CALIFORNIA
HEALTH BENEFITS REVIEW PROGRAM

Abbreviated Analysis

California Assembly Bill 1254: Mobile Stroke Units

Analysis to the 2021–2022
California State Legislature
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Prepared by
California Health Benefits Review Program
www.chbrp.org

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SUMMARY

The Assembly Committee on Health requested that the California Health Benefits Review Program (CHBRP) conduct an abbreviated analysis of California Assembly Bill (AB) 1254. AB 1254 would require a state-regulated health care service plan contract or a health insurance policy[1] to provide coverage for mobile stroke units (MSUs).[2] MSUs provide emergency treatment, imaging, and transportation for patients who may be suffering from a stroke. An MSU is a special type of ambulance that houses an onboard computed tomography (CT) scanner and ability to administer intravenous tissue plasminogen activator (tPA)[3] for ischemic stroke thrombolysis.

A wide variety of systems in California deliver emergency ground medical transport (EGMT)[4]. An estimated 20 MSUs operate in the U.S. — two in California. Nationally, each MSU responds annually to a median 600 dispatches and administers a median 30 tPA thrombolysis treatments. Approximately two-thirds of these treatments are administered to persons aged 65 years and older, who are likely to be Medicare beneficiaries rather than persons with benefit coverage that would be subject to AB 1254.

Benefit Coverage. CHBRP estimates that 100% of enrollees in Department of Managed Health Care (DMHC)- and California Department of Insurance (CDI)-regulated plans and policies have coverage for EGMT. AB 1254 would affect the benefit coverage of enrollees in DMHC-regulated plans and CDI-regulated policies as well as the benefit coverage of Medi-Cal managed care beneficiaries regulated by DMHC that currently have coverage for EGMT. All plans and policies subject to state-level benefit mandates, with the exception of CDI large group, are required to cover EGMT. AB 1254 would not exceed the definition of essential health benefits (EHBs) in California.

MSU Finances. Limited reimbursement has appeared to constrain MSUs, which were developed to address delays between stroke symptom onset and therapeutic treatment. Initial acquisition costs of an MSU are approximately $1 million, while annual operating costs can range from $500,000 to $1 million or more, with large variation depending on the staffing model.

Despite the potential for MSUs to charge for their advanced services, a recent survey of MSU programs in the United States found that all but one MSU program reported negative financial performance. The two MSU programs in California do not currently appear to bill for their services.

Fiscal Impact of AB 1254. CHBRP estimates no measurable fiscal impact or utilization increase due to AB 1254 in the short term. Existing MSUs have largely relied on grants and philanthropy. In the long term, an increased number of MSUs could drive up use of expensive services/medications (like tPA) and put pressure on usual, customary, and reasonable (UCR) rates with private payers, or other approaches to bill for services in MSUs.

Stroke Incidence and Treatment. Nationally, approximately 34% of people hospitalized for stroke were under age 65. Stroke treatment varies depending on the type of stroke and how quickly the stroke is recognized and diagnosed.

Policy Context. California's 33 local emergency medical services agencies (LEMSAs) exercise most direct authority over the day-to-day operation of the state's emergency medical services. LEMSAs set the maximum cost of ambulance transportation. The two LEMSAs with current MSU operations (Los Angeles County and San Mateo County) include policies that specify how MSUs operate within the local EMS delivery system.

[1] Issued, amended, or renewed on or after January 1, 2022.
[2] AB 1254 would define a "mobile stroke unit" as a state-recognized mobile unit facility that serves as a hybrid emergency response ambulance and operates under the direction of a local emergency services agency.
[3] Tissue plasminogen activator (tPA), branded as Alteplase, is the only FDA-approved medication for thrombolysis in acute strokes. If no other contraindications exist, tPA may be administered in ischemic strokes (blood clots in brain) within 3 to 4.5 hours after symptom onset following CT or MRI confirmation that there is no bleeding in the brain.
[4] EGMT is provided by public entities (fire departments, public ambulance districts, hospital systems) and private nonprofit or for-profit entities (hospitals and ambulance companies). Alternatively, DHCS uses the acronym "GEMT" (ground emergency medical transport).

POLICY CONTEXT

On February 22, 2021, the California Assembly Committee on Health requested that the California Health Benefits Review Program (CHBRP) conduct a limited, evidence-based assessment of the impacts of Assembly Bill (AB) 1254, Mobile Stroke Units. Per the Committee's request, CHBRP focused on fiscal and policy analysis with a limited review of the effectiveness literature. However, CHBRP did not conduct a full medical effectiveness or public health analysis.

AB 1254 would require a state-regulated health care service plan contract or a health insurance policy issued, amended, or renewed on or after January 1, 2022, to provide coverage for mobile stroke units (MSUs). AB 1254 would define a "mobile stroke unit" as a state-recognized mobile unit facility that serves as a hybrid emergency response ambulance and operates under the direction of a local emergency services agency to provide emergency treatment, imaging, and transportation for patients who may be suffering from a stroke.

The bill applies to DMHC-regulated plans (including DMHC-regulated Medi-Cal managed care plans) and California Department of Insurance (CDI) policies that provide coverage for emergency services. Potentially, large-group CDI policies may not cover emergency services since they are exempt from basic health care services (further definitions provided in this section). However, for the purposes of this analysis, CHBRP has assumed that 100% of these policies do provide coverage for emergency ground medical transport (EGMT).

Federal Policy

Federal agencies funded and oversaw emergency medical services (EMS) systems until 1981, when the federal government turned this authority over to states and their counties (for more on this history, please see the *Background* section in CHBRP's 2020 analysis of AB 2625[5]). The federal Office of EMS, under the National Highway Traffic Safety Administration (NHTSA), currently provides guidance and leadership through data collection, publication of service guidelines, and convening stakeholders to define best practices in the EMS industry. Federal funding is provided through the Department of Health and Human Services (HHS) block grants, which states may spend on EMS provision (IOM, 2007).

