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
General MDM Stakeholder Community Broad range of 200+ stakeholders including : • 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.	• 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	• Listen and respond to concerns and considerations regarding MDM placement, use, cost, and impact. • Provide performance reporting transparency and support open communication exchanges
"Technical Stakeholders" Stakeholders with direct MDM and technology intervention experience including: • 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	• Initiation meeting In July • Ongoing electronic discussion and subject matter expert review and input	• Listen and respond to experiences, recommendations, concerns and considerations regarding MDM placement, use, cost, and impact.
MDM Vendor Community (8 vendors)	• Provided Regular Communications • Engaged in detailed product characterization • Established initial cost estimates	• Listen and respond to experiences and recommendations. • Build product characterization information set directly with vendor community.
Original MDM Forecast Authors	• Included detailed walkthrough of Calculation Engine	• 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 <u>only if they address the reasons</u> for non-adherence
   A. *Reasons Addressed by MDM's* **-** Medication regimen complexity, forgetfulness, confusion, other cognitive deficits (FCDs)
   B. *Reasons <u>NOT</u> 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?

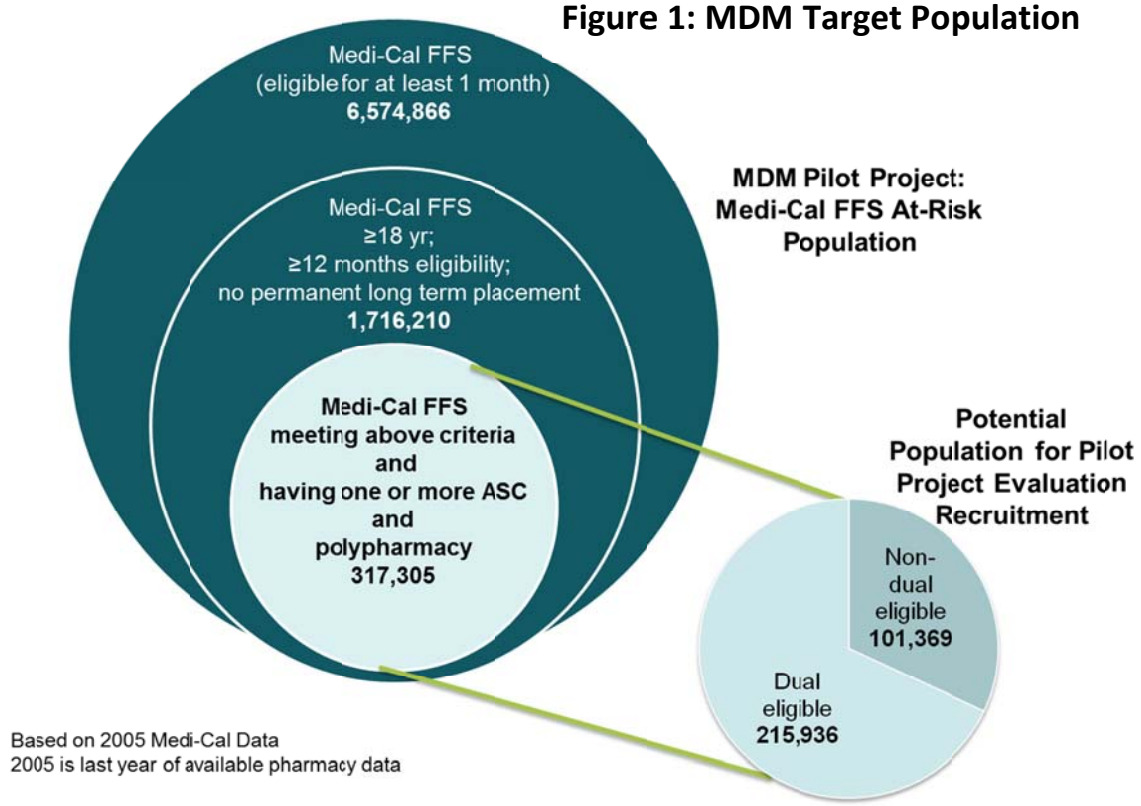
A3: The answer depends what is meant by "Effectiveness"

- 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 Both (Duals + Non-Duals) NF Only (n=317,305)	Before Costs	$6.3 M	$11.8 M	$25.6 M
	After Costs	($88.9 M)	($83.4 M)	($69.6 M)
Original Analysis Both (Duals + Non-Duals) NF Only (n=27,503 presented to DHCS)	Before Costs	$2.0 M	$25 M	$171 M
	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

Medi-Cal MDM Pilot Project: Cost Savings Assessment and Proposed Evaluation Design

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Executive Summary

The California Department of Health Care Services (DHCS) and the California Medicaid Research Institute (CaMRI) contracted with the UC Davis Center for Healthcare Policy and Research (CHPR) to assess the potential project cost savings and propose an evaluation design for the *Home and Community-Based Medication Dispensing Machine (MDM) Pilot Project* prior to DHCS implementing this complex and expensive project. Per SB 72, the MDM Pilot Project targets fee-for-service (FFS) Medi-Cal beneficiaries who are at risk of preventable adverse events due to medication non-adherence. The California state legislature projects approximately $140 million in annual net savings due to averted emergency department (ED) visits and hospital and nursing facility admissions caused by medication non-adherence.

Findings in this report are based on an evidence-based literature review and a cost model with sensitivity analyses to assess potential savings to help inform decisions about proceeding with project implementation. In addition, this report includes a proposed study design to evaluate the potential cost/savings and MDM effectiveness in the Medi-Cal FFS population.

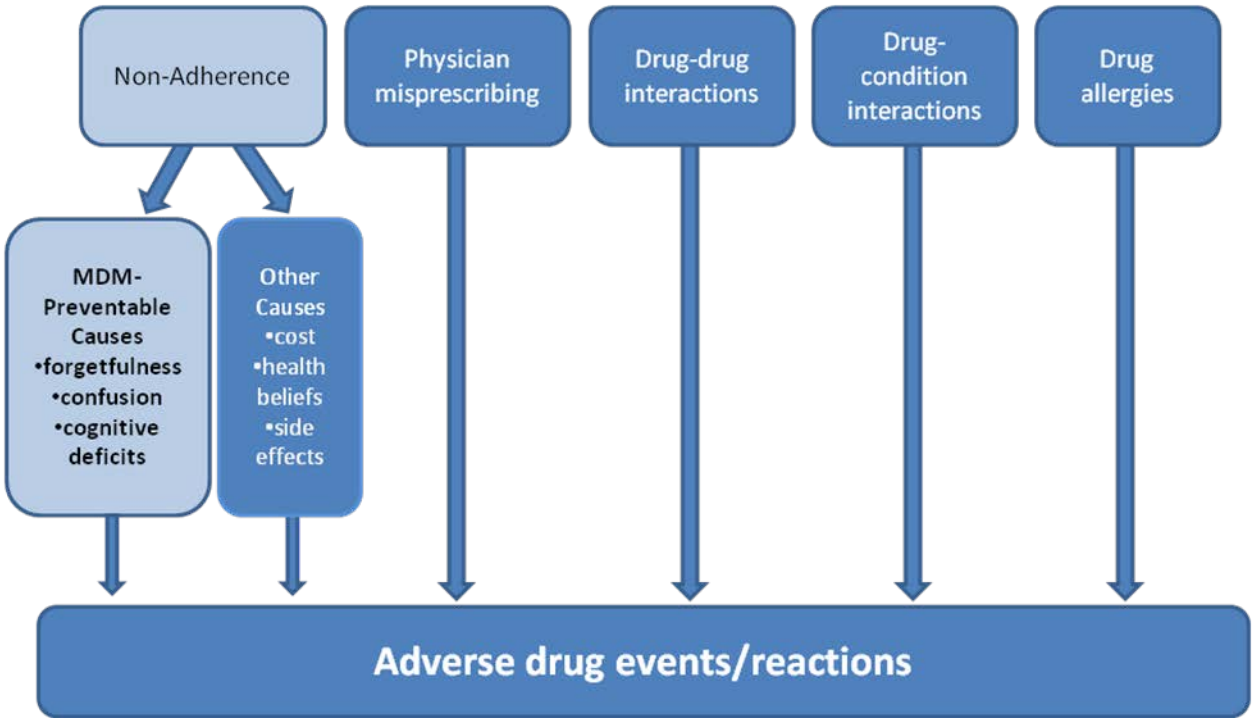
Understanding Causes of Medication Non-Adherence

Understanding the causes of medication non-adherence is critical to estimating the effectiveness of interventions designed to improve adherence—this understanding is important to properly identify the at-risk population that might benefit, as well as pairing the proper intervention with the barrier(s) it can influence.

Adverse drug events (ADEs) or adverse drug reactions (ADRs) may be caused by one of several factors resulting in either preventable (i.e., drug-drug interactions) or non-preventable (i.e., drug allergies) health care utilization. Medication non-adherence is one factor causing preventable adverse events (Figure ES-1). Contributors to non-adherence include characteristics of the patient, the medicine regimen, and the system of care. Patient factors include low health literacy, inadequate medication knowledge, personality factors such as conscientiousness, and distracters such as substance abuse. Regimen factors include cost, side effects, and complexity (including number of medicines, number of doses per day, and overall pill burden). System factors include poor prescriber communication and inadequate social support.

CHPR assumes that MDMs primarily will assist patients who are non-adherent due to forgetfulness, confusion or other cognitive deficits (FCD-NA).

Figure ES-1: Medication non-adherence is one of many factors contributing to adverse drug events and adverse drug reactions, which may result in additional health care service use. Many events are preventable.



Literature Review Summary

CHPR, with the assistance of a medical librarian, searched the literature for evidence of the effectiveness of medication dispensing machines (MDMs)—home-based machines that are programmed to dispense proper medications at proper times, thereby reminding patients to take medications and ensuring proper levels of adherence. CHPR made every attempt to include those studies with populations that resemble FFS Medi-Cal beneficiaries. The following findings inform the cost model and identify characteristics of the at-risk population most likely to benefit from such intervention.

- There is insufficient evidence in the peer-reviewed literature to assess the effectiveness of MDMs.
- CHPR found evidence that unspecified medication non-adherence contributes to about 5% of all ED visits (range=3% to 10% across different populations). Forgetfulness is one of many factors causing non-adherence leading to adverse drug events. A single study suggests that very few ED visits (<=1%) are caused by forgetting to take medications. These findings will inform certain cost model assumptions about medication non-adherence related to ED use.
- The most relevant study to the MDM pilot project suggested that just short of 5% of hospital admissions are due to non-adherence *related to forgetfulness or confusion.*
- CHPR could find no literature estimating the rate of nursing facility admissions related to medication non-adherence. (We found no evidence of an oft-cited statistic that 23% of nursing facility stays were due to (all-cause) non-adherence [Strandberg, 1984]). Therefore,

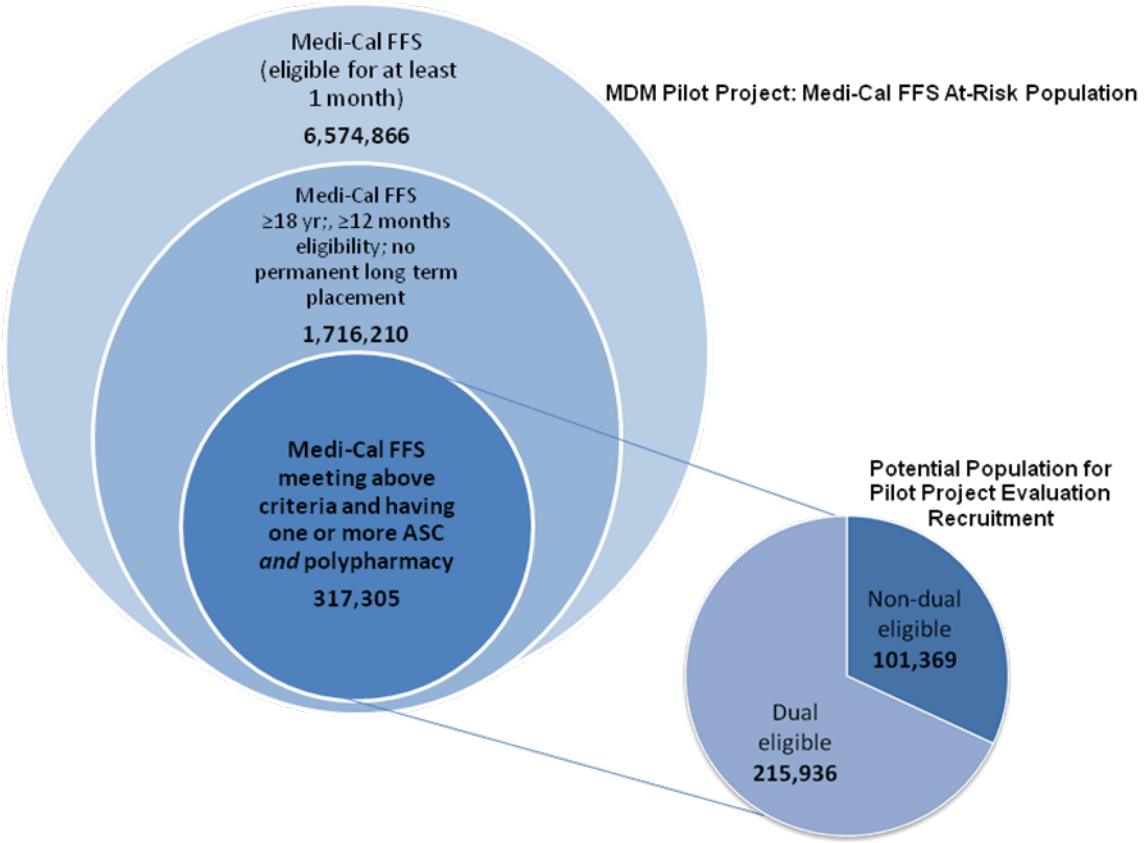
CHRP extrapolates from the evidence about ED and hospital admissions as we assume that the majority of medication non-adherent-nursing facility admissions would occur at the end of a series of contacts with the health care system (ED visit to hospitalization to nursing home admission).

Identifying the At-Risk Population

Understanding the size and characteristics of the potential populations that will benefit most from an MDM program will help target the distribution of machines, thus maximizing potential savings (and minimizing costs) to Medi-Cal (see Section I). Figure ES-2 illustrates the target population examined in the cost model. We applied the following criteria to 2005 Medi-Cal claims data (2005 is the last year for which Medi-Cal pharmacy data are readily available):

- fee-for-service (FFS) beneficiaries
- adults aged ≥18 years
- ≥12 months eligibility
- no permanent long term care aide codes
- diagnosed with ≥1 ASCs
- prescribed multiple medications (≥5 prescription medications taken concurrently for 90 days or more)

Figure ES-2. Criteria applied to Medi-Cal FFS at-risk population eligible for MDM pilot project to determine potential target population for evaluation (2005 DHCS claims data)



The last two criteria are based on the literature: ASCs include most of the diagnoses defined as ambulatory-sensitive by Bindman et al. (1995) plus serious mental health disorders: We include angina, asthma, hypertension, coronary heart disease, congestive heart failure, chronic obstructive pulmonary disorder, diabetes, major depressive disorder, schizophrenia and bipolar disorder. Polypharmacy of ≥5 medications is supported by the literature. Studies have shown that non-adherence increases as number of medications and dosing complexity increase (Field et al., 2007; Hajjar et al., 2007; Vik et al., 2004).

The potential population for the MDM intervention is 215,936 dual eligibles and 101,369 non-dual eligibles. Table ES-1 provides descriptive statistics about the utilization and cost of key health care services by the two subsets of the FFS Medi-Cal population.

Table ES-1. Medi-Cal utilization and cost* of key health care services for certain FFS Medi-Cal populations (2005)

Medi-Cal Populations of Interest	# of Eligibles	Nursing Facility Admissions	ALOS (days)	Average Cost/ Admission	Hospital Admissions	ALOS (days)	Average Cost/ Admission	ED Visits	Average Cost/Visit	Percent Discharged Hospital to LTC
Non-dual Eligibles with ASC-Polypharmacy	101,369	2,640	227	$30,868	47,999	5.4	$7,527	89,096	$1,219	11%
Dual Eligibles with ASC-Polypharmacy	215,936	12,060	200	$24,220	103,091	6.0	$1,556	88,772	$251	15%

*Cost is defined as reimbursements paid only by Medi-Cal (includes both state general fund and federal financial participation contributions)
Note: Differences in average cost/admission between the dual eligible and non-dual eligible populations are assumed to be attributable to Medicare reimbursements on behalf of the dual eligibles.
Note: About one-third of non-dual FFS Medi-Cal beneficiaries will be transitioning into Medi-Cal managed care in 2012, thus some reduction in the baseline population and their associated health care use can be assumed.

Should the MDM pilot project proceed, CHPR suggests targeting a portion of the dual eligible population in an evaluation study for several reasons.

- First, the dual eligible ASC-polypharmacy population represents two-thirds of the entire ASC-polypharmacy population and experience more than four times more nursing facility stays and two times more hospital admissions (the most costly of heath care services) than non-dual eligibles (Table ES-1).
- Second, a cross tabulation analysis of ASC and polypharmacy with the non-dual and dual population resulted in 27% of dual eligibles meeting both criteria compared with 11% of non-duals. We believe this indicates that a more highly-enriched population exists within the dual eligible population.
- Third, SB 72 directs DHCS to recover shared-savings from Medicare where possible. The costs represented in Table ES-1 are borne by Medi-Cal only, and although it initially appears that more hospital dollars may be recovered through the non-dual population, this table does not include the additional shared savings that may be available through Medicare. See Section II for details.
- Lastly, in the proposed evaluation design (Section III), we suggest using the State's existing alternative long term care programs as the primary infrastructure for patient recruitment. These programs generally target the elderly who are more likely to be a dual eligible. Once the evaluation is complete, study findings may be applied to the entire ASC/polypharmacy population to select the most highly-enriched population that will benefit from a fully implemented MDM program.

Cost Model Summary

The aim of cost modeling is to estimate potential net savings or costs to the government by implementing a Medication Dispensing Management (MDM) pilot project for a subset of the Medi-Cal population. We present a base case model, and "pessimistic" and "optimistic" analyses using the best available evidence. Such estimates are highly dependent upon the:

- definition (size) of the target population;
- proportion of hospitalizations and nursing home admissions that are attributable to specific types of non-adherence;
- effectiveness of MDM machines; and
- way in which costs (and savings) are split between Medi-Cal and Medicare.

Although these estimates are imprecise, CHPR believes it is highly unlikely that the MDM pilot project can achieve $140 million in net annual savings to the State of California. This is because, in any conceivable scenario, a large number of MDMs will be provided to patients who will not benefit because:

- they will not experience non-adherence due to forgetfulness, confusion or other cognitive deficits; or
- they will not incur a high cost inpatient stay; or
- or both

Essentially the high cost of administering the program (most notably, machine rental costs) outweighs the cost of averted episodes of care. **Table ES-2 summarizes potential savings/losses to the Medi-Cal and Medicare programs as estimated in the cost model's base case scenario and sensitivity analyses.** For more detail, please see Tables 2, 3 and 4 in this report.

Table ES-2. Summary of potential savings (losses) to the government (Medi-Cal and Medicare) based on the cost model for dually-eligible Medi-Cal FFS adult beneficiaries provided with MDMs (in $ millions)

Medi-Cal Population	ESTIMATED SAVINGS/LOSSES TO GOVERNMENT WITH MDMs					
	Base Case		Pessimistic Scenario		Optimistic Scenario	
	Medi-Cal	**Medicare**	Medi-Cal	Medicare	Medi-Cal	Medicare
Dual eligible (n=215,936)	**($43.4)**	**$17.6**	($54.3)	($33.3)	($22.7)	$72.1

Note: 2005 data are not adjusted for inflation

The savings (or losses) accrue to the entire Medi-Cal budget — both the State general fund (SGF) and the federal financial participation portions (FFP). Therefore, the Medi-Cal savings (or loss) to the SGF is 50% of the total presented in Tables ES-2, 2, 3, 4 and 5 (and Tables D-1, D-2, and D-3 in Appendix D).

Several factors contribute to these lower-than-expected-savings for both dual and non-dual populations. Even in the optimistic scenario, the *total number of averted episodes of care* attributable to MDMs is a small fraction of the *total number of episodes* incurred by this population (15,284/215,936=7%) This is due in part to the relatively low proportion of all episodes that can reasonably be ascribed to FCD-NA. Additionally, we modeled costs and savings in a population of 215,936 individuals (representing 12.6% of the original source population of 1,716,210 Medi-Cal adults). Applying the models to a smaller population would decrease program expenses but also limit potential savings.

In conclusion, all model scenarios for the dual and non-dual eligible populations result in a net loss to the Medi-Cal program, with the exception of the *non-dual* eligible optimistic scenario achieving an estimated savings of $12.1 million. In the dual eligible population, if federal shared savings are realized under the optimistic scenario, estimated losses could convert to savings. See Section II and Appendices C and D for further explanation.

The cost model findings are predicated on assumptions from fairly weak evidence about health care service utilization related to FCD-NA. Conducting a research study may help improve the quality of available evidence, but only if the study is of sufficient power and rigorous design. A primary objective of such a study would be to develop a more accurate means of predicting who is most likely to benefit from an MDM.

On a case-by-case basis, some cost savings are achievable, but the challenge is to prospectively identify, on a population basis, those at-risk individuals who will use health care services because of FCD-NA. To our knowledge, no prediction tool with these properties has been described.(See Section III for further discussion of validated risk prediction tools.)

Summary of Proposed MDM Study Design

The California Legislature has directed the Department of Health Care Services to implement a pilot MDM program. The **advantages** of performing a research study before full-scale deployment of MDMs are several. A properly designed study will:

1. create opportunities to better define the target population of beneficiaries most likely to benefit from MDMs.
2. provide a chance to develop and test protocols for MDM delivery and support and possibly to compare vendors in terms of reliability, customer satisfaction, and total costs.
3. allow policymakers to estimate with appropriate precision the health benefits (or harms) and financial gains (or losses) that would accrue should an MDM program be implemented at scale.

The primary **aim** of the randomized control trial (RCT) is to determine the effectiveness of MDMs in improving clinical outcomes and decreasing costs. The primary clinical outcome is a composite of death, hospitalization, or nursing home stays. The primary economic outcome is health care costs from the perspective of the government.

In Section III of this report, CHPR presents several design options and recommends a randomized experimental design with adequate sample size (in this case, 3,186 participants). RCTs can support strong inferences about causality permitting researchers and policymakers to know, within a pre-specified band of uncertainty, the economic costs (or savings) as well as the health benefits of the program. No other design option offers this level of rigor. Further, we recommend that randomization occur through an existing state program (i.e., Alternative Long Term Care Program) to facilitate recruitment.

The proposed study duration is 3 years, including 6 months for planning and preparation, 3 months for baseline surveys, 1 year of observation (and collection of baseline Medi-Cal and Medicare claims data), 3 months for follow-up surveys, 9 months for analysis (subject to Medi-Cal and Medicare claims data availability for the intervention period), and 3 months for report preparation and presentations to State officials. We estimate the cost of the research to be between $3 and $3.5 million.

INTRODUCTION

Pursuant to SB 72, the California Department of Health Care Services (DHCS) is charged with establishing the *Home and Community-Based Medication Dispensing Machine (MDM) Pilot Project*, which targets fee-for-service Medi-Cal beneficiaries who are at risk of preventable adverse events due to medication non-adherence. The California state legislature projects approximately $140 million in annual net savings due to averted emergency department (ED) visits and hospital and nursing facility admissions caused by medication non-adherence.

DHCS and the California Medicaid Research Institute (CaMRI) contracted with the UC Davis Center for Healthcare Policy and Research (CHPR) to assess potential project cost savings and propose an evaluation design for the project prior to DHCS implementing this complex and expensive project. CHPR uses a cost model and two-tailed sensitivity analyses to assess potential savings to help inform decisions about whether to proceed with project implementation. The assumptions and parameters in the model and the proposed evaluation design draw heavily on evidence gleaned from our literature review.

What is a medication dispensing machine (MDM)?

Common attributes of these programmable machines include in-home, automatic dispensing of medications up to multiple times per day with visual and auditory cues to remind patients. SB 72 requires pilot program machines maintain telephonic monitoring and reporting services. Machines will promptly alert caregivers of patient non-adherent behavior. Machines range in size between pill bottle caps to coffee maker size.

This report does not begin with a cost savings goal in mind, but rather relies on evidence-based literature and DHCS claims data to derive estimates of the costs or cost savings from an MDM pilot project. Section I of the report provides a review of evidence-based literature and Medi-Cal cost and utilization data; Section II employs a cost model to project pilot project costs, outcomes and potential savings. Should the pilot project proceed, Section III of the report provides criteria for targeting an at-risk population likely to benefit from MDMs and presents a discussion of study design options to evaluate the costs and benefits of implementing an MDM program.

Statutory Context for the MDM Pilot Project Assessment

Prescription medication non-adherence is one cause of preventable emergency department (ED) visits, and hospital and nursing facility admissions (Esposito et al., 2009; Doggrell, 2010; Schulz et al., 2011). SB 72, signed into law in Spring 2011, requires DHCS to establish a pilot project for use of medication dispensing machines by fee-for-service (FFS) Medi-Cal beneficiaries at risk of preventable adverse events and subsequent use of health care services caused by medication non-adherence (CWIC, 2011) (see Appendix A for statutory language).

SB 72 requires that DHCS, in conjunction with Department of Social Services, establish criteria to identify at-risk FFS Medi-Cal beneficiaries who have one or more specific characteristics,[1] and experience numerous ED visits or hospital or nursing facility admissions as a result of medication non-adherence. The legislation requires that the at-risk population be of a sufficient number to achieve the projected $140 million in annual net savings through improved medication adherence. Additionally, eligible Medi-

[1] Includes aged (seniors), persons with a disability, and multiple prescribed medications.

Cal beneficiaries must have telephone connectivity to facilitate the mandated telephonic monitoring and reporting service feature. SB 72 also requires that participation be voluntary.

Additionally, DHCS is directed to seek federal funding, through waivers or other methods, from the Centers for Medicare and Medicaid Services to cover the cost of this demonstration project, which may result in Medicare "shared savings" for those dual eligibles (beneficiaries who are dually eligible for Medicare and Medi-Cal) enrolled in the MDM pilot project.

DHCS also is required to submit to the California Department of Finance periodic reports on program implementation and evaluation of achieved savings. If the project fails to achieve projected savings, the Department of Finance may request modifications or alternative options to achieve the full $140 million in savings. Should full savings not be attainable despite modifications, the Department of Social Services shall reduce authorized hours for in-home supportive services (IHSS) recipients to achieve the full savings required.

I. Review of Evidence-Based Literature and FFS Medi-Cal Utilization and Cost Data

This section presents findings from an evidence-based literature review, and an analysis of health care service utilization and related costs for the FFS Medi-Cal population aged 18 years and older. This literature review serves as the foundation for the assumptions and parameters used to inform the cost model and sensitivity analysis in Section II of this report.

