

Medi-Cal's Home and Community Based
Medication Dispensing Machine (MDM) Pilot Project

Decision Analysis Report – January 6, 2012



PHARMACY BENEFITS DIVISION
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Summary

Signed into law in late March 2011, California Senate Bill 72 (SB 72) requires the Department of Health Care Services (DHCS or Department) to establish a Home and Community Based Medication Dispensing Machine (MDM) Pilot Project.

The Pilot Project aims to assist Medi-Cal recipients that are at high risk of medication non-adherence with taking their prescribed medications through the use of an automated medication dispensing machine that includes remote monitoring and telephonic reporting services.

Improving medication administration adherence for Medi-Cal recipients is intended to avoid substantial costs of care incurred when recipients do not take their medications properly. The 2011 Budget Act assumed the Pilot Project will provide an annualized savings of \$140 million General Fund.

The bill requires the Department of Finance to evaluate savings to the General Fund as a result of the Pilot Project as a measure of the efficacy of this Pilot Project. In support of this savings evaluation, DHCS completed an evidenced-based literature review and an MDM product characterization review. This information was used to identify potential Medi-Cal participants, assess potential project cost savings, and suggest an evaluation design to evaluate project performance.

On analysis of this information, DHCS concluded that predicted savings and costs were too uncertain, indicating a significant likelihood of program losses rather than savings. DHCS also concluded that significant additional investigative investment would be required before the program prescribed by SB 72 could be considered for implementation.

To prepare for this analysis, DHCS focused on four key action areas:

1. Stakeholder Outreach & Analysis
2. MDM Product / Service Characterization
3. Independent Review & Analysis
4. Integrated Analysis

Each of these key action areas is summarized below and followed by a conclusion.

Stakeholder Outreach & Analysis

The following table illustrates the broad range of stakeholders that were engaged, examples of engagement actions, and the general purpose of engagement.

Stakeholder Organization	Engagement Actions	General Purpose
<p>General MDM Stakeholder Community Broad range of 200+ stakeholders including :</p> <ul style="list-style-type: none"> members of the Olmstead Advisory Committee, members of the Alzheimer's Disease and Related Disorders Advisory Committee, representatives from In-Home Support Services (IHSS), SEIU, Department of Finance, Department of Aging, Department of Social Services, several counties, and many other advocates. 	<ul style="list-style-type: none"> Established Public Web Site & Email Provided Monthly Progress Reports Provided All Stakeholder Conference Call / Q&A Session in August Presented at Olmstead Advisory Committee in August 	<ul style="list-style-type: none"> Listen and respond to concerns and considerations regarding MDM placement, use, cost, and impact. Provide performance reporting transparency and support open communication exchanges
<p>“Technical Stakeholders” Stakeholders with direct MDM and technology intervention experience including:</p> <ul style="list-style-type: none"> Center for Technology and Aging, AgeTech, Partners in Care Foundation, California Association for Health Services at Home, Home & Health Care Management Inc., and Center for Connected Health 	<ul style="list-style-type: none"> Initiation meeting In July Ongoing electronic discussion and subject matter expert review and input 	<ul style="list-style-type: none"> Listen and respond to experiences, recommendations, concerns and considerations regarding MDM placement, use, cost, and impact.
<p>MDM Vendor Community (8 vendors)</p>	<ul style="list-style-type: none"> Provided Regular Communications Engaged in detailed product characterization Established initial cost estimates 	<ul style="list-style-type: none"> Listen and respond to experiences and recommendations. Build product characterization information set directly with vendor community.
<p>Original MDM Forecast Authors</p>	<ul style="list-style-type: none"> Included detailed walkthrough of Calculation Engine 	<ul style="list-style-type: none"> Focused on understanding dimensions and mechanics of original cost (savings) model

MDM Product / Service Characterization

DHCS reviewed the MDM device landscape and identified products that met the requirements for MDMs that were described in SB 72. DHCS next gathered information about qualifying MDM products and related services to understand their features, capabilities, and intervention costs. To gather this information DHCS developed two tools:

- MDM Product/Service Characterization (PSC) Tool
- MDM Product/Service Cost Characterization (PSCC) Tool

The PSC Tool enabled the collection of detailed characterization data for each of the qualifying MDM products and their corresponding services. The PSC Tool resulted from DHCS research as well as external inputs provided by the vendor community and by stakeholders with experience and knowledge in this area of technology. All vendors completed their self-evaluation with the PSC Tool.