EMS is not led by any single U.S. federal department or agency. In addition to NHTSA's Office of EMS, other federal departments that support and regulate EMS include Defense, HHS, Homeland Security, and the Federal Communications Commission (FCC).

Effective January 1, 2019, Medicare provided a new Modifier for Expanding the Use of Telehealth for Individuals with Stroke (CMS, 2018). Section 50325 of the Bipartisan Budget Act of 2018 amended section 1834(m) of the Act by adding a new paragraph that provides special rules for telehealth services furnished on or after January 1, 2019, for purposes of diagnosis, evaluation, or treatment of symptoms of an acute stroke (acute stroke telehealth services), as determined by the Secretary. Specifically, section 1834(m)(6)(A) of the Act removes the restrictions on the geographic locations and the types of originating sites where acute stroke telehealth services can be furnished. Acute stroke telehealth services can be furnished in any hospital, critical access hospital, mobile stroke units (as defined by the Secretary), or any other site determined appropriate by the Secretary, in addition to the current eligible telehealth originating sites. Section 1834(m)(6)(C) of the Act limits payment of an originating site facility fee to acute stroke telehealth services furnished in sites that meet the usual telehealth restrictions under section 1834(m)(4)(C) of the Act. This new modifier may be used by MSUs to bill Medicare for telehealth evaluation and management or consultation codes, but the modifier does not appear to allow for Medicare billing of other diagnosis (e.g., imaging) or treatment (e.g., thrombolysis) services on an MSU.

[5] Available at https://chbrp.org/completed_analyses/index.php

State Policy

State Oversight: The California Emergency Medical Services Authority (EMSA) serves as the pass-through for federal funds and oversees county and multicounty local EMS agencies (LEMSAs). EMSA manages licensing and practice standards for the California EMS workforce, publishes standards for and approves LEMSA implementation plans, coordinates EMS services among LEMSA jurisdictions, regulates the statewide trauma system, and directs the statewide poison control system (EMSA, 2021).

County Oversight: California's 33 LEMSAs exercise the most direct authority over the day-to-day operation of the state's emergency medical services. Organized on a county or multicounty basis, LEMSAs plan, implement, monitor, and evaluate local EMS systems and establish the roles and responsibilities of the various system participants in implementing the plan (EMSA, 2021). LEMSAs set the maximum cost of ambulance transportation. LEMSAs also write and enforce contract terms with public and private providers, issue ambulance licenses, and grant exclusive operating area (EOA) rights to EGMT providers. Ambulances, including MSUs, cannot operate within any LEMSA region(s) without approval and licensing from the LEMSA(s).

Local Guidelines for Prehospital Stroke Care: As part of their broad local regulatory authority, each LEMSA establishes medical control policies that guide EMS providers in their care of patients outside of the hospital setting. Though the state EMSA's scope of practice regulations limit the procedures and medications authorized for EMS providers, LEMSAs are responsible for creating detailed guidelines within these limits. EMS providers within each county or multicounty LEMSAs are required to follow these medical treatment protocols established by the LEMSA's medical directors. For some EMS treatment protocols (e.g., stroke and traumatic injury), these protocols also direct EMS providers to transport patients to specific hospitals with specialty services (Glober et al., 2016). The two LEMSAs with current MSU operations (Los Angeles County and San Mateo County) include policies that specify how MSUs operate within the local EMS delivery system[6].

Emergency Ground Medical Transport in California

On Dec. 27, 2020, the No Surprises Act was signed into law as part of the Consolidated Appropriations Act of 2021.[7] The No Surprises Act addresses surprise medical billing at the federal level. Starting January 1, 2022, it will be illegal for providers to bill patients for more than the in-network cost sharing due under patients' insurance in almost all scenarios where surprise out-of-network bills arise, with the notable exception of ground ambulance transport (Adler et al., 2021).[8] Though the federal Affordable Care Act (ACA) does require health plans and policies regulated by DMHC and CDI to cover out-of-network EGMT at usual, customary, and reasonable (UCR) rates, there are no specific standards as to what usual, customary, and reasonable should be. Health plans and insurers often set their UCR rates much lower than what an ambulance provider charges, leaving patients open to liability for the remainder of the charges. However, CHBRP does not see evidence of billing enrollees by MSUs.

For enrollees in DMHC-regulated plans and CDI-regulated policies, health professionals and facilities are categorized as in network or out of network. In-network health facilities and professionals have a contract with the enrollee's plan or insurer that defines a contracted rate for payment for services (and no balance billing of the enrollees is allowed). However, when an out-of-network provider's billed charge is more than

[6] For further details on each LEMSA's MSU policies, see Los Angeles County's Reference 817 https://dhs.lacounty.gov/emergency-medical-services-agency/home/resources-ems/prehospital-care-manual/ and San Mateo County's OPS-36 https://www.smchealth.org/general-information/ems-policy-procedure-manual.
[7] H.R. 133; Division BB – Private Health Insurance and Public Health Provisions.
[8] Health plans must treat these out-of-network services as if they were in network when calculating patient cost sharing. The legislation also creates a new final-offer arbitration process to determine how much insurers must pay out-of-network providers. If an out-of-network provider is dissatisfied with a health plan's payment, it can initiate arbitration. The arbitrator must select between the final offers submitted by each party, taking into consideration several factors including the health plan's historical median in-network rate for similar services.

the plan/insurer will pay, the provider may then seek[9] to recoup the difference, or balance bill, directly from the enrollee (Fedor, 2006).

The ACA requires nongrandfathered group health plans and policies to cover emergency services at out-of-network hospitals at the same copayment or coinsurance level as in-network hospitals.[10] This requirement, however, does not extend to ambulance services, including EGMT. EGMT is not included in this definition of emergency services because it is not provided in (or at) *an emergency department of a hospital*.

