

# Medication Therapy Management 2.0

## A New and Technological Life-Saving Alternative to Failed Patient Education Approaches

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### Executive Summary

Medication mismanagement is a lethal killer, taking more than 125,000 lives and costing America more than \$300 billion annually. For nearly a decade, an approach called Medication Therapy Management (MTM) has been both heralded and mandated by the government and other “experts” as the way to address this problem.

However, to date, MTM has been built around patient education programs which have uniformly failed to slow down the growth of medication mismanagement.

Recently, a few innovators have looked to the past for answers to the future. Two generations ago, pharmaceutical drug manufacturers changed the formulation and packaging of medicines away from individually-compounded powders and liquids and toward mass-produced pills and tablets and capsules filled with uniform doses of precisely-compounded medicines.

Now, new innovators are looking to help those most at risk to medication mismanagement – those who take five or more prescriptions daily. Their helpful, nearly foolproof solution, involves taking all of a patient’s single doses of medicines, the ones prescribed to be taken together at a given time of day, and placing them into a single-dose vacuum-sealed package.

This new approach has the potential of accomplishing what a decade of MTM has failed to do – help patients, and their caregivers, to avoid accidental medication mismanagement, as well as avoiding the costly and potentially deadly effects of medication mismanagement.

## Introduction to the Underlying Medical Problem

Medication Therapy Management (MTM) is a new approach to delivering a workable solution designed to address a medical problem that kills 125,000 Americans annually, while costing America’s healthcare system more than \$300 billion dollars. This white paper addresses this innovative concept in providing and administering prescription drugs to America’s most at-risk populations, including the elderly and the chronically ill. It is based on the author’s previously-published work on the underlying need for MTM.

As was demonstrated in this author’s previously-published White Paper, “*Hidden Deadly Disease: The Fifth Largest Disease-Like Killer of Americans Remains Virtually Unknown*” (June, 2012), and as confirmed by the Centers for Disease Control and Prevention (CDC) and the Journal of the American Medical Association, medication mismanagement is the fifth leading cause of death in America:

• Heart disease:	599,413
• Cancer:	567,628
• Chronic lower respiratory diseases:	137,353
• Stroke (cerebrovascular diseases):	128,842
• <b>Medication Mismanagement</b>	<b>125,000</b>
• Accidents (unintentional injuries):	118,021
• Alzheimer's disease:	79,003
• Diabetes:	68,705
• Influenza and Pneumonia:	53,692
• Nephritis, nephrotic syndrome, and nephrosis:	48,935
• Intentional self-harm (suicide):	36,909
• HIV/AIDS	17,774

The factors which cause this deadly, costly misuse of medications include the following:

- Misreading of amber-bottle prescription labels by patients and caregivers
- Taking the wrong medicines
- Taking the wrong combination of medicines
- Taking the right medicines at the wrong time
- Taking the right medicine in the wrong dosage
- Forgetting to take the right medicine, or the right combination of medicines, at the right time
- Forgetting to take the right medicine, or the right combination of medicines, at all

The Institute of Medicine reports that at least 1.5 million Americans experience at least one adverse drug reaction each year, with those taking five or more different prescription medicines per day at greatest risk for adverse reactions from medication mismanagement. The CDC reports that 37 percent of all Americans over age 60 take five or more medicines per day.

The CDC, along with the authoritative Becker's Hospital Review and the American Heart Association, report that 10 percent of all U.S. hospital admissions in 2009 – 3.94 million individual hospital admissions – were due to “medication non-compliance.” The American Heart Association goes further, reporting that 23 percent of all nursing home admissions are due to patients failing to take their own prescription medicines properly.

Clearly, there is a huge and under-served medical crisis in America, one that leads to 125,000 deaths and nearly 4 million hospital admissions, at a cost of more than \$300 billion dollars annually.

A related problem which adds hugely to the overall cost related to medication mismanagement involves the 30-day readmission crisis. Becker's Clinical Quality & Infection Control reports that among the five most common readmission diagnoses, roughly 20 percent of all such hospital patients are readmitted within 30 days of discharge.

These most common diagnoses are:

- Heart Failure
- Myocardial Infarction
- Pneumonia

- Cardiovascular Disease
- Respiratory Disease

The major causes for hospital readmission within 30 days of discharge under these five most common readmission diagnoses includes both direct or indirect medication mismanagement. Direct medication mismanagement leads to readmission as a direct consequence of medication mis-use. Indirect medication mismanagement causes a flare-up of the original diagnosis, which then triggers a readmission.