This information was intended to enable DHCS to evaluate device alignment with the requirements of the study design, the participant selection process, and a best value procurement of devices and related services. DHCS recognizes that selected participants may have a wide range of needs that would likely be met through a wide range of MDM products and services, rather than a single product and related services. The list of qualifying devices and vendors is provided below.

MDM Device**	Product/Service Vendor
1. Dispense-A-Pill (DAP) Personal Medication Manager; Models HOM-DAP-1& 3	HealthOneMed
2. Electronic Medication Management Assistant - EMMA®	In Range Systems
3. GlowCap®	Vitality, Inc.
4. MedSmart® Medication Management System Model 650	American Medical Alert Corp.
5. Philips Medication Dispensing Service Model PMD 100	Philips
6. TabSafe Comfortkeepers Model 102	Comfortkeepers
7. TabSafe CST MMS 502 - Model AMA23624/AMA23625	Critical Signal Technologies (CST)
8. MedReady CST MMS 501 -Model 1650 FL/FLLF	Critical Signal Technologies (CST)
9. MedReady MedReady 2070	Valued Relationships, VRI

** Some devices changed with PSCC Tool submissions

The PSCC Tool was focused on developing a full understanding of the intervention cost associated with each MDM product/service offering. Intervention cost is a key consideration when selecting participants and modeling potential savings. Vendors were asked to complete the PSCC Tool, which was focused on gathering “preliminary” cost information so that it could

be used to inform the participant selection process as well as broader decisions regarding next steps in the MDM Pilot Project.

The Independent Review and Analysis work described in the next subsection of this report utilized an average monthly intervention cost of \$50 for the lease/rental of an MDM device and required services/support. Although there was significant variability in the preliminary cost estimates provided through the PSCC Tool, that information indicated that \$50/month was a valid estimate of monthly intervention cost for the purposes of the Independent Review and Analysis work.

Independent Review & Analysis

The Department of Health Care Services engaged the California Medicaid Research Institute (CaMRI) to assist in the implementation of the MDM Pilot Project by performing an evidenced-based literature review and using that information to identify potential Medi-Cal participants, assess potential project cost savings, and suggest an evaluation design to evaluate project performance. CaMRI engaged the UC Davis Center for Healthcare Policy and Research (CHPR) as part of the “CaMRI Team” to perform this work and capture this information in a report to DHCS (See the Attachments section for the “CaMRI Report”).

The following is a summary of the CaMRI Report:

Purpose of the Report

1. To inform a decision to implement a Medication Dispensing Machine (MDM) Pilot Project - for Fee-For-Service (FFS) Medi-Cal beneficiaries who are at risk of preventable health care service utilization due to medication non-adherence
2. To recommend an appropriate Study Design - to evaluate (cost and clinical) effectiveness of MDMs

Key Assumptions

1. Dual eligibles comprise a large proportion of the potential target population
2. MDMs improve med adherence only if they address the reasons for non-adherence
 - A. *Reasons Addressed by MDM's* - Medication regimen complexity, forgetfulness, confusion, other cognitive deficits (FCDs)
 - B. *Reasons NOT Addressed by MDM's* - Affordability, side effects, discordant health beliefs

Key Questions and Answers Addressed by the Evidence-Based Literature Review

Q1: What is the prevalence of clinically significant non-adherence?

A1: Non-adherence is common: Patients take their meds as directed 30%-100% of the time.
 FCD-Related Non-adherence is common: Responsible for up to 40% of med non-adherence among the elderly

Q2: How often does non-adherence lead to high-cost health care events?

A2: Consequences of Non-adherence are mixed: Non-Adherence does not always lead to deterioration in health or excess health care utilization

- Non-adherence contributes to 3%-10% of Emergency Department (ED) visits... 1-5% due to FCD
- Non-adherence contributes to 4%-23% of Hospital Admissions... ~5% due to FCD
- Non-adherence contributes to unknown % of Nursing Facility (NF) Stays... Unknown% due to FCD

Q3: How effective are MDMs in overcoming non-adherence & preventing high-cost events?