CHPR staff, with the assistance of a medical librarian, searched the literature for evidence to determine the effectiveness of MDMs in reducing preventable hospitalizations and nursing facility placements by improving medication adherence. The lack of evidence of MDM effectiveness in peer-reviewed literature required further review of the literature to answer alternative, but related questions to inform the cost model and identify characteristics of the at-risk population most likely to benefit from MDMs (see Appendix B for literature search methods and tables summarizing study findings). Specifically, CHPR reviewed evidence-based literature on baseline adherence rates, and adherence-related ED visits, hospitalizations, and nursing facility stays and made every attempt to include those studies with populations generalizable to the FFS Medi-Cal beneficiaries. Our literature search emphasized the inclusion of studies with populations that are elderly or diagnosed with chronic conditions. The sparse literature regarding MDM effectiveness and other medication management methods is summarized at the end of the literature review section.

In addition to the literature search, CHPR worked closely with a CaMRI data programmer to estimate the health care service utilization and associated costs of various FFS Medi-Cal populations using Medi-Cal claims data from 2005. The specific population of interest in this report is those persons who have at least one adherence-sensitive condition (ASC) and polypharmacy (5 or more prescription medications). [2] The most recent and comprehensive pharmacy claims data available to DHCS is from 2005. The

[2] CHPR defines adherence-sensitive conditions as those chronic conditions whose clinical outcomes are sensitive to proper medication management. We derived the idea from the related concept of "ambulatory sensitive conditions," which are conditions that benefit from high quality ambulatory care that averts preventable emergency visits or hospitalizations. This list of adherence-sensitive conditions includes most of the diagnoses defined as ambulatory-sensitive by Bindman et al. (1995) plus serious mental health disorders: Our list includes angina, asthma, hypertension, coronary heart disease, congestive heart failure, chronic obstructive pulmonary disorder, diabetes, major depressive disorder, schizophrenia and bipolar disorder. Polypharmacy is defined as 5 or more oral prescription medications taken concurrently for 90 days or more.

Medicare Modernization Act of 2003 shifted the prescription drug reimbursement responsibility to Medicare in 2006; thus DHCS no longer has direct access to pharmacy claims data for a large proportion of the Medi-Cal population (those who are dually eligible for both Medicare and Medi-Cal). No recent Medicare data were available for this report.

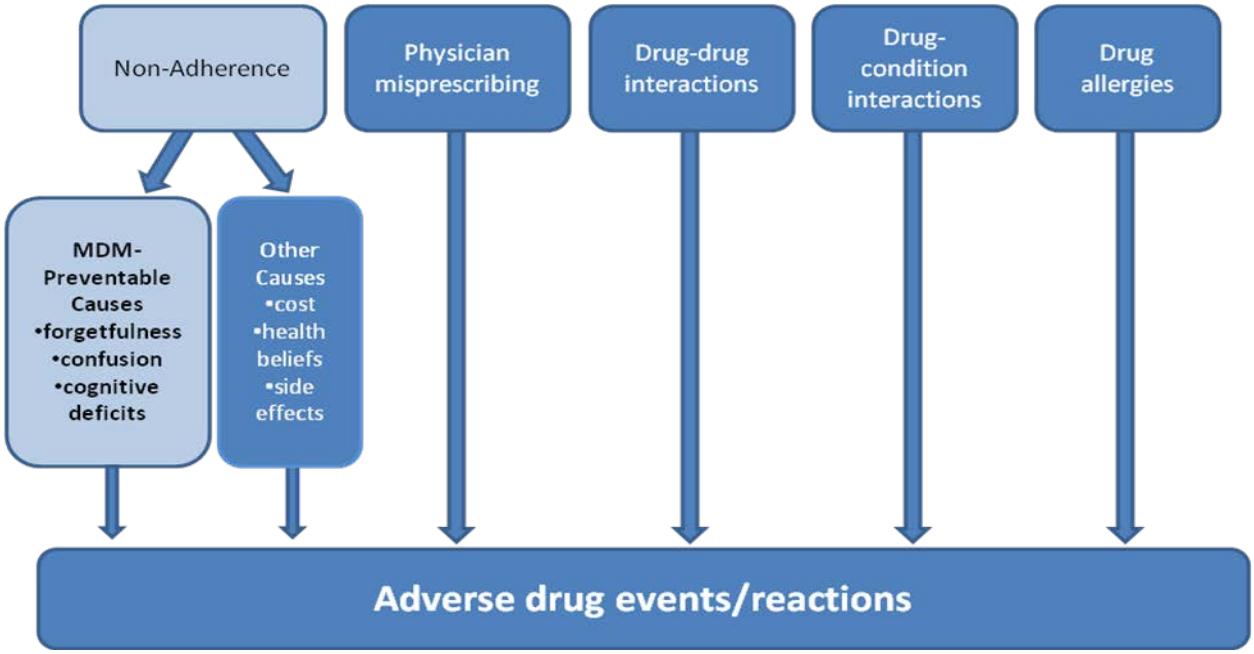
The 2005 data provide an estimate of the baseline costs and potential savings to the State, and the cost model in Section II provides an estimate of savings specifically attributable to an MDM program.

Ia. Evidence-based Literature

Baseline Adherence Rates

Adverse drug events (ADEs) or adverse drug reactions (ADRs) may be caused by one of several factors resulting in either preventable (i.e., drug-drug interactions) or non-preventable (i.e., drug allergies) health care utilization (Gurwitz, 2003). Medication non-adherence is one of these causal factors of preventable adverse events (Figure 1). Overall rates of medication adherence[3] range from 30% to more than 100%[4] (Doggrell, 2010; George et al., 2008; Vik et al., 2004; Osterberg and Blaschke, 2005) and are influenced by a variety of socio-medical constructs and patient characteristics. Barriers to medication adherence include low health literacy, inadequate medication knowledge, poor prescriber communication, and inadequate social support. From the patient perspective, cost, side effects, substance abuse, and polypharmacy (i.e., complexity of dosing regimen, pill burden) all contribute to non-adherence (Vlasnik, 2005). Non-adherence may also be characterized as intentional or unintentional (Nair et al., 2011).

Figure 2: Medication non-adherence is one of many factors contributing to ADEs/ADRs, which may result in additional health care service use. Many events are preventable.



[3] Adequate adherence is commonly defined as consumption of ≥80% of prescribed medications, which presumes enough medication consumed to produce desired therapeutic effect. This threshold appears to be arbitrary (Vik et al., 2004).
[4] Over-adherence=taking more than the prescribed dosage ("two is better than one"); refilling prescriptions early.

This report summarizes seven reviews and studies that are representative of the literature regarding rates of medication adherence and persistence (see Appendix B). Though the reviews are recent publications, most of the studies cited were published in the 1980s and 1990s. In their literature review, Gelland et al. (2011) noted that the lack of standardized medication adherence metrics make it difficult to draw conclusions about adherence barriers, rates and their consequences. Furthermore, "adherence can vary markedly by disease state: studies have shown adherence rates of 30-70% for asthmatic patients, 20-90% for schizophrenic patients, and 5-90% for hypertensive patients" (DiMatteo et al., 2011). Yeaw et al. (2009) found similar variation between six drug classes related to six chronic diseases and concluded that medication adherence and persistence was "variable, but uniformly suboptimal," ranging between 35-72% for 12-month adherence rates.

Measuring adherence rates is difficult and subject to various biases (Hughes, 2007). Patient surveys relying on self-reports of non-adherence may underestimate rates due to patient recall bias or social desirability bias (to avoid provider disapproval) (Col et al., 1990; George et al., 2008); however other research indicates that self-reports may be reasonably reliable (Vik et al., 2004). Methods that use refill and pharmacy claims data may either overestimate or underestimate adherence depending on completeness of records. Pill counts may overestimate non-adherence because of a patient's refilling prescriptions before the current supply is finished (Vik et al., 2004). According to Vik et al. (2004), there is consensus that those who report non-adherence are truly non-adherent and a portion of those reporting adherence may not be. It has been proposed that using more than one measure of adherence may capture the true adherence rates.

Additionally, clinical complications arising from non-adherence vary in severity and by condition. For example, missing several doses of hypertensive medications may not result in negative outcomes or added health care service use, but mismanagement (too much or too little) of insulin in type 1 diabetes, anti-infectives for AIDS and TB, or blood thinners (Warfarin) may result in severe complications and added health care costs.

Depending on the cause of non-adherence, effective interventions vary greatly and depend on the relevant barrier. CHPR staff assumes the primary individual patient barriers addressed by MDMs are forgetfulness, confusion, and mild cognitive deficits, but other barriers such as physical impairment (e.g., dexterity, impaired vision) or low health literacy also may be addressed by this technology. These barriers likely interact with the complexity of the medical regimen; a function of the *number* of prescribed medications the *number of doses per day* for each medication (Hajjar et al., 2007), and other factors such as food-dosing restrictions (George et al., 2008). MDMs are unlikely to remove barriers relating to cost, negative side effects, health beliefs (e.g., asymptomatic persons refusing medication) or number of dispensing pharmacies used.

Several studies considered the role of memory lapse or forgetfulness in medication non-adherence: a systematic review[5] reported that four of 75 studies of medication non-adherence in community-dwelling seniors considered forgetfulness as a barrier, and the median proportion of non-adherence that could be attributed to forgetfulness was 16% (range 10.6% to 58%) (Vik et al., 2004). These rates of non-adherence were lower than other reasons for non-adherence, such as adverse effects (47%-95%)

[5] Systematic reviews=systematic method to thoroughly review and synthesize all results of high quality research related to a single question. Adherence to review methods minimizes bias. Quantitative analysis, known as meta-analysis, may be included in systematic reviews and provide a statistical summary of the relevant research. Cochrane reviews are a highly respected source upon which much evidenced-based medicine is founded.

and specific health beliefs (particularly the belief that medication was not needed in the absence of symptoms, accounting for 15%-52% of non-adherence). Nair et al. (2011) administered a telephone survey to 8,692 non-adherent hypertensive patients (mean age 63 years) to determine which patient-identified barriers precluded proper medication adherence. The telephone survey response rate was 28.2% with 62% of respondents (Medicare and commercial) citing forgetfulness. However, the 62% figure may be biased upwards by survey non-response and social desirability bias. In contrast, in a review by Doggrell (2010) cost was cited as the most common cause of non-adherence (27.6%) and forgetfulness as the second most common barrier to adherence (21.3%). However, due to the passage of the federal Medicare Modernization Act in 2003, which covers the bulk of prescription drug costs for seniors, medication cost appears to be less of a barrier for the Medi-Cal FFS dual eligible population than earlier studies suggest (McWilliams et al., 2011).

It should be noted that better adherence does not always lead to improved health outcomes, particularly if the prescribed treatment is negligible or harmful (Vik et al., (2004). For example, recent research on tightly controlled glucose levels and blood pressure in certain diabetic populations revealed that morbidity and mortality increased (Choe et al., 2010; Bangalore et al 2011; Gerstein et al., 2011).

The results from a study by Col et al. (1990) are particularly germane to this report. The researchers interviewed 315 elderly patients consecutively admitted to an acute care hospital and determined that 11% of admissions were due to medication non-adherence and 17% were due to adverse drug reactions. Of the patients with admissions related to non-adherence, 25% self-reported forgetfulness, 15% reported confusion, and 35% reported side effects as reasons for non-adherence. Other reasons included cost (15%), “unnecessary meds” (10%) “more is better” (10%), inadequate instruction (10%), and “dislikes taking meds” (5%) (more than one response permitted).

Although counterintuitive, perfect adherence to prescribed treatment can be harmful if the treatment is inappropriate (i.e., the expected benefit of the treatment is low compared to potential harms). For example, the Action to Control Cardiovascular Risk in Diabetes [ACCORD] study found that “intensive glucose control increased mortality and did not prevent cardiovascular events in type 2 diabetes” (Gerstein et al., 2011). A meta-analysis of RCTs reported that tightly controlled blood pressure (<130 mm Hg) for Type 2 diabetics resulted in no benefit regarding the risk of other macrovascular or microvascular (cardiac, renal and retinal) events, and an increased risk of serious adverse events (Bangalore et al., 2011).

CHPR concurs with other researchers’ conclusions that variation in terminology and definitions, study designs, and inclusion criteria make it difficult to estimate specific rates of adherence or even interventions that are effective in improving adherence rates (George et al., 2008, Conn et al., 2009). Non-adherence is a complex problem often confounded by other factors. Thus, it is challenging to ascertain the extent to which a subset of contributing factors (forgetfulness, confusion and other cognitive deficits) contributes to medication non-adherence.

Conclusion: CHPR estimates that forgetfulness, confusion or other cognitive deficits may contribute up to 40% of medication non-adherence among the elderly (Osterberg, 2005; Alemagno et al., 2004). However, non-adherence does not always lead to deterioration in health or excess health care utilization. This point is addressed in the next section.

Evidence-based Literature on the Rates of Adherence-related ED Visits, Hospitalizations, and Nursing Facility Admissions

Proper adherence to medications is critical to alleviating symptoms and managing or curing disease. But, as noted earlier, effects of non-adherence on adverse events and health care costs vary depending on the disease, the treatment, and degree of non-adherence (Kravitz and Melnikow, 2004). This section seeks to answer ***to what extent does non-adherence contribute to preventable health care services utilization?*** CHPR found 21 studies (5 systematic reviews, 12 retrospective studies and 4 prospective studies) that considered effects of non-adherence or interventions to reduce non-adherence on emergency department (ED) visits, and hospital or nursing facility admissions. About half the studies were disease specific (i.e., diabetes, epilepsy, heart failure, etc.) and half were non-specific. CHPR found only one study that calculated rates of health care service utilization (ED visits in this case) associated specifically with non-adherence due to forgetfulness, confusion or other cognitive deficits.

Evidence-based Literature on Rates of Adherence-related ED Visits

CHPR found five studies measuring medication adherence and related emergency department (ED) visits. Faught et al. (2009) analyzed Medicaid claims data from 33,658 epilepsy patients (≥18 years) to determine adherence-related ED and hospital admission rates. They found non-adherence was associated with a statistically significantly higher incidence rate ratio[6] for ED visits of 1.19 (95% CI: 1.18-1.21) and additional ED costs of $303 per quarter. Roebuck et al. (2011) studied nine U.S. employers' integrated medical and pharmacy claims data related to four chronic vascular diseases and found that annual ED visits were "fractionally lower" for adherent patients than the non-adherent (0.01 to 0.04 visits per patient per year depending on disease state).

Another retrospective cohort study of Medicare and Medicaid pharmacy claims data estimated that adherent heart failure patients were 3% less likely to have an ED visit and 10% fewer visits per person than non-adherent patients (Esposito et al., 2009). A study of a large Canadian tertiary care hospital found 3% (n=34) of ED visits were classified as non-adherence related, although the percentage of non-adherence *due to forgetfulness* was not reported (Zed et al., 2008).

In the most relevant study to ED utilization, Malhotra et al. (2001) administered surveys to 578 elderly patients admitted to the ED in a tertiary care hospital in India. The researchers found that 7.6% (n=44) of the ED visits were related to non-adherence, and less than 1% (n=3) of all ED visits were attributable to forgetting to take medication.

[6] Incidence rate ratio= a relative measure of the rate of disorder in a group exposed to a certain factor compared to the rate of a disorder in a group that is unexposed to that factor.

Conclusion: CHPR found evidence that unspecified medication non-adherence contributes to about 5% of all ED visits (range 3% to 10% across different populations). Forgetfulness is one of many factors causing non-adherence leading to adverse drug events. A single study suggests that very few ED visits (≤1%) are caused by forgetting to take medications. These findings will inform certain cost model assumptions about medication non-adherence related to ED use.

Evidence-based Literature on Rates of Adherence-related Hospital Admissions

Winterstein et al. (2002) conducted a systematic review of 15 studies related to prevalence of preventable[7] drug-related hospital admissions (PDRAs). They found a median PDRA prevalence of 4.3% (interquartile range [IRQ] 3.1-9.5%). In a systematic review, Doggrell (2010) reported that cost was the leading factor associated with non-adherence and related hospital admissions. Forgetfulness was the second most common cause of non-adherence (21.3%). Thus, by extrapolation, CHPR estimates that less than 1% (.043 x .213 =.00916) of hospitalizations could be attributed to forgetting to take medications. Another study cited "inadequate instruction" as the most common reason for non-adherence leading to hospital admissions (25.4%). Sullivan et al. (1990) reviewed the literature and found that hospital admissions attributable to non-adherence ranged from 2.9% to 19.5%, with a weighted average of 5.3% (excluding psychiatric studies). The proportion of those non-adherent admissions due to forgetfulness or any other cause is unknown and the patient ages were unrestricted except for one study which enrolled patients aged 50 years or older. Only a fraction of these non-adherence-related admissions (perhaps up to 21%, relying on data from Doggrell) are potentially ascribable to forgetfulness.

Of the nine studies found regarding adherence-related hospital admissions, one retrospective claims analysis of 900 adult managed care enrollees with type 2 diabetes found that non-adherent patients were hospitalized more often than adherent (≥80%) patients (OR 2.53, 95% CI 1.34, 4.64). The rate of hospitalization for 100% adherent patients was 4.1% compared with 14.8% when adherence dropped below 40% (Lau and Nau, 2004). Another large retrospective review of pharmacy and medical claims data of employer-sponsored insurance beneficiaries compared the effects of adherence rates for patients with heart failure (CHF), hypertension, diabetes and dyslipidemia. Adherent patients had fewer inpatient hospital days (5.72, 2.1, 2.3, and 1.88, respectively) than the non-adherent and had reduced average annual medical expenditures (by $8,881, $4,337, $4413, and $1,860, respectively) (Roebuck et al., 2011). Esposito (2009) found that adherent, dual beneficiaries with CHF were less likely to have a hospital admission than non-adherent CHF patients (47.5% versus 47.9%, p<.01). Adherent patients also had 13% fewer hospital admissions and two fewer inpatient days than the non-adherent. Likewise, total medical costs were 15% less for the adherent population: $17,655 (≥95% adherence) compared with $25,324 (<80% adherence).

Faught et al. (2009) applied a retrospective cohort design to Medicaid claims data of 33,658 epilepsy patients (≥18 years) to determine adherence-related hospital admission rates and found non-adherence was associated with higher admission rates (IRR 1.86 (95% CI 1.84, 1.88) and inpatient days (IRR 1.39 (95% CI 1.37, 1.41). Hospital costs (as cost to Medicaid only) were an additional $4320/quarter (95% CI $4077 to $4564).

[7] Preventable ADE= An ADE due to a preventable medication error, or the failure of a planned action to be completed as intended (commission) or the use of a wrong plan/failure to act (omission) (Thomsen et al., 2007).

Two retrospective cohort studies found non-adherent adults experienced higher rates of admission than adherent adults. The first study showed that non-adherent adults with diabetes and coronary artery disease (CAD) experienced higher hospital admission rates than those who were adherent. Specifically, all-cause hospitalization for adherent diabetic patients was 19.2% compared with 23.2% ($p<0.001$) for non-adherent diabetic patients. Medication non-adherence increased the risk of hospitalization (OR 1.58, 95% CI 1.38, 1.81 $p<0.001$) (Ho et al., 2006). The hazard ratios (similar to relative risks) for cardiovascular-related hospital admissions were statistically significant at 1.10, 1.35, and 1.40 for non-adherence to beta-blockers, statins, and ACE inhibitors, respectively (Ho et al., 2008). The other study classified rates of medication adherence into 5 subsets: 0-20%, 21-40%, 41-60%, 61-80%, and greater than 80% adherence to detect associations with hospitalization risk and health care costs. Disease-related healthcare costs and hospitalization risk were generally inversely correlated with each of the levels of medication adherence for patients <65 years with diabetes, hypertension, hypercholesterolemia, and congestive heart failure. Hospitalization risks for adherent patients (≥80% adherence) versus non-adherent patients[8] were as follows: diabetes (13% for adherent vs. 24% for non-adherent), hypertension (19% vs. 23%), hypercholesterolemia (12% vs. 14%) and CHF (57% vs. 63%) (Sokol et al., 2005).

Hepke et al. (2004) measured the total costs (medical and pharmaceutical) for adult diabetic patients and found that the cost of ED visits and inpatient hospital admissions declined as medication adherence increased; however, total health care costs did not decrease due to a positive correlation between adherence and pharmaceutical costs.

In the study by Col et al. (1990) referenced previously, the authors analyzed 315 consecutive elderly hospital admissions and found that 11.4% (36) of admissions were due to non-adherence. The top reasons for non-adherence among those admitted were side effects (35%) forgetfulness (25%), and confusion (15%) (Col et al., 1990). Extrapolating from these results, up to 4.6% of admissions among the elderly (.11 x [.25+.15]) may be due to forgetfulness or confusion concerning medications (and thus potentially avertable by MDMs).

In a prospective, 12-week observational study of randomly selected ED patients in a Canadian tertiary care hospital, 36.9% of 122 adverse drug event (ADE) patients seen in the ED were admitted to the hospital for a median LOS of 8 days, or 2.5 days longer than the median stay for those ED visits not associated with an ADE. The probability of hospital admission was about two times greater for the ADE population than those with no drug-related ED visit (OR 2.18, 95% CI 1.46-3.27 $p<0.0001$) (Zed et al., 2008).

Conclusion: CHPR finds that the proportion of hospital admissions due to medication non-adherence or ADEs ranges from 4% to 20% depending on study design, definitions, and condition. Perhaps the most relevant study to the MDM pilot project (by Col et al.) suggested that just short of 5% of hospital admissions are due to non-adherence *related to forgetfulness or confusion.*

[8] Non-adherent composite calculated by CHPR as a single, weighted average of risks across 4 levels of "non-adherence: 0-20%, 21-40%, 41-60%, 61-79% and compared to Sokol's reported adherence rates of 80% or more.

Evidence-based Literature on Rates of Adherence-related Nursing Facility Admissions

The literature on adherence-related nursing facility admissions is sparse. A few journal articles cited an article from 1984 in which the author, Strandberg, reported that 23% of nursing facility admissions were attributable to patients' inability to self-administer medications (Strandberg, 1984). However, CHPR was unsuccessful in finding the original research that appears to have been produced by the Oregon Senior Services Division in 1981 (Smith, 1984). There are a number of studies that identify predictors of nursing home admissions; however, CHPR found no studies that directly estimate nursing facility admission rates due to medication non-adherence. The following five studies provide some context for understanding factors leading to nursing facility admissions.

A meta-analysis of studies on the effects of home visitation programs on functional status and preventing nursing home admissions found the effect on nursing home admissions depended on the number of visits during follow-up to a health care service. Based on 13 trials, the pooled relative risk for the upper tertile (>9 visits) was 0.66 (95% CI 0.48, 0.92) but 1.05 (95% CI 0.85, 1.30) for lowest tertile (0-4 visits). This translates to an estimated 34% reduction in the risk of admission for interventions with >9 visits (Stuck et al., 2002).

Another meta-analysis pooled various indicators from 77 reports (across 12 data sources) to determine significant predictors of nursing home admissions. Three or more activities of daily living (ADL) dependencies (OR=3.25, 95% CI 2.56, 4.09), cognitive impairment (OR=2.54, 95% CI 1.44, 4.51), and prior nursing home use (OR = 3.47, 95% CI 1.89, 6.37) were the strongest predictors of nursing home admission (Gaugler et al., 2007).

The authors of a study about the impact a comprehensive, pharmacist-driven medication management system had on nursing facility admission rates for 273 Medicaid beneficiaries (control group=800) found that six beneficiaries (2%) in the intervention group and 40 (5.0%) in the control group were admitted to a nursing facility during a 12-month period. Those in the control group were 2.94 times more likely to be admitted to the nursing facility than beneficiaries in the intervention group. The intervention consisted of a calendar card containing multiple blister packs dispensed by a pharmacy and a health care coordinator who communicated with pharmacists, physicians, clients, care givers and case managers to identify and address medication problems quickly (Schulz et al., 2011).

Ahmed et al. (2003) conducted a retrospective chart review of 983 Medicare patients hospitalized for heart failure. Eighty-three (8%) patients were admitted to a nursing facility and more than 80% of those had a prior nursing facility visit. They found 908 patients with no prior nursing home admission and 15 (2%) patients were newly admitted to the nursing facility upon hospital discharge. For those newly admitted, in addition to age and LOS, diabetes (OR 6.46, 95% CI 1.58, 26.41) was independently associated with a new admission.

Finally, one study considered the effect on nursing home admissions of two state Medicaid programs limiting drug coverage to 3 prescriptions per month. Although the study is not directly related to non-adherence, it provides a context for understanding the impact of consuming less medication than clinically recommended. In this case, the baseline admission rates were 2.3% and 2.1% prior to the cap on prescription medications. After policies imposing a prescription drug cap were in place, the nursing facility admission rates increased to 10.6% and 6.6%, respectively. With

the cap in place, 32% stayed 6 months or less while 57% stayed longer than 12 months (Soumerai et al., 1991).

Conclusion: CHPR could find no literature estimating the rate of nursing facility admissions related to medication non-adherence. Therefore, CHRP will extrapolate from the evidence about ED and hospital admissions as we assume that the majority of medication non-adherent-nursing facility admissions would occur at the end of a series of contacts with the health care system (ED visit to hospitalization to nursing home admission).

On balance, CHPR believes that up to 5% of hospitalizations, emergency department visits, and nursing home stays may be attributable to non-adherence due to forgetfulness, confusion, or cognitive deficits. This places an upper bound on the prevalence of preventable utilization. The specific subset of patients who are non-adherent due to forgetfulness, confusion, or other cognitive deficits—the primary population helped by MDMs— represents only a fraction of the population sampled in the reviewed studies.

Evidence of Effectiveness of MDMs and Other Medication Management Interventions on Improving Medication Adherence

Evidence of Effectiveness of MDMs

There is insufficient evidence available to determine the effectiveness of the MDMs on health outcomes or the intermediate outcomes of medication adherence. After an extensive literature search (see Appendix B), CHPR found four published articles and three on-going studies addressing this key question of machine efficacy.[9] One additional study listed through clincialtrials.gov regarding the MD.2 machine does not appear to be active. CHPR attempted to investigate the study's progress, but received no response from the Principal Investigator (Farris, 2006).

The most robust and generalizable study, a randomized control trial (RCT), assigned 500 elderly patients into three arms: a) Medplanner (i.e., a pill box organizer) + nurse coordinator; b) MD.2 (a brand of MDMs) + nurse coordinator; and c) usual care. No study results or data are currently available for review, although the researcher expects to publish clinical outcome results in Fall 2011 and follow with Medicare claims data analysis in 2012 (due to data lag time). The researcher[10] reports that both the MD.2 and the Medplanner groups had significantly better clinical outcomes (GDS, SF36, MMSE, PPT[11]) when compared to the control group at 12 months. However, there were no significant differences between the MD.2 group and the planner group in the clinical outcomes. The researcher concludes that the nurse care coordinator was the factor making the difference. (*Note*: Each machine type may differ in its rates of effectiveness, and this study may not be generalizable to other MDM products.)

[9] Efficacy refers to how well an intervention works in a controlled research setting; effectiveness refers to how well the intervention works in the general population, which is subject to greater variation and accounts for other outcomes such as side effects, user error, etc.

[10] Personal communication. Karen Marek, PhD, Arizona State University, College of Nursing & Allied Health Innovation, July, 2011.

[11] GDS= Geriatric Depression Scale; SF 36=Short Form 36 health survey; MMSE=Mini Mental State Examination; PPT=Physical Performance Test

Another study, which randomized 61 elderly patients in an independent living facility (mean age=87 years) into three arms, reported improvements in adherence for the machine group, but no statistically significant improvements in health outcomes (reduced hospitalizations) as compared with those receiving pre-poured pill boxes and a control group of patients dispensing their own medications. Family (42.5%), staff (22.5%), self (20%), agency nurses (12.5%) and physicians (2.5%) referred patients to the management program under study. Study participants were capable of following simple directions, had a "medication mismanagement episode," and a hospitalization related to medication non-adherence or an illness in which proper management necessitated medication accuracy (Winland-Brown and Valiente, 2000).

