

Abbreviated Analysis:

Analysis of California Assembly Bill (AB) 2084 Medi-Cal Coverage for Comprehensive Medication Management (CMM) Services

Analysis Provided to the 2015–2016 California State Legislature, April 2016



AT A GLANCE

AB 2084 would provide coverage for comprehensive medication management (CMM) services in Medi-Cal (both in Medi-Cal managed care plans and fee-for-service [FFS]). This abbreviated CHBRP analysis was requested by the Legislature on February 26, 2016.

- **Medical effectiveness.** CHBRP found insufficient evidence about the impact of CMM services on health care utilization, clinical outcomes, mortality, medication adherence, and appropriateness of prescribing.
- **Medical effectiveness of pharmacists direct care services.** CHBRP found a preponderance of evidence that pharmacists' direct patient care interventions and services that do not include a comprehensive component are more effective than "usual care" for a variety of patient outcomes related to decreased utilization, cost, and mortality, as well as enhanced clinical outcomes.
- **Return on Investment (ROI).** CHBRP estimates a realistic estimate of ROI ranges from a slight loss to a potential gain, or 0.8:1.0 to 3.5:1.0. There is growing consensus that such interventions, particularly in the context of medical home and team-based coordination of care, can be cost effective. In broader or more spread-out programs, the interventions generate lower ROI.
- **Prevalence.** 60+ million Americans have multiple chronic conditions, with average per-patient prescriptions ranging from 15 to over 50. In FFS Medi-Cal, the top 1% of beneficiaries had \$416 million in drug costs.
- **Economic Impact.** CDPH estimates the economic impact of chronic diseases on Californians to be over \$98 billion, accounting for ~42% of the state's total health care costs.
- **Other States.** 15 state Medicaid programs provide some form of medication therapy management program.
- **Policy considerations.** 78% of Medi-Cal beneficiaries are in Managed Care. AB 2084 would allow plans to develop their own CMM programs. However, the dual (Medicare-Medicaid) population (nearly 1.4 million) has Medicare as primary, and it covers most of its drug costs. Although this population may have the greatest number who meet the CMM criteria, most savings would accrue to Medicare, although Medi-Cal would pay the cost.

BILL SUMMARY

AB 2084 (as introduced, on February 17, 2016) would provide coverage for comprehensive medication management (CMM) services in Medi-Cal (both in Medi-Cal managed care plans and fee-for-service [FFS] Medi-Cal) for beneficiaries taking three or more prescription drugs or biologics to treat or prevent one or more chronic conditions (or who have been identified as "high risk" for medication-related problems). Utilizing the clinical services of a primary care physician or pharmacist, working in collaboration with other providers and in direct communication with the beneficiary, CMM services shall include the following:

- Assessment of health status, prescription drug use and problems;
- Documentation of the beneficiary's current clinical status and clinical goals;
- Assessment of each medication for appropriateness, effectiveness, safety, and adherence;
- Development and implementation, in collaboration with the beneficiary, of a written medication treatment plan;
- Follow-up evaluation and monitoring; and
- An average of three to four visits per year with a CMM primary care physician or pharmacist.

Medi-Cal Managed Care Plans would be permitted to establish criteria for frequency and duration of therapy, delineate specific billable procedures, and enforce prior authorization requirements. And, the Department of Health Care Services (DHCS) shall evaluate the effectiveness of CMM on quality of care, patient outcomes, and total program costs, and shall include a description of any savings generated that can be attributed to the coverage of CMM services.

According to the bill author, this bill is intended to address the current problem of poor treatment of chronic

disease through the use of medications, which is the primary mechanism for treating chronic conditions/diseases. This problem results in worsening health outcomes for individuals with chronic disease which in turn results in high health expenditures for the costs of treatment. The Centers for Disease Control and Prevention reports that about half of all adults in the United States have one or more chronic diseases, and that treating chronic disease accounted for 86% of all health spending in 2010.^{1 2}

BACKGROUND

Used appropriately, medications can alleviate distressing symptoms that compromise physical and psychological well-being, help prevent the onset of many acute and chronic illnesses, and improve patient health outcomes. Often, however, medications are not used appropriately.³ In the United States in 2001, adverse drug events led to an estimated 4.3 million ambulatory visits. In addition to problems involving adverse drug events, many patients do not receive optimal pharmaceutical prescriptions. Even when optimal therapy is prescribed, patient inability to adhere closely to medication regimens may lead to poor health outcomes.⁴

- Patients with chronic disease often visit an array of healthcare providers and take multiple medications.⁵ In 2012, among civilian, noninstitutionalized US adults, approximately half (49.8%, or 117 million) had at least 1 of 10 selected chronic conditions.⁶ In California, it is estimated to be about 38% population wide, and

in Medi-Cal (overall), it is estimated to be 44.19%⁷ (note that the demographics by age and sex are a bit different in Medi-Cal than U.S. and California population demographics as a whole). The prevalence of adults who have multiple chronic diseases, such as heart disease, stroke, cancer, arthritis, hepatitis, and asthma, is increasing in the United States.⁸ Among adults with at least one chronic condition, more than half (approximately 60 million) had multiple chronic conditions (MCC). This translates into both higher spending per patient and number of prescriptions.