Another key interaction of AB 1254 is with existing state law and regulations contained within the Knox-Keene Act.[11] Health Care Service Plans that provide basic health care services cannot require prior authorization or refuse to pay for any ambulance or ambulance transport services provided to an enrollee as a result of a 911 emergency response system request for assistance if either of the following conditions apply:

- The request was made for an emergency medical condition, and ambulance transport services were required.
- An enrollee reasonably believed that the medical condition was an emergency medical condition and reasonably believed that the condition required ambulance transport services.[12]

There is an exemption for health care service plans paying for any ambulance or ambulance transport services if the plan determines that the ambulance or ambulance transport services were never performed, an emergency condition did not exist, or upon findings of fraud, incorrect billings, the provision of services that were not covered under the member's current benefit plan, or membership that was invalid at the time services were delivered for the pending emergency claim.

Emergency health care services are defined in Knox-Keene[13] as those that include ambulance and ambulance transport services and out-of-area coverage. "Basic health care services" includes ambulance and ambulance transport services provided through the 911 emergency response system. It stipulates that "emergency health care services that shall be available and accessible to enrollees on a 24-hour-a-day, 7-days-a-week basis within the health care service plan area. Emergency health care services shall include ambulance services for the area served by the plan to transport the enrollee to the nearest 24-hour emergency facility with physician coverage, designated by the health care service plan."[14]

Current state law[15] explicitly allows balance billing for medical transportation for DMHC- and CDI-regulated plans and policies.

Within Medi-Cal, current law[16] prohibits ambulance service providers from "balance billing" Medi-Cal beneficiaries[17] in addition to the beneficiaries generally not having any cost-sharing requirements.

A "surprise medical bill" is a bill from an out-of-network provider or facility that was not expected by the patient or that came from an out-of-network provider not chosen by the patient (Garmon and Chartock, 2017). Surprise medical bills cause financial anxiety and have been linked to unavoidable medical debt (Hamel et al., 2016). California already has protections in place against surprise billing by individual

[9] Medi-Cal managed care beneficiaries pay no cost sharing and current law prohibits ambulance service providers from balance billing them.
[10] 29 CFR § 2590.715-2719A(b).
[11] H&SC § 1371.5 (emergency response ambulance or ambulance transport services).
[12] The determination as to whether an enrollee reasonably believed that the medical condition was an emergency medical condition that required an emergency response is not based solely upon a retrospective analysis of the level of care eventually provided to, or a final discharge of, the person who received emergency assistance.
[13] H&SC § 1345.
[14] 28 CCR § 1300.67. Scope of Basic Health Care Services.
[15] H&SC § 1367.11 and IC § 10352.
[16] WIC § 14019.4.
[17] Personal Communication, W. White, DHCS, March 2020.

doctors that are not chosen by consumers but are out of network, such as anesthesiologists. However, the law does not currently apply to out-of-network EGMT services.[18] An MSU may bill a patient's insurance at a higher rate than UCR rates (but at or below the county limits), potentially creating a surprise medical bill from EGMT, including an MSU. This bill would not appear to address such events, and CHBRP is unable to quantify the frequency of this possibility.

AB 1254 would not require coverage for a new state benefit mandate and therefore does not exceed the definition of essential health benefits (EHBs) in California.

Other States

CHBRP is aware of only one other state has had recent legislation introduced related to MSUs[19], and that bill does not address state-regulated health insurance coverage for MSUs. CHBRP is not aware of any laws in other states that address health insurance coverage of MSUs.

Table 1. Recent Mobile Stroke Unit–Related Legislation in Other States

State	Bill No.	Summary	Status
New Mexico	SB 414	Provides for the purchase of a mobile stroke unit at the University of New Mexico health sciences center $800,000 to fund MSU purchase and operation. Requires the Dept. of Health to establish a stroke emergency trauma help task force and a stroke education and training program $500,000 to provide for medical staff specializing in neurological trauma care$100,000 to fund stroke education and training program	2019 Pending

Source: PoliticoPro Search, March 29, 2021.

[18] For more background on surprise medical billing and prevalence, as well as impacts on public health (related to Emergency Services and Air Ambulances prior to enacted legislation), please see CHBRP's completed analysis of AB 1611 in 2019, and CHBRP's analysis of Air Ambulance Legislation AB 651, also completed in 2019, available on CHBRP's website at https://chbrp.org/completed_analyses/index.php.
[19] Legislative search through PoliticoPro, conducted between March 15, 2021, and March 29, 2021.

BACKGROUND ON MOBILE STROKE UNITS

Stroke Epidemiology and Burden

Stroke occurs when blood flow to the brain is disrupted due to blood vessel blockage or rupture within the brain (Conroy et al., 2016). Most strokes (87%) are classified as ischemic strokes, caused by a blocked blood vessel or blood clot in the brain; the remaining 13% are largely hemorrhagic strokes, caused by a ruptured blood vessel and bleeding in the brain. Stroke risk increases with age and uncontrolled high blood pressure is the single largest stroke risk factor (Conroy et al., 2016). Nationally, approximately 34% of people hospitalized for stroke were under age 65 years (CDC, 2021). Approximately 800,000 Americans across all age groups experience a new or recurrent stroke each year, suggesting about one stroke every 40 seconds and one stroke death every 4 minutes (Adeoye et al., 2019). Stroke is the leading cause of long-term disability in the United States (CDC, 2021). However, stroke patients who present at the emergency department within three hours of initial stroke symptom onset often have less disability following the stroke than other patients who delay care (CDC, 2021). Among stroke survivors aged 65 years and older, over half suffer from reduced mobility (CDC, 2021). Indirect costs, such as missed work and productivity losses, typically exceed the direct medical costs of stroke treatment and rehabilitation (Joo et al., 2014). Indirect costs can also include the time and opportunity cost of informal caregiving from family and friends who may assist stroke survivors with instrumental and basic activities of daily living, although these informal caregiving costs are often not quantified in studies. Though direct medical costs may be similar in stroke patients of all ages, the indirect costs of stroke morbidity are substantially greater in stroke survivors younger than 65 years due to their greater productivity and potential life expectancy losses (Joo et al., 2014).