Sather et al. (2007) conducted a small case series study that found after three months, the MD.2 machine improved adherence for all three patients (99.2-100%) from their baseline of 4-5 doses missed/week. Eight of the eleven episodes of non-adherence over the 3 months were attributed to caregiver error or a patient hospital admission. No health outcomes were measured.

Additionally, two articles summarized outcomes from a total of four different studies (Buckwalter et al., 2004; Naditz, 2008). Samples sizes for the studies were n=12, n=89 and two were unreported. Insufficient data were available in both articles to assess the study quality and statistical significance of findings.

Searches of two government sponsored websites (clinicaltrials.gov and controlled-trials.com) yielded three current clinical trials of the effectiveness of MDMs (specifically the EMMA machine and Vitality GlowCaps). Two studies focus on the EMMA machine, which permits health care providers to remotely program and dispense medication. One study, set in the United Kingdom with 156 patients and 156 caregivers, seeks to measure medication adherence using the Morisky Scale and/or Medication Adherence Rating Scale at baseline and at 4-month follow up. Secondary outcomes include health and mental health assessments, patient satisfaction, health service utilization, health care costs, and medication administration errors. The second EMMA study has a $1 million budget to train and study stages of acceptance of machine use by 165 veterans with traumatic brain injury who are in a VA hospital setting or at home. The machine is referred to as the Telepharmacy Robotic Medicine Delivery Unit. Studies end in 2011 and 2012, respectively (Bond, 2011; Touchette and Winters 2010).

The third clinical trial measures medication adherence rates associated with the use of Vitality GlowCaps (electronic pill bottle cap). Secondary measures include assessment of product usability and satisfaction. The product reminds patients to take their medication, uses an embedded wireless radio to monitor adherence and responds to missed doses with automated phones calls to patients. It also sends adherence progress reports to patients, and their designated physicians and care givers. The study randomized 139 hypertensive patients who take less than three anti-hypertensive medications (or less than five medications) into three arms: a) de-activated GlowCap, which provides passive data collection (control group); b) GlowCap, with active reminders to take medication and refill medication, weekly/monthly progress reports to physician and social support provider, and additional support from call center (intervention group); c) GlowCap, with the same functions as Group 2, as well as receiving an additional financial incentive based on their six-month adherence in the study (intervention-plus group). Final data collection occurred in August 2010. No published study results are currently available (Watson, 2011).

Conclusion: Although there are several published studies, the effectiveness of the MDMs is unknown due imprecise estimates (small sample sizes) and lack of data on clinically meaningful health outcomes. Furthermore, there is insufficient information available to judge MDM effectiveness in specific subgroups (older age, multiple chronic conditions, or multiple medications). No completed studies show a detectable difference in health outcomes, and there is no evidence that utilization of health care services decreases due to improved adherence (an intermediate outcome measure). Additionally, findings from small, underpowered studies in narrow subpopulations are unreliable and may not generalize to a broader population of Californians. In short, there is insufficient peer-reviewed evidence to assess the effectiveness of MDMs, either alone or in combination with clinical support, on improving adherence, improving health outcomes, or reducing health care utilization and costs.

Evidence of Other Medication Management Interventions Improving Medication Adherence

During CHPR's search for evidence regarding MDM effectiveness, we found studies about other interventions used to improve medication adherence. These studies provide some context for the potential to improve adherence. We include six systematic reviews or meta-analyses that address adherence-improving interventions in community-based environments (Appendix B). These reviews represent the large body of literature regarding adherence improvement strategies, which are heterogeneous in their populations, complexity of intervention design, geography, and outcomes measured.

The reviews generally conclude that complex systems of care using multiple interventions (e.g., in-person and telephone counseling, self-monitoring, reminder cards, home visits, etc) by patients, care givers, and health care providers improve proximal and distal health outcomes more than single interventions (DiMatteo et al., 2011; Misono et al., 2010). Notably, the systems of care that use health care providers (i.e., nurses, pharmacists, physicians) appear to produce better outcomes than a single intervention (Haynes et al., 2008). One systematic review regarding allied health professionals' role in improving medication adherence found that counseling and medication reviews, in combination with patient education programs for the elderly, resulted in improvements in short-term adherence more than single interventions. The review also reported no studies comparing the effectiveness of different interventions, and little analysis about the cost benefits of different interventions to determine the most cost-effective interventions for the elderly (Doggrell, 2010).

The studies in the systematic reviews overlapped very little, which demonstrates the variety of interventions, study methods, and breadth of evidence available. The Cochrane systematic review by Haynes et al. (2008) reviewed 70 RCTs of interventions to improve adherence for long-term treatments. Thirty-six of 83 interventions were associated with improvements in adherence and 25 interventions showed improvements in at least one treatment outcome. All interventions demonstrating statistically significant improvements were complex in nature, and none of the interventions resulted in large improvements in adherence or outcomes. Similar to the studies of effectiveness of MDMs, most of these studies relied on small sample sizes. A World Health Organization (WHO) literature review of multiple systematic reviews and meta-analyses on rational use of medicines concluded that improving adherence to long term treatment requires multifaceted interventions, but still does not achieve a large improvement in outcomes or adherence (Holloway and van Dijk, 2011). George et al. (2008) reviewed eight controlled studies of community or hospital-

pharmacist interventions with community-dwelling elderly and found ambiguous results, with half the studies showing a mean improvement of 11.4% in adherence in intervention groups (-13% to +55%).

Conn et al. (2009) performed a meta-analysis of RCTs on interventions to improve adherence. Despite study heterogeneity, the interventions found to improve adherence the most were those using a stimulus (e.g., sound) to take the medication (as compared with those that did not provide stimulus) (effect size =1.06)[12] and those interventions with self-monitoring of medication effects as compared with interventions that did not require this activity (effect size=1.18). The authors concluded that research regarding adherence and health outcomes is unclear and warrants further study.

Conclusion: In summary, there is consistent evidence that coordinated, multifaceted interventions yield improved medication adherence rates, and that they are more effective than single-pronged interventions. The evidence also indicates that human involvement improves adherence. However, most interventions have been associated with modest improvements in adherence rates. The evidence on health-related outcomes is scant.

Ib. Analysis of FFS Medi-Cal Health Care Services Utilization and Cost Data

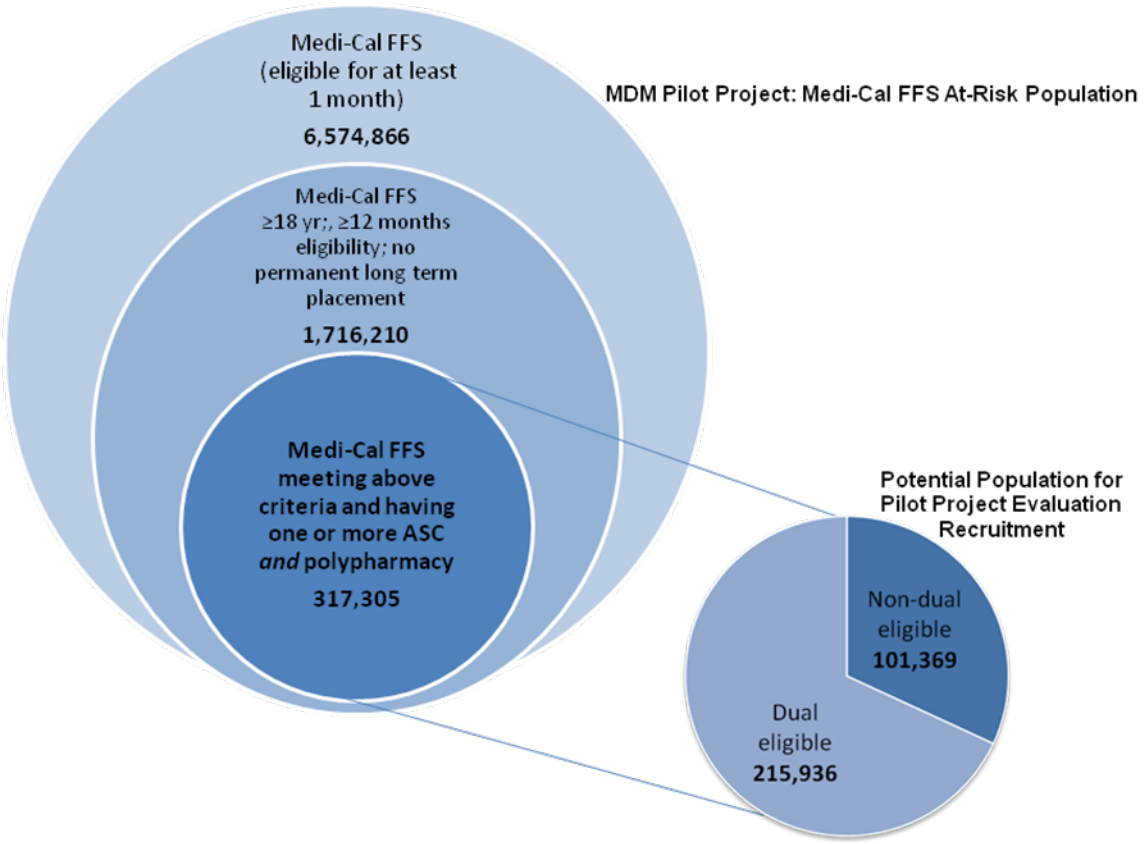
At-Risk Population Identification and Selection

Understanding the size and characteristics of the potential populations that will benefit most from an MDM program will help target the distribution of machines, thus maximizing potential savings (and minimizing costs) to Medi-Cal. Using 2005 Medi-Cal claims data (2005 is the last year for which Medi-Cal pharmacy data are readily available), Table 1 provides descriptive statistics about the utilization of key health care services and costs by two subsets of the FFS Medi-Cal population. These numbers were derived from the base number of 6,574,866 persons eligible for FFS Medi-Cal services for at least one month in CY 2005. We identified 317,305 individuals (19% of FFS Medi-Cal beneficiaries) who would most likely benefit from MDMs (see Appendix C for detailed methodology) using the following criteria:

- adults aged ≥18 years,
- ≥12 months Medi-Cal eligibility,
- no permanent long term care aide codes,
- have one or more adherence-sensitive conditions (ASCs include most of the diagnoses defined as ambulatory-sensitive by Bindman et al. [1995]) or serious mental health disorders (angina, asthma, hypertension, coronary heart disease, congestive heart failure, chronic obstructive pulmonary disorder, diabetes, major depressive disorder, schizophrenia and bipolar disorder),
- taking multiple medications (≥5 prescription medications taken concurrently for 90 days or more was the chosen cut-off based on evidence in the literature [Hajjar et al., 2007; Vik et al., 2004])

[12] In research parlance, "effect size" (specifically, Cohen's d) is defined as the absolute difference in outcomes between two groups, divided by the pooled standard deviation of the outcome. An effect size of 0.5 is considered moderate and an effect size of 0.8 to 1.0 or greater is considered large (Kazis et al., 1989).

Figure 2. Criteria applied to Medi-Cal FFS at-risk population eligible for MDM pilot project to determine potential target population for evaluation (2005 DHCS claims data)



Should the MDM pilot project proceed, CHPR staff suggests targeting a portion of the dual eligible population in an evaluation study for several reasons.

- First, the dual eligible ASC-polypharmacy population represents two-thirds of the entire ASC-polypharmacy population and experience more than four times more nursing home and two times more hospital admissions (the most costly of heath care services) than non-dual eligibles (Table 1).

- Second, a cross tabulation analysis of ASC and polypharmacy with the non-dual/dual populations resulted in 27% of dual eligibles meeting both criteria compared with 11% of non-duals. We believe this indicates that a more highly-enriched population exists within the dual eligible population.

- Third, SB 72 directs DHCS to recover shared-savings from Medicare where possible. The costs represented in Table 1 are borne by Medi-Cal only, and although it initially appears that more hospital dollars may be recovered through the non-dual population, this table does not include the additional shared savings that may be available through Medicare. The cost model in Section II will explain this assumption more fully.

- Lastly, in the proposed evaluation design (Section III), we suggest using the State's existing alternative long term care programs as the primary infrastructure for patient recruitment. These programs generally target the elderly who are more likely to be a dual eligible than not. Once the evaluation is complete, study findings may be applied to the entire ASC/polypharmacy population to select the most highly-enriched population that will benefit from a fully implemented MDM program.

Table 1. Utilization and cost* of key health care services for certain FFS Medi-Cal populations (2005)

Medi-Cal Populations of Interest	# of Eligibles	Nursing Facility Admissions	ALOS (days)	Average Cost/ Admission	Hospital Admissions	ALOS (days)	Average Cost/ Admission	ED Visits	Average Cost/Visit	Percent Discharged Hospital to LTC
Non-dual Eligibles with ASC-Polypharmacy	101,369	2,640	227	$30,868	47,999	5.4	$7,527	89,096	$1,219	11%
Dual Eligibles with ASC-Polypharmacy	215,936	12,060	200	$24,220	103,091	6.0	$1,556	88,772	$251	15%

*Cost is defined as reimbursements paid only by Medi-Cal (includes both state general fund and federal financial participation contributions)

Note: Differences in average cost/admission between the dual eligible and non-dual eligible populations are assumed to be attributable to Medicare reimbursements on behalf of the dual eligibles.

Note: About one-third of non-dual FFS Medi-Cal beneficiaries will be transitioning into Medi-Cal managed care in 2012, thus some reduction in the baseline population with ASC and polypharmacy and their associated health care use can be assumed. However, lack of timely access to pharmacy data from Medicare prevented an analysis of the most current relevant population. We would expect that the cost-savings ratio would be similar under this new managed care policy.

II. Cost Model

Purpose

The aim of this cost modeling exercise is to estimate potential net savings or costs to the government of implementing a Medication Dispensing Management (MDM) pilot project for a subset of the Medi-Cal population. As discussed in more detail below, such estimates are highly dependent upon the definition of the target population; the proportion of hospitalizations and nursing home admissions that are attributable to specific types of non-adherence; the effectiveness of MDM machines; and the way in which costs (and savings) are split between Medi-Cal and Medicare.

Approach

Our modeling approach begins by defining the target population. We assume that the population of interest includes fee-for-service Medi-Cal patients who are at high risk of adherence-related emergency department (ED) visits, hospitalizations, and nursing facility (NF) stays. Based on SB 72, we know that the objective is to provide MDM machines to patients who are likely to incur such adherence-sensitive events in the absence of an MDM machine, but not in its presence. Based on the literature on risk factors for non-adherence and for subsequent health care utilization, we identified two major risk factors for adherence-related utilization that are readily available from administrative data (currently, administrative data are the only source of health information available for this project).

"…our general modeling approach was to estimate the number of episodes of care that could theoretically be averted by MDM systems, then multiply by the presumed effectiveness of the machines and by the cost to the State and to the Federal government of each averted episode."

The first risk factor is the presence of one or more adherence-sensitive conditions (ASCs). ASCs are conditions for which highly effective medicines are available – medicines which, when taken as instructed, can avert ED use, hospitalizations, and nursing home admissions. The second risk factor is the use of five or more routine, oral medications dispensed concurrently for a minimum of 90 consecutive days, a level of polypharmacy that not only increases the risk of non-adherence but also serves as a proxy for complex disease (Hajjar et al., 2007; Vik et al., 2004). Complex disease is in itself a risk factor for ED visits, hospitalizations, and NF stays. Because of the heterogeneity of the adult Medi-Cal population, we do not include age *per se* as a risk factor, despite information suggesting that age is a major risk factor for both non-adherence and health care utilization.

From 2005 data, we identified 215,936 fee-for-service dual eligible Medi-Cal patients aged 18 years and older who were continuously enrolled for 12 months, and had one or more ASCs and ≥5 medications. (See in Section III, *Identifying Suitable Target Population*). We used 2005 data because this is the last year for which pharmacy data could be made available to DHCS in a timely fashion (more recent data are available through the Medicare Part D program but could not be accessed within the timeframe available for this project). These 215,936 beneficiaries experienced a total of 12,060 NF stays, 103,091 hospitalizations, and 88,772 ED visits during the year. This population is the focus of our analysis here in

the main text, but we also constructed models relevant to the experience of the *non-dual* FFS Medi-Cal beneficiaries who met the same qualifying criteria. We present results from that exercise in Appendix D.

For both populations, our general modeling approach was to estimate the number of episodes of care that could theoretically be averted by MDM systems, then multiply by the presumed effectiveness of the machines and by the cost to the State and to the Federal government of each averted episode. We then performed two sensitivity analyses: an "optimistic" analysis making generous assumptions about avertable episodes and machine effectiveness, and a more "pessimistic" analysis based on more conservative assumptions (see Appendix C: Cost Model Approach and Assumptions for details).

Results

The following cost model (Table 2) and two-way sensitivity analyses (Tables 3 and 4) focus on the target population and provide a window into likely MDM pilot project cost savings (or losses) from the perspective of Medi-Cal and Medicare. Actual savings or losses from a pilot project would depend on the number of Medi-Cal beneficiaries enrolled and their actual risk for adherence-sensitive utilization of high-cost care (particularly hospitalizations and nursing facility stays). The model assumptions about health care utilization (related to medication non-adherence) are based on the best available evidence. Although these estimates are imprecise, CHPR believes it is highly unlikely that the MDM pilot project can achieve $140 million in net annual savings to the State of California. This is because, in any conceivable scenario, a large number of MDMs will be provided to patients who will not benefit (either because they will not experience non-adherence due to FCD, because they will not incur a high cost inpatient stay, or both).[13] **None of the scenarios include the DHCS cost of administering the MDM pilot project (other than device rental costs).**

Table 2 presents the base case model, or the most realistic estimate of potential savings achievable. These estimates rest on two key assumptions: 1) the percentage of nursing facility stays, hospital stays, and emergency department visits due to FCD-NA; and 2) machine effectiveness. We attribute 5% of stays and ED visits to FCD-NA based upon the Col study, which is the only study we found that measures admissions due to non-adherence from forgetfulness and confusion (Col et al., 1990). We use 90% as an estimate of machine effectiveness based on studies of other medication management interventions, in the absence of published RCTs on MDMs. While limited observational evidence suggests that MDMs may prevent up to 98% of missed doses under ideal circumstances, 90% is a more realistic estimate of effectiveness in the real world, accounting for machine malfunctions, human errors, etc. and reflects the upper end of successful medication management interventions presented in the literature. The disparity in savings (or losses) between Medicare and Medi-Cal is attributed to the dominance of hospital costs in the total cost of all services used by the target population. Medicare is the primary payor of hospital costs for this population; therefore, more savings are realized by Medicare. *The net loss to Medi-Cal is estimated to be $43.4 million while Medicare is estimated to save about $17 million.*

Table 3 provides a "pessimistic" scenario in which assumptions about the fraction of health care service utilization associated with FCD-NA come from the lower end of the literature-based evidence (3% nursing facility admissions, 2% hospital admissions and 5% ED visits). Device performance is reduced to 80% effectiveness, meaning that in actual use, MDMs ensure adequate adherence 80% of the time.

[13] Preventive services researchers will not be surprised by this conclusion. In preventive services research, the cost-effectiveness of an intervention depends not only on how well the intervention works (effectiveness) but on who is targeted to receive the intervention.

Under this scenario, we estimate that *total loss to government payors would be approximately $87.6 million with Medi-Cal shouldering about $5.3 million of the loss.*

Table 4 presents an "optimistic" scenario that increases the literature-supported assumptions for hospital and ED use by 50% (i.e. from 5% to 7.5%). This model also assumes (generously) that 10% of nursing facility stays are FCD-NA. Additionally, Table 4 assumes almost perfect device performance (98% effectiveness) based on manufacturer claims and some literature. In the aggregate, we believe these assumptions are unrealistic, but they do reflect assumptions used in other modeling and are included to demonstrate that, even under the most positive circumstances, large savings are difficult to achieve. As applied to 215,936 dual eligibles with ≥1 ASC and ≥5 medicines, this scenario produces an *estimated net loss of approximately $22.7 million to Medi-Cal (to be divided evenly between the State general fund [SGF] and federal financing participation [FFP] budget categories) and a savings of $72.1 million to Medicare*. Were California successful in obtaining a shared savings agreement with the federal government, some savings might be achieved by the State.

Essentially the model assumes that MDMs will avert a certain (small) percentage of total inpatient stays and ED visits. Multiplying the number of episodes averted times the average cost per episode gives an estimate of gross savings, which are offset by program expenses, most notably the machine rental costs.

Why are estimated savings well below the statutory goal of $140 million?
Several factors contribute to these lower-than-expected-savings for both dual and non-dual populations. Even in the most optimistic scenario, the *total number of averted episodes of care* attributable to MDMs is a small fraction of the *total number of episodes* incurred by this population (15,284/215,936=7%). This is due in part to the relatively low proportion of all episodes that can reasonably be ascribed to FCD-NA. Additionally, we modeled costs and savings in a population of 215,936 individuals (representing 12.6% of the original source population of 1,716,210 Medi-Cal adults). Applying the models to a smaller population would decrease program expenses. However this would require a more accurate risk prediction tool than is currently available.

TABLE 2. BASE CASE ANALYSIS[a]: DUAL ELIGIBLES					
Target Population: Dual Eligibles Age ≥ 18 with ASC and Polypharmacy[b] (n=215,936 based on 2005 data)					
	NF	**Hosp**	**ED**	**Total**	**Notes**
Episode Count	12,060	103,091	88,772		Number of nursing facility stays, hospital admissions, and ED visits among the target population (2005).
Proportion due to FCD-NA	0.05	0.05	0.05		Literature supports assumption that approximately 5% of hospital admissions and ED visits are due to FCD-related non-adherence (FCD-NA=forgetfulness, confusion, cognitive deficit due to non-adherence). We assume the same figure for nursing facility stays despite a paucity of data.
Number due to FCD-NA	603	5,155	4,439		Product of episode count times proportion due to FCD-NA .
Relative risk reduction attributable to MDM	0.90	0.90	0.90		Assumes that MDMs will prevent 90% of FCD-NA episodes. Theoretically, MDMs are capable of eliminating 100% of health services use due to FCD-NA (i.e., 5% of all admissions in base case). However, we must account for some machine-malfunctions, operator errors, etc. See Appendix C for details.
Episodes averted	543	4,639	3,995		Product of FCD-NA episodes times MDM-related relative risk reduction (90%).
Estimated Costs/Episode	**NF**	**Hosp**	**ED**	**Total**	
Medicare costs/episode	$7,880	$16,284	$651		We assume cost-sharing arrangements exist between Medicare and Medi-Cal for the dual eligible population. Calculations were derived from a combination of DHCS LOS data and grey literature regarding Medicare cost/day for each service type. See Appendix C for details
Medi-Cal costs/episode	$24,220	$1,556	$251		Based on DHCS 2005 claims data (cost and utilization) for the ASC + polypharmacy population and grey literature: See Appendix C for details.
Total costs/episode	$32,100	$17,840	$902		Estimated cost to the government (Medi-Cal + Medicare) of each episode type (nursing facility stay, hospital admission, ED visit). See Appendix C for details.
Estimated Gross Savings	**NF**	**Hosp**	**ED**	**Total**	
Estimated gross **Medicare** savings	$4,276,476	$75,543,023	$2,600,576	$82,420,075	Product of episodes averted times cost per episode to the Medicare program.
Estimated gross **Medi-Cal** savings	$13,144,194	$7,218,432	$1,002,680	$21,365,306	Product of episodes averted times cost per episode to the Medi-Cal program.
Estimated **Total** gross savings to government	$17,420,670	$82,761,455	$3,603,255	$103,785,380	Product of total episodes averted times total cost per episode (represents gross savings to Medi-Cal and Medicare combined).
Estimated MDM Expenses					
Assumed federal share of MDM expenses @ $300 per machine				$64,780,800	Total cost of MDM machine rental to federal government for the entire target population at $50/month.
Assumed Medi-Cal MDM expenses @ $300 per machine				$64,780,800	Total cost of MDM machine rental to Medi-Cal for the entire target population at $50/month.
Assumed **total** MDM expenses @ $600 per machine				$129,561,600	DHCS expects that the devices will be eligible for a 50/50 split between the state General Fund (GF) and Federal Financial Participation (FFP) based on their interpretation that the devices fall under current DME definitions for both Medicaid and Medicare, and that this program is likely to operate under a waiver.
Estimated Net Savings[c]					
Estimated net savings (loss) to **Medicare**				$17,639,275	Net savings (loss) to the federal government assuming MDMs are distributed to the entire target population
Estimated net savings (loss) to **Medi-Cal**				($43,415,494)	Net savings (loss) to the Medi-Cal budget assuming MDMs are distributed to the entire target population
Estimated net savings (loss) to Medi-Cal and Medicare combined				($25,776,220)	Total net savings (loss) to the government assuming MDMs are distributed to the entire target population

TABLE 3. SENSITIVITY ANALYSIS: PESSIMISTIC SCENARIO[a]: DUAL ELIGIBLES					
Target Population: Dual Eligibles Age ≥18 with ASC and Polypharmacy[b] (n=215,936 based on 2005 data)					
	NF	**Hosp**	**ED**	**Total**	**Notes**
Episode Count	12,060	103,091	88,772		Number of nursing facility stays, hospital admissions, and ED visits among the target population (2005).
Proportion due to FCD-NA	0.03	0.02	0.05		Takes low-end estimates from literature on hospital admissions and ED visits due to FCD-related non-adherence (FCD-NA=forgetfulness, confusion, cognitive deficit due to non-adherence).
Number due to FCD-NA	362	2,062	4,439		Product of episode count times proportion due to FCD-NA.
Relative risk reduction attributable to MDM	0.80	0.80	0.80		Assumes low end estimate for product performance (80%). Theoretically, MDMs are capable of eliminating 100% of health service use due to FCD-NA. However, we must account for machine-malfunctions, operator errors, user acceptance, adequate training, etc.) See Appendix C for details.
Episodes averted	289	1,649	3,551		Product of FCD-NA episodes times MDM-related relative risk reduction (80%).
Estimated Costs/Episode	**NF**	**Hosp**	**ED**	**Total**	
Medicare costs/episode	$7,880	$16,284	$651		We assume cost-sharing arrangements exist between Medicare and Medi-Cal for the dual eligible population. Calculations were derived from a combination of DHCS LOS data and grey literature regarding Medicare cost/day for each service type. See Appendix C for details.
Medi-Cal costs/episode	$24,220	$1,556	$251		Based on DHCS 2005 claims data (cost and utilization) for the ASC + polypharmacy population and grey literature: See Appendix C for details.
Total costs/episode	$32,100	$17,840	$902		Estimated cost to the government (Medi-Cal + Medicare) of each episode type (nursing facility stay, hospital admission, ED visit). See Appendix C for details.
Estimated Gross Savings	**NF**	**Hosp**	**ED**	**Total**	
Estimated gross **Medicare** savings	$2,280,787	$26,859,742	$2,311,623	$31,452,152	Product of episodes averted times cost per episode to the Medicare program.
Estimated gross **Medi-Cal** savings	$7,010,237	$2,566,554	$891,271	$10,468,061	Product of episodes averted times cost per episode to the Medi-Cal program.
Estimated **Total** gross savings to government	$9,291,024	$29,426,295	$3,202,894	$41,920,213	Product of total episodes averted times total cost per episode (represents gross savings to Medi-Cal and Medicare combined).
Estimated MDM Expenses					
Assumed federal share of MDM expenses @ $300 per machine				$64,780,800	Total cost of MDM machine rental to federal government for the entire target population at $50/month.
Assumed Medi-Cal MDM expenses @ $300 per machine				$64,780,800	Total cost of MDM machine rental to Medi-Cal for the entire target population at $50/month.
Assumed **total** MDM expenses @ $600 per machine				$129,561,600	DHCS expects that the devices will be eligible for a 50/50 split between the state General Fund (GF) and Federal Financial Participation (FFP) based on their interpretation that the devices fall under current DME definitions for both Medicaid and Medicare, and that this program is likely to operate under a waiver
Estimated Net Savings[c]					
Estimated net savings (loss) to **Medicare**				($33,328,648)	Net savings (loss) to the federal government assuming MDMs are distributed to the entire target population
Estimated net savings (loss) to **Medi-Cal**				($54,312,739)	Net savings (loss) to the Medi-Cal budget assuming MDMs are distributed to the entire target population
Estimated net savings (loss) to Medi-Cal and Medicare combined				($87,641,387)	Total net savings (loss) to the government assuming MDMs are distributed to the entire target population