- Patients with two or more chronic conditions have an average of 14.3 prescriptions annually; 22.8 average prescriptions for three chronic conditions; 30.8 for four chronic conditions; and 50.2 for five chronic conditions per year.⁹
- Average annual prescription drug spending per capita for two to five chronic conditions ranges from \$1,197 annually to \$4,145 (2010 figures).
- The estimated prevalence of MCC varied by specific subpopulations of U.S. adults. The prevalence of MCC was higher among non-Hispanic white adults, non-Hispanic black adults, and non-Hispanic adults of other races than among non-Hispanic Asian adults and Hispanic adults.¹⁰
- The percentage of adults with MCC (both two MCC and three or more) increases with age. MCC prevalence was also greater among adults with

¹ Ward BW, Schiller JS, Goodman RA. Multiple chronic conditions among US adults: a 2012 update. Available at <http://dx.doi.org/10.5888/pcd11.130389>.

² Gerteis J, Izrael D, Deitz D, et al. Multiple Chronic Conditions Chartbook. Agency for Healthcare Research and Quality; 2014. Available at www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf.

³ Medication Therapy Management Interventions in Outpatient Settings. www.ncbi.nlm.nih.gov/books/NBK294482/.

⁴ Medication Therapy Management Interventions in Outpatient Settings. www.ncbi.nlm.nih.gov/books/NBK294482/.

⁵ Enthoven AC. Integrated delivery systems: the cure for fragmentation.

⁶ Gerteis J, Izrael D, Deitz D, LeRoy L, Ricciardi R, Miller T, Basu J. Multiple Chronic Conditions Chartbook. AHRQ Publications No, Q14-0038. Rockville, MD: Agency for Healthcare Research and Quality. April 2014.

⁷ Ad hoc analysis of 2014 California Health Interview Survey Findings provided to CHBRP by UCLA Center for Health Policy Research on April 12, 2016. This figure is of Medi-Cal enrollees across all categories, age 18-64 with one or more chronic conditions, including asthma, diabetes, high blood pressure, heart disease, congestive heart disease/failure, overweight/obesity, blind/deaf.

⁸ Ward BW, Schiller JS, Goodman RA. Multiple chronic conditions among US adults: a 2012 update. *Preventing Chronic Disease* 2014;11:E62.

⁹ AHRQ Multiple Chronic Conditions Chart Book, 2010. www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf.

¹⁰ AHRQ Multiple Chronic Conditions Chart Book, 2010. www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf.

public coverage than among adults with private or some other type of coverage.¹¹

Most people living with more than one chronic disease take multiple medications to manage their conditions and related comorbidities but commonly receive uncoordinated and fragmented care with little follow-up.¹²

Pharmacists are increasingly becoming more integrated into chronic-care delivery teams and offer the potential to improve health outcomes, particularly for patients managing multiple chronic conditions.¹³ Pharmacists practice in a variety of health care settings. Although they are most often associated with dispensing medications in retail pharmacies, their role is evolving to include providing direct care to patients as members of integrated health care provider teams. Although this bill does not limit CMM programs just to pharmacists, the evolving scope of practice in health care is one of the evolving dynamics in health care delivery that this bill touches on.

Although there is limited literature on the implementation of CMM programs as outlined in this bill, there is a growing body of peer-reviewed published and grey literature for interventions collectively labeled medication therapy management (MTM).

MTM is a term coined by Medicare but used by many without the same requirements and in a much broader context.

Background of Clinical Medication Management and Medication Therapy Management Programs

CMM is an intense, evidence-based, physician-approved, pharmacist-led, preventive clinical service intended to improve health outcomes for high-risk patients while decreasing health care costs.

¹¹ AHRQ Multiple Chronic Conditions Chart Book, 2010. www.ahrq.gov/sites/default/files/wysiwyg/professionals/prevention-chronic-care/decision/mcc/mccchartbook.pdf.

¹² U.S. Department of Health and Human Services. The Challenge of Managing Multiple Chronic Conditions. www.hhs.gov/ash/initiatives/mcc/article.html. Accessed April 6, 2016.

¹³ The National Governor's Association (NGA). *The Expanding Role of Pharmacists in a Transformed Health Care System*. January, 2015.

MTM programs are intended to ensure optimum therapeutic outcomes for targeted beneficiaries through improved medication use. Especially intended to reduce the risk of adverse events and costs,¹⁴ these programs are developed in cooperation with licensed and practicing pharmacists and physicians. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) expanded patient access to MTM services and established the requirements under Medicare Part D for sponsors to meet a variety of requirements related to MTM programs. Under Medicare Part D, MTM requires patients to meet three distinct criteria including a specified number of medications, number of chronic diseases, and expected annual drug expenditures.

CHBRP HAS PREPARED TABLE 1 AT THE BACK OF THIS ANALYSIS COMPARING THE FEATURES OF MTM VERSUS CMM PROGRAMS.

POLICY CONTEXT

This section provides some background on evolving pharmacist training and scope of practice changes in recent years as well as national efforts around comprehensive medication management in Medi-Cal, other Medicaid programs, Medicare, and other state programs/legislative efforts.

With the rise of health care costs, patients with chronic conditions, and shortages of primary care physicians in certain areas, there has been an effort by pharmacists across the country to expand their scope of practice. This may help ease the burden of primary care provider shortages.