Though 2.3% of California adults report prior history of any stroke, stroke prevalence rises to 8.5% among California adults aged 65 years and older (Conroy et al., 2016). Among Californians under age 65 years, stroke prevalence ranges from 0.2% in those aged 18 to 34 years to 3.1% in those aged 55 to 64 years. While stroke is the fifth leading cause of death in the United States, stroke ranks as the third leading cause of death in California (Conroy et al., 2016). In 2014, there were 178.4 age-adjusted stroke hospitalizations per 100,000 in California and 34.6 per 100,000 age-adjusted stroke deaths. Stroke hospitalization rates in California have not significantly changed over time, whereas the age-adjusted California stroke mortality rate has decreased by 40% between 2000 and 2014, largely due to reductions in various stroke risk factors (CDC, 2021).

Stroke Diagnosis and Treatment

Stroke treatment and clinical outcomes vary considerably depending on the type of stroke and how quickly the stroke is recognized and diagnosed. Stroke recognition typically begins with one of many validated stroke scales (which commonly assess facial droop/smile, arm strength, grip, and/or speech) to help identify a suspected stroke. Though these physical and neurological status examinations can be helpful, imaging with a computed tomography (CT) scan or magnetic resonance imaging (MRI) scan is necessary during stroke diagnosis. Imaging may detect brain bleeding (i.e., a hemorrhagic stroke) and may also provide helpful information about severity of ischemic strokes as well. In hemorrhagic strokes, treatment may begin with medication-based blood pressure control and anticoagulant reversal followed by neurosurgical intervention to stop or remove bleeding. In ischemic strokes, intravenous medication thrombolysis, or fibrinolytic therapy (the breakdown of blood clots in vessels) is commonly considered if it can be provided within 3 to 4.5 hours of stroke onset. Mechanical thrombectomy (interventional procedure to physically remove the clot) may also be provided after thrombolysis or up to 24 hours after stroke onset for more severe strokes.

Stroke Systems of Care

Stroke systems of care are organized on the premise that stroke morbidity and mortality can be minimized by coordinating stroke care along the entire continuum from primary prevention through rehabilitation. The eight domains of a stroke system of care include education and prevention, emergency medical services (EMS) response, acute stroke treatment, secondary prevention, stroke rehabilitation, and continuous quality improvement (Adeoye et al., 2019). Only about half of hospitalized stroke patients initially arrive at the hospital via EMS, meaning that many potential stroke patients arrive at hospitals without adequate stroke diagnosis and treatment capabilities (Adeoye et al., 2019). The MSU was developed to address two components, EMS response and acute stroke treatment, by initiating stroke treatment during the EMS response phase (Wira and Aydin, 2020).

Stroke Center Hospitals

Hospitals have differing capabilities for stroke treatment. Hospitals with local, state, and/or national accreditation in stroke treatment are termed stroke centers (The Joint Commission, 2019). Primary stroke centers have the capability to rapidly diagnose strokes via onsite CT or MRI scan and in-person or telemedicine assessment by a stroke neurologist. These primary stroke centers can treat ischemic strokes with intravenous thrombolysis and can initiate transfer to comprehensive stroke centers for hemorrhagic and more severe ischemic strokes. Comprehensive stroke centers build on the capabilities of primary stroke centers but also offer neurosurgical treatment of hemorrhagic stroke and mechanical thrombectomy treatment for ischemic stroke. In addition to these two classifications, there are two newer classifications as well. Acute stroke–ready hospitals, commonly located in rural areas, are similar to primary stroke centers in that they can treat ischemic strokes with intravenous thrombolysis; however, they do not have designated stroke unit recovery beds. Thrombectomy-capable stroke centers are also similar to primary stroke centers; however, they can also treat the ischemic strokes with mechanical thrombectomy if necessary. Given the four available types of stroke centers, MSUs may play a role in more accurately triaging patients to the most appropriate stroke center hospital, as CT imaging is more sensitive and specific than standard stroke scale examinations performed by EMS providers (Czap et al., 2020; Wira and Aydin, 2020).

Existing EMS Delivery Systems

Emergency ground medical transportation (EGMT) is provided by emergency medical technicians (EMTs) and/or paramedics who staff ambulances. EMTs, who receive approximately 150 hours of training, can provide noninvasive basic life support (BLS) maneuvers such as oxygen therapy, cardiopulmonary resuscitation (CPR), and bleeding control. Paramedics, who receive approximately 1,100 hours of training beyond EMTs, can provide invasive advanced life support (ALS), such as intravenous (IV) therapy, medication administration, and breathing tube insertion. In response to 911 calls, trained emergency medical dispatchers use software to triage whether an emergency is life threatening (necessitating a paramedic-level ALS response) or non–life threatening (necessitating an EMT-level BLS response). In most systems, suspected stroke symptoms generate an ALS response so paramedics can provide a more detailed assessment and wider treatment options (Glober et al., 2016). BLS ambulances consist of two EMTs, whereas ALS ambulances are staffed by either two paramedics or one paramedic and one EMT. Payer reimbursement rates typically are higher for life-threatening emergencies with ALS ambulances than for non–life-threatening emergencies with BLS ambulances. In addition to the transportation charge, there are sometimes additional charges such as mileage, oxygen, and miscellaneous supplies (Jacobs et al., 2017).