TABLE 4. SENSITIVITY ANALYSIS: OPTIMISTIC SCENARIO[a]: DUAL ELIGIBLES					
Target Population: Dual Eligibles Age ≥18 with ASC and Polypharmacy[b] (n=215,936 based on 2005 data)					
	NF	**Hosp**	**ED**	**Total**	**Notes**
Episode Count	12,060	103,091	88,772		Number of nursing facility stays, hospital admissions, and ED visits among the target population (2005).
Proportion due to FCD-NA	0.10	0.075	0.075		Increased the literature-supported assumptions by 50% to 7.5% of hospital and ED use due to FCD-NA --the highest plausible estimate for hospital admissions, emergency department visits, and assumed a generous 10% of nursing facility admits due to FCD-NA (FCD-NA=forgetfulness, confusion, cognitive deficit due to non-adherence).
Number due to FCD-NA	1,206	7,732	6,658		Product of episode count times proportion due to FCD-NA.
Relative risk reduction attributable to MDM	0.98	0.98	0.98		We assume that MDMs will prevent 98% of FCD-NA episodes, which is based on device manufacturer claims and a few small studies. See Appendix C for details.
Episodes averted	1,182	7,577	6,525		Product of FCD-NA episodes times MDM-related relative risk reduction (98%).
Estimated Costs/Episode	**NF**	**Hosp**	**ED**		
Medicare costs/episode	$7,880	$16,284	$651		We assume cost-sharing arrangements exist between Medicare and Medi-Cal for the dual eligible population. Calculations were derived from a combination of DHCS LOS data and grey literature regarding Medicare cost/day for each service type. See Appendix C for details.
MediCal costs/episode	$24,220	$1,556	$251		Based on DHCS 2005 claims data (cost and utilization) for the ASC + polypharmacy population and grey literature: See Appendix C for details.
Total costs/episode	$32,100	$17,840	$902		Estimated cost to the government (Medi-Cal + Medicare) of each episode type (nursing facility stay, hospital admission, ED visit). See Appendix C for details.
Estimated Gross Savings	**NF**	**Hosp**	**ED**	**Total**	
Estimated gross **Medicare** savings	$9,313,214	$123,386,938	$4,247,607	$136,947,759	Product of episodes averted times cost per episode to the Medicare program.
Estimated gross **Medi-Cal** savings	$28,625,134	$11,790,105	$1,637,710	$42,052,949	Product of episodes averted times cost per episode to the Medi-Cal program.
Estimated **Total** gross savings to government	$37,938,348	$135,177,043	$5,885,317	$179,000,708	Product of total episodes averted times total cost per episode (represents gross savings to Medi-Cal and Medicare combined).
Estimated MDM Expenses					
Assumed federal share of MDM expenses @ $300 per machine				$64,780,800	Total cost of MDM machine rental to federal government for the entire target population at $50/month.
Assumed Medi-Cal MDM expenses @ $300 per machine				$64,780,800	Total cost of MDM machine rental to Medi-Cal for the entire target population at $50/month.
Assumed **total** MDM expenses @ $600 per machine				$129,561,600	DHCS expects that the devices will be eligible for a 50/50 split between the state General Fund (GF) and Federal Financial Participation (FFP) based on their interpretation that the devices fall under current DME definitions for both Medicaid and Medicare, and that this program is likely to operate under a waiver.
Estimated Net Savings[c]					
Estimated net savings (loss) to **Medicare**				$72,166,959	Net savings (loss) to the federal government assuming MDMs are distributed to the entire target population
Estimated net savings (loss) to **Medi-Cal**				($22,727,851)	Net savings (loss) to the Medi-Cal budget assuming MDMs are distributed to the entire target population
Estimated net savings (loss) to Medi-Cal and Medicare combined				$49,439,108	Total net savings (loss) to the government assuming MDMs are distributed to the entire target population

Note to Table 4: If the optimistic assumptions for FCD-NA-induced nursing home admissions, hospitalizations and ED visits were increased to 23%, 10% and 15% respectively, we would expect to see a savings of $20 million to Medi-Cal and net total savings to Medicare and Medi-Cal of $150 million. This estimate is included only to demonstrate that state-specific savings are still relatively low under exceptionally optimistic assumptions.

Footnotes for Tables 2, 3, and 4

(a) See Appendices C and D for details on methods and assumptions

(b) CHPR defines adherence-sensitive conditions as those chronic conditions whose clinical outcomes are sensitive to proper medication management. We derived the idea from the related concept of "ambulatory sensitive conditions:"these are conditions that benefit from high quality ambulatory care in the sense that good ambulatory care can avert subsequent emergency visits or hospitalizations. This list of adherence-sensitive conditions includes most of the diagnoses defined as ambulatory-sensitive by Bindman et al. (1995) or serious mental health disorders. Our list includes angina, asthma, hypertension, coronary heart disease, congestive heart failure, chronic obstructive pulmonary disorder, diabetes, major depressive disorder, schizophrenia and bipolar disorder. The target population was identified using 2005 data. No recent Medicare data were available to calculate the polypharmacy population. Instead, we relied on 2005 Medi-Cal data before Medi-Cal was relieved of paying outpatient prescription drugs by Part D under the MMA 2003 (see Appendix D for methods description).

(c) Assumes that Medi-Cal and Medicare would equally share the cost of the MDM devices. If no waiver is granted, Medi-Cal will absorb greater losses in the base case model due to paying for the entire cost of the device.

Note: The savings (losses) accrue to the entire Medi-Cal budget, both the State general fund (SGF) and the federal financial participation portions (FFP). Therefore, the Medi-Cal savings (or loss) to the SGF is 50% of the total presented in Tables 2, 3, 4 and 5 (and Tables D-1, D-2, and D-3 in Appendix D).

The savings (losses) accrue to the entire Medi-Cal budget, both the State general fund (SGF) and the federal financial participation portions (FFP). Therefore, the Medi-Cal savings (or loss) to the SGF is 50% of the total presented in Tables 2, 3, 4 and 5 (and Tables D-1, D-2, and D-3 in Appendix D).

Conclusion: All model scenarios for the dual and non-dual eligible populations result in a net loss to the Medi-Cal program, with the exception of the *non-dual* eligible optimistic scenario, which achieves an estimated savings of $12.1 million. In the dual eligible population, if federal shared savings are realized under the optimistic scenario, estimated losses could convert to savings. Although CHPR characterizes this as a best-case scenario, we believe it is highly unlikely such savings would be achieved.

The cost model findings are predicated on assumptions from fairly weak evidence about health care service utilization related to FCD-NA. Conducting an evaluation study may help improve the quality of available evidence, but only if the study is of sufficient power and rigorous design. A primary objective of such a study would be to develop a more accurate means of predicting who is most likely to benefit from an MDM.

III. Proposed MDM Study Design

So far in this Report, we have summarized the literature pertinent to Medication Dispensing Machines and generated estimates of the government savings or losses that could be realized if MDMs were made widely available to Medi-Cal beneficiaries. One inescapable conclusion is that key assumptions about critical parameters in the cost models rely on sparse empirical data. In particular, there are no high quality studies that directly answer the following questions:

1. *To what extent can patients who are most likely to benefit from MDMs be prospectively identified?* We know some of the risk factors for inpatient services utilization (e.g. age, burden of illness, prior utilization), and we know some of the risk factors for non-adherence (sickness, regimen complexity, cognitive deficits). However, there are no prospectively validated multivariable models identifying patients who are non-adherent and who, as a result of non-adherence, are likely to require admission to hospital or nursing home over the next year.
2. *Among Medi-Cal patients as a whole and within important subgroups, what proportion of nursing facility stays, hospital admissions, and emergency department visits are due to medication non-adherence? What proportion of these adherence-related admissions are, in turn, due to forgetfulness, confusion, or other cognitive deficits – problems that can potentially be overcome through use of MDM systems?* Among all hospital admissions and nursing home stays, some are due to non-adherence. Among those that are due to non-adherence, fewer still are due to the kinds of physical, cognitive, or sensory deficits that an MDM system could logically address. Although we believe 5% is a reasonable middle ground estimate, hard data are lacking.
3. *How effective are MDM systems in reducing adherence-related NF stays, hospital admissions, and ED visits?* Available information on machine effectiveness is mostly anecdotal. Results of a moderately sized randomized trial (n=500 elderly patients) have not yet been published; preliminary results suggest that MDMs may add little beyond careful monitoring by the health care team.

As a result of sparse data informing these questions (Section I), estimates of net costs or savings attached to any statewide MDM program are sensitive to model assumptions (Section II). The California Legislature has directed the Department of Healthcare Services to implement a pilot MDM program. The advantages of performing a research study before full-scale deployment of MDMs are several. First, a study creates opportunities to better define the target population of beneficiaries most likely to benefit from MDMs. Second, a study provides a chance to develop and test protocols for MDM delivery and support and possibly to compare vendors in terms of reliability, customer satisfaction, and total costs. Third, a properly designed study allows policymakers to estimate with appropriate precision the health benefits (or harms) and financial gains (or losses) that would accrue should an MDM program be implemented at scale.

Key Assumptions and Study Design Options for Evaluating MDMs

In developing this proposal for evaluating MDMs, CHPR staff considered several design options. Development of this list of options is predicated on several assumptions. In this subsection, we first specify the assumptions, then present three design options DHCS to consider.

Key Assumptions

- The goal of the evaluation is to ascertain with reasonable precision what savings (or costs) can be expected when and if the MDM program is fully implemented.

- According to statute, the target of the pilot project is Medi-Cal fee-for-service (FFS) patients who are at high risk of medication non-adherence resulting in related health care utilization. The majority of these patients are over age 65, disabled, or both. Nearly 65% of this report's population of interest (1,716,210) is seniors or persons with disabilities (SPDs); they comprise 93% of the dual eligible (750,096) and 46% (358,763) of the non-dual eligible populations (see Appendix D). In any given year, only a minority of these patients will incur an inpatient stay (hospital or nursing home), and of those stays, only a small proportion (roughly 5%, according to the estimates presented in Sections I and II) are likely due to non-adherence – or at least the type of non-adherence that MDMs are designed to interrupt.

- An important policy objective is to identify subgroups of patients most likely to benefit from MDMs. It is important to realize, though, that no prediction instrument is perfect. Patients most likely to benefit from a MDM are those who are at high risk for an adherence-related health event due to forgetfulness, confusion, or other cognitive deficits (FCD-NA) and who are comfortable adopting new technologies (or, alternatively, have sufficient social and/or clinical support to operate the machines properly). However, there are no validated prediction rules for identifying these patients. In addition, if patients are more than mildly confused or demented, they will be unable to operate the MDM without substantial, daily assistance.

- The main outcome of interest is costs to the State general fund, particularly health care costs related to emergency department visits, hospital admissions, and nursing home stays. (Outpatient visits and ambulatory surgeries are ignored in this analysis, in part because they are less costly in the aggregate and, in part, because they are thought to be less sensitive to medication non-adherence.) However, CHPR cannot ignore other outcomes, particularly medication adherence, survival (mortality), and quality of life.

Design Options

Taking into account these assumptions, there are three broad study design options for evaluating an MDM program. In presenting these options, we consider MDMs as a class and ignore differences among vendors and among machines. Each option could, in theory, be expanded to include an evaluation of specific vendors or machines within the larger evaluation of MDM program effectiveness. Within each design option, there are two possible approaches. One is to randomly assign participants to two or more different vendors or machine types. The other is to try to match vendors or machine types to patients based on their specific needs or preferences. Both approaches would increase the complexity of the study and increase sample size requirements.

1. **Design Option 1** is a simple pre-post evaluation of economic and health outcomes comparing patients' experiences in the year before receiving an MDM with their experiences in the year after. Under this option, DHCS identifies a study population, recruits them through mailings and "cold calls," provides them with MDMs, and works with a research team to compare healthcare utilization patterns for the year before and year after the date the machines are allocated. The research team also collects information from the MDM vendor and from patients, focusing on implementation of the program and ease of use.

The advantages of this approach include simplicity and relatively low cost. The disadvantage is that pre-post designs, lacking a contemporaneous control group, are subject to bias due to history, maturation, selection, and regression to the mean (Campbell and Stanley, 1963). An improvement in health or economic outcomes from year to year could reflect myriad factors completely unrelated to MDMs (history). Patients with chronic illnesses tend to get sicker as they age (maturation). Patients willing to sign up for the MDM pilot may differ in important ways from patients who would ultimately be eligible to receive machines (selection). For example, if the pilot enrolls a cohort of enthusiastic "early adopters," their experience may be misleading; completely different results might be obtained from a broader population. Finally, if we select patients for enrollment based on high utilization during the initial (baseline) year, these patients will tend, by chance, to "regress to the mean" – health care service utilization in the subsequent year will be lower. This is analogous to selecting patients for a blood pressure medication trial based on 1 or 2 blood pressure measurements exceeding 140/90. Blood pressure tends to fluctuate, sometimes spiking higher or dipping lower depending on diet, activity, stress, and other factors. Patients selected for a study based on an initial "outlier" measurement will tend, on subsequent measurement, to exhibit findings closer to the group average. They have "regressed to the mean," purely by chance, and this will happen even if they are taking placebo.

2. **Design Option 2** is a pre-post, demonstration-control quasi-experiment (sometimes called a "pre-post study with concurrent controls"). Under this design, 6-12 geographic clusters (defined by county, catchment area, or alternative long term care program [ALTCP]) are assigned to receive an MDM program. For each cluster assigned to the MDM program, researchers would work with DHCS to identify a suitable "matched" control cluster. Depending on cluster size, each cluster contributes 100-200 patients to the study. Economic and health data are collected from patients within the clusters for one year before and one year after the "go live" date (which may vary for each demonstration-control matched pair). As in Option 1, the research team collects descriptive information from the MDM vendor and from patients.

   The advantage of this approach is that compared with Option 1, this kind of quasi-experiment is associated with less bias. In addition, if natural clusters of patients can be identified that ease recruitment (e.g., patients clustered within community health centers), costs may be reduced, at least relative to a classic, parallel group randomized controlled trial (Option 3). However, matching of intervention and control clusters by the investigators is much less effective as a guarantor against bias than randomization.

3. **Design Option 3** is a randomized controlled trial (RCT). In this design, patients at high risk of non-adherence-related utilization are randomly assigned to receive an MDM or usual care. Large RCTs are the gold standard for assessing the effectiveness of interventions. Through randomization, factors that influence outcomes (independent of the intervention) are equally balanced between groups. As a result, any observed difference in health or economic outcomes between the groups can be attributed to the intervention. In a variation on this RCT design, clusters or units are randomized and then all consenting patients within those clusters/units are assigned to receive MDMs or usual care (depending on their cluster/unit). For example, if community clinic A were randomized to the MDM arm, all eligible consenting patients within clinic A would receive an MDM. If community clinic B were randomized to the usual care arm, all eligible consenting patients within clinic B would receive usual care.

CHPR recommends a randomized experimental design with adequate sample size (see below) because such designs can support strong inferences about causality. This means that, upon completion of the experiment, researchers and policy makers would *know*, within a pre-specified band of uncertainty, the economic costs (or savings) as well as the health benefits of the program. No other design option offers this level of rigor. Randomization could occur at the level of the patient or at the level of some higher-order unit/cluster (e.g., a geographic region or an Alternative Long Term Care Program).

Compared to non-randomized designs, RCTs can be more difficult, labor intensive and expensive to carry out. In particular, if patients or care providers have a strong belief that one treatment is superior to another, they may be reluctant to be randomized. Additionally, if eligibility criteria are stringent, the results of some RCTs may not be applicable to the broader target population. However, RCTs with broad inclusion criteria, simple-to-collect measures, and large samples can provide singularly informative data.

Randomized controlled trials are used infrequently in evaluating government programs. We view this as unfortunate, because RCTs are uniquely informative and can often "settle the argument" in a way that no other research design can. A recent and telling example is the Oregon Medicaid Experiment (Baicker and Finkelstein, 2011). In this trial, 10,000 Oregonians were randomly assigned to receive or not receive Medicaid coverage (lack of State funds precluded coverage for all). Early results are clear and compelling: persons assigned to receive Medicaid coverage use 25% more health services, receive more cancer screenings, and report substantial increases in well being and reduced medical debt. Although observational and quasi-experimental research designs can supply high-quality information, policymakers looking for definitive answers to important policy questions should strongly consider randomized trials. As this report illustrates, the effectiveness of MDMs as well as the true impact of FCD-related non-adherence on health care utilization are poorly understood. Applying rigorous study methodology to this issue would add greatly to the body of research.

Identifying a Suitable Target Population

Identifying the population that would benefit most from a MDM program is challenging in terms of maximizing health benefits while minimizing MDM program costs. The evidence CHPR found in peer-reviewed literature supports many of the initial criteria suggested in SB 72 to identify an appropriate population at risk of medication non-adherence and subsequent use of health care services. These criteria include age, disability, multiple prescribed medications, and experience with multiple emergency department visits or hospital or nursing facility admissions in the past.

CHPR finds that community-dwelling, FFS Medi-Cal beneficiaries who are aged ≥65 years, take five or more prescription medications for chronic conditions, and have one or more adherence-sensitive conditions are at elevated risk for inpatient and emergency utilization and may therefore be well-suited for enrollment in the MDM study. Older age is a well-established risk factor for hospitalization and nursing home admission: the hospitalization rate for persons over 65 is roughly three times the rate in persons aged 45-64 (National Center for Health Statistics, 2010). Furthermore, DHCS 2005 claims data show that nearly 65% of the target population in this report are seniors or persons with disabilities and comprise 93% of dual eligibles.

Similarly, medication regimen complexity has been associated with adverse events including inpatient stays. For example, one study found that the risk of adverse drug events for individuals on five or more medications was roughly double that of patients taking no medicines or only one (Field at al., 2004). Finally, proper outpatient management of conditions like diabetes, congestive heart failure, and asthma

can prevent unnecessary use of inpatient and emergency health care services. Bindman calls these conditions "ambulatory sensitive" (Bindman, 1995). Medication adherence is an essential component of disease management; therefore, these conditions are likely sensitive not only to ambulatory care but to medication adherence (AHRQ, 2004).[14]

In 2005, after excluding individuals under age 18, those living in long term care facilities, and those continuously eligible for less than 12 months, there were **1,716,210** Medi-Cal FFS beneficiaries aged 18 years or older who were not in permanent long term care facilities and had at least 12 months of eligibility. From a policy perspective it would not be feasible or desirable to provide all of these individuals with MDMs. The question then becomes how to identify in advance those individuals most likely to incur adherence-related inpatient stays. Applying criteria related to age/disability status (using "dual eligibility" as a proxy), polypharmacy, and adherence-sensitive conditions goes a long way: as reported in Section II, there were **215,936** such patients; together they incurred some 103,000 hospital admissions and 12,000 nursing home stays, for an overall rate of 533 inpatient episodes per 1000 persons per year. Because some individuals incur more than one stay per year, these 533 episodes are accounted for by about about 350 people; the other 650 per 1000 have *no* stays. Providing those 650 with MDMs on December 31, 2004 would have had *zero* impact on their inpatient utilization in 2005. But – our methods cannot distinguish between the 350 per 1000 destined to have hospital or nursing facility stays and the 650 per 1000 who will never be admitted. Indeed, providing MDMs to the 650 would be a waste of resources – if we knew who they were in advance. But we do not.

Can we do better at distilling the population simultaneously most at risk for an inpatient admission and most likely to benefit from MDMs? Perhaps. For a start, CHPR staff recommends analyzing Medicare prescription drug data once it becomes available. Identifying users of specific chronic medications, or combinations of medications may help winnow the target population. For example, patients on oral anticoagulants and digoxin are at higher-than-average risk of incurring adverse drug-related events (Budnitz et al., 2007). In addition, time permitting, research staff with the assistance of a **Scientific Advisory Council** may be able to develop a multivariable predictive index based on available administrative data. Candidate variables would include age, gender, ethnicity, neighborhood income (based on place of residence), number and type of adherence sensitive conditions, number and type of medications, and health care utilization history (e.g., ED visits, hospitalizations, and nursing home stays in the past year). The purpose of applying such an index would be to enrich the study's participant pool with patients even more likely to benefit from MDMs than the patients represented in our cost models (Section II). Such preliminary analysis could be incorporated into the proposed study design.

Having considered key assumptions, presented design options, and emphasized the challenges in developing accurate risk prediction models, we now turn to presenting a framework for our recommended study design – a randomized controlled trial (RCT) of MDMs. In so doing, we are aware that the State may have reasons for favoring an alternative design. These reasons may include economic, pragmatic, or political concerns. While the research team favors an RCT on scientific grounds, other approaches can provide useful information. Therefore, it would be perfectly reasonable to select an alternative design after taking into account both scientific and practical considerations. However, a full description of these alternatives is beyond the scope of this document.

[14] To Bindman's list CHPR has added 3 mental health conditions (major depression, bipolar illness, and schizophrenia) that are known to require good medication adherence for remission of symptoms.

Aim of Study Design

The primary aim of the RCT is to determine the effectiveness of medication dispensing machines (MDMs) in improving clinical outcomes and decreasing costs. The primary clinical outcome is a composite of death, hospitalization, or nursing home stay. The primary economic outcome is health care costs from the perspective of the government.

Proposed Study Design

The proposed design is an RCT with patients sampled from participating units in one or more alternative long term care programs (ALTCPs) such as the Multipurpose Senior Services Program (MSSP). Within participating units (clusters), eligible patients will be randomly assigned to the intervention (MDM plus technical and nursing support) or to usual care. Although there are other reasonable alternatives (such as sampling patients directly from lists supplied by the State), we suggest this approach for three reasons. First, ALTCPs may be in a good position to help assess (or confirm) eligibility of their clients. Second, ALTCPS can coordinate recruitment of subjects, eliminating the need for a research group to make "cold calls" to the households of potential research participants. Third, our literature review suggests that the most effective programs for enhancing adherence are multiphasic, and nearly all include human support. ALTCPS already provide human support, allowing us to estimate the *marginal* (added) effects of introducing MDMs.

Sampling of local alternative long term care programs (ALTCPs). Sampling will occur in two phases. First, between 10 and 20 ALTCPs will be selected based on the following criteria:

a) geographically diverse, representing both Northern and Southern California;
b) serving at least 100 patients potentially eligible for the pilot project[15];
c) willing to participate in all aspects of the pilot, including training, randomization, and follow-up.

In collaboration with DHCS officials, research staff will approach leadership of selected ALTCPs and attempt to recruit them to the study. Consenting programs will provide a list of encoded client/patient identifiers along with sufficient data to determine their patients' potential eligibility for the study (see below for inclusion and exclusion criteria). Recruitment will occur by telephone and will be coordinated by a survey research group experienced in the conduct of behavioral RCTs with vulnerable older patients. Patients who appear eligible will be asked to participate and then randomized to the MDM intervention or to usual care.

Sampling of patients within ALTCPs. During the run-in phase, research staff in collaboration with the study's Scientific Advisory Council will consider and refine subject selection criteria. Final criteria will be chosen with the goal of maximizing the probability that enrolled patients are at high risk of adherence-related hospital and nursing facility stays and are capable of benefiting from MDMs. Provisional criteria are as follows:

Provisional inclusion criteria

- Served by a participating ALTCP
- Living at home or in a (nonskilled) assisted living facility
- Medi-Cal FFS beneficiary
- Age 65 and older;

[15] ALTCPs vary greatly in size, but some are quite large. For example, SCAN Independence at Home (one of two MSSP Programs in Los Angeles City) has 900 MSSP clients (personal communication with R. Kravitz, 8/19/11).

- Not working or going to school outside of the home (predominantly homebound);
- Presence of at least one "adherence-sensitive condition" and currently taking at least 5 chronic, regularly scheduled prescription medications (not prns).
- If non-English speaking, has an at-home companion or caregiver who speaks and understands English well enough to manage an MDM and to answer survey questions as the patient's proxy
- Have phone connectivity in home

Provisional exclusion criteria:

- Currently receiving daily infusion therapy
- Patients receiving skilled nursing services (provided by RN or LVN) more than 3 times per week
- Patients on dialysis
- Enrolled in hospice program or identified by ALTCP staff as having limited life expectancy (<1 year)
- Disabilities preventing use of machine
- Unsuitable for trial in opinion of ALTCP staff
- Known to be intentionally non-adherent
- Already receive medications through a monitored dosage system

Consent and randomization. Within each participating ALTCP, eligible patients or their legal proxies will be asked to provide informed consent to participate in the study (the survey subcontractor will be provided a list of patients in random order and will proceed until the quota for that ALTCP is full). Consent will be obtained prior to randomization. Using a random number generator, the study statistician (or his/her proxy) will allocate patients to the intervention or control group in blocks of 12 (6 experimental, 6 control per block). The purpose of blocking is to assure that there is roughly equal (balanced) allocation to the 2 groups within each ALTCP (i.e., to avoid a situation where by chance alone, a large proportion of participants in a given ALTCP are assigned to one experimental group or the other).

Intervention. The "intervention" is installation of a Medication Dispensing Machine within a patient's home, along with all necessary *technical support* and *clinical coordination*. *Technical support* includes help with setting up and operating the machine as well as assuring that any interruption in service results in prompt repair or use of an alternative method to safely deliver prescribed medications. Technical support also includes training for the patient and/or his or her caregiver (be it a paid assistant, friend, or family member) in use of the machine, dealing with contingencies, and how to seek help (preferably by way of a 24-hour help line). Both initial training and ongoing support will be provided by the vendor (i.e., the manufacturer or manufacturer's representative). We propose establishing an "MDM Oversight Committee" to assist with selection of vendors, provide advice on "matching" specific MDM vendors or machines to specific client types, and establish standards for technical support. *Clinical coordination* means clarifying the current medication regimen and assuring there is common understanding of the regimen among the patient, caregiver, prescribing physician, and dispensing pharmacist. Clinical coordination is needed to assure that patients/caregivers can receive help when the machine unexpectedly runs out of medication, the machine does not deliver medication as expected, the patient is instructed to change medications before the next machine fill cycle, or the patient/caregiver simply becomes confused about what to do next. A basic package of clinical coordination services will be provided to both intervention and control patients by the ALTCP after training conducted jointly by the research team and the vendor.