California, Montana, New Mexico, and North Carolina have created the advanced practice pharmacy (APP) designation to expand pharmacists' scope of practice through collaborative practice agreements.¹⁵ This designation allows pharmacists to provide direct patient care, including primary care. The characteristics of an

¹⁴ Hutchison RW Jr., Hash RB, Nault EC. A multidisciplinary team of a physician and clinical pharmacists managing hypertension. *Journal of Research in Interprofessional Practice and Education*. 2012;2:296-302. Available at: www.jripe.org/index.php/journal/article/view/82. Accessed April 5, 2016.

¹⁵ NGA Working Paper. *The Expanding Role of Pharmacists in a Transformed Health Care System*. January, 2015.

APP, however, including educational requirements, provider status, service offerings, prescribing authority, and compensation, vary across those states.¹⁶

California Senate Bill 493 (2013), which was law passed on October 1, 2013, authorizes APP pharmacists to perform a series of expanded functions.¹⁷ SB 493 also grants pharmacists provider status, but does not expressly authorize Medicaid reimbursement for professional APP services.

No previous CMM legislation has been introduced in California. Laws that closely resemble AB 2084 are present in Washington¹⁸ and Minnesota.¹⁹

The National Conference of State Legislatures reports that 16 states, Colorado, Florida, Iowa, Minnesota, Mississippi, Missouri, New Mexico, New York, North Carolina, Ohio, Oregon, Utah, Vermont, Virginia, Wisconsin, and Wyoming, have implemented an MTM program for at least some of their Medicaid beneficiaries. Washington State has piloted a program for its public employees. Some states, such as Connecticut, have reported promising results from demonstration pilots. Effective January 2015, Washington law provides for pharmacist reimbursement to provide CMM for Medicaid managed care patients with MCCs. North Dakota enacted MTM legislation in April 2015. Florida recently submitted a 1115 demonstration waiver renewal request for its MEDS-AD waiver, which recently passed Demonstration Year 10, to serve approximately 40,000 Medicaid beneficiaries. Both New Jersey and Tennessee legislatures have pending legislation requiring MTM for their Medicaid populations.

¹⁶ Giberson S, Yoder S, Lee M. *Improving Patient and Health Systems Outcomes Through Advanced Pharmacy Practice: A Report to the US Surgeon General (Office of the Chief Pharmacist, US Public Health Service)*.

www.usphs.gov/corpslinks/pharmacy/documents/2011AdvancedPharmacyPracticeReporttotheUSSG.pdf. Accessed April 6, 2016.

¹⁷ California Legislative Information. SB-493 Pharmacy practice. http://leginfo.ca.gov/faces/billTextClient.xhtml?bill_id=201320140SB493.

¹⁸ See Washington State Legislature. SB 5213 - 2013-14. <http://apps.leg.wa.gov/billinfo/summary.aspx?bill=5213&year=2013>.

¹⁹ See 2015 Minnesota Statutes. 256B.0625 Covered Services, Subdivision 13h.

California Medicaid–Medi-Cal

Currently, there is no broadly available Medi-Cal benefit for CMM, thus few Medi-Cal beneficiaries currently receive them. However, CHBRP found among four Medi-Cal Managed Care Plans responding to a CHBRP survey, two had no CMM or MTM programs, one had a narrow program for disease management, and one had a comprehensive program in place.

For the Medi-Cal Managed Care Plan that has a CMM program in place, the plan noted that approximately 0.65% of its members are enrolled in its CMM program. The plan's minimum criteria is that the member must be on six or more long-term drugs, have six or more chronic disease states, and have a drug expenditure of at least \$784 per quarter. The eligibility criteria in this plan may be more restrictive than what is suggested in AB 2084. CHBRP found that a limited number of MTM Current Procedural Technology (CPT) codes exist with Medi-Cal; for the most part, they appear to enable data collection. There are no current requirements or guidance for Medi-Cal FFS beneficiaries. Medi-Cal Managed Care Plans may offer disease management programs similar to CMM, but are not required to do so, and are at each plan's discretion and control. No MTM costs appear to be reimbursed by DHCS.²⁰

In recent years, overall enrollment in Medi-Cal has grown while the ratio of managed care to FFS enrollment has changed. As of November 2015, 78% of the Medi-Cal beneficiaries were in Medicaid managed care plans (10.2+ million), and 22% (almost 3 million) are in FFS.²¹ Based on the legislative language, the Medi-Cal managed plans would be allowed to develop their own CMM programs.

Medicare-Medicaid Duals (1.4 million) appear to be Medi-Cal beneficiaries targeted for CMM on the basis of health needs and costs. This population has Medicare as the primary coverage, which includes prescription drug coverage. It would appear under AB 2084 that Medi-Cal would bear program costs, but any potential financial benefits would largely be realized by Medicare FFS or Medicare Advantage plans.

²⁰ Personal communication, C Brookings, March 24, 2016.

²¹ Research and Analytic Studies Division, March 2016. *Medi-Cal Monthly Enrollment Fast Facts, November 2015*. California Department of Health Care Services.

In January 2005, a pilot program to evaluate MTM services for patients with HIV/AIDS began in California, allowing 10 HIV/AIDS specialty pharmacies to receive compensation for the MTM services that they provided to HIV/AIDS patients. Over a 3-year period, adherence increased, and there was no significant difference in total patient costs between the intervention and control groups.²²

Other State Medicaid Programs

Medicaid programs using MTM in Iowa, Minnesota, and Connecticut have demonstrated increases in appropriate medication use, resolution of drug problems, and cost savings. In Iowa, operators observed a 12.5% increase in the medication appropriateness index, and a 24% decrease in use of medications considered inappropriate for the age group. In Minnesota, among 259 participants, 789 drug therapy problems were resolved (3.1 drug therapy problems per recipient), and health care expenditures were reduced by \$20 per member per month.²³ The Connecticut program saved an average of \$1,123 in drug costs and \$472 in medical, hospital, and emergency department charges per patient. Per-person program costs were estimated at \$638, resulting in \$912 per patient savings and a final return on investment estimate of 150%.