Current EMS Stroke Care in California

As discussed previously, in California, local EMS agencies (LEMSAs) establish local medical treatment protocols, so EMS stroke care varies somewhat across California's LEMSA regions. In 2016, several

California EMSA medical directors compared the 33 distinct EMS stroke protocols for consistency (Glober et al., 2016). Results showed that:

- 85% of LEMSAs directed the use of a defined stroke scale to recognize suspected strokes and an additional 9% recommended specific neurological exams that include key portions of a stroke scale.
- As hypoglycemia is a common stroke mimic, 100% of LEMSAs recommended blood glucose evaluation in suspected stroke patients, while 73% recommended intravenous glucose treatment for identified hypoglycemia in stroke patients.
- 52% of LEMSAs directed transport directly to a hospital stroke center whereas 88% recommended hospital notification from the field of suspected stroke.
- 61% of LEMSAs directed EMS providers to limit on-scene time prior to transport, recognizing the role of expediency in stroke treatment.

As of 2016, no LEMSAs recommended triaging patients to different hospital stroke centers based on severity. However, both LEMSAs with current MSUs (Los Angeles County and San Mateo County) now require paramedics to assess stroke severity and to selectively triage more severe stroke patients to comprehensive stroke centers rather than primary stroke centers.

Mobile Stroke Units

The mobile stroke unit (MSU) concept was envisioned in 2003 as a novel means to address delays between stroke symptom onset and therapeutic treatment (Calderon et al., 2018). After extensive planning, particularly in the development of a mobile CT scanner, the first MSU was introduced in Homburg, Germany, in 2010. This specialized ambulance included a CT scanner, point-of-care laboratory diagnostics, and a telemedicine system (or in-person stroke neurologist) to support stroke diagnosis, and early tissue plasminogen activator (tPA)[20] medication-based stroke treatment prior to hospital arrival. A second MSU was introduced in Berlin, Germany, in 2011. Having demonstrated the feasibility of an ambulance-mounted mobile CT scanner, MSUs were subsequently launched in other areas, such as the first MSU in the United States in Houston in 2014 (Wira and Aydin, 2020). Whereas a traditional ambulance is typically staffed by two paramedics or emergency medical technicians (EMTs), a functioning MSU requires at least four personnel: a paramedic, a critical care nurse, a CT technologist, and an EMT driver. If a stroke neurologist is not physically present, telemedicine can be used for the physician to remotely examine the patient (and patient's associated diagnostics) and to order appropriate treatment. For hemorrhagic strokes, MSUs can identify the brain bleed, administer blood pressure control and anticoagulant reversal medications as necessary, and triage the patient to a hospital with neurosurgical capabilities. For ischemic strokes, MSUs can rule out bleeding and begin intravenous tPA thrombolysis while triaging the patient to a hospital with mechanical thrombectomy capabilities if necessary.

MSUs Currently in California

Two areas in California are currently served by MSUs: one in Los Angeles County and one in San Mateo County. The first California MSU was introduced in Los Angeles County in September 2017 (UCLA Health, 2020). This MSU is operated by UCLA Health and began as a partnership with one fire department to offer services for 10 hours per day, four days per week, in alternating weeks. As of September 2020, the UCLA Health MSU operates with six fire departments in three distinct geographic regions, offering coverage for 10 hours per day, seven days a week, alternating between the three regions on a weekly basis. Since introduction, the UCLA Health MSU responded to 632 911 calls and transported 145 patients; of these 145 patients, 47 were aged 20 to 70 years and 98 were aged 71 years and older; 65% were diagnosed with ischemic stroke, 13% with hemorrhagic stroke, and 22% with other

[20] Tissue plasminogen activator (tPA), branded as Alteplase, is the only FDA-approved medication for thrombolysis in acute strokes. If no other contraindications exist, tPA may be administered in ischemic strokes (blood clots in brain) within 3 to 4.5 hours after symptom onset following CT or MRI confirmation that there is no bleeding in the brain.

neurological conditions. Of the 487 911 calls that did not result in transport, 26% of the calls were cancelled in route by paramedics and 74% received an assessment but did not warrant further MSU admission and transportation. The second California MSU was introduced in San Mateo County in December 2018 (Sutter Health, 2018). The San Mateo County MSU, operated by Sutter Health, is based at one site. As of October 2019, 10 patients were treated by the Sutter Health MSU (Sutter Health, 2019). Initial acquisition and ongoing operation costs for both MSUs in California are funded through private philanthropic grants, and to a lesser extent, municipal grants.

Stroke and MSU Disparities

As discussed previously, stroke prevalence and incidence is higher among older adults. In California, stroke incidence is highest among multiracial and African American adults and is lowest in Asians (Conroy et al., 2016). Age-adjusted, per-capita stroke hospitalization and mortality are both approximately 50% greater among African Americans than Californians overall. Stroke frequency is similar among Californians of all education and income levels. Some of these racial/ethnic disparities may be partially explained by predisposing medical risk factors and stroke symptom awareness (Adeoye et al., 2019). Racial/ethnic minorities are also less likely to utilize 911 and EMS, suggesting that they may be disproportionately underserved by MSUs (Adeoye et al., 2019). Furthermore, MSUs are typically located in dense urban areas, which are usually served by comprehensive stroke centers in relatively close proximity. Though rural residence is associated with increased stroke incidence and mortality, rural areas are often distant from stroke centers. While some MSUs cover suburban areas, no MSUs in the United States and one MSU in Canada are known to provide coverage in rural areas (Mathur et al., 2019; Shuaib et al., 2018).

MSU Finances and Utilization

Initial acquisition costs of an MSU are approximately $1,000,000, much of which is attributed to the CT scanner and specialized shielding rather than the ambulance itself (Schencker, 2016; Zoler, 2017). Annual operating costs can range from $500,000 to $1.2 million, with large variation depending on the staffing model (onboard versus telehealth stroke neurologist) and hours of operation (Schenker, 2016; Zoler, 2017; and Reimer, 2020). Given their advanced capabilities, MSUs may be able to bill for their additional services beyond emergency ground medical transportation. A recent study explored the average baseline reimbursements for potential MSU services, such as the CT scan and tPA thrombolysis administration (Reimer et al., 2020). These standard Medicare reimbursements, in 2017 dollars, are below in Table 1. Of note, this study did not include the reimbursement associated with the tPA medication itself, estimated to be reimbursed at $6,400 by Medicare in 2014 (Kleindorfer et al., 2017).