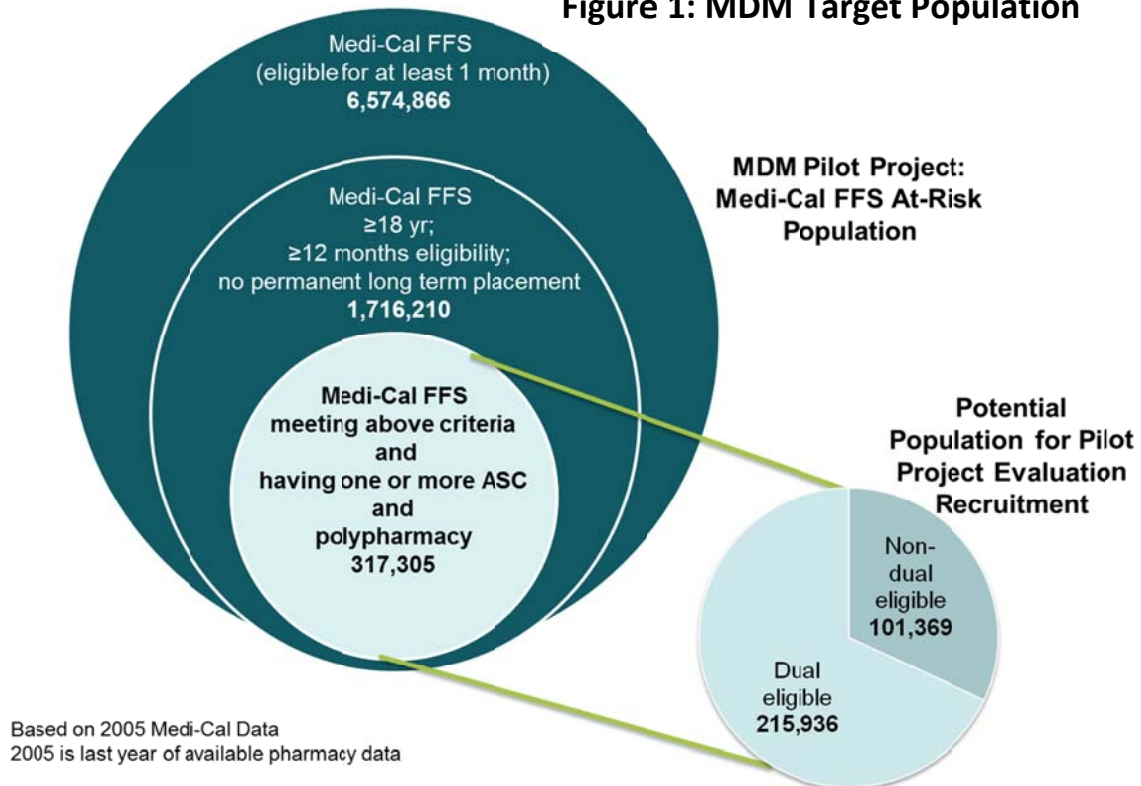
A3: The answer depends what is meant by "Effectiveness"

- Few studies published (small sample size, lack of health outcomes): claims as high as 98%
- No evidence that machines improve health outcomes or that service utilization decreases due to improved adherence
- Multi-faceted interventions yield moderate improvements in adherence but little evidence on outcomes

Target Population

1. Started by identifying people at high risk of Non-Adherence-Related Utilization
2. Looked at Validated Risk Factors (for Non-Adherence, High-Cost Events, or Both) including:
 - Regimen characteristics: complexity (# of drugs, # of doses), cost
 - Patient characteristics: age, socioeconomic status, health literacy, mental health (cognition, mood), clinical vulnerability (medical conditions, frailty)
 - System characteristics (e.g. unstable insurance)
3. Criteria Used for FFS Medi-Cal Beneficiaries in this analysis
 - ≥ 18 years
 - ≥12 months eligibility
 - No permanent Long Term Care (LTC) Aid codes
 - Polypharmacy... 5 or more prescription medications for chronic conditions
 - Adherence-sensitive conditions (ASC)
 - ✓ Angina, asthma, hypertension, CAD, CHF, COPD, diabetes, major depressive disorder, schizophrenia and bipolar disorder
 - Dual & Non-Dual Eligible sub-populations analyzed
 - Dual population size of 215,936; Non-Dual population size of 101,369; Combined population of 317,305