Medicare

The Centers for Medicare & Medicaid Services is planning a Medicare Part D Enhanced Medication Therapy Management Model in 11 states (California is not included) to go into effect in 2017.^{24,25}

²² Hirsch JD, Gonzales M, Rosenquist A, Miller TA, Gilmer TP, Best BM. Antiretroviral therapy adherence, medication use, and health care costs during 3 years of a community pharmacy medication therapy management program for Medi-Cal beneficiaries with HIV/AIDS. *Journal of Managed Care Pharmacy*. 2011;17;213-223.

²³ Evaluating Effectiveness of the Minnesota Medication Therapy Management Care Program.

<http://archive.leg.state.mn.us/docs/2008/mandated/080113.pdf>.

²⁴ CMS.gov. Part D Enhanced Medication Therapy Management Model. <https://innovation.cms.gov/initiatives/enhancedmtm/>.

²⁵ The states include: Arizona, Florida, Iowa, Louisiana, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Virginia, and Wyoming.

Medical Effectiveness

As discussed previously, AB 2084 would require Medi-Cal health plans to provide coverage for CMM services. The goals of CMM are to improve quality outcomes for beneficiaries and to lower overall health care costs by optimizing appropriate medication use linked directly to achievement of the clinical goals of therapy.

Research Approach and Methods

Studies of CMM services were identified through searches of multiple bibliographic databases of medical, scientific, and economic literature, as well as websites maintained by organizations that produce and/or index meta-analyses and systematic reviews (see CHBRP's website [under analysis methodology] for full list of databases and websites)²⁶. The current search was limited to abstracts of peer-reviewed research studies that were published in English in 2000 to present.

The medical effectiveness review included studies of the CMM services by physicians or non-physicians, typically pharmacists, to patients. AB 2084 specifically includes comprehensive management and patient assessment to ensure medication safety, efficacy, and appropriateness. This review encompasses studies of patients with a wide range of diseases and conditions because the bill would require coverage and reimbursement for all enrollees who are existing patients in a provider's practice. Additionally, CMM studies that did not include a comprehensive management component, such as those that included only an annual comprehensive medication review followed by periodic targeted medication reviews or episodic medication-oriented interventions were excluded from this review.

Because there are a very limited number of research studies that examine CMM services, CHBRP also looked at literature on programs that include one or more pharmacy services, but do not include a comprehensive management component, which is the defining component of CMM. These studies, commonly referred to as MTM programs, may include pharmacists' direct patient care interventions and services such as programs including medication review, patient-directed education, care

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http://www.chbrp.org/analysis_methodology/medical_effectiveness_analysis.php.

coordination, and opportunity for follow-up. Many of these interventions only address medications for a specific disease and do not include a comprehensive review of all medications prescribed to patients. Additionally, although most of the studies found concern interventions provided by pharmacists, some are based on physician intervention and some are a physician and pharmacist team based model of care. In cases in which physicians and pharmacists collaborate to deliver an intervention, the effects of the two types of health professionals on patient outcomes cannot be disentangled.

Of the 513 articles found in the current literature review, 22 were reviewed for potential inclusion in this report. Studies were eliminated because they did not report findings from clinical research studies, did not focus on CMM services, or were of poor quality. In total, 6 studies were included in the medical effectiveness review for AB 2084, based on the quality of the studies and their relevance to the specific bill language.

Methodological Considerations

Most studies pertinent to AB 2084 compared CMM services to usual care and assessed whether adding CMM to usual care improved outcomes.

Outcomes Assessed

Because AB 2084 would apply to many different situations, CHBRP assessed the medical effectiveness of the proposed CMM services with regard to five sets of outcomes: (1) health care utilization, such as the number of emergency department visits, hospitalizations, and hospital readmissions; (2) clinical outcomes, including anticoagulation, blood pressure, hemoglobin A1c, and low-density lipoprotein (LDL) cholesterol; (3) mortality rates; (4) medication adherence; and (5) appropriateness of prescribing.

Study Findings

Taken together, CHBRP found insufficient evidence about the impact of comprehensive medication management (CMM) services on health care utilization, clinical outcomes, mortality, medication adherence, and appropriateness of prescribing. A grade of *insufficient evidence* indicates that there is not enough evidence available to know whether or not a treatment is effective, because there are too few studies of the treatment and

because the available studies have weak research designs. It does not indicate that a treatment is not effective.

CHBRP found a *preponderance of evidence* that pharmacists' direct patient care interventions and services *without a comprehensive management component* are more effective than usual care for outcomes including health care utilization, clinical outcomes, medication adherence, and mortality. It is important to note that many studies of direct pharmacist care concern more narrowly focused interventions than CMM, so the findings may not generalize to CMM.

These findings are discussed in further detail in the sections that follow.