Main outcomes measures. The primary policy outcome will be total health care costs to the state. Costs will be reported as components including outpatient care, emergency services, hospitalizations,

nursing facility, and "other." It is anticipated that these data will not be available for at least 6 months after completion of the 1-year intervention. The primary clinical outcome will be the one-year risk of death, hospitalization, or nursing home stay. Other clinical outcomes will include survival and quality of life as measured with the SF-36, a well-accepted, comprehensive, 36-item measure of health status and well being that includes subscales for physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role-limitations due to emotional problems, and mental health. Survival will be assessed using the California death registry. Like the cost data, these data may not be available for 6 months or more after the end of the one-year intervention period. Health-related quality of life will be measured within 1 month of randomization and at the end of the one-year study using a telephone-administered SF-36 (with conversion to a utility-based measure, a necessity for calculating quality adjusted life years needed for cost-effectiveness analysis, using standard methods). Health care utilization will include number and cost of ED visits, hospital admissions (and length of stay), nursing facility admissions (and length of stay), and "other. Where possible, costs will be allocated to Medi-Cal, Medicare, and "other."

In addition to the outcomes described above, we also recommend collecting data on putative *mediators* and *moderators* of the intervention's effects. *Mediators* are variables that are involved in the chain of causation between the intervention and outcome. For example, if the intervention improves adherence, and improved adherence in turn improves outcome, then adherence is a mediator. *Moderators* are variables that alter the impact of the intervention on the outcome. For example, if the intervention is highly effective in women but not in men, then gender is a moderator of the effect of the intervention on outcome.

- Putative mediators of improved survival, health, and avoidance of unnecessary health services utilization
    - Medication persistence for critical therapies. Persistence is a subtype of adherence, defined as days taking medication without exceeding a permissible gap
    - Degree of ALTCP nurse or family involvement with medication management, measured by self-report (e.g., "During the past month, did anyone help you with your medicines on a regular basis? If yes, how often did they help you? Would you say more than once a day, about once a day, less than once a day but more than once a week, about once a week, or less than once a week?")
- Putative moderators of effect of Medication Dispensing Machines on outcomes
    - Educational attainment (of patient and of primary caregiver)
    - Cognitive functioning using the Telephone Interview for Cognitive Status-modified (Knopman et al. 2009)
    - Race/ethnicity
    - Specific ALTCP program (i.e., study "site")

Finally, to adequately evaluate how well the MDM program was implemented, we recommend tracking the following formative measures: 1) patient satisfaction with MDM program; 2) caregiver satisfaction with MDM program; 3) promptness with which machines are installed in patients' homes and repaired when "down"; 4) as a window into vendor responsiveness: number of calls to "call center," average time on hold, number of hang-ups, satisfaction with call center courtesy and responsiveness; and 5) number of home service calls and outcomes in terms of alacrity and satisfaction.

Analysis. Differences in time-to-death, hospital admission, or nursing facility admission between intervention and control arms will be assessed using survival analysis and proportional hazards

modeling, the standard approach for dealing with time-to-event data. Differences in health status at follow-up will be modeled as a function of study group, health at baseline, and other relevant covariates such as age and health conditions (particularly if randomization results in chance imbalance in these characteristics). The economic analysis will use a "difference in differences" approach, comparing changes in utilization and costs for *both groups* (intervention and control) during the one year before randomization to the year after. The primary health and economic analyses will focus on patients "as randomized" (i.e. "intention to treat"). A secondary analysis will examine patients "as treated" (i.e., focus on patients who actually received the intervention). The "as randomized" analysis is more conservative and accounts for dropout due to technical and clinical issues that might arise in actual practice. The "as treated" analysis provides a better estimate of the best possible results obtainable with the intervention under ideal conditions.

The statistical approach will account for the clustering of patients within ALTCPs (acknowledging that patients within the same ALTCP will share similar characteristics – measured and unmeasured – leading to similar outcomes).

As asserted earlier, the primary aims of this study are to determine whether the MDM program can save costs while supporting equal or better health outcomes. There are four possibilities:
1) the program saves costs and improves outcomes;
2) the program saves costs but worsens outcomes;
3) the program incurs additional costs and improves outcomes; or
4) the program incurs additional costs and worsens outcomes.

Cost-effectiveness analysis strives to estimate the marginal costs of a program (in this case the costs of an MDM program versus usual care) divided by the marginal effectiveness (in this case quality adjusted life years for patients randomized to MDM versus usual care). In the event that Scenario 3 prevails, the research team will be able to estimate the cost-effectiveness of MDMs from the perspective of the government payer by using a combination of claims data, survival data, and survey data. Estimating cost-effectiveness from other perspectives (e.g. from the perspective of society) would require collecting more data on health and non-health expenditures by individuals enrolled in the trial and by their families.

Power and sample size. Additional DHCS data are needed to generate accurate estimates of baseline outcome probabilities and costs in the population of interest. At this point, we present only very rough sample size calculations based on a single, relatively crude outcome: the proportion of patients who experience death, hospitalization, or nursing home admissions within one year. These calculations do not account for the baseline data from the previous year, which will help to reduce variance and improve power.

For the primary clinical outcome (composite of death, hospitalization, or NF stay), a sample size of 2,655 provides 80% power to detect a 20% hazard reduction (from 25% to 20%). Assuming 20% attrition (patients dropping out for various reasons), a starting sample size of **3,186** (1,593 per group) is needed. Sample size requirements for detecting cost differences are more modest because costs are a continuous variable.

Assumptions and Limitations of the Proposed Approach. Study recruitment assumes use of an established program structure from which to identify and enroll study participants. Random contact with Medi-Cal eligibles would be inefficient and unlikely to enroll enough participants. The recent

changes to state supported programs are diminishing access to such programs (elimination of ADHC, downsizing of IHSS and MSSP); however they remain the best structures we know of on which to build this study. Also, we assume the technical training materials for MDMs are (or will be) fully developed by the vendor and require only a modest review by an MDM oversight committee. Further training material development would require additional time and funding.

The proposed approach has limitations. Health status measures are self-reported. Complete utilization and cost data may not be available for all patients. Results may not be generalizable to patients who are not connected to an ALTCP. Nevertheless, compared to alternative designs, we think the proposed design has the best chance of providing a valid estimate of the effects of MDMs on health outcomes and health care costs related to adherence-sensitive utilization.

Estimated Study Duration and Costs

The study will last for 3 years, which includes 6 months for planning and preparation, 3 months for baseline surveys, 1 year of observation (collection of baseline Medi-Cal and Medicare claims data), 3 months for follow-up surveys, 9 months for analysis (subject to Medi-Cal and Medicare claims data availability for the intervention period), and 3 months for report preparation and presentations to State officials. Key tasks to be accomplished during the 6-month run-up period include: 1) convening of a Scientific Advisory Council; 2) finalization of a detailed study protocol; 3) testing of alternate risk prediction models for use in subject selection; 4) selection of a final sampling frame, including specific partner organizations (e.g. alternative long term care programs); 5) selection of a survey research consulting group and development of survey research instruments; and 6) cleaning and preliminary analysis of baseline datasets. An additional 3 months is provided for conducting baseline participant surveys. At this point the MDMs are installed (probably in a phased fashion) in the homes of patients randomized to the intervention, and both intervention and control patients' utilization patterns are observed for 1 year, which is a reasonable time in which to assess change in utilization patterns. After a year of observation, surveys are repeated and (assuming that Medi-Cal and Medicare claims data are available), analysis begins in earnest. Research costs are estimated at approximately $3 to $3.5 million over 3 years and include patient incentive, but excludes machine rental cost.

Figure 3. Three-year timeline for MDM RCT

*Planning process includes such tasks as convening Scientific Advisory Council, recruiting ALTCPs, finalizing study protocol, testing prediction models, developing survey tool, etc.

Appendix A: Statutory Language

CALIFORNIA CODES: WELFARE AND INSTITUTIONS CODE (Originating from SB 72 in 2011)

14132.957. (a) (1) It is the intent of the Legislature to adopt measures that will assist individuals who are living in the community to remain within their home environment and avoid unnecessary emergency room usage and hospital and nursing facility admissions due to those individuals not taking medications as prescribed.

(2) The Legislature finds and declares that certain seniors, persons with disabilities, and other Medi-Cal recipients are at high risk of not taking medications as prescribed and that measures to assist them in taking prescribed medications will advance the state's objectives to save lives, reduce health care costs, and assist individuals to continue living independently in their homes.

(3) The Legislature has determined that the achievement of these objectives will result in a net annual savings of one hundred forty million dollars ($140,000,000) to the General Fund, after fully offsetting costs for implementing and administrating the pilot project.

(4) The Legislature therefore authorizes the establishment of the Home and Community Based Medication Dispensing Machine Pilot Project for utilization of an automated medication dispensing machine with associated monitoring and telephonic reporting services to assist Medi-Cal recipients with taking prescribed medications. All Medi-Cal recipients who participate in the pilot project shall do so voluntarily and shall be selected using criteria that demonstrates their susceptibility to not taking their medications as prescribed without monitoring or assistance.

(b) On and after the effective date of this section, the department, in consultation with the State Department of Social Services, shall begin implementation of the pilot project described in subdivision (a) and shall do all of the following:

(1) Establish criteria to identify at-risk Medi-Cal recipients who demonstrate susceptibility to not taking medications as prescribed. These criteria shall be based on Medi-Cal, In-Home Supportive Services program and Medicare data and may include factors such as age, disability, multiple prescribed medications, and experience with or a high risk of experience with, numerous emergency department visits or hospital or nursing facility admissions within a specified time period as a result of not taking medications as prescribed.

(2) Identify an at-risk portion of Medi-Cal recipients of a sufficient number to achieve the intended savings. Recipients identified for this pilot project shall be limited to individuals who obtain Medi-Cal benefits through fee for service, who are not required to be enrolled on a mandatory basis in a Medi-Cal managed care health plan, and who are able to manage the medication dispensing machine independently or with the assistance of a family member or care provider and have a home environment capable of supporting the machine and associated telephonic reporting service that includes an active telephone line.

(3) To the extent necessary, the department shall do all of the following:

(A) Select and procure the automated medication dispensing machines, including costs for installation in a participant's home, as well as monitoring and repair services associated with operation of the machines.

(B) Provide an in-home, automated medication dispensing machine with telephonic reporting service for monitoring and assisting with taking medication, including installation, maintenance, alerts, training, and supplies at no cost to the recipient.

(4) Seek federal funding from the Centers for Medicare and Medicaid Services Innovation Center for the cost of the demonstration and other expenses, and to receive Medicare shared savings realized from the pilot project.

(5) Assess the potential for federal financial participation for these machines and any other expenses associated with this pilot project as well as receipt of federal reimbursement for savings accrued to the Medicare program. If the department determines that federal financial participation is available under Title XI or XIX of the federal Social Security Act, the department shall seek a waiver or other federal approval, or submit a Medicaid State Plan amendment to implement the pilot project.

(c) (1) The department shall provide quarterly reports, beginning October 1, 2011, to the Department of Finance and the appropriate fiscal and policy committees of the Legislature, describing the number of recipients participating in the pilot project, the number of medication dispensing machines in use, costs of implementing and administering the pilot project, and any available data regarding medical and pharmacy utilization.

(2) The department shall also conduct an evaluation of the pilot project, including effects on service utilization, spending, outcomes, projected savings to the Medi-Cal program and the federal Medicare program, recommendations for improving the pilot project and maximizing savings to the state, and identification of other means of General Fund savings related to improving quality and cost-effectiveness of care, and shall report the evaluation to the appropriate policy and fiscal committees of the Legislature by December 31, 2013.

(3) (A) If the Department of Finance determines that the quarterly reports do not demonstrate the ability of the pilot project to achieve at least the estimated net annual savings of one hundred forty million dollars ($140,000,000) to the General Fund, after fully offsetting implementation and administrative costs, the Director of Finance shall notify the Chair of the Senate Committee on Budget and Fiscal Review and the Chair of the Assembly Committee on Budget of this determination, in writing, by April 10, 2012. Within 10 days following this notification, the Department of Finance shall convene a meeting with legislative staff to review the estimates related to its determination.

(B) Subsequent to the meeting pursuant to subparagraph (A), the Department of Finance shall request that the Legislature enact legislation on or before July 1, 2012, to either modify the pilot

project, if necessary, or provide alternative options to achieve the balance of the net annual savings of one hundred forty million dollars ($140,000,000) to the General Fund, after fully offsetting implementation and administrative costs, or both.

(d) (1) Notwithstanding any other provision of law, if the Department of Finance determines after July 1, 2012, that the actions pursuant to subdivisions (b) and (c) will fail to achieve the net annual savings of one hundred forty million dollars ($140,000,000) to the General Fund, after fully offsetting implementation and administrative costs, the Department of Finance shall notify the State Department of Social Services and the department, and the State Department of Social Services, in consultation with the department, shall implement a reduction in authorized hours for in-home supportive services recipients beginning October 1, 2012, in accordance with Section 12301.03, to achieve a net annual savings of one hundred forty million dollars ($140,000,000) to the General Fund, after fully offsetting implementation and administrative costs of the pilot project and after taking into account any savings achieved pursuant to subdivisions (b) and (c).

(2) No earlier than 30 days after submission of the evaluation required by paragraph (2) of subdivision (c), the Department of Finance may adjust the amount of the reduction to meet net annual savings of one hundred forty million dollars ($140,000,000) to the General Fund after fully offsetting implementation and administrative costs and after taking into account any savings achieved pursuant to subdivisions (b) and (c). The calculations shall be based on updated data contained in the evaluation.

(e) For the purpose of implementing this section, the director may enter into exclusive or nonexclusive contracts on a bid or negotiated basis, or utilize existing provider enrollment or payment mechanisms. Any contract, contract amendment, or change order entered into for the purpose of implementing this section shall be exempt from Chapter 5.6 (commencing with Section 11545) of Part 1 of Division 3 of Title 2 of the Government **Code**, the Public Contract **Code**, and any associated policies, procedures, or regulations under these provisions, and shall be exempt from review or approval by any division of the Department of General Services and the California Technology Agency.

(f) Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government **Code**, the department may implement this section through all-county letters, provider bulletins, or similar instructions, without taking regulatory action.

(g) (1) Notwithstanding paragraph (2) of subdivision (c), the department may terminate operation of the pilot project if and to the extent that any of the following events occurs:

(A) Funding to implement and administer the pilot project is not appropriated in the 2012-13 fiscal year or annually thereafter.

(B) The Director of Finance notifies the Legislature that the pilot project is not projected to achieve a net annual savings or results in an overall increased cost.

(C) The pilot project conflicts with one or more provisions of

state or federal law necessary to implement the pilot project.

(D) The department is unable to obtain from the Medicare program the data necessary to implement this pilot project, and the high-risk Medi-Cal only population is insufficient to conduct the pilot project.

(E) The department receives substantiated reports of adverse clinical outcomes indicating that continuing the pilot project poses unacceptable health risks to participants.

(2) Termination of the pilot project pursuant to paragraph (1) does not provide the department or the State Department of Social Services with authority to implement a reduction in authorized hours pursuant to Section 12301.03. Any reduction in authorized hours pursuant to Section 12301.03 shall comply with the requirements of subdivision (d).

(3) The department shall notify the appropriate fiscal and policy committees of the Legislature 30 days prior to terminating the pilot project.

Appendix B: Literature Search Methods

CHPR performed a literature search of both peer-reviewed and grey literature in conjunction with a UCD medical librarian. We retrieved more than 200 English-only abstracts from MEDLINE, Cumulative Index of Allied Health Literature (CINAHL), EMBASE, National Institute for Health and Clinical Excellence (NICE), Cochrane Library, International Pharmaceutical Abstracts (IPA), and GoogleScholar. The literature search initially focused on the effectiveness of medication dispensing machines (MDMs), but expanded to include studies about medication adherence rates, adherence rates associated with non-MDM interventions, and utilization rates of emergency departments due to non-adherence, utilization rates of hospital services due to non-adherence, utilization rates of nursing facilities due to non-adherence. Key words and search terms varied according to databases searched: prescription drug*, medication, auto* dispensing machines, technology, cost-effectiveness, cost, service utilization, emergency department, hospital, nursing home/facility, adheren*, nonadheren*, compliance, noncompliance, and adverse drug events. References from retrieved articles were also considered. CHPR also searched the FDA medical device website for studies regarding the efficacy of MDMs, and two National Institutes of Health-sponsored registries of clinical trials. Additionally, CHPR reviewed information submitted to DHCS by interested parties.

CHPR used criteria similar to that of the United States Preventive Services Task Force Manual on Methods and Process when appraising studies for inclusion in this report (http://www.uspreventiveservicestaskforce.org/uspstf08/methods/procmanualap7.htm). Systematic reviews, meta-analyses and randomized control trials were of greatest interest because of study methodology rigor. Those studies that focused on the elderly, especially those enrolled in Medicare/Medicaid and/or related to determining or improving adherence rates were reviewed in-depth. When few systematic reviews or RCTs were found for various subjects, CHPR included individual studies using less rigorous research methodologies such as cohort studies. Selected studies are included in the following tables: Tables B1-B4.

Table B1. Study Findings About Rates of Medication Adherence					
Citation	**Research Design/Description**	**Non-Adherence Rates**	**Other Findings**	**Calculated Adherence**	**Calculated Non-Adherence**
Col et al *Arch Intern Med* (1990)	Observational study; Interviewed 315 consecutive elderly pt admitted to hospital to determine percent of admits due to non-adherence	32.7% (n=103) NA w/in last year	Common forms of non-adherence: Underuse: 81% (83) Overuse 17% (18) Misuse 2% (2)	67.3%	32.7%
Conn et al *The Gerontologist* (2009)	Meta-Analysis 33 published and unpublished RCTs about medication adherence (MA)knowledge, health outcomes and health care utilization		Larger effect sizes for special med packaging, dose modification, participant monitoring succinct written instructions, but study heterogeneity in magnitude of effects (Also cites Van Eijken 26-59% NA)		
DiMatteo et al *Health Psychology Review* (2011)	Narrative review of research on (non)adherence (large scale population-based studies and meta-analyses w/ 400+ participants)	24.8% of all HTN patients nonadherent;	<50% of published adherence-enhancing interventions demonstrate improved adherence/outcomes 400 HTN pts decreased HTN-related mortality by 53.2% with 3-pronged intervention (Morisky) Multi-faceted interventions better for diabetes mgmt than uni-dimensional	75.2%	24.8%
Doggrell *Drugs and Aging* (2010)	Systematic review of adherence to medicines in the older-aged w/ chronic conditions	Nonadherence ranges from 40-70% in elderly	Reasons: Cost , adverse effects, vision, depression, cognition, number of meds, # of pharmacies used,	30-60%	40-70%

Table B1. Study Findings About Rates of Medication Adherence					
Citation	**Research Design/Description**	**Non-Adherence Rates**	**Other Findings**	**Calculated Adherence**	**Calculated Non-Adherence**
			forgetfulness, arthritis,		
Faught et al *Epilepsia* (2009)	Retrospective review of claims data of Medicaid pts with epilepsy >18 yrs.	26% nonadherent (at ≤80% level)	Older age, female, nonwhite, higher Charlson comorbid score (2.72 nonadh vs 1.98 adh)	74%	26%
George et al *Drugs and Aging* (2008)	Systematic Review of 8 studies of community dwelling seniors w/ 3+ chronic meds w/ baseline adherence measures and follow-up of >4 weeks to determine effectiveness of interventions to improve MA	Reported average adherence 75.2% (DiMatteo, 2004)	Baseline percents of adherence from 8 studies worldwide: 33.9; 38.9;73; 61.4; 80; 37.6; 53; 64	75.2%	28.4%
Holloway and van Dijk *WHO* (2011)	Report on rational use of medicines	50% pts. in developed countries are compliant		50%	50%
Nair et al *Patient Preference and Adherence* (2011)	Telephone survey 8692 non-adherent hypertensive HMO patients (MPR<80%) Response rate 28.2%; mean age 63 yrs; 37% Medicare members;	Mean MPR 61%	<u>REASONS</u> **Forgetfulness** cited by 62% Medicare/61% commercial members **Side effects**<1% **Too busy** 3% Medicare **Copay barrier** 5% "**Other**" 22% Medicare (travel, hospitalization, disrupt-tion daily events, inability to get to pharmacy.	61%	39%
Osterberg *NEJM* (2005)	Review Article	Average adherence rates range 43-78% in clinical trials Barriers to adherence (based on one survey questionnaire) 30% of nonadherence due to self-reported forgetfulness; 16% other priorities; decision to omit doses	Complex regimens, literacy, cost, and lifestyle can also contribute to NA	43-78%	22-57%

Table B1. Study Findings About Rates of Medication Adherence					
Citation	**Research Design/Description**	**Non-Adherence Rates**	**Other Findings**	**Calculated Adherence**	**Calculated Non-Adherence**
		(11%); lack of information 9(%) (27% did not respond)			
Vik et al *Annals of Pharmacotherapy* (2004)	Systematic Review of measurement correlates and health outcomes of med. adherence in community-dwelling older adults. Studies w/ N>100 included. +75 studies reviewed. Aged 60 yrs.+	Adherence ranged 43.7-100% Reasons for NA: 4 studies reported **forgetting** (range 58.5%-10.6%), 8 studies reported adverse effects (47-8%) and 6 studies "not needed"/asymptomatic (range 52-13.4%)	Little consensus regarding determinants of nonadherence other than polypharmacy and poor provider relationships. Few studies examine association b/t NA and health outcomes 3 studies said drug-related hospitalizations due to NA ranged 8-11%; two studies report no increased risk.	43.7-100%	56.3-0% (% of NA reportiing forgetfulness 10.6-58% as reason)
Winland-Brown and Valiente *Outcomes Management for Nursing Practice* (2000)		Cited other studies of adherence -- 58% for antipsychotics; 65% antidepressants; 76% for physical disorders; and 40-75% took recommended amount of medications			
Yeaw et al *Journal of Managed Care Pharmacy* (2009)	Retrospective analysis of pharmacy claims database of 100 health plans from which 167,907 patients (all ages)were identified with any of 6 drug classes (related to 6 chronic conditions) in 2005	Mean 12 mo. Adherence rates prostaglandin analogs 37%; statins 61%; bisphosphonates 60%; oral antidiabetics 72%; angiotensin II receptor blockers 66%; overactive bladder meds 35%	All drug classes decreased in persistence and adherence over a 2 yr period. Adherence and persistence across 6 chronic therapies found variable but uniformly suboptimal medication use patterns (calculated by total days supplied meds for 360 day period/360 days)		

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
Col et al *Arch Intern Med* (1990)	Observational Interviewed 315 consecutive elderly pt admitted to hospital to determine percent of admits due to non-adherence	Nonspecific	Reasons for non-adherence: **Pt w/N-A History** Forgetfulness 38 (40%), Confusion 11 (12%)	--	89 (28%) hospital admits drug related; **36 due to non-adherence (11.4%)** and 53 (16.8%) due to ADR. 103 had history of non-adherence (32.7%); Ave # of Rx=4 w/ 6.5 pills/day **Pts with N-A Admit** Forgetfulness 5 (25%), Confusion 3 (15%) (Other reasons include unpleasant side effects, unnecessary, cost, dislikes taking meds, futility feelings)	--	**Drugs Assoc with N-A Admit**=furosemide, theophylline, warfarin, metaproterenol. N-A Admits=cardiac (47.6%), COPD (28.6%) metabolic disturbances (9.5%) Hospital admissions due to N-A=$77,000 or $2,150/admit (1990) Hospital admissions related to N-A accounted for $77,000 or $2150/admission (1990)
Conn et al *The Gerontologist* (2009)	Meta-analysis of 33 published and unpublished RCTs about adherence, health outcomes and health care service utilization (11,827 patients)	Nonspecific	--	--	Poor MA may account for up to 10% hospital admissions (Col 1990; Sullivan, Kreling 1990) Poor MA can exacerbate disease severity (DiMatteo	---	Interventions significantly improved MA (Effect size [ES] = 0.33), knowledge (ES = 0.48), and diastolic blood pressure (ES = 0.19). Nonsignificant effects were found for systolic blood pressure

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
	Calculates size of effect of various interventions				2002)		(ES = 0.21), other health outcomes (ES = 0.04), and health services utilization (ES = 0.16). Moderator analyses showed larger adherence ESs for interventions using special medication packaging, dose modification, participant monitoring of medication effects and side effects, succinct written instructions, and std. interventions.
Esposito et al *Am J Manag Care* (2009)	Retrospective cohort design 1998-1999 Medicaid and Medicare pharmacy claims data for Arkansas, CA, Indiana, and NJ Reported at adherence threshold at 80% and as continuous variable	CHF (10.7% dually enrolled)		3% less likely to have ED visit 10% fewer visits per person	Adherent ppl were less likely to have a hospitalization (0.4%), 13% fewer hospitalizations per person 2+ fewer days spent in the hospital	--	Adherence rate of 95% or over had 15% lower total health care costs Over 95% - $17665 80-95% - $20747 Among adherent dual-eligible's: $7913 lower annual health care costs than nonadhernet ppl $2859 lower costs compared to nonadherent dual-

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
							eligibles Predicted Medicare savings: If 60% Medicare bens are nonadherent, and adherence to increases 80% → $6.6 billion in savings (if 65% are nonadhernet at baseline, savings is $5 billion)
Faught et al *Epilepsia* (2009)	Retrospective cohort design of **Medicaid** data from FL, IA, NJ 1997-2006 of 33,658 epilepsy patients ≥18 yrs (5,188 ≥65 yrs). Adherence calculated quarterly	Epilepsy	MPR[16] = 26% non-adherent	Incident rate ratio (IRR) For non-adherence, ED visits 1.19 (1.18-1.21) ED costs $303 add'l cost/quarter	Incident rate ratio (IRR[17]) Hospital Admits IRR = 1.39 (1.37-1.41) IIR during NA was 39% higher for hospital Inpt days = 1.76 (1.75-1.78): IIR during NA 76%	--	Non-adherence associated w/ lower pharmacy and outpt costs likely due to non-adherent behavior Costs are calculated as cost to Medicaid only: therefore analysis excludes costs for quarters when pt is

[16] MPR=Medication Possession Ratio-days of medication supply dispensed divided by number of days between prescription refills. (The number of days for hospital stays is subtracted from the denominator.) This is a common proxy measure for calculating rates of adherence from claims data. Most literature uses arbitrary cutoff at ≥80% adherence to be considered adherent. Limitations to measure include medically-advised disruption and unknown (timely) ingestion of prescriptions.