Despite the potential for MSUs to charge for their advanced services, a recent survey of American MSU programs found that all but one MSU program reported their overall financial performance as “negative” (Reichenbach et al., 2021). Of the 15 MSU programs that responded with their billing practices, 53% reported billing for the CT scan, 53% for telemedicine, 47% for emergency ambulance transport, 21% for the tPA medication, 5% for critical care services, and 5% for laboratory services; however, collections were poor. As a result, 100% of the MSU programs reported that they rely on grants, philanthropy, and/or institutional support to financially sustain their MSU program. The two MSU programs in California do not currently appear to bill for their services — initial capital costs and ongoing operations are funded by private philanthropy and county/municipal grants.

The recent survey of MSU programs discussed above, which was presented in March 2021, also described average MSU utilization (Reichenbach et al., 2021). Of the 20 existing MSU programs in the United States, 19 returned surveys. MSU programs responded to a median of 600 dispatches per year and covered a median 240 square mile service area. The MSU programs reported that they administered a median of 30 tPA thrombolysis treatments in the 12 months prior to the survey.

Table 2. Baseline Mobile Stroke Unit Costs and Potential Reimbursements

MSU Service or Component	Baseline cost [Range]
CT scan	$253 [190, 316] (a)
tPA administration fee	$188 [141, 235] (a)
tPA medication	$6,400 (b)
Observation after tPA	$71 [53, 89] (a)
Emergency department visit for acute ischemic or hemorrhagic stroke	$749 [563, 964] (a)
Annual cost of MSU operations	$600,000 [500,000, 1,200,000] (a) and (c)
Initial acquisition cost of MSU	$1,000,000 (c)

Notes: (a) In 2017 U.S. dollars, estimated Medicare reimbursement from Reimer et al., 2020.
(b) In 2014 U.S. dollars, estimated Medicare tPA reimbursement from Kleindorfer et al., 2017.
(c) In 2016 U.S. dollars, from Schencker, 2016; and Zoler, 2017.

Review of Available Outcomes Evidence

As part of this abbreviated analysis, CHBRP conducted a review of the available evidence pertaining to MSUs. This evidence largely pertains to time-based process outcomes and clinical outcomes for stroke diagnosis and treatment, as well as limited cost-effectiveness analyses. Given the novelty of MSUs, particularly in California, and the inherent delays in publishing peer-reviewed studies, CHBRP recognized the need to include other forms of evidence in our analysis. These include peer-reviewed abstracts from scientific conferences, news articles, hospital press releases, and presentations to the public.

Time-based Process Outcomes for Stroke Diagnosis and Treatment

MSUs were originally designed with the goal of speeding time to stroke diagnosis and treatment by integrating diagnosis and treatment into the EMS response phase (Calderon et al., 2018; Wira and Aydin, 2020). As such, most of the published research examining MSU outcomes is focused on the measurement of time intervals in stroke diagnosis and treatment. The first published study in 2012 found that the German MSU reduced median time from EMS dispatch to treatment decision by 41 minutes (35 minutes in MSU compared to 76 minutes in control group) (Walter et al., 2012). In the United States, the Cleveland Clinic's MSU reported a reduction in EMS dispatch to CT scan completion (33 minutes in MSU, 56 minutes in control group) and in EMS dispatch to thrombolysis (56 minutes in MSU, 94 minutes in control group) (Taqui et al., 2017). Recent data from seven MSU sites across the United States compared MSU to standard EMS management, finding a significant reduction in time from last known well (the time immediately prior to onset of stroke symptoms) until thrombolysis treatment (72 minutes in MSU, 108 minutes with standard management) (Grotta et al., 2021).

As thrombolysis in ischemic strokes must be initiated within 3 to 4.5 hours of stroke symptom onset, several studies examined whether MSUs increased the proportion of ischemic stroke patients who were treated with intravenous thrombolytics. In Germany, 33% of MSU patients received thrombolysis compared to 22% of control group patients (Ebinger et al., 2015). The seven MSU site study also found that 97% of MSU patients who were thrombolysis treatment eligible received treatment, as compared to 79% in the standard management control group (Grotta et al., 2021).

Among patients who require hospital-based mechanical thrombectomy, one study demonstrated that Houston's MSU decreased median door-to-mechanical-thrombectomy-treatment initial time (door-to-puncture time[21]) by 54 minutes, compared to a conventional treatment control group (Czap et al., 2020).

[21] Door-to-puncture time refers to the time interval from emergency department arrival to initiation of mechanical thrombectomy treatment in acute ischemic strokes. It is one of several standardized performance measures used to

Clinical Outcomes

Until recently, there was little evidence that MSUs improved patient outcomes in addition to the process outcomes discussed above. A recent nonrandomized, controlled study in Berlin reported that MSU treatment was significantly associated with lower global disability at 3 months post-stroke, as compared to conventional treatment (Ebinger et al., 2021). Of stroke patients treated by the MSU, 51% had no disability from their stroke, compared to 42% of conventional ambulance patients. The Houston study that examined door-to-puncture time[22] also found that the MSU's shorter door-to-puncture time was correlated with greater reduction in stroke symptoms following treatment (Czap et al., 2020). Preliminary data from the recent seven MSU site study also found that MSU treatment was associated with a significantly lower disability score at 3 months post-stroke (Grotta et al., 2021). CHBRP was unable to identify any randomized controlled trials; the first prospective randomized multicenter study (BEST-MSU) is currently collecting data, with results expected in 2022 (Yamal et al., 2018).