Findings for Comprehensive Medication Management Services

Healthcare Utilization

CHBRP found one study that examined the impact of CMM interventions on health care utilization. This matched-control study (N = 470) found no significant difference between the CMM intervention group and the comparison group, which received usual care, in the number of hospital readmissions during the 6 months following hospital discharge (odds ratio [OR]: 0.678, 95% confidence interval [CI]: 0.318–1.449). The same study found no significant difference between subjects receiving CMM services or usual care with regard to the number of emergency department visits during the 6 month period following hospital discharge (OR: 0.949, 95% CI: 0.430–2.098).²⁷

Due to the limited research, based on this one study, there is insufficient statistical power to detect statistically significant differences in hospital readmissions and emergency department visits. Therefore, CHBRP concludes there is insufficient evidence about the impact of CMM services compared to usual care on health care utilization.

²⁷ Westberg SM, Swanoski MT, Renier CM, Gessert CE. Evaluation of the impact of comprehensive medication management services delivered posthospitalization on readmissions and emergency department visits. *J Manag Care Spec Pharm*. 2014; 20(9): 886-893.

Clinical Outcomes

CHBRP found one study that examined the impact of CMM interventions on clinical outcomes. A study in a large health system in Minnesota with an intervention group found 40% of patients in CMM interventions achieved 5 “optimal care” treatment benchmarks for patients with diabetes (e.g., meeting all 5 benchmarks for hemoglobin A1c levels, LDL cholesterol levels, blood pressure, aspirin use, and tobacco cessation) compared with the statewide average of 17.5% of patients.²⁸

Due to the limited research and the weak research design of this study, there is insufficient evidence about the impact of CMM services compared to usual care on clinical outcomes.

Mortality Rates

CHBRP found one study that examined the impact of CMM interventions on mortality outcomes. Although there was a lower mortality rate in the CMM intervention group than the usual care group (3% vs. 5.6%), the difference was not statistically significant (OR: 0.587, 95% CI: 0.188–1.826).²⁷ This study was not powered to look at mortality, so it would be difficult to detect a statistically significant difference in this outcome. Therefore, there is insufficient evidence about the impact of CMM services compared to usual care.

Medication Adherence

CHBRP found one study that examined the impact of CMM interventions on medication adherence. This study, a retrospective analysis using pharmacy claims of employees in a large Midwest health system, compared medication adherence measured using proportion of days covered (PDC) in employees who received CMM with employees who did not (comparison group). The CMM group showed significant improvements in medication adherence (i.e., the extent to which patients have filled their prescriptions) across multiple chronic disease medication classes.²⁹

²⁸ Isetts BJ, Brummel AR, De Oliveira DR, Moen DW. Managing drug-related morbidity and mortality in the patient-centered medical home. *Med Care*. 2012; 50(11): 997-1001.

²⁹ Brummel A and Carlson AM. Comprehensive Medication Management and Medication Adherence for Chronic Conditions. *J Manag Care Spec Pharm*. 2016;22(1):56-62.

Due to the limited research and the weak research design of this study, there is insufficient evidence about the impact of CMM services compared to usual care on medication adherence.

Appropriateness of Prescribing

CHBRP found no studies of CMM services compared to usual care on medication appropriateness (e.g. unwarranted polypharmacy, suboptimal schedules).

Findings for Pharmacists’ Interventions/Services

Despite insufficient evidence that CMM services improve outcomes compared to usual care, CHBRP found a *preponderance of evidence* that pharmacists’ direct patient care interventions/services are more effective than usual care for outcomes including health care utilization, clinical and quality of life outcomes, medication adherence, adverse drug events, and mortality. These studies did not look at comprehensive medication management for all medications that a patient takes for all diseases they have but rather, at medication management of particular disease states, such as diabetes. *It is important to note that many studies of direct pharmacist care concern more narrowly focused interventions than CMM. Thus, their findings may not generalize to CMM.*

Much of this research is based on two large systematic review and meta-analyses examining the effects of pharmacists’ direct patient care interventions and services on therapeutic, safety, and health outcomes.^{30 31}

Viswanathan conducted a systematic review and meta-analysis of 21 randomized control trials(RCT), 4 non-randomized control trials, and 19 cohort studies. Most studies compared an MTM intervention with usual care (no MTM intervention). All studies used pharmacists to deliver MTM services, specifically medication review,

³⁰ Chisholm-Burns MA., Kim Lee J, Spivey CA, Slack M, Herrier RN, Hall-Lipsy E, Graff Zivin J, Abraham I, Palmer J, Martin JR, Kramer SS And Wunz T. Us Pharmacists' Effect As Team Members On Patient Care: Systematic Review And Meta-Analyses. *Med Care*. 2010;48(10): 923-933.

³¹ Viswanathan M, Kahwati LC, Golin CE, Blalock SJ, Coker-Schwimmer E, Posey R, Lohr KN. Medication Therapy Management Interventions in Outpatient Settings [Internet]. Rockville (MD): Agency for Healthcare Research and Quality (US); 2014 Nov. (Comparative Effectiveness Reviews, No. 138.) Results. <http://www.ncbi.nlm.nih.gov/books/NBK294494/>.

patient-directed education, care coordination, and opportunity for follow-up. Despite these 4 common features, MTM interventions differed considerably across the studies.³¹

Viswanathan found insufficient evidence to draw any conclusions about effectiveness for outcomes, including the effect on anticoagulation (imprecise, single RCT body of evidence with medium limitations), blood pressure (direct, but inconsistent and imprecise, findings from a single RCT and two cohort studies with medium limitations), hemoglobinA1c (inconsistent and imprecise body of evidence from two RCTs with medium limitations and two observational studies with high study limitations), and LDL cholesterol (imprecise, single RCT body of evidence with medium limitations and an imprecise observational body of evidence of two studies with high limitations).³¹