## Medication Therapy Management The Current, Failed Educational Approach

In 2004, eleven national pharmacy organizations adopted this definition of Medication Therapy Management (MTM): “A distinct service or group of services that optimizes drug therapy with the intent of improved therapeutic outcomes for individual patients.”

Under this definition, MTM includes a broad range of professional activities such as:

- Formulating a medication treatment plan
- Enhancing medication adherence through patient education and “empowerment”
- Performing patient assessments
- Conducting comprehensive patient medication reviews
- Monitoring the safety and efficacy of prescribed therapeutic pharmaceuticals
- Documenting and communicating MTM services to prescribers

As currently implemented, MTM includes five specific components:

- Personal Medication Record (PMR)
- Medication Therapy Review (MTR)
- Medication-Related Action Plan (MAP)
- Medication Intervention and Referral (MIR)
- Medication Documentation and Follow-up (MDF)

The Medicare Modernization Act of 2003 requires Medicare Part D prescription drug plans to include Medication Therapy Management services which will be delivered by qualified healthcare professionals, including pharmacists. These services are especially

intended to target those who have several chronic conditions, including diabetes, asthma, hypertension, congestive heart failure, diseases such as HIV/AIDS and post-transplant individuals.

The requirements of the law are clear, but the implementation of those requirements, especially by the private sector, has been far less clear.

A leading force in implementing patient education programs has been found among the larger Pharmacy Benefits Management groups (PBMs). These organizations are often found conducting some limited level of patient education. This is usually a part of a larger and more comprehensive effort to get their constituent patients to take overall better care of themselves. Smaller PBMs, those in the industry's mid-level, see medication therapy management as a new responsibility. It is one of many they feel they are required to address. However, most of these smaller groups are operationally-oriented, and tend to believe – as institutions – that comprehensive patient education, including ways to avoid medication mismanagement, isn't their responsibility. They look to others – the CDC and National Institutes of Health, as well as academic and not-for-profit organizations – to handle this responsibility.

Setting aside all of the government and non-profit organization jargon, the essence of Medication Therapy Management involves ways of educating people, encouraging people, and making it possible for even health-impaired people to take their medications when they should, at the right time and in the right dosage.

What is clearly needed, after nearly a decade of ineffectual wrangling among many “official” interest groups, is a mechanism that will make it easier for patients – assisted by their care-givers – to take their medicines appropriately. Where education has failed, it is time for technology to step in.

As recently as 75 years ago, personal-dose medications were compounded by professional pharmacists on-demand. Patients often received their medicines as liquids or powders that required per-dose measurements. It was only in the post-war period that pharmacies became more corporate, and pharmaceutical manufacturers moved away from creating the raw materials, and began packaging medicines in single-dose pills, capsules or tablets. Dispensing went from loose powders or liquids to amber bottles filled by pharmacists, and finally to factory-packaged 30-day doses of tablets, pills or capsules.

Education efforts had to contend with the fact that pharmaceuticals were packaged in multi-dose lots – typically sufficient for 30, 60 or 90 days of as-prescribed doses. As a result, these patient education programs tended to only be effective – and frequently,

even only moderately effective – if the patients themselves had first experienced a life-changing diagnosis or surgery. It is a fact of human nature and educational science that motivated students tend to learn – based on rational self-interest – but “forced” students with no prior buy-in tend to skimp on learning and forget, or ignore, their lessons.

In pharmaceutical education, the instruction works only when the patients who receive that instruction already recognize that they actually have a serious and generally chronic/ongoing health problem that threatens their life or lifestyle.

Absent that kind of motivation, patients tend not to care. However, even with that kind of life-or-death threat, patients must overcome:

- Denial – the “it can’t really happen to me” belief
- Awareness – many patients, especially those with several chronic illnesses and many prescriptions – may have their ability to focus and remember impaired by their condition – or their medication
- Inconvenience – they prove unable to work proper medication processes into their ongoing lives

These, of course, all preclude those who cannot afford to buy their medications, and therefore try to develop work-arounds that will keep them healthy without draining their monthly budget with medication purchase.

Another factor that has inhibited the effect of education such as the kinds mandated by federal laws and regulations, it is a fact that far too many people refuse to (or ignore suggestions that they) seek out education. Especially technically-oriented education requires patients’ keen and motivated attention, as well as a commitment to what will be a life-long ongoing (and annoying) set of behavior changes and actions.

Absent personal, one-on-one motivated and informed “buy-in,” education alone will not suffice to reduce the incidents of medication mismanagement. Clearly, almost a decade after the law passed mandating patient medication therapy management education, statistics regarding the mortality and morbidity – and cost – stemming from medication mismanagement proves that education is not working, and perhaps that, in this case, education cannot and will not work.