[17] Incident Rate Ratio (IRR) > 1.0 =higher incidence rate for non-adherent period relative to non-adherent period

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
				(CI-$273-$334) due to NA	higher for inpt days Hospital costs $4320 add'l cost/quarter (CI $4077-$4564)		+65 yrs and Medicare is primary payor
Gaugler et al *Geriatrics* (2007)	Literature review of 77 studies and meta-analysis of 12data sources using longitudinal and U.S. community-based samples	Nonspecific	Not measured	--	--	Strongest predictor of NH admissions was ≥3 ADL dependencies, cognitive impairment, prior NH use. No mention of med. adherence in the systematic review.	
Gurwitz et al *JAMA* (2003)	Prospective cohort study of 27,617 Medicare enrollees (30,397 person yrs of observation) in HMO group practice 1999-2000 using physician reports, discharge	Nonspecific	21.1% (n=89) of pADEs due to errors involving patient adherence	--	--	--	**ADEs**: 1523 identified ADEs. 421 ADEs considered preventable. (13.8 preventable ADEs/1000 person years)

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
	summaries, ED notes, clinic notes and medication error incident reports.						
Hepke et al *Am J Manag Care* (2004)	Retrospective cohort design using 1 year of claims data in open access nonmanged care setting of 57,687 diabetic patients. 90% aged 40 yrs+	Diabetes	45.5% (80-100% adherent)* 25.5% (40-79% adherent)*	--	Threshold effect at 20-39% adherent before decreased use of in-patient and ED services was realized.	--	
Ho et al *Arch Intern Med* (2006)	Retrospective cohort study 11,532 diabetics 18+ yrs in CO HMO (data from HMO diabetes registry). Observation period 240-365 days	Diabetes	21.3 non-adherent	--	Proportion days covered (PDC[18]) cutoff (%): OR (CI) If adherent … <50: 1.66(1.34-2.04) <60: 1.66(1.34-2.04) <70 : 1.49 (1.26-1.77 <80: 1.58 (1.38-1.81) <90: 1.48 (1.32-1.66 <100: 1.35 (1.24-1.50) **SUMMARY HOSPITAL OR=**	--	All cause hospitalization for adherent 19.2% and nonadherent 23.2% (P<.001)—a 4% difference in hospitalization. Intermediate outcome measures of BP, LDL etc. available 25% increase in adherence=sig reduction in all-cause hospitalization OR=0.83 (0.79-0.88 P<.01)

[18] PDC=proportion of days covered-total number of days supplied for filled Rx divided by observation time interval (in this case, 240 days and max. of 365 days)

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
					1.58 (1.38-1.18 P<.001) **Hazard Ratio shows higher risk for hospitalization(any cause) HR 1.37 (1.25-1.51 P<.001)**		
Lau and Nau *Diabetes Care* (2004)	Retrospective analysis of managed care claims for 900 adult enrollees with type 2 diabetes	Diabetes Antihyperglyc e-mic meds Anti-HTN meds Lipid-modifying meds	 28.9% 18.8% 26.9%	--	Odds Ratio 2.53 (1.38-4.64) (at <80% adherence) Not sig. Not sig. Rate of hospitalization: 4.1% at 100% adherent to 14.8% when adherence <40%	--	
Malhotra et al *Postgrad Med J* (2001)	ED visits in India To determine proportion of medical emergency admissions that were secondary to nonadherence and causes/predictors of nonadherence. 578 patients 65yrs + admitted to ED	Nonspecific	21.3% with past history of non-compliance due to forgetfulness 6.8% of ED visit related to noncomplian ce due to	7.6% (44) visits caused by noncompliance . ED visit due to non-compliance:	--	--	15.3% of ED visits due to non-adherence were CVD related; 7.4% Respiratory; 6.9% metabolic; 3.3% CNS

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
	between Jan-July 2000		forgetfulness				
Rodriguez-Monguio et al *Pharmacoeconomics* (2003)	Literature review that includes: Dennehy et al 1994 study of 1260 patients of which 49 (3.9%) had ADE Senst et al 1998 random sample 3187 admissions in 4 US hospitals in 53 days	Nonspecific		Incidence: 3.9% (49) of all ED visits were pADE related; 66% (28) considered preventable (ave. cost $678/visit)	5 pADE required hospitalization (5/1260= ALOS for ADE=3.4 days Incidence of admissions caused by ADEs was 3.2% 76% considered preventable		Overall, proportion of preventable ADEs occurring in ambulatory settings that result in hospitalization range from 43.3% to 80% (9 studies worldwide)
Roebuck et al *Health Affairs* (2011)	Retrospective review of claims data for 135,008 people with employer-sponsored insurance using CVS Caremark	CHF HTN Diabetes Dyslipidemia	MPR[3] CHF: 0.40 HTN: 0.59 Adherence rates ranged 34%-51% (>80% adherent)	Adherent patients had ED visits between 0.01 and 0.04 per patient per year (need baseline population from DHCS to calculate OR=.01/baseline)	Adherent patients had fewer inpatient hospital days (among those 65+) CHF – 5.87 fewer days HTN – 3.14 fewer days Diabetes - 3.41 fewer days Dyslipidemia – 188 fewer days	--	Adherence = increased pharm spending CHF - $1058 more HTN - $429 Diabetes - $656 Dyslipidemia - $601 Adherence = reduced overall medical spending CHF - $8,881 less HTN - $4,337 Diabetes 0 $4,413 Dyslipidemia - $1,860 Annual per person

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Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
							savings due to adherence(65+) CHF - $7893 HTN - $5824 Diabetes – $5170 Dyslipidemia - $1847 Cost-benefit ratio from adherence (65+): CHF 8.6:1 HTN 13.5:1 Diabetes 8.6:1 Dyslipidemia 3.8:1
Schulz et al *Am J Geriatric Pharm* (2011)	Prospective cohort study of a state **Medicaid** home and community-based waiver program comparing nursing home admission rates in intervention (n=273 enrolled in a Medication Mgmt. System (per CMS)) and control group (n=800). 30-day intervention w/ 1 yr follow-up. Intervention used blister packs and	Nonspecific	--	--	--	Intervention group 66% less likely to be admitted to NH Control patients were 2.94 times more likely to have NH admission Participation in the intervention was	Adjusted OR Intervention group 0.34 OR of being admitted to NH (compared to control group) • Renal failure: 2.281 • Seizure: 2.547 • HTN: 0.408 • Emphysema: 0.397 After 120 days with no intervention, nursing home rate for intervention group increased to a similar

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Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
	coordinating service to promote communication b/t case manager, caregivers, providers (pharmacists/physicians)					associated w/ avoiding 5 NH admits/100 persons	rate in control group No LOS reported;
Sokol et al *Medical Care* (2005)	Retrospective cohort design of 137,277 patients <65 yrs. w/ single employer-sponsored insurance. 12 mon. time frame Med. Adherence measured by days of supply	Diabetes HTN Hypercholester-olemia CHF	--	--	Weighted ave. risk calculated from study **Diabetes** 17.8% **HTN** 20.08% **Hypercholesterolemia** 18.01% (not sig.) **CHF** 78.35% (not sig.)	--	All-cause hospital risk significantly higher for lowest level of adherence Cited other adherence at 45%-50%
Soumerai et al *NEJM* (1991)	Retrospective 36 mos. claims data analysis of matched cohort in Medicaid NH (n=411) and NJ (n=1375) to study impact of 3-drug limit policy in NH, as compared with no limit policy in NJ. Adults 60 yrs +with at least 3 meds (1 chronic med.)/mo	Nonspecific	NA	--	--	Baseline: 2.3% NH vs. 2.1% in NJ After rx policy cap: 10.6% NH vs. 6.6% NJ RR of admission with cap: 1.8 Risk of	

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Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
						admission was greatest among those who were sicker: RR=2.2 14.4% of NH bens regularly taking 3+ drugs entered LTC LOS: 32% stayed 6months or less and 57% stayed 12+ months	
Stuck et al JAMA (2002)	Systematic Review and meta-analysis of 18 trials (worldwide) of the effect of home visits to prevent nursing home admission and functional decline in elderly people (+65 yrs)	Nonspecific	Not measured	--	--	---	Effect of NH admission was greater for more frequent home visits: pooled RR was 0.66 (CI 0.48-0.92) for >9 visits but 1.05 (CI 0.85-1.30) for 0-4 visits. Preventive home visits with multiple follow up visits and multi-dimensional geriatric

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Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
							assessments, targeted at persons at lower risk of death (72-77 yrs vs. 80-81 yrs) appear to be effective in reducing functional decline and NH admits.
Thomsen et al *Annals of Pharmacotherapy* (2007)	Systematic Review of 29 studies (worldwide) of incidence and characteristics of preventable ADE (pADE) in ambulatory care Study heterogeneity in outcomes, population, methods, definitions of ADEs		--	--	36.6% (median) of pADEs requiring hospitalization are due to NA Related studies report % (n) 20.9 (14) 23.1 (9) 34.4 (33) 38.8 (69) 41 (15) 46 (23)	--	
Winterstein *Annals of Pharmacotherapy* (2002)	Systematic review of 15 studies (worldwide, published 1980-1999) on preventable drug-related admissions (PDRA)	Nonspecific	--	--	15 studies showed a median PDRA prevalence of 4.3% (IQR 3.1, 9.5%);	--	No meta-analysis due to high degree of study heterogeneity
Zed et al *Canadian Medical Association Journal* (2008)	Prospective observational study randomly selected ED patients over 12 week period. Of 1017	Nonspecific		12% ED visits (n=122) attributed to ADE of which 68% were	36.9% of 122 ADE patients were admitted to hospital for median LOS of 8 days	--	??3.3% of ADE visits are adherence related? [12% (total ED visits related to ADE) x 27.9% (nonadherence)

Table B2. Study Findings About Probabilities of Adherence-Related ED Visits, Hospital or Nursing Facility Admissions							
Citation	**Study Methodology**	**Condition**	**Measure of (Non) Adherence (%)**	**ED Visit Measures**	**Hospital Admission Measures**	**Nursing Facility Admission Measures**	**Other Outcome Measures**
	enrolled, 122 (12%) were drug related Canadian tertiary care hospital			deemed preventable 27.9% (n=34)of ADE visits (122) deemed nonadherence related (3.3% ED visits nonadherence related [1017/34=3.3] for OR 1.03)			] Polypharmacy (mean=5 meds) and comorbid conditions (mean=2.5) significantly assoc. with ADE visits

Table B3. Study Findings About Effectiveness of Medication Dispensing Machines (MDMs)				
Citation	**Study Methodology**	**Outcome Measures**	**Findings**	**Notes**
Buckwalter et al *Journal of Gerontological Nursing* (2004)	Review of two preliminary studies: **A) Iowa VNA recruited 12 patients aged 33-86 yrs** with medical and/or psychiatric Dx w/ 3 mos baseline-12 mos follow-up	1) Frequency home health visits; 2) dispensing rates; 3)# of technical support requests for machine	Machine in home averaged 5.1 mos (2-+7 mos.) **Frequency of home visit** did not change, but less time spent on adherence issues; **adherence rate** improved after initial adjustment 98.2% (65 missed of 3,737 doses monitored); 10 **technical support requests** for 3,737 doses (7-maintenance and 3 improper loading)	Relied on status reports generated by the machine. Studies are unpublished in peer-reviewed medical journals. No evidence for review is available.
	B) **CA Health Professionals Plus Home Health Care Mgmt**: MD.2 with 89 elderly or disabled pts and control group of 45 elderly or disabled adults used Medi-sets (pill boxes) over 6 mos.	1) Hospital admissions 2) ED visits 3) # of meds taken 4)Missed Meds	1) **Hospitalization/pt** for MD.2=0.09 and 0.42 Medi-Set 2) **ED visit/pt** for MD.2=0.18 and 0.42 for Medi-Set 3) **# of Rx/Pt** for MD.2= 7.62 and 8.65 for Medi-Set 4) **Missed dose/pt** MD.2=0.62 and Medi-Set 3.39 (over 2 mos) **Total missed doses/ pt** over 6 mos MD.2=2.9 and 7.31 for Medi-Set	Statistical significance/CI not reported
Farris (2006-2008) *"MD.2 Medication Dispenser Medication Adherence Study"*	RCT; 300 patients randomized.	Primary Outcomes • The rate of hospitalizations and emergency room visits will be compared between the MD.2 and control clients [Time Frame: per month (30 client days) over 6 consecutive months] Secondary Outcome	Research status unknown	Results unpublished Study status unknown at clinicaltrials.gov No response to UCD email inquiry

Table B3. Study Findings About Effectiveness of Medication Dispensing Machines (MDMs)				
Citation	**Study Methodology**	**Outcome Measures**	**Findings**	**Notes**
		Measures: • Compare the length of time in case management for MD.2 clients to control clients. [Time Frame: Over 6 consecutive months.] • Measure changes in caregiver stressors and burden between those with the MD.2 and those with their usual medication routine. [Time Frame: Over 6 consecutive months] • Determine if cognitive and functional characteristics influence compliance rates among the frail elderly using the MD.2. [Time Frame: Over 6 consecutive months]		
Naditz *Telemedicine and e-Health* (2008)	Grey literature summarizing 2 studies	Adherence ED visits	Med-eMonitor: **Baseline adherence** 40%-50%; improved to 90%-95% Dispense-a-Pill : **ED visits** reduced by 60% for CHF patients	Neither study found in peer-reviewed medical literature. No data for review could be found.
Marek (study funded 2006-2011)	RCT –500 elderly pts; three arms to the trial, one with the MD2 machine and a nurse coordinator, one with a medplanner and a	At least adherence and health outcomes and maybe related health care costs	"Both the MD2 and the [med]planner groups had significantly better clinical outcomes (GDS geriatric depression survey, SF36 Health Status survey, MMSE, PPT) when compared to the	Unpublished results to date: expected publication Fall 2011.

Table B3. Study Findings About Effectiveness of Medication Dispensing Machines (MDMs)				
Citation	**Study Methodology**	**Outcome Measures**	**Findings**	**Notes**
	nurse coordinator, and a control group.		control group at 12 months. However, there were no significant differences between the MD2 group and the planner group in the clinical outcomes. The nurse care coordinator was the factor making the difference. Nurses visited the subjects at least every 2 weeks and filled either the machine or planner. In addition, they followed up with the subjects prescribing providers and monitored the subjects for health problems."—per researcher's communication with UCD via email, July 2011.	
Sather et al *J of Am Pharmacists Association* (2007)	Non-controlled case series 3 patients with MD.2 in home for 3 months	Adherence and refill persistence	**Baseline Adherence**: 4-5 doses/week missed – **post intervention adherence** 99.2-100% recorded over 3 mos. (0-2 doses missed during time period) **Refill persistence** improved for 2 patients (3rd used 90-day Rx)	Relied on status reports generated by the machine (reports included doses dispensed on time/early, missed doses, calls made to caregivers) Most non-adherence events (8 of 11) attributed to caregiver error or pt absence due to hospital admission
Touchette and Winters (study funded 2010)	Non-randomized 2 arm: intervention receives "Telepharmacy Robotic Medicine Delivery Unit (TMRDU)" plus medication management; control group receives only medication management in hospital-based setting.	Primary Outcome Measures: Adherence as measured by pill counts and self report (Morisky 8-item) at baseline, one, two and three months Secondary Outcome Measures: pain, psychological well-being, health related quality of life, cost at baseline, one, two, three months	None available: Study end date: June 2011	Increased number of patients with combat related impairments (traumatic brain injury, post traumatic stress disorder and polytrauma)has lead to sub- optimal medication self management. TRMDU is a medical device developed by INRange Systems Inc. that delivers medications and emits a sound alert to assist the patient. It can be used in a hospital, clinic, or residential setting and remotely

Table B3. Study Findings About Effectiveness of Medication Dispensing Machines (MDMs)				
Citation	**Study Methodology**	**Outcome Measures**	**Findings**	**Notes**
				accessed by the health care professionals. It allows physicians and other prescribers to remotely change scheduling or adjust prescriptions.
Winland-Brown and Valiante *Outcomes Management in Nursing Practice* (2000)	RCT: 61 pts, mean age 87 yrs 3 arm **a)** automated dispenser (n=24) vs. **b)** pre-poured pill-box (n=16) vs **c)** control group (n=21). 40 randomly assigned to mgmt program and 21 were matched to form control group.	Adherence measured at 1,3 and 6 mo. by pill count and health outcomes	At 6 mo,: **Group a)** 2.0 missed dosages (mean 19.7) **Group b)** 12.2 missed dosages (mean 15.1) **Group c)** 17.7 missed dosages (mean 1.7) Findings are statistically sig at P< .0001	Service Utilization **Group a)** all 24 had prolonged hospital visit pre-study; 3 hospitalized during study **Group b)** 7 hospitalized pre study; 4 hospitalized during study **Group c)** hospitalization not reported pre-study; 12 hospitalized during study

Table B4. Study Findings About Non-MDM Interventions to Improve Medication Adherence				
Citation	**Study Methodology**	**Intervention**	**Outcomes Measured**	**Conclusion**
Conn et al *The Gerontologist* (2009)	Meta-analysis of 33 published and unpublished RCTs about adherence, health outcomes and health care service utilization (11,827 patients)		Mean effect sizes (ES) for med adherence (MA), knowledge, health outcomes and health services utilization	Interventions significantly improved MA (Effect size [ES] = 0.33), knowledge (ES = 0.48), and diastolic blood pressure (ES = 0.19). Nonsignificant effects were found for systolic blood pressure (ES = 0.21), other health outcomes (ES = 0.04), and health services utilization (ES = 0.16). Moderator analyses showed larger adherence ESs for interventions using special medication packaging, dose modification, participant monitoring of medication effects and side effects, succinct written instructions, and std. interventions
George et al *Drugs and Aging* (2008)	Systematic Review	8 controlled studies of community dwelling elderly taking 3+ long term meds. Studies had min. 60 pts/arm, >4 weeks follow-up w/ baseline and post-intervention adherence. Interventions were conducted by community or hospital pharmacists	Change in adherence	4 of 8 studies showed significant improvement: Relative change in adherence in intervention groups ranged from -13% to +55% (mean +11.4%).
Haynes et al *Cochrane* (2008)	Updated Systematic Review summarizing results of RCTs of interventions to improve adherence. (70 RCTs for long term trmts)	Range in complexity and number: information, counseling, reminders (pill packaging, refill reminders), self-monitoring, family therapy, rewards (pay, reduced visits)	Adherence and trmt outcome	For long term trmts: 36 of 83 interventions reported in 70 RCTs were associated with improvements in adherence and 25 interventions showed improvement in at least 1 trmt outcome. All interventions with stat. sig success were complex, however even the most effective interventions did not result in

Table B4. Study Findings About Non-MDM Interventions to Improve Medication Adherence				
Citation	**Study Methodology**	**Intervention**	**Outcomes Measured**	**Conclusion**
				large improvements in adherence or treatment outcomes.
Holloway and van Dijk *WHO* (2011)	Report on rational use of medicines (Literature review)			Multiple systematic reviews meta-analyses find that adherence to long term treatment requires multifaceted intervention but do not achieve large improvement in outcomes or adherence
Misono et al *AJMC* (2010)	Systematic review of 13 RCTs (worldwide) of HIT used to improve medication adherence for diabetes or HTN	McKenney study: Electronic pill cap w/ audiovisual alarm and dispensing tracking for 35 seniors (control group 35) for 2- 12 week phases	MPR calculated by pill count Calculated Cohen's effect size for 1-way reminder systems; 2-way interactive systems to asses interventions' magnitude of effectiveness	Adherence 95.1% and 94.6% (phases 1 and 2) week intervention group vs. 78% and 79% control group (phases 1 and 2) Stat sig. differences Overall Review concluded: Little data about HIT efficacy in improving med. adherence for cardiovascular disease and diabetes, although simple reminder systems appear effective. 7 studies had very small ES, 2 had small ES and 1 had large ES (3 could not be calculated)
Schulz et al *Am J Ger Pharmacotherapy* (2011)	Prospective cohort study of 1073 community-dwelling Medicaid beneficiaries (mean age 72 yrs). 120 day study period with "post-period" representing 30 days past last Rx dispensed.	273 elderly received Rx medications dispensed into a calendar card (blister packs) at local pharmacies and were supported by health educator to coordinate medication-related problems (by phone for patients and providers). Matched control group of 800 persons received no intervention	Nursing home admissions	Statistically significant fewer nursing home admissions occurred in the intervention group using service coordinator and blister packs than the control group (post-intervention 5 nursing home admissions per 100 persons were avoided)
Van Eijken et al *Drugs and Aging* (2003)	Systematic Review of 14 RCTs to improve med adherence in community dwelling elders	Telephone reminder calls, automated dispenser, pill organizers, charts, educational interventions (oral and written instructions,)	Adherence	Multifaceted interventions improved adherence more than single interventions; tailored (to age-related barriers) interventions seemed to

Table B4. Study Findings About Non-MDM Interventions to Improve Medication Adherence				
Citation	**Study Methodology**	**Intervention**	**Outcomes Measured**	**Conclusion**
		computer feedback, reminder calendars, pharmacist and nurse support		increase success more than generalized interventions. Ambiguous results for pharmacist-led interventions with some studies showing improved adherence and other showing no effect.

Appendix C: Cost Model Approach, Assumptions, and Caveats

This appendix defines the various cost model inputs and the assumptions and limitations informing them.

Target population used in Cost Modeling Exercise

This report presents two cost models each with their own sensitivity analyses. In both models, the denominator population is composed of FFS Medi-Cal beneficiaries 18 years and older with at least one ASC[19] and using ≥5 chronic condition medications concurrently[20]. The cost model in the body of the report presents the outcomes related to the *dual eligible* population (n=215,936) and Appendix D presents the outcomes of the cost model focusing on the *non-dual eligible* population (n=101,369). We focused on dual eligibles based on requirements in SB 72 to recover Medicare cost-savings through a state-federal share-of-savings agreement. Additionally, seniors, as a population, have a higher likelihood of multiple chronic conditions and polypharmacy, and literature indicates this to be a high yield population for medication non-adherence. As explained in Section I: *Review of Evidence-Based Literature* of this report, the two key criteria (ASC and polypharmacy) are the most promising predictors of non-adherence when using administrative data exclusively to identify the target population who will benefit most from MDMs.

These are the UCD-Center for Healthcare Policy and Research's (CHPR) best estimates of appropriate target populations—although another set of criteria (e.g., nursing home or hospital admission within the previous 12 months) could be applied to either population before commencing the evaluation to further winnow the highest risk population. DHCS may not agree with this method and is not obligated to implement this method.

BASE CASE MODEL

Episode Count: Using DHCS data, counts the number of nursing facility stays, hospital admissions, and ED visits experienced by the target population in 2005. 2005 is the most recent year for which DHCS has pharmacy claims data, which was necessary to determine the polypharmacy population. (As a result of "Part D: Prescription Drug Coverage" implemented by the Medicare Modernization Act in 2006, Medicaid agencies no longer provide prescription drug coverage to dual eligibles and, thus no longer have timely access to pharmacy claims data.) DHCS 2005 claims data are the best available data to estimate the target population's polypharmacy experience.

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[19] CHPR defines adherence-sensitive conditions as those chronic conditions whose clinical outcomes are sensitive to proper medication management. We derived the idea from the related concept of "ambulatory sensitive conditions:"these are conditions that benefit from high quality ambulatory care in the sense that good ambulatory care can avert subsequent emergency visits or hospitalizations. This list of adherence-sensitive conditions includes most of the diagnoses defined as ambulatory-sensitive by Bindman et al. (1995) plus serious mental health disorders. Our list includes angina, asthma, hypertension, coronary heart disease, congestive heart failure, chronic obstructive pulmonary disorder, diabetes, major depressive disorder, schizophrenia and bipolar disorder.

[20] Polypharmacy is defined as five or more routine oral medications dispensed concurrently for a minimum of 90 consecutive days. When possible, 2009 Medi-Cal data were used to calculate costs and service use. However, the target population was identified using 2005. Because no recent Medicare data were available to calculate the polypharmacy population, we relied on 2005 Medi-Cal data before Medi-Cal was relieved of paying outpatient prescription drugs by Part D under the Medicare Modernization Act 2006 (see Appendix D for data extraction description).

Proportion of episodes due to FCD-NA: Literature supports the assumption that approximately 5% of hospital admissions and emergency department visits are due to forgetfulness-, confusion-, or cognitive deficit-related non-adherence (FCD-NA) (See Section I: *Review of Evidence Based Literature*) CHPR applied the same figure to nursing home stays, despite a paucity of data. CHPR assumes that MDMs are more likely to avert short stays (in which the clinical harm due to non-adherence is reversible) than long stays (which suggest permanent damage or progressive functional decline). Our estimates, therefore, represent an upper bound for the effect of MDMs on nursing home costs.

Number due to FCD-NA: Product of episode count times proportion due to FCD-NA.

Relative Risk Reduction Attributable to MDMs: We assume that MDMs will prevent 90% of FCD-NA episodes. Theoretically, MDMs are capable of eliminating 100% of nursing home stays, hospital admissions, and ED visits due to FCD-NA. However, this is true only with perfect implementation (no machine-malfunctions, no operator errors, 100% appropriate response to alarms, etc.).

In the base case model, we assume that MDMs avert 90% of FCD-NA episodes. This assumption accommodates a series of possible machine failures or operator errors. Because there is a lack of strong evidence regarding the effectiveness of MDMs, we extrapolated results from other studies regarding human-machine interactions; specifically the effectiveness of computerized medication reconciliation tools to decrease medication discrepancies in hospitals. Results from those studies demonstrate that when providers used the system correctly, medication discrepancies were reduced, but not by 100%. Researchers reported operator error (defined as lack of knowledge, confusion, training or acceptance by clinicians) as a key reason for reduced effectiveness (Metzger, et al., 2010; Schnipper et al., 2009; Galanter et al., 2010). Additionally the 90% assumption is not necessarily incompatible with claims that MDMs produce adherence rates of 98% in the population at large. MDMs may eliminate a large proportion of non-adherence but have less impact on health care service utilization because, as discussed in this report, non-adherence does not always result in health care utilization.

Episodes Averted: Product of FCD-NA episodes times MDM-related relative risk reduction (90%).

Medicare, Medi-Cal and Total Government Estimated Costs per Episode:
DHCS does not have routine access to Medicare data; therefore, Medicare costs per episodes are based on evidence from the literature and DHCS claims data.

Average Cost of Nursing Facility/episode: $40,077: We considered four different sources for Medicare's average cost of nursing home stays with the average cost per day ranging between:

- $131/day (Medicaid) and $165/day (private payor) (Stewart et al, 2006))
- $192/day (all payor) (Kaiser Commission on Uninsured, 2006)
- $227/day (Medicare) and $185/day (Medicaid) *(OSHPD LTC Facilities Utilization and Financial Trends,* Spring 2010)

Ultimately, we chose to use a combination of 2005 DHCS data, which estimated an average cost to Medi-Cal of $24,221/episode (ALOS of target population=200 days and used $192/day [Kaiser, 2006]) as a midpoint between the high and low Medicare estimates ($227/day vs. $165/day). In 2005, Medi-Cal's dual eligible ASC/polypharmacy population had an average length of stay of 200 days with an average cost of $129 for days 101-200. Generally, Medicare pays for the first 20 days of nursing facility care provided the recipient meets certain criteria (at least a 3 day hospital stay, physician orders, etc.). We assume that $192 x first 20 days = $3,840. For days 21-100, we assume Medi-Cal pays the $141.50 copayment for dual eligibles and Medicare generally pays the remaining balance of the facility bill ([$192 - $141.50] x 80 days =

$4,040. The total Medicare obligation for a 200-day nursing facility stay is estimated to be $4,040 + $3,840 = $7,880 (see Tables 2 and D-1).

The total Medi-Cal obligation for a dual eligible's 200-day stay is estimated to be $24,220. Thus, the total estimated cost for a nursing facility admission of 200 days is $7,880 + $24,220 = $32,100. Although this total is a little lower than the average annual cost of cost of nursing facility care reported in the published literature ($67,525 to $70,000/year [OSHPD, 2010; Stewart et al, 2006]), this 200-day ALOS is presumed to be on the high end for *an FCD-NA-related admission*. This is the closest California-specific estimate that CHPR can find.