Cost Effectiveness Literature

The ongoing BEST-MSU study will also be the first comprehensive MSU cost-effectiveness study. Nevertheless, several more limited studies have analyzed the cost-effectiveness of the MSU. A study using Cleveland Clinic MSU data found a $70,613 incremental annual cost per MSU compared to standard EMS, but also noted that the MSU avoided 76 secondary interhospital transfers and 76 emergency department encounters; the cost savings from avoiding secondary interhospital transfers can account for approximately 35% of annual MSU operating costs (Reimer et al., 2020). Another study calculated that MSU care for ischemic stroke patients in the United States compared to standard EMS care ranged from $9,354 to $17,498 per disability-adjusted life year, depending on model parameters (Sriudomporn et al., 2019). In Germany, an earlier study found that MSU care compared to standard ambulance care achieved an incremental cost-effectiveness ratio of €32,456 per quality-adjusted life year (Gyrd-Hansen et al., 2015).

MSU Evidence Challenges

CHBRP noted that nearly all available MSU studies were authored by MSU program physicians and associated researchers who may have potential bias. Additional published perspectives from other medical disciplines describe the gaps in morbidity and mortality outcomes for MSU patients (Bledsoe, 2017; Erich, 2018; Wira and Aydin, 2020; Zoler, 2017). Given the high costs of MSUs and the limited cost-effectiveness studies, these perspectives suggest that investments in EMS provider training and stroke triage may be more efficient (Bledsoe, 2017; Erich, 2018) in producing positive outcomes for stroke patients. CHBRP identified several individual studies that examined time-based process outcomes and clinical outcomes for stroke diagnosis and treatment. These studies reported that an MSU may reduce the time interval from EMS dispatch to initial CT scan, tPA thrombolysis, and mechanical thrombectomy; higher rates of tPA administration in MSU patients compared to standard management were also reported. With regard to clinical outcomes, several individual studies reported that MSU treatment was associated with lower global disability or greater reduction in stroke symptoms. CHBRP was unable to identify any relevant systematic reviews, meta-analyses, or generalizable and high-quality randomized controlled trials.

determine how quickly stroke patients receive treatment. More information can be found here: https://www.heart.org/idc/groups/ahaecc-public/@wcm/@gwtg/documents/downloadable/ucm_491528.pdf or here https://www.acr.org/-/media/ACR/NOINDEX/Measures/2019_Measure_413_MIPSCQM.pdf.

[22] Ibid.

POPULATION AFFECTED

Effect on Population

If enacted, AB 1254 would affect the health insurance of approximately 21.9 million enrollees (55.7% of all Californians). This represents 100% of the 21.9 million Californians who will have health insurance regulated by the state that may be subject to any state health benefit mandate law — health insurance regulated by the California Department of Managed Health Care (DMHC) or the California Department of Insurance (CDI). If enacted, the law would affect the health insurance of enrollees in DMHC-regulated plans and CDI-regulated policies (with the exception of CDI large group), as well as the insurance of Medi-Cal managed care beneficiaries regulated by DMHC.

FISCAL IMPACTS

CHBRP estimates no measurable fiscal impact or expected utilization increase due to AB 1254 in the short term. CHBRP notes that (1) the availability of mobile stroke units (MSUs) in California will likely remain low; and (2) existing MSUs have been largely reliant on grants and philanthropy. Even with the passage of AB 1254, their ability to recover costs may be constrained by the fee schedules set at the local level for emergency ground medical transportation (EGMT). In addition, the population affected (mostly under age 65 years) has a low stoke incidence rate; therefore, CHBRP expects very low utilization over the long term even if MSUs were to increase.

Approach

CHBRP considered the current use of MSUs with the understanding that of the 20 presently in the United States, few if any, presently bill commercial insurers (Reichenbach et al., 2021). Medicare provides limited coverage for MSUs beyond the normal reimbursement for EGMT (under the telehealth benefit)[23] and 66% of stroke hospitalizations occur in people over the age of 65.[24] Presently, there are about 20 MSUs operating in the United States (Reichenbach et al., 2021). CHBRP is aware of two MSUs currently in operation in California. The costs following enactment of AB 1254 are a function of the increased supply and increased use of MSUs for non-Medicare stroke patients.

CHBRP believes the increased supply of MSUs will be constrained by their initial investment and operating costs in relation to the reimbursement rate. Estimates of initial costs for MSUs are approximately $1 million each. Annual operating costs for each MSU are approximately $500,000 to $1.2 million (Reimer et al., 2020). Limited reimbursement rates (with the likely finite number of eligible stroke patients) appear unlikely to cover the expected annual financial costs. For example, if emergency transport rates, controlled by each county in California, were similar to those for usual emergency transport rates, an MSU would not cover its costs. With current Medicare reimbursement, there are only a couple of MSUs in California. It seems unlikely that new reimbursement will be high enough to make investing in new MSUs attractive for the additional 34% of stroke patients (the non-Medicare stroke population). There may be other reasons to invest in more MSU capacity (e.g., a healthcare system might use it for advertising or as a loss leader), but this suggests modest investments in the supply of MSUs, congruent with no estimated impact on utilization or overall costs.

Assuming a modest increase in the availability of MSUs due to the coverage requirement in AB 1254, there is significant uncertainty about the cost impact. This is because the population affected by an increase in MSUs (if there is one at all) will also be small. The number of patients affected will be small because most strokes do not occur in the population covered by AB 1254. Approximately two out of every three patients having a stroke will be covered by Medicare; leaving roughly a third of stroke patients who are not Medicare beneficiaries. Of these (third of all California stroke patients), a smaller proportion of them are covered by health plans and policies subject to the mandate. About 16,000 Californians under age 65 years with state-regulated health plans are likely to have a stroke each year outside of a hospital, but nearly half of adults diagnosed with stroke at an emergency department arrived via ambulance (Kamel et al., 2012). This suggests about 8,000 people who might potentially utilize MSUs if they existed. However, many of these individuals may live in areas not served by MSUs since MSUs are typically located near high-technology medical centers in large cities. Assuming 10% of the 8,000 live in an area serviced by new MSUs and 10% of the time an MSU is available and sent when and where it is needed, CHBRP estimates that there could be an estimated 80 potential patients in state-regulated plans or policies in which to consider a potential impact on utilization and overall costs.