To evaluate the effectiveness of MTM patient education, all you have to do is look at the statistics surrounding deaths, acute reactions and nationwide budgets to see that medication mismanagement education is an ongoing failure.

Well-intentioned doctors, hospitals, pharmacists, insurers and Pharmacy Benefits Management groups have all tried to implement effective patient-oriented medication therapy management education programs.

None of these efforts has been successful because, as noted, patients are inherently resistant to change that doesn't also immediately and "measurably" change their lives for the better.

Short-term programs don't manifest significant change, and long-term programs are, to date, less effective. The older the patient is, or the sicker the patient is, the less likely they are to respond to unsought-after patient education, and the less likely they are to make new life-altering changes.

## Medication Therapy Management The Future Technology-Based Solution

If mandated patient education doesn't work – and, as the steadily-mounting statistics in terms of deaths and costs from medication mismanagement demonstrate, mandated patient education doesn't work – we must find another solution.

This other solution should be one that takes personal choice, awareness and the willingness to make motivated personal changes out of the equation. Choice should be replaced by technology that all but rules out even the chance of making accidental medication mismanagement mistakes.

Just as technology changes vastly improved the pharmaceutical field – by transforming individually-compounded powders or liquid medicines without pre-determined doses into standard-dose pills, capsules and tablets – those who seek to ameliorate or resolve the medication mismanagement risks must look, in the future, to technology. They must find new ways of further repackaging medications to reduce or eliminate the possibility of accidental medication mismanagement.

While there may be other soon-to-emerge solutions as well, the one market-tested solution now available can be found in the process of putting an individual patient's

medications into fool-proof individually-wrapped packages. This kind of per-dose packaging makes it very much harder for the patients to make mistakes. As long as they (or their caregiver) can read a label, a clock and a calendar, they will immediately recognize a mistake, before they can act on that mistake.

The Medication Management education process is completed the instant a patient or care-giver switched over to this new technology, one that allows them to confidently give a patient all of the proper meds, and at the proper times.

One early technology leader in the search for solutions to MTM that don't require patient education is AmerisourceBergen, a company which has developed an automated packaging system. Technicians input into the equipment all of a patient's prescription orders, including the medicines' dosages and frequency, and the packaging system produces a connected and perforated string of packages.

Each of these packages contains all of the medicines a given patient is supposed to take at any given time. To help make it even easier, the individual-dose package is labeled with the day and time, as well as the patient's name and the list of medicines contained in the package.

In this way, so long as the patient or caregiver can read and tell the time of day, mistakes in dosages become a thing of the past.

Currently, this technology is being used at major hospitals and other institutions, but this technology will be brought into the marketplace in 2013 by AmerisourceBergen's new strategic ally. This ally, a licensed Florida-based pharmaceutical company, has been created to introduce this new technology to the consumer marketplace. The combination of patented technology and a patented process/delivery system offer one dynamic solution to the MTM challenge of improving drug compliance and reducing the incidence of medication mismanagement.

With 125,000 deaths, nearly 4 million hospitalizations and more than \$300 billion dollars in costs at stake, this new technology could well accomplish what a decade's worth of education has failed to address.

## Sources

The following are some of the sources reviewed during the development of this White Paper. While these sources were helpful, all conclusions (and any mistakes) are those of the author, and not of the sources.

- Centers for Disease Control and Prevention
- Medication Therapy Management in Pharmacy Practice – Core Elements of an MTM Service Model
  - American Pharmacists Association
  - National Association of Chain Drug Store Foundations
- National Vital Statistics Report (NVSR), “Deaths: Final Data for 2009”
- Center on Budget and Policy Priorities
- U.S. Census Bureau, 2010 U.S. Census
- Feinberg School of Medicine, Northwestern University
- Journal of the American Medical Association (JAMA)
- American Heart Association
- Institute of Medicine (IOM)
- A Place for Mom
- Professional Society of Pharmacists
- National Care Planning Council
- Institute for Public Affairs  
In These Times
- Dispose My Meds
- AmerisourceBergen
- Ft. Lauderdale Sun Sentinel (daily newspaper)
- Wall Street Journal
- Becker’s Hospital Review
- Becker’s Clinical Quality & Infection Control
- American Journal of Hospital Pharmacy
- Medicare Prescription Drug, Improvement and Modernization Act of 2003, Public Law 108-173
- Caregiver’s Home Companion
- Saint Louis University (<http://www.slu.edu/school-for-professional-studies-home/organizational-health-initiative/how-ohi-can-help-you>)
- The Lancet (<http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2809%2960571-7/fulltext>)