Figure 1: MDM Target Population



Cost Model Results

1. Savings included avoided Nursing Facility stays, Emergency Department Visits, and Hospital Admissions.
2. Data utilized was from 2005 since this was the last year that Medi-Cal had complete pharmacy data. Projected costs in 2011 dollars were calculated in the Summary Analysis section of this report.
3. Results indicated significantly lower than expected savings, largely due to a lower than expected reduction in service utilization and higher than expected population treatment costs.

Recommended Study Design

1. The report recommended a Randomized Control Trial study design to allow for sufficient power to estimate cost savings variables before programmatic implementation.

Integrated Analysis

This action area focused on cost analysis, using the analysis detail from the CaMRI Report as a basis for further calculations. The next two summary sheets below demonstrate different views of costs:

1. Figure 2: Summary of Potential Savings to the State General Fund – adjusted to 2011 dollars with no federal share savings included
2. Figure 3: Summary of Potential Savings to the State General Fund – adjusted to 2011 dollars with federal share savings included

The results in Figure 2 for all “scenarios” indicate significant potential losses in either subpopulation as well as the entire at-risk population.

Figure 2 Summary of Potential Savings (Losses) to SGF*
^^^ NO Federal Savings Share Included ^^^
2005 Corrected to 2011 dollars**

Based on the cost model for FFS adult beneficiaries who use the MDM
 Includes Avoided Service Costs for Nursing Facility Stays, ED Visits, Hospital Admits

Medi-Cal Population	Pessimistic Scenario	Base Case Scenario	Optimistic Scenario
Dual eligible (n=215,936)	(\$57.5 M)	(\$49.8 M)	(\$35.3 M)
Non-dual eligible (n=101,369)	(\$22.0 M)	(\$13.0 M)	(\$0.64 M)
Both (Duals + Non-Duals) (n = 317,305)	(\$79.4 M)	(\$62.9 M)	(\$36.0 M)

* Study Costs and Non-Machine Operational Costs are NOT included; Assumes we get an FMAP of 50/50

** Correction of 2005 to 2011 dollars used an annual growth rate of approximately 6%

Assumptions based on literature:

Pessimistic: 2-5% of service use attributable to FCD-NA... % Compliance Improvement w/ MDM: 80%

Base case: 5% of service use attributable to FCD-NA... % Compliance Improvement w/ MDM: 90%

Optimistic: 7.5-10% of service use attributable to FCD-NA... % Compliance Improvement w/ MDM: 98%

The results in Figure 3 also indicate significant potential losses in two of the base case estimates. Savings are only significant in the “optimistic” scenarios for Dual Eligibles. Optimistic scenarios are highly unlikely to occur. Figure 3 also indicates the wide range of uncertainty in cost forecasts, indicating a large variation in cost estimating variables.

Figure 3 Summary of Potential Savings (Losses) to SGF *

^^^Federal Savings Shares Included** ^^^

2005 Corrected to 2011 dollars***

Based on the cost model for FFS adult beneficiaries who use the MDM
Includes Avoided Service Costs for Nursing Facility Stays, ED Visits, Hospital Admits

Medi-Cal Population	Pessimistic Scenario	Base Case Scenario	Optimistic Scenario
Dual eligible (n=215,936)	(\$35.4 M)	\$7.9 M	\$60.5 M
Non-dual eligible (n=101,369)	(\$22.0 M)	(\$13.0 M)	(\$0.64 M)
Both (Duals + Non-Duals) (n = 317,305)	(\$57.4 M)	(\$5.2 M)	\$59.9 M

* Study Costs and Non-Machine Operational Costs are NOT included; Assumes we get an FMAP of 50/50

** Savings Harvested before Costs Assessed. Federal Share of 50% of Medicare savings was harvested

*** Correction of 2005 to 2011 dollars used an annual growth rate of approximately 6%

Assumptions based on literature:

Pessimistic: 2-5% of service use attributable to FCD-NA... % Compliance improvement w/ MDM: 80%