Viswanathan found insufficient evidence to draw conclusions about the effect of MTM on the number of outpatient visits, laboratory tests, emergency department visits, and the number of hospitalizations for unspecified conditions, congestive heart failure, or chronic obstructive pulmonary disease. The authors reported that the results were inconsistent for the same outcome (i.e., may have raised the use of health care services in one study and lowered it in another) and could not interpret these results as either benefits or harms.³¹

Viswanathan found insufficient evidence to draw conclusions about the effect of MTM on adverse drug events (inconsistent and imprecise findings from two RCTs: one with low study limitations and one with medium limitations) and mortality (RCT with medium study limitations and two observational studies, with high study limitations).³¹ Viswanathan found low strength of evidence that MTM had an effect on the medication adherence measured as the percentage of people adherent to at least 80 percent of prescribed doses (inconsistent evidence with primarily nonsignificant findings of effects and high study limitations). There was insufficient evidence to evaluate the effect of MTM on medication adherence as measured by self-report (inconsistent and imprecise evidence and magnitude, high study limitations).³¹

Viswanathan found low strength of evidence for the effect of MTM on medication appropriateness (indirect, precise evidence from one small RCT).³¹

Viswanathan also included a very large, retrospective cohort study of Medicare Part D MTM programs operating in 2010 which focused on beneficiaries with congestive heart failure, chronic obstructive pulmonary disease, and diabetes. The authors reported that, despite improvement in medications among patients with congestive heart failure or diabetes, these improvements did not consistently translate to fewer condition-specific hospitalizations and emergency department visits.³²

Viswanathan found insufficient evidence to draw conclusions about the effect of MTM on gastrointestinal bleeding (direct but imprecise findings from one observational study with high study limitations) and cognitive and physical function (direct but imprecise findings from one RCT, inconsistent and imprecise findings from two RCTs, both with medium study limitations).³¹

Viswanathan found MTM did not improve most measures of health-related quality of life (low strength of evidence for no benefit). The various patient satisfaction items also showed no impact from MTM programs (low strength of evidence for no benefit). Additionally, the authors found no evidence on activities of daily living, work or school absenteeism, and patient and caregiver participation in medical care and decision making.³¹

Chisholm-Burns conducted an older, larger systematic review and meta-analysis of 298 studies. All studies cited evidence of pharmacist involvement in direct patient care, used a comparison group, and reported patient-related outcomes (outcomes must be therapeutic, safety, or humanistic). The interventions included chronic disease management and prospective and retrospective drug utilization review.

The Chisholm-Burns meta-analysis/systematic review found that 51.4% (18 of 35) studies included in the review reported that pharmacist interventions were associated with a decrease in hospitalizations or readmissions, and 52% (13 of 25) reported a decrease in emergency department visits.³⁰

Chisholm-Burns found improvement in multiple diseases and conditions in clinical outcomes for patients in the

³² Perloth D, Marrufo G, Montesinos A, et al. *Medication Therapy Management in Chronically Ill Populations: Final Report*. Baltimore, MD: Center for Medicare & Medicaid Innovation, Centers for Medicare & Medicaid Services; 2013.

pharmacist intervention groups compared to usual care. This study showed a significant increase from baseline in the percentage of patients at goal in the intervention group for hemoglobin A1c, low-density lipoprotein (LDL) cholesterol, blood pressure compared to usual care.³⁰

Chisholm-Burns found decreased mortality rates for pharmacist interventions compared to usual care. In 72.2% of the 18 studies, pharmacist intervention groups showed significantly decreased mortality rates compared to usual care.³⁰

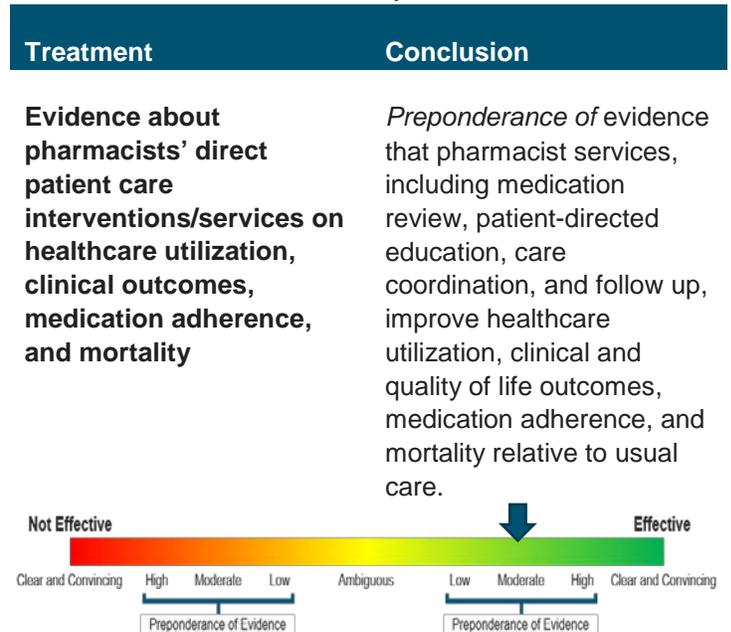
Chisholm-Burns found decreased adverse drug events for pharmacists' interventions compared to usual care. The odds ratio was 0.53 (95% CI: 0.33–0.83), which represents a significant reduction in the odds of adverse drug events in the pharmacist-provided care group versus the comparison group.³⁰