Table C1. Cost-sharing between Medicare and Medi-Cal for Dual Eligible Nursing Facility Stays (ALOS=200 days)

Payor	Day 1-20	Days 21-100	Days 101-200	Total Payor Obligation
Medicare	$192 x 20 = $3840	([$192 - $141.50] x 80 = $4,040	$0	$3840 + $4040 =$7,880
Medi-Cal	$0	$141.50 x 80 = $11,320	$ 129 x 100 = $12,800	$11,320 + $12,900 =$24,220

(The average cost of nursing facility/episode ($30,867) for the *non-dual* population is based exclusively on 2005 Medi-Cal reimbursement claims data.)

Average Cost of Inpatient Hospitalization/ Admission $17,840: Two sources were considered for calculating the average cost of an inpatient admission, both from the Agency for Healthcare Research and Quality (AHRQ). The first source studied the elderly age 65 and older in the Medical Expenditure Panel Survey (MEPS) and estimated the 2006 average expenses as $2,714/diem (inclusive of payments from all sources for physician and facility billed services) (Machlin, 2009). The second AHRQ source relied on the Healthcare Cost and Utilization Project (HCUP), which calculated the 2008 hospital charge-to-cost ratio at $9,300/stay (ALOS = 4.5 days) or $2,066/day (Stranges et al, 2011). These numbers were very similar, although they used different datasets from 2006 and 2008. Another source, America's Health Insurance Plans, reports the net inpatient revenue per day (using OSHPD data) for 2005 was $1,647 (Medi-Cal) and $1,818 (Medicare) (AHIP, 2010). **For this cost model, we chose to use the Machlin MEPS data because it focused on the elderly population rather than the general population (which has fewer characteristics in common with the MDM target population). Furthermore, the Machlin analysis explicitly included physician fees and reported average expenses for emergency room visits, the costs of which we also seek to capture in the models**. If this is an overestimate of cost, the marginal losses or savings to Medi-Cal would be minimal due to the relatively small number of averted episodes.

Using claims data, DHCS estimated that Medi-Cal paid $1,556/admission (close to the $1,132 Medicare deductible that Medi-Cal pays on behalf of dual eligibles) (Medicare and You, 2011). Using the Machlin per day cost, we estimate that Medicare would pay about $16,284/admission (6.0 days ALOS x $2,714 = $16,284). Therefore, we estimated a total cost to the government of$17,840/admission ([Medicare]$16,284 + $1,556 [Medi-Cal] =$17,840 [total government payment]).

(The average cost of inpatient hospitalization/admission ($7,527) for the *non-dual* population is based exclusively on 2005 Medi-Cal reimbursement claims data.)

Average Cost of ED Visits $902: We considered three sources that used MEPS data to estimate the average total payment for ED visits (from all sources) ranging from $560 (2003) to $651 (2006) (Machlin, 2006; Machlin,2009; Hsai et al 2008). **We chose the Machlin MEPS analysis ($651/visit), for the aforementioned reasons that the population more closely aligned with the MDM target population and the analysis reported average inpatient hospital costs, therefore the data source was consistent for two of the variables in this cost model.** DHCS claims data indicates that Medi-Cal pays about $251 per ED visit for the target population, thus $651 (Medicare) + $251(Medi-Cal) = $902 (total government payment).

(The average cost of ED visits ($1,219) for the *non-dual* population is based exclusively on 2005 Medi-Cal reimbursement claims data.)

Estimated gross savings to Medicare: Product of episodes averted times cost per episode to Medicare.

Estimated gross savings to Medi-Cal: Product of episodes averted times cost per episode to Medi-Cal.

Estimated total gross savings to government (Medicare and Medi-Cal): Product of total episodes averted times total costs per episode.

MDM expenses @$600 per capita: DHCS expects that the devices will be eligible for a 50/50 split between the state General Fund (GF) and Federal Financial Participation (FFP) based on their interpretation that the devices fall under current DME definitions for both Medicaid and Medicare, and that this program is likely to operate under a waiver. Therefore, 50% of costs for the device rental are allocated to Medi-Cal and 50% are allocated to Medicare. If no waiver is granted, the full cost burden of MDM deployment rests with Medi-Cal and cost savings /losses will be reduced/increased accordingly.

Estimated net savings (loss) to Medicare: Net loss to the government assuming MDMs are distributed to the entire population of dual eligibles meeting specified clinical criteria (n=215,936, based on 2005 data), and that Medi-Cal and Medicare share equally the cost of devices. If no 50/50 split in cost sharing is available through a waiver or FFP, Medi-Cal would assume the total loss.

Estimated net savings (loss) to Medi-Cal: Net loss to the Medi-Cal budget (SGF and FFP) assuming MDMs are distributed to the entire population of dual eligibles meeting specified clinical criteria (n=215,936, based on 2005 data) and that Medi-Cal and Medicare share equally the cost of devices.

Estimated net savings (loss) to government: Net savings (loss) to Medi-Cal and Medicare combined: Net savings (loss) to the government assuming MDMs are distributed to the entire population of dual eligibles meeting specified clinical criteria (n=215,936, based on 2005 data)

SENSITIVITY ANALYSES

Scenario 1: Pessimistic Model

The pessimistic scenario assumes that the proportion of hospital admission due to FCD-NA is 2%, which is a little lower than reported in many studies but still clinically plausible. We also adjusted nursing facility admissions to 3% and ED visits to 5%. In addition, we changed the relative risk reduction to 80% to account for human error, training problems, potential issues with technology acceptance by elderly

recipients, machine malfunctioning, etc. (Metzger, et al., 2010; Schnipper et al., 2009; Galanter et al., 2010). These adjustments offer a more conservative estimate of the effect of the device on preventable admissions due to FCD-NA and possible savings.

Scenario 2: Optimistic Model

The optimistic scenario assumes 10% of nursing home admissions are related to non-adherence, which CHPR considers a generous assumption based on the lack of evidence (see conclusions from literature review). It also assumes a 50% increase in the base case proportion of hospital admissions and ED visits (from 5% to 7.5%). We also increase the device performance to 98% effective, which reflects the best case scenario according to literature and manufacturer claims.

Appendix D: Cost Model and Sensitivity Analysis for Non-Dual FFS Medi-Cal Population

The results of the non-dual eligible cost model and sensitivity are very similar to the dual eligible population presented in Section II.

Table D-1 presents the base case model, or the most realistic estimate of potential savings achievable. These estimates rest on two key assumptions: 1) the percentage of nursing facility stays, hospital stays, and emergency department visits due to FCD-NA; and 2) machine effectiveness. We attribute 5% of stays and ED visits to FCD-NA based upon the Col study (1990) and 90% as an estimate of machine effectiveness based on studies of other medication management interventions, in the absence of published RCTs on MDMs. *The net loss to Medi-Cal is estimated to be $5.6 million.*

Table D-2 provides a "pessimistic" scenario in which assumptions about the fraction of health care service utilization associated with FCD-NA come from the lower end of the literature-based evidence (3% nursing facility admissions, 2% hospital admissions and 5% ED visits). Device performance is reduced to 80% effectiveness, meaning that in actual use, MDMs ensure adequate adherence 80% of the time. Under this scenario, we estimate that *Medi-Cal would lose about $18 million.*

Table D-3 presents an "optimistic" scenario that includes more generous assumptions about the prevalence of FCD-NA related nursing home admissions (10%), hospital admissions (7.5%) and ED visits (7.5%). Additionally, Table 3 assumes almost perfect device performance (98% effectiveness) based on manufacturer claims and some literature. In the aggregate, we believe these assumptions are unrealistic, but are included to demonstrate that, even under the most positive circumstances, large savings are difficult to achieve. This scenario produces an *estimated savings of approximately $12 million to Medi-Cal (to be divided evenly between the State general fund [SGF] and federal financing participation [FFP] budget categories)*. Under all scenarios, net savings are generally proportional to the number of Medi-Cal beneficiaries enrolled. If MDMs were provided to one-quarter of the 215,936 target population, savings would be about one-fourth as large.

Several factors contribute to these lower-than-expected-savings for both dual and non-dual populations: Even in the most optimistic scenario, the number of averted episodes attributable to MDMs is a small fraction of the total number of episodes incurred by this population. This is due in part to the relatively low proportion of all episodes that can reasonably be ascribed to FCD-NA. Additionally, we modeled costs and savings in a population of 101,369 individuals (representing 6% of the original source population of 1,716,210 Medi-Cal adults). Applying the models to a smaller population would decrease program expenses but also limit potential savings. On a case-by-case basis, some cost savings are probably achievable; however, this would require a more accurate risk prediction tool than is currently available.

TABLE D-1. BASE CASE ANALYSIS[a]: NON-DUAL ELIGIBLES					
Target Population: Non-Dual Eligibles Age ≥ 18 with ASC and Polypharmacy[b] (n=101,369 based on 2005 data)					
	NF	**Hosp**	**ED**	**Total**	**Notes**
Episode Count	2,640	47,999	89,096		Number of nursing facility stays, hospital admissions, and ED visits among the target population (2005).
Proportion due to FCD-NA	0.05	0.05	0.05		Literature supports assumption that approximately 5% of hospital admissions and ED visits are due to FCD-related non-adherence (FCD-NA=forgetfulness, confusion, cognitive deficit due to non-adherence). We assume the same figure for nursing facility stays despite a paucity of data.
Number due to FCD-NA	132	2,400	4,455		Product of episode count times proportion due to FCD-NA.
Relative risk reduction attributable to MDM	0.90	0.90	0.90		Assumes that MDMs will prevent 90% of FCD-NA episodes. Theoretically, MDMs are capable of eliminating 100% of health services use due to FCD-NA (i.e., 5% of all admissions in base case). However, we must account for some machine-malfunctions, operator errors, etc. See Appendix C for details.
Episodes averted	119	2,160	4,009		Product of FCD-NA episodes times MDM-related relative risk reduction (90%).
Estimated Costs/Episode	**NF**	**Hosp**	**ED**	**Total**	
Medi-Cal costs/episode	$30,867	$7,527	$1,219		Based on DHCS 2005 claims data (cost and utilization) for the ASC + polypharmacy population and grey literature. See Appendix C for details.
Estimated Gross Savings	**NF**	**Hosp**	**ED**	**Total**	
Estimated gross Medi-Cal savings	$3,667,000	$16,257,981	$4,887,361	$24,812,342	Product of episodes averted times cost per episode to the Medi-Cal program.
Estimated MDM Expenses					
Assumed federal share of MDM expenses @ $300 per machine				$30,410,700	Total cost of MDM machine rental to federal government for the entire target population at $50/month.
Assumed Medi-Cal MDM expenses @ $300 per machine				$30,410,700	Total cost of MDM machine rental to Medi-Cal for the entire target population at $50/month.
Assumed **total** MDM expenses @ $600 per machine				$60,821,400	DHCS expects that the devices will be eligible for a 50/50 split between the state General Fund (GF) and Federal Financial Participation (FFP) based on their interpretation that the devices fall under current DME definitions for both Medicaid and Medicare, and that this program is likely to operate under a waiver.
Estimated Net Savings[c]					
Estimated net savings (loss) to Medi-Cal				($5,598,358)	Net savings (loss) to the Medi-Cal budget assuming MDMs are distributed to the entire target population.

Note: About one-third of non-dual FFS Medi-Cal beneficiaries will be transitioning into Medi-Cal managed care in 2012, thus some reduction in the baseline population with ASC and polypharmacy and their associated health care use can be assumed. However, lack of timely access to pharmacy data from Medicare prevented an analysis of the most current relevant population. We would expect that the cost-savings ratio would be similar under this new managed care policy.

TABLE D-2. SENSITIVITY ANALYSIS: PESSIMISTIC SCENARIO[a]: NON-DUAL ELIGIBLES					
Target Population: Non-Dual Eligibles Age ≥18 with ASC and Polypharmacy[b] (n=101,369 based on 2005 data)					
	NF	**Hosp**	**ED**	**Total**	**Notes**
Episode Count	2,640	47,999	89,096		Number of nursing facility stays, hospital admissions, and ED visits among the target population (2005).
Proportion due to NA/FCD	0.03	0.02	0.05		Takes low-end estimates from literature on hospital admissions and ED visits due to FCD-related non-adherence (FCD-NA=forgetfulness, confusion, cognitive deficit due to non-adherence).
Number due to NA/FCD	79	960	4,455		Product of episode count times proportion due to FCD-NA.
Relative risk reduction attributable to MDM	0.80	0.80	0.80		Assumes low-end estimate for product performance (80%). Theoretically, MDMs are capable of eliminating 100% of health service use due to FCD-NA. However, we must account for machine-malfunctions, operator error, user acceptance, adequate training, etc. See Appendix C for details.
Episodes averted	63	768	3,564		Product of FCD-NA episodes times MDM-related relative risk reduction (80%).
Estimated Costs/Episode	**NF**	**Hosp**	**ED**	**Total**	
Medi-Cal costs/episode	$30,867	$7,527	$1,219		Based on DHCS 2005 claims data (cost and utilization) for the ASC + polypharmacy population and grey literature. See Appendix C for details.
Estimated Gross Savings	**NF**	**Hosp**	**ED**	**Total**	
Estimated gross **Medi-Cal** savings	$1,955,733	$5,780,616	$4,344,321	$12,080,670	Product of total episodes averted times total cost per episode to the Medi-Cal program.
Estimated MDM Expenses					
Assumed federal share of MDM expenses @ $300 per machine				$30,410,700	Total cost of MDM machine rental to federal government for the entire target population at $50/month.
Assumed Medi-Cal MDM expenses @ $300 per machine				$30,410,700	Total cost of MDM machine rental to Medi-Cal for the entire target population at $50/month.
Assumed **total** MDM expenses @ $600 per machine				$60,821,400	DHCS expects that the devices will be eligible for a 50/50 split between the state General Fund (GF) and Federal Financial Participation (FFP) based on their interpretation that the devices fall under current DME definitions for both Medicaid and Medicare, and that this program is likely to operate under a waiver.
Estimated Net Savings[c]					
Estimated net savings (loss) to Medi-Cal				($18,330,030)	Net savings (loss) to the Medi-Cal budget assuming MDMs are distributed to the entire target population.

Note: About one-third of non-dual FFS Medi-Cal beneficiaries will be transitioning into Medi-Cal managed care in 2012, thus some reduction in the baseline population and their associated health care use can be assumed. Lack of timely access to pharmacy data from Medicare prevented an analysis of the most current relevant population. Nevertheless, we would expect that the cost-savings ratio would be similar under this new Medi-Cal policy.

TABLE D-3. SENSITIVITY ANALYSIS: OPTIMISTIC SCENARIO[a]: NON-DUAL ELIGIBLES					
Target Population: Non-Dual Eligibles Age ≥18 with ASC and Polypharmacy[b] (n=101,369 based on 2005 data)					
	NF	**Hosp**	**ED**	**Total**	**Notes**
Episode Count	2,640	47,999	89,096		Number of nursing facility stays, hospital admissions, and ED visits among the target population (2005).
Proportion due to NA/FCD	0.10	0.075	0.075		Increased the literature-supported assumptions by 50% to 7.5% of hospital and ED use due to FCD-NA –the highest plausible estimate for hospital admissions, ED visits, and assumed a generous 10% of nursing facility admits due to FCD-related non-adherence (FCD-NA=forgetfulness, confusion, cognitive deficit due to non-adherence).
Number due to NA/FCD	264	3,600	6,682		Product of episode count times proportion due to FCD-NA.
Relative risk reduction attributable to MDM	0.98	0.98	0.98		We assume that MDMs will prevent 98% of FCD-NA episodes, which is based on device manufacturer claims and a few small studies. See Appendix C for details.
Episodes averted	259	3,528	6,549		Product of FCD-NA episodes times MDM-related relative risk reduction (98%).
Estimated Costs/Episode	**NF**	**Hosp**	**ED**		
Medi-Cal costs/episode	$30,867	$7,527	$1,219		Based on DHCS 2005 claims data (cost and utilization) for the ASC + polypharmacy population and grey literature: Seep Appendix C for detailed explanation.
Estimated Gross Savings	**NF**	**Hosp**	**ED**	**Total**	
Estimated gross **Medi-Cal** savings	$7,985,910	$26,554,703	$7,982,690	$42,523,303	Product of episodes averted times cost per episode to Medi-Cal program.
Estimated MDM Expenses					
Assumed federal share of MDM expenses @ $300 per machine				$30,410,700	Total cost of MDM machine rental to federal government for the entire target population at $50/month
Assumed Medi-Cal MDM expenses @ $300 per machine				$30,410,700	Total cost of MDM machine rental to Medi-Cal for the entire target population at $50/month.
Assumed **total** MDM expenses @ $600 per machine				$60,821,400	DHCS expects that the devices will be eligible for a 50/50 split between the state General Fund (GF) and Federal Financial Participation (FFP) based on their interpretation that the devices fall under current DME definitions for both Medicaid and Medicare, and that this program is likely to operate under a waiver.
Estimated Net Savings[c]					
Estimated net savings (loss) to Medi-Cal				$12,112,603	Net savings (loss) to the Medi-Cal budget assuming MDMs are distributed to the entire target population.

Note: If the assumptions for FCD-NA-induced nursing home admissions, hospitalizations and ED visits were increased to 23%, 10% and 15% respectively, we would expect to see a savings of $20 million to Medi-Cal and net total savings to Medicare and Medi-Cal of $150 million. This estimate is included only to demonstrate that state-specific savings are still relatively low under exceptionally optimistic assumptions.

Footnotes to Tables D-1, D-2, and D-3

(a) See Appendices C and D for details on methods and assumptions

(b) CHPR defines adherence-sensitive conditions as those chronic conditions whose clinical outcomes are sensitive to proper medication management. We derived the idea from the related concept of "ambulatory sensitive conditions:"these are conditions that benefit from high quality ambulatory care in the sense that good ambulatory care can avert subsequent emergency visits or hospitalizations. This list of adherence-sensitive conditions includes most of the diagnoses defined as ambulatory-sensitive by Bindman et al. (1995) or serious mental health disorders. Our list includes angina, asthma, hypertension, coronary heart disease, congestive heart failure, chronic obstructive pulmonary disorder, diabetes, major depressive disorder, schizophrenia and bipolar disorder. The target population was identified using 2005 data. No recent Medicare data were available to calculate the polypharmacy population. Instead, we relied on 2005 Medi-Cal data before Medi-Cal was relieved of paying outpatient prescription drugs by Part D under the MMA 2003 (see Appendix D for methods description).

(c) Assumes that Medi-Cal and Medicare would equally share the cost of the MDM devices. If no waiver is granted, Medi-Cal will absorb greater losses in the base case model due to paying for the entire cost of the device.

Note: The savings (losses) accrue to the entire Medi-Cal budget, both the State general fund (SGF) and the federal financial participation portions (FFP). Therefore, the Medi-Cal savings (or loss) to the SGF is 50% of the total presented in Tables 2, 3, 4 and 5 (and Tables D-1, D-2, and D-3 in Appendix D).

Appendix E: Data Extraction Methods, Definitions, and Parameters from Medi-Cal 2005 Data

Appendix E presents analysis of nursing facility, inpatient hospital, and emergency room admissions that occurred to a subset of Medi-Cal eligibles in CY 2005, who were both polypharmacy (simultaneously taking 5 or more medications for a minimum of 90-days) and were diagnosed with an adherence-sensitive condition. CY 2005 was selected because beginning in 2006, drugs were paid by Medicare Part D and thus not found in Medi-Cal claims data. Furthermore, since reimbursements are of interest to this analysis, it was restricted to fee-for-service Medi-Cal. It is also important to keep in mind that reimbursement amounts in this report reflect actual Medi-Cal costs and do not reflect any payments made by Medicare. Medicare data was not available for this study. Also of import is that these Medi-Cal reimbursements are eligible for federal financial participation, meaning that the federal government will likely reimburse the state for about half of these expenditures.

The non-availability of Medicare data also presents another limitation to this analysis. Some unknown number of claims may be found in Medicare claims that are not reflected in Medi-Cal claims, thus the counts of admissions herein are conservative when considering the impact upon Medicare, but do not affect Medi-Cal counts and dollars.

The analysis is presented in 4 sections:

I. A description of the persons eligible for the analysis,
II. Definitions of the polypharmacy and adherence-sensitive conditions, and counts of such individuals,
III. The methodologies for identifying admissions and summarizing reimbursements, and
IV. Results: Tables presenting the results separately for dual-eligibles (those eligible for both Medi-Cal and Medicare) and non-dual-eligibles.

Data extracted from Medi-Cal eligibility and claims current as of 7/31/2011.

Section I: Persons Eligible for the Analysis

There were 6,574,866 individuals eligible for fee-for-service Medi-Cal for at least 1 month during CY 2005. From these the following exclusions were applied to identify our study population:

- Persons under 18 years of age as of mid-year 2005
- Persons who have less than 12 months of eligibility within the year,
- Persons in permanent long-term care aid (LTC) aid codes ('13' = Aged LTC, '23' =Blind LTC, '53' =Mentally Impaired LTC, '63'=Disabled LTC) for the entire year of interest.

Before these exclusions were employed, 3,452,211 were 18 years of age or older as of mid-year 2005 (See Table E-1). Non-adults will be excluded from this analysis.

Table E-1. Number of Medi-Cal Eligibles in CY 2005
By Age and Dual Eligibility

	Age		
Eligibility	**<18**	**18 or Older**	**All**
Non-Dual	3,122,482	2,425,338	5,547,820
Dual	173	1,026,873	1,027,046
All	3,122,655	3,452,211	6,574,866

A second exclusion was made for individuals without 12 months of Medi-Cal eligibility. Table E-2 shows that 1,695,350 such persons are excluded, leaving 1,756,861 in the study population.

Table E-2. Number of Adult Medi-Cal Eligibles
By Months of Eligibility in CY 2005 and Dual Eligibility

	12 Months of Eligibility		
Eligibility	**No**	**Yes**	**All**
Non-Dual	1,503,988	921,350	2,425,338
Dual	191,362	835,511	1,026,873
All	1,695,350	1,756,861	3,452,211

Finally, individuals with 12 month of eligibility in a permanent LTC aid code are excluded from the study population. Table E-3 shows that 40,651 individuals were in a permanent LTC aid code, leaving 1,716,210 in the study population.

Table E-3. Number of Adults with 12 Months of Medi-Cal Eligibility in CY 2005
By LTC Aid Code and Dual Eligibility

	Permanent LTC Aid Code		
Eligibility	**No**	**Yes**	**All**
Non-Dual	919,023	2,327	921,350
Dual	797,187	38,324	835,511
All	1,716,210	40,651	1,756,861

Table E-4 presents our final study population showing counts of persons in aid codes that indicate the individual is a senior or person with a disability (SPD). These codes include: '10', '14', '16', '20', '24', '26', '36', '60', '64', '66', '1E', '1H', '2E', '2H', '6A', '6C', '6E', '6G', '6H', '6J', '6N', '6P', '6V'. Nearly 65% of our study population are SPDs, comprised of 93% of the dual-eligibles and 46% of the non-duals.

Table E-4. Number of Adults with 12 Months of Medi-Cal Eligibility Without Permanent LTC Aid Codes in CY 2005 By Seniors and Persons with Disabilities Aid Code, and Dual Eligibility

	SPD		
Eligibility	**No**	**Yes**	**All**
Non-Dual	560,260	358,763	919,023
Dual	47,091	750,096	797,187
All	607,351	1,108,859	1,716,210

Section II: Polypharmacy and Adherence-Sensitive Conditions

Polypharmacy

Polypharmacy individuals are defined as those who routinely take 5 or more simultaneous medications. To identify these individuals, only medications that were taken orally and where a minimum of a 90-day supply was dispensed in 2005 were included in this analysis. The Hierarchical Ingredient Code List was used to equate similar medications that may be provided under varying doses and brand names. A 10-day lapse between the end of a supply and the next refill was allowed when calculating whether or not a combination of multiple dispensing instances met the 90-day threshold for inclusion. Finally the temporal relationship among the provision of these medications was examined.

Table E-5 shows the distribution of eligibles by the number of medications simultaneously dispensed. Twenty-eight percent (28%) of the study population were provided 5 or more medications simultaneously; herein these are referred to as *polypharmacy* individuals.

Table E-6 shows counts of polypharmacy individuals by dual-eligibility. Forty-five (45%) of dual eligibles and 14% of non-duals were polypharmacy.

Table E-5. Distribution of Eligibles Age 18 or Older by the Maximum Number of Oral Medications (90 day supply or greater) Simultaneously Dispensed in CY 2005

MED COUNT	Nbr Eligibles	%
0	523,121	30.5%
1	417,703	24.3%
2	104,911	6.1%
3	100,923	5.9%
4	88,438	5.2%
5 or More	**481,114**	**28.0%**

Table E-6. Count of Polypharmacy Eligibles Age 18 and Older By Dual Eligibility, CY 2005

Dual Eligible	Polypharmacy No	Polypharmacy Yes	All
No	792,956	126,067	919,023
Yes	442,140	355,047	797,187
All	1,235,096	481,114	1,716,210

Adherence-Sensitive Conditions

Individuals with conditions that are sensitive to non-adherence with a physician's directions are identified through diagnoses codes on claims. Primary and secondary diagnosis codes on claims headers and diagnosis codes on the claims detail were examined to identify persons with one or more of adherence-sensitive conditions. See Table E-7 for a list of these conditions and their frequency of occurrence among the study population. Thirty-four percent (34%) of our study population had one or more adherence-sensitive conditions, comprised of 44% of the dual-eligibles and 25% of the non-duals (See

Table E-8). Note that some unknown number of persons with adherence-sensitive conditions is not identified by this method because an individual may not have had a clinician visit under an ASC diagnosis code during the study period. For example, persons who had only pharmacy claims (which do not typically carry diagnosis codes) for diabetes medications would be missed.

Table E-7. Distribution of Adherence-Sensitive Conditions in CY 2005 Among Eligibles Age 18 and Older

Condition	N	%
Total Eligibles	*1,716,210*	*100.0%*
Asthma	61,187	3.6%
Hypertension	249,535	14.5%
Coronary Artery Disease	87,026	5.1%
CHF	52,904	3.1%
COPD	147,564	8.6%
Diabetes	183,320	10.7%
Major Depressive	49,423	2.9%

Schizophrenia	63,479	3.7%
Manic Recurrent	22,250	1.3%
Adherence-Sensitive Condition	**582,485**	**33.9%**

Table E-8. Counts of Eligibles 18 and Older
By Diagnoses of an Adherence-Sensitive Condition and Dual Eligibility

Dual Eligible	ASC		
	No	Yes	All
No	686,939	232,084	919,023
Yes	446,786	350,401	797,187
All	1,133,725	582,485	1,716,210

Cross Tabulation of Polypharmacy and Adherence-Sensitive Conditions

317,305 (19%) individuals in our study population were both polypharmacy and had an adherence-sensitive condition (See Table E- 9). Table E-10 and Table 11 show the cross tabulations of these two groups separately for dual-eligibles and non-duals. Among dual-eligibles 27% were both polypharmacy and ASC. Among the non-duals 11% were both polypharmacy and ASC.

