Coverage, Utilization, and Cost

CHBRP has considered whether continued implementation during the second year of the benefit coverage requirements of AB 2258 would have a substantially different impact on utilization of either the

³⁷ International Doula Institute. Doula Salary. Available at: <u>https://internationaldoulainstitute.com/doula-salary/;</u> University of Washington Center for Health Innovation & Policy Science. The Doula Option, an Opportunity to Improve Birth Outcomes in Washington State. Available at: <u>https://depts.washington.edu/uwchips/docs/brief-doula-option.pdf;</u> Office of the Secretary of State, Oregon. Permanent Administrative Order DMAP 19-2018. Available at: <u>https://www.oregon.gov/oha/HSD/OHP/Polices/130-0015-04022018.pdf</u>.

³⁸https://www.kff.org/medicaid/state-indicator/spending-on-acute-care/

tests, treatments or services for which coverage was directly addressed, the utilization of any indirectly affected utilization, or both. CHBRP reviewed the literature and consulted content experts about the possibility of varied second-year impacts and determined the second year's impacts of AB 2258 would be substantially the same as the impacts in the first year (see Table 1).

APPENDIX D INFORMATION SUBMITTED BY OUTSIDE PARTIES

In accordance with the California Health Benefits Review Program (CHBRP) policy to analyze information submitted by outside parties during the first 2 weeks of the CHBRP review, the following parties chose to submit information.

The following information was submitted by Tanya Johnson in February 2020.

University of California, San Francisco School of Nursing, Johnson T. Application of doula programs to reduce high premature birth rates among African American neonates. Master's Comprehensive Examination submitted by e-mail. February 26, 2020, which offered the following citations:

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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.

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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.

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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