Base case: 5% of service use attributable to FCD-NA... % Compliance Improvement w/ MDM: 90%

Optimistic: 7.5-10% of service use attributable to FCD-NA... % Compliance Improvement w/ MDM: 98%

Figure 4

Comparing CaMRI/UCD to Original Analysis – NF Cost/Savings Only*

NO Federal Savings Shares Included

All Data Corrected to FY 2011 dollars

Cost Model		Pessimistic Scenario	Base Case Scenario	Optimistic Scenario
CaMRI/UCD	Before Costs	\$6.3 M	\$11.8 M	\$25.6 M
Both (Duals + Non-Duals)				
NF Only (n=317,305)	After Costs	(\$88.9 M)	(\$83.4 M)	(\$69.6 M)
Original Analysis	Before Costs	\$2.0 M	\$25 M	\$171 M
Both (Duals + Non-Duals)				
NF Only (n=27,503 presented to DHCS)	After Costs	(\$142 M)	\$16.9 M	\$163 M**

* Note: Nursing Facility (NF) Cost/ Savings are only used because the Original Model, built by Sellers Dorsey, only includes NF Cost/Savings and does not include ED Visit or Hospital Admission costs/savings included in CaMRI/UCD work. Study Costs and Non-Machine Operational Costs are NOT included; Assumes DHCS gets an FMAP of 50/50

** Note: Optimistic forecast presented to DHCS by Sellers Dorsey based on 2008 Data

Figure 4 presents a comparison of the CaMRI/UCD cost predictions versus the Original Analysis cost predictions. The Original Analysis Model was used as a foundation for the estimates that underlie the projected savings for the MDM Pilot Project, outlined in SB 72.

DHCS utilized the Original Analysis cost estimation tool, which allowed for several cost variables to be adjusted. These adjustments allowed DHCS to input values for these variables that

reflected the evidence-based information identified in the CaMRI Report. This allowed for a comparison of pessimistic, optimistic, and base case calculations between the two cost models (CaMRI/UCD Model versus Original Analysis Model). Since the Original Analysis Model only reflected Nursing Facility stay avoidance, the CaMRI/UCD model was constrained to Nursing Facility stay avoidance for this comparison.

The results in Figure 4 indicate that the savings forecast in SB 72 was built using “optimistic” estimation variables. Additionally, the following list summarizes the most significant reasons for the differences between these models:

1. Original Analysis Uses High Value (23%) for % of NF Stays due to Non-Adherence. CaMRI/UCD uses 5% as “Base Case” value.
2. Original Analysis Calculates Savings for all causes of Non-Adherence, which misses a Savings Population Adjustment by “% Non-Adherence Due To MDM Controllable Condition”.
3. Original Analysis Results are impacted significantly by “Case Assessment” variable... which impacts Population Number Needed to Treat (Pop NNT) Costs.
4. Original Analysis Pop NNT set to 4.0... Treat 4 to Prevent 1 Event
CaMRI/UCD Pop NNT estimated at ~ 400... Treat 400 to Prevent 1 Event.
5. CaMRI /UCD Base Tx Population 11X larger (costlier) than Original Analysis Tx Population.
6. CaMRI/UCD Service Event Population 12X smaller (less savings) than Original Analysis Event Population.

Conclusions

The following bullets summarize the conclusions for this report:

1. **Savings Are Highly Uncertain** - Variables predicting savings are highly uncertain (unmeasured) in Both Models. Even “Base” estimates are highly uncertain. For example...
 - Non-Adherence events due to MDM Controllable Condition
 - %NF Stays due to Non-Adherence
2. **Costs Are Highly Uncertain** - Variables predicting a Treatment Population are highly uncertain and unrefined which leads to very small costs in Original Analysis Model and very high costs in CaMRI/UCD Model. For example...
 - Treatment Population qualifiers
 - Case Management Success Factors
3. **“Study” Required Before Implementation** - Both Models suggest “Study” required to reduce savings and cost uncertainties as a minimum step before program deployment and performance measurement.



Attachments

1. “CaMRI Report” -- Medi-Cal MDM Pilot Project: Cost Savings Assessment and Proposed Evaluation Design