Chisholm-Burns showed better medication adherence for pharmacists interventions compared to usual care. Thirteen studies were included in this meta-analysis.³⁰

Due to the incongruity in the conclusions, it's important to note the differences between these two large studies. The Chisholm-Burns review included a total of 298 articles, comprising any studies that cited evidence of pharmacist involvement in direct patient care, including chronic disease management and prospective and retrospective drug utilization review. Chisholm-Burns did not omit any studies with a high risk of bias from their analyses. In contrast, Viswanathan included 44 studies and excluded many studies because of the variability in participants and outcomes. Viswanathan based their strength-of-evidence grades in this review on only studies with no more than medium risk of bias. Thus, it is impossible to make a direct comparison of findings between these two reviews.

Based on findings from these two systematic reviews, CHBRP concludes that there is a preponderance of evidence that pharmacist direct care services improve clinical and quality of life outcomes, medication adherence and reduce mortality, adverse drug events, and use of acute care services.

Figure 1. Pharmacists' Direct Patient Care Interventions/Services Summary



Source: California Health Benefits Review Program, 2016.

CHBRP concludes that there is a preponderance of evidence that pharmacist services, including medication review, patient-directed education, care coordination, and follow up; improve healthcare utilization, clinical and quality of life outcomes, medication adherence, and mortality relative to usual care. Many studies of direct pharmacist care concern more narrowly focused interventions than CMM so the findings may not generalize to CMM.

Benefit Coverage, Utilization, and Cost

Given the wide parameters and tremendous scale and complexity of the entire Medi-Cal population of qualifying beneficiaries, using CHBRP's traditional cost methodology approach was not feasible for this analysis. Instead, CHBRP focused on findings generated from a variety of programs and pilots, which varied in size and quality.

Although there is limited literature on the cost effectiveness of CMM programs, there is a growing body of peer-reviewed published and grey literature for

interventions collectively labeled MTM that report on cost outcomes.³³ The results of those MTM programs are the focus of our review. The programs identified were targeted to chronically ill adult populations in Medicare, Medicaid, or employer groups; the programs that focused on Medicare and Medicaid populations are most similar to what is proposed in this legislation.

The MTM interventions for which effects on cost have been studied vary in their: (1) target populations (any chronic disease, specific disease conditions such as diabetes or hypertension, number of prescribed medications); (2) patient selection and retention; (3) type of intervention (in person, telephone, other); and (4) measures of outcome. They consider outcomes specific to medication management, improved prescription drug adherence, changes in prescriptions, and reduction of potential adverse interactions. They also measure changes in health status and use of other medical services, including visits to the emergency room or hospitalizations).

According to the bill language, “Medi-Cal Managed Care plans would be permitted to establish criteria for frequency and duration of therapy, delineate specific billable procedures, and enforce prior authorization requirements as appropriate.” A California Department of Public Health Report on CMM Pilot Programs in Southern California noted “improvements in clinical, fiscal, and quality measures.”³⁴ The same report also noted challenges to implementing CMM pilots related to reimbursement mechanisms, alignment of financial incentives, robust electronic health information exchange, quality and outcomes tracking systems, patient and provider awareness, and adequate staffing.

³³ Goldfarb, N., et al. (2004) helps to identify which chronic conditions (asthma, diabetes, heart failure, and migraine) demonstrate successful benefits from MTM.

Truong, H. A., et al. (2015) showed that the highest ROI based on the time spent during billable face-to-face encounters ranged from 1:5 to 1:25 to 1. Selection of which chronic diseases to focus on is important to MTM success. Those chronic conditions (asthma, diabetes, heart failure, and migraine) that require multiple drug treatment will provide greatest ROI. Also, those patients with multiple comorbid conditions — a diabetes patient with congestive heart failure, a high blood pressure, and lipid disorder — would be the ones to focus on.

³⁴ Butler, et al., California Department of Public Health. *Comprehensive Medication Management Programs: Descriptions, Impacts, and Status in Southern California*, 2015. Sacramento, CA.

The studies reviewed used the return on investment, or ROI, to report their results. ROI measures the savings that are achieved by a program compared to the cost of administering the program. An ROI below 1.0:1.0 (which is ‘cost neutral’) means the program cost more than the health care savings that were achieved, in which case health care premiums would increase. An ROI above 1.0:1.0 indicates savings were achieved that exceeded the program’s costs, in which case health care premiums would decrease. CHBRP found the reported ROI can range from no effect (ROI = 1.0:1.0), to an ROI of 5.0:1.0, indicating savings are 5 times the program cost. Programs with the greatest savings were focused on specific conditions with strict participation criteria. Programs with lower levels of savings or no savings had broader participation criteria, and had higher costs for identifying program participants. Taken together, *CHBRP estimates a realistic ROI ranging from a slight loss to a potential gain, or 0.8:1.0 to 3.5:1.0, but notes this is an estimate and actual savings or costs could vary based on program design, program effectiveness, and other factors.*

Measurement of ROI for such programs is difficult because of challenges in isolating the effect of the MTM program from other drug utilization management or case management programs. A CMM program, which is generally more intensive than the MTM programs reviewed, will have higher administrative costs. Because it is more intensive, it may also show greater savings if the individuals who may participate are those with the most complex conditions. The ROI will be highly dependent on how broad the eligibility criteria are for participation, how individuals are identified as eligible, and whether the administering agency has the ability to both identify potential participants in real time and has the ability to communicate effectively with the medical providers and the individual.