## Appendix One

Facts about at-risk populations and the misuse of prescription medications (source: Nationwide PharmAssist)

- There are 40,267,984 senior citizens in the United States. (Source: U.S. Census Bureau, 2010 Census.)
- Senior citizens represent 13% of the population of the United States (Source: U.S. Census Bureau, 2010 Census)
- The Journal of the American Medical Association recently reported that if adverse drug reactions were classified as a disease, it would rank as the fifth leading cause of death in the United States.”
- A recent study from the Feinberg School of Medicine at Northwestern University indicated that a stunning sixty percent of paid caregivers made mistakes when they were sorting medications for people in their care. It also indicated that a third of the caregivers had trouble reading directions for medications.
- Regardless of age group, up to 59% of those on five or more medications per day are taking them improperly. (Source American Heart Association AHA)
- *According to the Institute of Medicine (IOM), at least 1.5 million Americans experience adverse drug events (ADE) annually*
- 58% of all seniors make some kind of mistake taking their meds (Source: A Place For Mom, Inc.)
- Over 200 billion dollars per year spent as a result of medication mis-management complication
- Among older Americans (aged 60 and over), more than 76% use two or more prescription medications and 37% use five or more. . (Source: Centers for Disease Control and Prevention)
- Close to 32 million American prescribed three or more medications which can lead to drug interactions and confusion over schedule and dosages (Pharmacist Society Professionals)
- Older Americans account for over one third of all medical spending in the United States (Source: National Care Planning Council)
- Pharmaceuticals \$300 billion dollar industry (Source: In These Times And The Institute For Public Affairs)

- 4 billion prescriptions dispensed each year (Source: Dispose My Meds)
- The latest statistics calculate that \$400 billion of in-kind care is provided annually by family caregivers (Source: Sun Sentinel)
- 10% of all hospital admissions are due to patients failing to take prescription medications accurately; and the average length of stay in hospitals due to medication non-compliance is 4.2 days. (Source American Heart Association AHA)
- Number of discharges from nonfederal short-stay hospitals by persons age 65 and over: 12.9 million (Source: Centers for Disease Control and Prevention)
- 23% of nursing home admissions are due to patients failing to take prescription medications accurately. (Source American Heart Association AHA)
- 16,100 total nursing homes in the United States (Source: Centers for Disease Control and Prevention)
- 1.7 million total nursing home beds in the United States (Source: Centers for Disease Control and Prevention)
- 1.5 million total nursing home residents in the United States (Source: Centers for Disease Control and Prevention)
- Occupancy rate of Nursing Homes in the United States: 86 percent (Source: Centers for Disease Control and Prevention)
- The average length of time since admission within a nursing home is 835 days (Source: Centers for Disease Control and Prevention)
- 1.5 million total patients of Home Health Care in the United States (Source: Centers for Disease Control and Prevention)
- Home health care average length of service: 315 days (Source: Centers for Disease Control and Prevention)
- Life expectancy: 77.9 years (Source: Centers for Disease Control and Prevention)
- \$2.6 trillion that will be spent in health care this year (2011) (Source Wall Street Journal)
- Two-thirds of Americans currently use medications: 49% use prescription drugs and 30% use nonprescription drugs. (Source American Heart Association AHA)

## Appendix Two

Federal Budget Outlays by Budget Function (source – U.S. Government)

### Total outlays by budget function

<b>Function</b>	<b>Budget</b>
General Science, Space and Technology	\$30.991 billion
Energy	\$23.270 billion
Agriculture	\$19.173 billion
Community and Regional Development	\$31.685 billion

<b>Function</b>	<b>Budget</b>
Social Security	\$779 Billion
National Defense	\$716 Billion
Income Security (welfare benefits)	\$580 Billion
Medicare	\$485 Billion
Health	\$362 Billion
Net Interest Payment on National Debt	\$225 Billion
Education, Training Employment & Social Services	\$139 Billion
Veterans Benefits and Services	\$130 Billion
Transportation	\$103 Billion
Commerce (including housing credit)	\$80 Billion
Justice (including Federal Prisons)	\$62 Billion
International Affairs (including Foreign Aid)	\$56 Billion
Natural Resources & Environment (including EPA)	\$43 Billion
Government Operations	\$32 Billion
Community & Regional Development	\$32 Billion
General Science, Space & Technology	\$31 Billion
Energy	\$23 Billion
Agriculture	\$19 Billion