CHBRP then considered for this estimated patient population of 80 people what percent of the time might the MSU lead to differential outcomes and differential costs (e.g., getting more computed tomography

[23] https://www.medicare.gov/coverage/telehealth.
[24] For further details, please see https://www.cdc.gov/stroke/facts.htm.

[CT] scans and tissue plasminogen activator [tPA] when appropriate). While it is unknown how often expected differences occur in a real-world setting, there is research estimating the magnitude of the expected differences if they occur. The Cost Effectiveness Literature section above reviews economic evaluations of MSUs. Recently completed research (Reimer et al., 2020) concluded that "the budgetary impact of an MSU within a health system can vary significantly by clinical and geographic factors, which should be considered in the decision to set up and run an MSU service. A comprehensive cost-effectiveness analysis is required to determine the clinical and operational value of an MSU." This evidence base does not allow CHBRP to make a further projection on expected differences among the estimated 80 people identified above.

Long-Term Impacts

It is conceivable that in the future, there may be more economically viable ways to sustain an MSU service. For example, research from Germany suggests that by reducing expensive personnel (staffing the MSU with only a paramedic and a CT technician guided by hospital experts via telemedicine), the economic viability of MSUs may be increased. However, CHBRP notes that it is possible that in the long term, an increased number of MSUs could drive up use of expensive services/medications (like tPA), and put pressure on usual, customary, and reasonable (UCR) rates with private payers, or other approaches to bill for services in MSUs. Therefore, CHBRP estimates no measurable postmandate change in utilization or overall costs following enactment of AB 1254; the long-term impacts are less certain.

CHBRP estimates no measurable fiscal impact or expected utilization increase due to AB 1254 in the short term. However, in the long term, an increased number of MSUs could drive up use of costly services/medications (like tPA), and put pressure on UCR rates with private payers, or other approaches to bill for services in MSUs.

APPENDIX A TEXT OF BILL ANALYZED

On February 22, 2021, the California Assembly Committee on Health requested that CHBRP analyze AB 1254.

ASSEMBLY BILL **NO. 1254**

Introduced by Assembly Member Gipson

February 19, 2021

An act to add Section 1371.57 to the Health and Safety Code, and to add Section 10126.67 to the Insurance Code, relating to health care coverage.

LEGISLATIVE COUNSEL'S DIGEST

AB 1254, as introduced, Gipson. Health care coverage: mobile stroke units.

Existing law, the Knox-Keene Health Care Service Plan Act of 1975, provides for licensure and regulation of health care service plans by the Department of Managed Health Care and makes a willful violation of that act a crime. Existing law also provides for the regulation of health insurers by the Department of Insurance. Existing law imposes certain requirements on health care service plans and health insurance policies, including requirements relating to coverage for ambulance services, as specified.

This bill would require a health care service plan or a health insurance policy that is issued, amended, or renewed on or after January 1, 2022, that provides coverage for emergency health care services to include coverage for services performed by a mobile stroke unit, as defined by the bill.

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

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

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

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

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

SECTION 1. Section 1371.57 is added to the Health and Safety Code, immediately following Section 1371.55, to read:

1371.57. (a) A health care service plan issued, amended, or renewed on or after January 1, 2022, that provides coverage for emergency health care services shall include coverage for services provided by a mobile stroke unit.

(b) For purposes of this section, "mobile stroke unit" means a state-recognized mobile unit facility that serves as a hybrid emergency response ambulance and operates under the direction of a local emergency services agency to provide emergency treatment, imaging, and transportation for patients suffering from a stroke.

SEC. 2. Section 10126.67 is added to the Insurance Code, immediately following Section 10126.65, to read:

10126.67. (a) A health insurance policy issued, amended, or renewed on or after January 1, 2022, that provides coverage for emergency health care services shall include coverage for services performed by a mobile stroke unit.

(b) For purposes of this section, "mobile stroke unit" means a state-recognized mobile unit facility that serves as a hybrid emergency response ambulance and operates under the direction of a local emergency services agency to provide emergency treatment, imaging, and transportation for patients suffering from a stroke.

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

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ABOUT CHBRP

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.

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** works with Task Force members in preparing parts of the analysis, and manages 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. Information on CHBRP's analysis methodology, authorizing statute, as well as all CHBRP reports and other publications, are available at www.chbrp.org.

CHBRP Staff

Garen Corbett, MS, Director
John Lewis, MPA, Associate Director
Adara Citron, MPH, Principal Policy Analyst
Karen Shore, PhD, Contractor*
An-Chi Tsou, PhD, Contractor*
*Karen Shore, PhD, and An-Chi Tsou, PhD, are Independent Contractors who work with CHBRP to support legislative analyses and other special projects on a contractual basis.

Faculty Task Force

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

Task Force Contributors

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

National Advisory Council

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

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Jeffrey Rollman, MPH, CHBRP contractor (and UCLA doctoral student), prepared the background and review of evidence sections. Jeffrey Hoch, PhD, of the University of California, Davis, prepared the cost impact analysis. Garen Corbett, MS, of CHBRP staff prepared the Policy Context and synthesized the individual sections into a single report. A subcommittee of CHBRP's National Advisory Council (see previous page of this report) and members of the CHBRP Faculty Task Force, Marilyn Stebbins, PharmD, of the University of California, San Francisco, and Nadereh Pourat, PhD, of the University of California, Los Angeles, reviewed the analysis for its accuracy, completeness, clarity, and responsiveness to the Legislature's request.

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

Garen Corbett, MS
Director

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