Table E- 9. Counts of Eligibles 18 and Older
By Polypharmacy and a Diagnoses of an Adherence-Sensitive Condition

	Polypharmacy		
ASC	**No**	**Yes**	**Total**
No	969,916	163,809	1,133,725
	56.5%	9.5%	66.1%
Yes	265,180	317,305	582,485
	15.5%	18.5%	33.9%
Total	1,235,096	481,114	1,716,210
	72.0%	28.0%	100.0%

Table E-10. Counts of Dual-Eligibles 18 and Older
By Polypharmacy and ≥ 1 Diagnosis of an Adherence-Sensitive Condition

ASC	Polypharmacy

	No	Yes	Total
No	307,675	139,111	446,786
	38.6%	17.5%	39.4%
Yes	134,465	215,936	350,401
	16.9%	27.1%	44.0%
Total	442,140	355,047	797,187
	55.5%	44.5%	100.0%

Table E-11. Counts of Non-Dual-Eligibles 18 and Older
By Polypharmacy and a Diagnoses of an Adherence-Sensitive Condition

	Polypharmacy		
ASC	**No**	**Yes**	**Total**
No	662,241	24,698	686,939
	72.1%	2.7%	74.7%
Yes	130,715	101,369	232,084
	14.2%	11.0%	25.3%
Total	792,956	126,067	919,023
	86.3%	13.7%	100.0%

Section III: Methodology for Identification and Analyses of Admissions to LTC Facilities, Inpatient Hospitals, and Emergency Rooms

Nursing Facility Admissions Methodology

Background: Skilled Nursing Facility Services and Medicare Coverage

Skilled nursing facility care is covered under Medicare Part A up to 100 days in a benefit period with certain restrictions. You must have a three day minimum inpatient stay for a related illness or injury and the doctor must certify that you need skilled care such as intravenous injections or physical therapy. A benefit period is defined as starting the day that the individual is admitted to the hospital or skilled nursing facility and ends when the individual hasn't received any inpatient hospital care or skilled nursing care in a nursing facility for 60 days in a row. If the benefit period ends, a new benefit period begins when the individual is admitted to an inpatient hospital or skilled nursing facility.

Skilled nursing facility services are 100% covered under Medicare for the first twenty days. From days 21-100, a Medicare beneficiary must pay up to $141.50/day. Medicare coverage is exhausted after day 100 in a benefit period. During the Medicare coverage period,

Medi-Cal expenditures would only reflect the costs not paid by Medicare. Potentially, there may be no skilled nursing facility expenditures for Medi-Cal eligibles in the first twenty days of a benefit period.

Identifying Instances of a Nursing Facility Admission

The objectives of this methodology are to identify instances of a nursing facility (NF) admission in CY 2005, calculate average length of stay, and calculate average Medi-Cal expenditures per admission. This methodology is applied to Medi-Cal paid claims for dates of service between Dec 1, 2004 and December 31, 2006.

Below is a list of data fields available on the header of the paid claims that are used in this methodology. These variables will be discussed in turn.

AKA_CIN: In Medi-Cal it is possible for an individual to have multiple client identifiers (AKA_CINs). When possible these are rolled up into a unique identifier (CIN). However, analysis of the population of dual-eligibles in this study showed less than 0.001 percent of these individuals had multiple AKA_CINs. Thus, to simplify programming, AKA_CIN was used to identify unique individuals.

VENDOR_CD identifies the general type of provider to which the claim was paid. Nursing facilities are identified by Vendor Code= '80'.

SVC_FROM_DT and SVC_TO_DT fields contain the dates of service for which the claims paid.

HDR_MEDI_CAL_PAID_AMT contains the amount of reimbursement paid by Medi-Cal. Paid claims to the NF are summed across each NF stay. Half of this amount is assumed to be eligible for federal financial participation, thus the remaining half is taken from the State general fund.

INPAT_ADMISSION_DT contains the admission date for current stay. Analysis shows that there is a valid date in this field for 87% of the NF claims.

FI_LTC_INPAT_STAT_CD indicates the status of the patient in LTC. More than 96% of the NF claims have a valid value for this field. See Table 12 for possible values. For this study, when FI_LTC_INPAT_STAT_CD is missing then it set to '00', "still under care".

Definition of a Nursing Facility Admission

For the purposes of this study, a NF admission must be in CY 2005. Since the admission date on the claims was missing on most of the NF claims, this is not a reliable indicator of an admission. Thus the following three rules were employed to define a NF admission. All must be true:

- The value in the admission date must be in 2005.
- There were no NF claims in the previous month, unless a given claim and the most recent claim prior to the given claim share the same admission date.

- The length of stay must be greater than one day.

If the INPAT_ADMISSION_DT is missing, then the SVC_FROM_DT on the claim is substituted. If the INPAT_ADMISSION_DT was greater than the SVC_FROM_DT, then the INPAT_ADMISSION_DT was assumed to be an error and the admission date taken from the SVC_FROM_DT.

Definition of a Nursing Facility Discharge

A nursing facility discharge is indicated in one of three ways.

1. The patient status code indicates a discharge. These codes include '02' '03' '04' '10' '11' and '12'. See Table **E-12** for interpretations.
2. There is a month without a NF claims, and the admission date on the claim prior to the lapse does not equal the admission date on the claim after the lapse.
3. The individual has no more NF claims as of December 31, 2006. The SVC_TO_DT on the last claim becomes the discharge date for that stay.

Table E-12. Nursing Facility Patient Status Codes

Patient Status	
00	Still under care
01	Admitted (interim bill)
02	Expired (Deceased)
03	Discharged to acute hospital
04	Discharged to home
05	Discharged to another Long Term Care facility
06	Leave of absence to acute hospital (bed hold)
07	Leave of absence to home
08	Leave of absence to acute hospital/discharged
09	Leave of absence to home/discharged
10	Admitted/expired
11	Admitted/discharged to acute hospital
12	Admitted/discharged to home
13	Admitted/discharged to other Long Term Care facility

Hospital Inpatient Admissions Methodology

The objectives of this methodology are to identify instances of an inpatient hospital admission in CY 2005, calculate average length of stay, and calculate Medi-Cal expenditures

per admission. This methodology is applied to Medi-Cal paid claims for dates of service between Jan 1, 2005 and December 31, 2006.

Below is a list of data fields available on the header of the paid claims that are used in this methodology. These variables will be discussed in turn.

- AKA_CIN: In Medi-Cal it is possible for an individual to have multiple client identifiers (AKA_CINs). When possible these are rolled up into a unique identifier (CIN). However, analysis of the population of dual-eligibles in this study showed less than 0.001 percent of these individuals had multiple AKA_CINs. Thus, to simplify programming, AKA_CIN was used to identify unique individuals.
- VENDOR_CD identifies the general type of provider to which the claim was paid. Inpatient Hospitals are identified by Vendor Codes '50' and '60'.
- SVC_FROM_DT and SVC_TO_DT fields contain the dates of service for which the claims paid.
- HDR_MEDI_CAL_PAID_AMT contains the amount of reimbursement paid by Medi-Cal. Paid claims for provider types likely associated with the hospital stay and dates of service that fall within the dates of the inpatient stay are summed across each inpatient hospital stay. Half of this amount is assumed to be eligible for federal financial participation, thus the remaining half is taken from the State general fund.
- INPAT_ADMISSION_DT contains the date of admission for an inpatient stay. 90% of inpatient claims have a valid value for this field. Where the value was missing, the SVC_FROM_DT was substituted.
- CLAIM_FORM_IND identifies if the claim form used to input the claim is a UB-92 or a HCFA - 1500 form. Inpatient claims that come in on the UB-92 form have a value of 'U" and use the values in Table E-13 to interpret the INPAT_ADMIT_TYPE_CD, all other inpatient claims use the values in Table E-14.
- INPAT_ADMIT_TYPE_CD indicates the type of admission. See Table E-13 & Table E-14 for lists of valid values depending on the value of the CLAIM_FORM_IND.
- POS_CD indicates the place of service.
-
- Table E-15 contains a list of valid values.
- INPAT_DISCHARGE_CD indicates the discharge status of the patient as of the SVC_TO_DT on an inpatient claim. More than 90% of the inpatient claims have a valid value for this field. See Table E-16 for valid values.

Table E-13. Reference for UB-92 INPAT_ADMIT_TYPE_CD

Code	Description
0	Unknown
1	Emergency
2	Urgent
3	Elective
4	Newborn

Table E-14. Reference for Non-UB-92 INPAT_ADMIT_TYPE_CD

Code	Description
0	Unknown
1	Emergency
2	Elective
3	Delivery
4	Emergency Transfer
5	Elective Transfer
6	Delivery Transfer

The inpatient admission on type codes labeled *Emergency* indicates that the inpatient admission began as an emergency room visit. *Urgent* indicates that the admission began at an Urgent Care Clinic/ Outpatient facility. *Elective* indicates that the admission was scheduled (e.g. scheduled surgery). *Delivery* indicates a birth. *Newborn* indicates that the newborn was born in the hospital and then admitted, but is not considered in this analysis.

Table E-15. Reference for POS_CD

Code	Description
0	Emergency Room
1	Inpatient Hospital
2	Outpatient Hospital
3	Nursing Facility
4	Home
5	Office, Lab, clinic
6	ICF-DD
7	Other
8	Transitional Inpatient

Table E-16. Reference for INPAT_DISCHARGE_CD

Code	Description
0	Unknown
1	Transfer to another hospital
2	Transfer to Transitional Inpatient Care
3	Transfer to long term care
4	Discharged - deceased
5	Discharge to home
6	Still a patient
8	Leave of absence

Definition of an Inpatient Hospital Admission

For the purposes of this study, an inpatient hospital admission must begin in CY 2005. The following three rules were employed to define an inpatient admission. All must be true.

1. The value in the admission date must be in 2005.
2. The claim header must have a VENDOR_CD = '50' or '60'. This includes acute care hospitals, but excludes extended care, long term care and rehabilitation hospitals.
3. The POS_CD must not contain a code ('0' or '2') indicating that this was an emergency room or an outpatient hospital.

If the INPAT_ADMISSION_DT is missing, then the SVC_FROM_DT on the claim is substituted.

Definition of an Inpatient Hospital Discharge

An inpatient hospital discharge is indicated by the maximum SVC_TO_DT among inpatient claims that share a common admission date. Summation of Medi-Cal Payments Associated with an Inpatient Hospital Stay Costs of care for an inpatient hospital stay include the hospital charges as well as the costs of a physician, lab work and other ancillary services which may be billed separately. As such, the Medi-Cal cost for an inpatient stay is defined as the sum of all paid claims to provider types (indicated in Table 17) that fall between the dates of admission and discharge.

Table E-17. Vendor Codes for Reimbursement Summations Associated with an Inpatient Stay

Vendor_CD	Description
50	County Hosp - Acute Inpatient
60	Comm Hosp - Acute Inpatient
20	Physicians
22	Physicians Group
24	Clinical Lab
19	Portable X-ray Lab
42	Medically Required Trans

Emergency Room Visits Methodology

The objectives of this methodology are to identify instances of an emergency department visit in CY 2005, and calculate the Medi-Cal expenditures per visit. This methodology is applied to Medi-Cal paid claims for dates of service between Jan 1, 2005 and December 31, 2005.

Below is a list of data fields available on the header of the paid claims that are used in this methodology. These variables will be discussed in turn.

- AKA_CIN: In Medi-Cal it is possible for an individual to have multiple client identifiers (AKA_CINs). When possible these are rolled up into a unique identifier (CIN). However, analysis of the population of dual-eligibles in this study showed less than 0.001 percent of these individuals had multiple AKA_CINs. Thus, to simplify programming, AKA_CIN was used to identify unique individuals.
- VENDOR_CD identifies the general type of provider to which the claim was paid. Outpatient. Hospitals are identified by Vendor Codes '52' and '62'.
- SVC_FROM_DT and SVC_TO_DT fields contain the dates of service for which the claims paid.
- PROC_CD is found on the claims detail table.
- Table E-18 contains a list of procedure codes that are specific to emergency room services.
- POS_CD indicates the place of service. Table E-19 contains a list of valid values.
- HDR_MEDI_CAL_PAID_AMT contains the amount of reimbursement paid by Medi-Cal. Paid claims for selected provider types (see
- Table E-20) on the date of ED visit are summed across for each visit. Half of this amount is assumed to be eligible for federal financial participation, thus the remaining half is taken from the State general fund.

Table E-18. Emergency Room Specific Procedure Codes

Procedure Code Description	Procedure Codes
Physician ER	'99281', '99282', '99283', '99284', '99285', '99288', '99289', '99290', '99466', '99467'
ER Use	'Z7501', 'Z7502'
ER Supplies	Z7610'

Table E-19. Reference for POS_CD

Code	Description
0	Emergency Room
1	Inpatient Hospital
2	Outpatient Hospital
3	Nursing Facility
4	Home
5	Office, Lab, clinic
6	ICF-DD
7	Other
8	Transitional Inpatient

Definition of an Emergency Department Visit

For the purposes of this study, an emergency department visit (ED) must occur in CY 2005. The following three rules were employed to define an ED visit. All must be true.

1. The SVC_FROM_DT must be in CY 2005.
2. The claim header must have a VENDOR_CD = '52' or '62'. This identifies outpatient hospitals.
3. The POS_CD must contain a code '0' or an emergency room specific procedure code is present, indicating that this was an emergency room service. Alternatively, ORIG_POS_CD values including "B" or '23' could be used.

Summation of Medi-Cal Payments Associated with an ED Visit

Costs of care for an ED visit include the ED charges as well as the costs of a physician, lab work and other ancillary services which may be billed separately. As such, the Medi-Cal cost for an ED visit is defined as the sum of all reimbursements to provider types indicated in Table 20 that have a POS_CD = 0 on the date of the ED visit. Medical Transportation (Vendor_CD=42) will not be restricted by the POS_CD.

Table E-20. Vendor Codes for Reimbursement Summations Associated with an Emergency Room Visit

Vendor_CD	Description
52	County Hosp - Outpatient
62	Comm Hosp - Outpatient
20	Physicians
22	Physicians Group
24	Clinical Lab
19	Portable X-ray Lab
42	Medically Required Trans

Note that the POS_CD is a field on claims detail (Claims_Dtl) table, not the claims header (Claims_Hdr) table. But because the sum of the claims detail reimbursement does not always reflect the total amount paid for that claim, the reimbursement amount should be taken from the claims header. Therefore, a claim header that is associated with at least one claim detail record that shows a POS_CD = 0, or one emergency room specific procedure code will be deemed to have a taken place in the emergency room, and thus eligible for inclusion in the cost of an ED visit.

Section IV: Results

This section provides the counts and reimbursements associated with admissions to nursing facilities, inpatient hospitals, and emergency rooms among individuals identified as both polypharmacy and having an adherence-sensitive condition (ASC). Tables for dual-eligibles and non-dual-eligibles will be presented separately. These populations differ in that Medicare pays some portion of the services to dual-eligibles while Medi-Cal pays the total cost for the non-duals.

Dual-Eligible Results

There were 215,936 polypharmacy dual-eligibles with an adherence-sensitive condition. Table 21 provides the counts of admissions, the average length of stay, and Medi-Cal reimbursement associated with these events.

Table E-21. Medi-Cal Hospital and Nursing Facility Visits/Stays
CY 2005 among Polypharmacy with Adherence-Sensitive Conditions
Dual-Eligibles Age 18 or Older

Measure		Stay/Visit Type		
N Dual Eligibles	215,936	Nursing Facility	Inpatient Hospital	Emergency Room
N Admissions		12,060	103,091	88,772
Admits per 100 Eligibles		6	48	41
Average LOS (days)		200	6.0	NA
Average Cost per Visit/Stay		$24,221.27	$1,555.93	$251.05
Number Individuals with	0 Visits/Stays	205,442	155,981	168,135
	1 Visit/Stay	9,192	41,695	30,728
	2 Visits/Stays	1,096	12,960	9,100
	3 Visits/Stays	161	3,405	3,628
	4 Visits/Stays	35	938	1,691
	5 Visits/Stays	8	379	873
	6 or more	2	578	1,781

Table E-22 provides the distribution of dual-eligible NF patient status at the end of a stay or the end of the study. The 51% that are “still under care” should not be interpret as the all were still under care; some of those are individuals for whom the last claim contained that designation, but there were no further claims indicating they were still in an NF.

Table E-22. Distribution of Nursing Facility Patient Status
At Discharge or End of Study Period
CY 2005 among Dual-Eligible Age 18 and Older

Discharge Type	N	%
Still under care	6,134	50.9%

Admitted (interim bill)	99	0.8%
Expired (Deceased)	202	1.7%
Discharged to acute hospital	568	4.7%
Discharged to home	3,354	27.8%
Discharged to another Long Term Care facility	237	2.0%
Leave of absence to acute hospital (bed hold)	1,167	9.7%
Leave of absence to home	9	0.1%
Leave of absence to acute hospital/discharged	191	1.6%
Leave of absence to home/discharged	7	0.1%
Admitted/expired	19	0.2%
Admitted/discharged to acute hospital	8	0.1%
Admitted/discharged to home	61	0.5%
Admitted/discharged to other Long Term Care facility	4	0.0%

* Missing discharge codes are set as still under care

Inpatient Hospital claims are coded with a discharge type code. Among dual-eligible polypharmacy individuals with adherence-sensitive conditions, 76% of inpatient stays were discharged to their home. Fifteen percent (15%) were transferred to a long-term care facility. The 7% who are *still a patient* are either coding errors, persons who may still be in the hospital as of Dec 31, 2006, or persons who may have had split bills that were not in paid claims (See Table E-23)

Table E-23. Discharge Type for Inpatient Hospital Stays CY 2005 among Dual-Eligible Age 18 and Older

Hospital Discharge Type	N	%
Unknown	11	0.0%
Discharge to home	78,822	76.4%
Discharged - deceased	529	0.5%
Still a patient	6,695	6.5%
Transfer to Transitional Inpatient Care	2	0.0%
Transfer to another hospital	1,767	1.7%
Transfer to long term care	15,299	14.8%

Summary Statistics for these admissions are presented in Table 24 (Nursing Facility Reimbursement), Table E-25 (Inpatient Reimbursement) and Table E-26 (Emergency Room Reimbursement).

Table E-24. Summary Statistics for Medi-Cal Reimbursement During Nursing Facility Stay CY 2005 among Dual-Eligible Age 18 and Older

Provider Type	N	Median	Mean	Std Dev	Min	Max
Nursing Facility	12,060	$7,083.48	$24,221.27	$32,492.05	$0.00	$387,675.07

Table E-25. Summary Statistics for Medi-Cal Reimbursement

During Inpatient Hospital Stay
CY 2005 among Dual-Eligible Age 18 and Older

Provider Type	N	Median	Mean	Std Dev	Min	Max
Total Medi-Cal	103,091	$191.13	$1,555.93	$4,404.41	-$85.33	$237,689.22
Inpatient Hospital	103,091	$0.00	$1,477.55	$4,227.06	$0.00	$229,678.25
Physician	103,091	$9.48	$72.60	$362.26	-$232.72	$25,448.31
Other Lab	103,091	$0.00	$0.42	$9.01	$0.00	$1,104.66
Portable X-ray	103,091	$0.00	$0.01	$0.82	$0.00	$97.17
Medical Transport	103,091	$0.00	$5.34	$69.97	-$112.20	$9,055.87

Table E-26. Summary Statistics for Medi-Cal Reimbursement
During Emergency Department Visits
CY 2005 among Dual-Eligible Age 18 and Older

Provider Type	N	Median	Mean	Std Dev	Min	Max
Total Medi-Cal	88,772	$2.38	$251.05	$830.21	-$440.83	$30,660.30
Emergency Room	88,772	$0.00	$233.72	$793.19	-$548.91	$30,660.30
Physician	88,772	$0.00	$7.87	$40.52	$0.00	$1,783.54
Other Lab	88,772	$0.00	$0.01	$0.60	$0.00	$75.06
Other X-Ray	88,772	$0.00	$0.00	$0.00	$0.00	$0.00
Medical Transport	88,772	$0.00	$9.45	$87.20	-$63.90	$12,572.83

Hospital admissions may be classified by admission type. Table E-27 shows the counts and reimbursement statistics for the inpatient hospital stays among these dual-eligible polypharmacy individuals with adherence-sensitive conditions. The 84,634coded as *emergency* indicate that these inpatient stays began with an emergency room visit and the ER charges are included in the cost of the inpatient stay. The 88,772 emergency room visits in Table 21 are ER visits that did not result in an inpatient admission. The 216 *urgent* admissions began as a visit to an Urgent Care Clinic/ Outpatient facility. The unexpected negative minimum reimbursement values in these reimbursement tables were investigated. Claims with negative reimbursement accounted for less than 1% of the inpatient claims and appear to be outliers in the administrative data.

Table E-27. Inpatient Hospital Admission Reimbursement Statistics
By Admission Type
CY 2005 among Dual-Eligible Age 18 and Older

Admission Type	N	Median	Mean	Std Dev	Minimum	Maximum
Emergency	84,634	$227.53	$1,571.29	$4,406.46	-$85.33	$237,689.22
Urgent	216	$38.75	$462.26	$840.10	$0.00	$7,636.84
Elective	17,798	$151.34	$1,518.35	$4,460.31	-$28.84	$149,591.58

Unknown	443	$40.31	$664.03	$1,928.21	$0.00	$19,266.85

Non-Dual-eligible Results

There were 101,369 polypharmacy non-dual-eligibles with an adherence-sensitive condition.

Table E-28 provides the counts of admissions, the average length of stay and Medi-Cal reimbursement associated with these events.

Table E-28. Medi-Cal Hospital and Nursing Facility Visits/Stays in CY 2005
Among Polypharmacy with Adherence-Sensitive Conditions
Non-Dual-Eligible Age 18 or Older

Measure		Stay/Visit Type		
N Eligibles	101,369	Nursing Facility	Inpatient Hospital	Emergency Room
N Admissions		2,640	47,999	89,096
Admits per 100 Eligibles		3	47	88
Average LOS (days)		227	5.4	NA
Average Cost per Visit/Stay		$30,867.56	$7,526.78	$1,218.82
Number Individuals with	0 Visits/Stays	98,915	80,658	68,329
	1 Visit/Stay	2,295	11,727	16,755
	2 Visits/Stays	138	4,258	6,897
	3 Visits/Stays	16	1,961	3,257
	4 Visits/Stays	4	1,067	1,888
	5 Visits/Stays	1	617	1,181
	6 or more	0	1,081	3,062

Table **E-29** provides the distribution of non-dual-eligible NF patient status at the end of a stay or the end of the study. The 51% that are “still under care” should not be interpret as the all were still under care; some of those are individuals for whom the last claim contained that designation, but there were no further claims indicating they were still in an NF.

Table E-29. Distribution of Nursing Facility Patient Status
At Discharge or End of Study Period
CY 2005 among Non-Dual-Eligible Age 18 and Older

Discharge Type	N	%
Still under care.	1,333	50.5%
Admitted (interim bill)	82	3.1%
Expired (Deceased)	42	1.6%
Discharged to acute hospital	88	3.3%
Discharged to home	688	26.1%
Discharged to another Long Term Care facility	38	1.4%
Leave of absence to acute hospital (bed hold)	257	9.7%
Leave of absence to home	7	0.3%
Leave of absence to acute hospital/discharged	54	2.0%
Leave of absence to home/discharged	1	0.0%
Admitted/expired	5	0.2%
Admitted/discharged to acute hospital	9	0.3%
Admitted/discharged to home	27	1.0%
Admitted/discharged to other Long Term Care facility	9	0.3%

*Missing Discharge codes are set to still under care

Inpatient Hospital claims are coded with a discharge type code. Among non-dual-eligible polypharmacy individuals with adherence-sensitive conditions, 73% of inpatient stays were discharged to their home. Eleven percent (11%) were transferred to a long-term care facility. The 13% who were *still a patient* are either coding errors, persons who may still be in the hospital as of Dec 31, 2006, or persons who may have had split bills that were not in paid claims (See Table 30).

Table E-30. Discharge Type for Inpatient Hospital Stays CY 2005 among Non-Dual-Eligible Age 18 and Older

Hospital Discharge Type	N	%
Discharge to home	35,042	73.0%
Discharged - deceased	219	0.5%
Still a patient	6,437	13.4%
Transfer to another hospital	1,234	2.6%
Transfer to long term care	5,075	10.6%

Summary Statistics for these admissions are presented in Table 31 (Nursing Facility Reimbursement), Table 32 (Inpatient Reimbursement) and

Table E-33 (Emergency Room Reimbursement).

Table E-31. Summary Statistics for Medi-Cal Reimbursement During Nursing Facility Stay CY 2005 among Non-Dual-Eligible Age 18 and Older

Provider Type	N	Median	Mean	Std Dev	Min	Max
Nursing Facility	2,640	$14,055.52	$30,867.56	$38,307.42	$0.80	$391,956.15

Table E-32. Summary Statistics for Medi-Cal Reimbursement During Inpatient Hospital Stay CY 2005 among Non-Dual-Eligible Age 18 and Older

Provider Type	N	Median	Mean	Std Dev	Min	Max
Total Medi-Cal	47,999	$4,471.23	$7,526.78	$11,642.78	$0.00	$373,952.34
Inpatient Hospital	47,999	$3,840.00	$6,648.46	$10,703.05	$0.00	$364,373.94
Physician	47,999	$429.66	$796.85	$1,294.32	-$505.87	$41,263.11
Other Lab	47,999	$0.00	$3.25	$30.43	$0.00	$1,309.43
Portable X-ray	47,999	$0.00	$0.12	$4.14	$0.00	$242.28
Medical Transport	47,999	$0.00	$78.10	$252.92	-$56.10	$20,396.51

Table E-33. Summary Statistics for Medi-Cal Reimbursement During Emergency Department Visits CY 2005 among Non-Dual-Eligible Age 18 and Older

Provider Type	N	Median	Mean	Std Dev	Min	Max
Total Medi-Cal	89,096	$484.24	$1,218.82	$1,845.00	-$450.48	$35,389.15
Emergency Room	89,097	$283.56	$1,015.97	$1,706.61	-$450.48	$27,145.77
Physician	89,097	$56.36	$95.69	$123.55	$0.00	$6,694.39
Other Lab	89,097	$0.00	$0.08	$1.95	$0.00	$101.55
Other X-Ray	89,097	$0.00	$0.00	$0.00	$0.00	$0.00
Medical Transport	89,097	$0.00	$107.07	$335.18	-$50.90	$31,371.85

Hospital admissions may be classified by admission type. Table E-34 shows the counts and reimbursement statistics for the inpatient hospital stays among these non-dual-eligible polypharmacy individuals with adherence-sensitive conditions. The 40,201 coded as *emergency* indicate that these inpatient stays began with an emergency room visit and the ER charges are included in the cost of the inpatient stay. The 89,096 emergency room visits in

Table E-28 are ER visits that did not result in an inpatient admission. The unexpected negative minimum reimbursement values in these reimbursement tables were investigated. Claims with negative reimbursement accounted for less than 1% of the inpatient claims and appear to be outliers in the administrative data.

Table E-34. Inpatient Hospital Admission Reimbursement Statistics By Admission Type CY 2005 among Non-Dual-Eligible Age 18 and Older

Admission Type	N	Median	Mean	Std Dev	Minimum	Maximum
Emergency	40,201	$4,412	$7,338	$11,083	$0	$346,702
Elective	7,787	$4,811	$8,492	$14,146	$0	$373,952
Unknown	11	$8,154	$13,246	$13,445	$1,415	$45,468

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