Because of the variability in the design of programs, their target populations, sample size, and outcome measures, the current evidence is low to insufficient to conclude that MTM programs are consistently cost effective. Because the parameters of the proposed CMM are broad, it is not possible to estimate the likely ROI for the proposed CMM program contained in AB 2084. At the same time, there is growing consensus that such interventions, particularly in the context of medical home and team-based coordination of care, can be cost effective.

From the studies CHBRP analyzed, we were able to determine some key themes: When the interventions are

focused on individuals with specific conditions and have strict participation requirements, experience has shown a positive ROI in medication management interventions. In broader or more spread-out programs, the interventions generate lower or no ROI. To fully evaluate the potential ROI for a Medi-Cal–based CMM, it would be necessary to clearly define which individuals would participate in the program, how eligible enrollees would be identified, the ability of Medi-Cal to gain participation by pharmacists, and the ability to provide pharmacists with real-time access to enrollees' claims experience.

enhanced use and management of medications, which is the primary mechanism for treating chronic conditions/diseases.

Economic Costs

The California Department of Public Health estimated that in 2010, the economic impact of chronic diseases on Californians to be over \$98 billion, accounting for approximately 42% of the state's total health care expenditures.³⁵ This estimate was limited to six conditions: arthritis, asthma, cancer, depression, diabetes, and heart disease; heart disease accounted for nearly 40% of the costs. Although the magnitude of statewide economic costs are significantly greater than the costs incurred among Medi-Cal beneficiaries (which is the population impacted by AB 2084), given the size of the Medi-Cal population, the statewide statistics may serve as useful context.

Combinations of multiple chronic conditions are associated with different costs. One study examined national data on costs associated with arthritis, diabetes, heart disease, and hypertension.³⁶ Patients with all four conditions had the highest annual average health care expenditures (\$20,016). The lowest costs were associated with adults diagnosed with both diabetes and hypertension (\$7,117). For combinations with two or three conditions, higher costs were associated with the inclusion of heart disease.

This bill is intended to address the current treatment challenges and high costs of chronic disease through the

³⁵ *Economic Burden of Chronic Disease in California 2015*. www.cdph.ca.gov/programs/cdcb/Documents/CDPHEconomicBurdenCD2015California.pdf.

³⁶ Meraya AM, Raval AD, Sambamoorthi U. Chronic condition combinations and health care expenditures and out-of-pocket spending burden among adults: Medical Expenditure Panel Survey, 2009 and 2011. *Preventing Chronic Disease*. 2015;12:E12.

Table 1. Comparison of AB 2084-Defined Comprehensive Medication Management vs. Medicare Medication Therapy Management

	Comprehensive Medication Management, as Defined by AB 2084 and Based on the Patient-Centered Primary Care Collaborative	Medicare Medication Therapy Management
Included medications	<ul style="list-style-type: none"> • Prescription drugs • Biologics • Over-the-counter medications/ supplements 	<ul style="list-style-type: none"> • Any Part D medication • Any chronic or maintenance drug covered under Part D
Eligibility criteria	<ul style="list-style-type: none"> • Beneficiaries must meet ≥ 1 of the following criteria: <ul style="list-style-type: none"> ○ ≥ 3 prescription drugs/biologics to treat/prevent ≥ 1 chronic disease(s), or identified by treating prescriber as high-risk for Rx- related problems and has ≥ 1 chronic disease(s) ○ Discharged from a hospital/care facility setting with ≥ 1 chronic disease(s), with need to enhance care coordination efforts ○ Referred by treating prescriber as patient that could benefit from CMM ○ Other criteria consistent with CMM 	<ul style="list-style-type: none"> • Beneficiaries must meet all of the following criteria: <ul style="list-style-type: none"> ○ Have multiple chronic health conditions ○ Taking multiple different medications (min. threshold 2-8) ○ Using medications that cost $> \\$3,507$ for the year combined (patient costs and the plan's cost) ○ Actual requirements may vary depending on particular Medicare plan. For example, a plan may require a min. of 2 or 3 conditions, or a beneficiary must have at least one of a specific condition (typically hypertension, diabetes, congestive heart failure, and osteoporosis).³⁷
Program components	<ul style="list-style-type: none"> • Review patient health status, medication compliance, and experience • Document current clinical status and clinical goals of therapy • Assess medication appropriateness, effectiveness, safety, and adherence • Identify all medication therapy problems • Develop and implement written medication treatment plan • Provide verbal education and training, information, support services, and resources • Conduct follow-up evaluation & monitoring of the medication treatment plan 	<ul style="list-style-type: none"> • Perform annual comprehensive medication review, which may result in a medication action plan <ul style="list-style-type: none"> ○ Identify and prioritize medication-related problems ○ Develop plan to resolve medication-related problems • Perform a quarterly targeted medication review with follow-up interventions when needed <ul style="list-style-type: none"> ○ Monitor unresolved problems ○ Identify new drug therapy problems ○ Assess transitions in care

Source: California Health Benefits Review Program, 2016.

³⁷ Source: 2016 Plan MTM Program Eligibility. <https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/mtm.html>.

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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.