



Medicare Rights Center

Making Medication Therapy Management a Cornerstone of Community-Based Care for People with Alzheimer's Disease and Other Forms of Dementia

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Executive Summary

People with Alzheimer's disease and other forms of dementia have a particular need for medication therapy management (MTM) services that improve compliance with drug regimens and address inappropriate prescribing. All Medicare Part D plans are required to establish medication therapy management programs, but plans have generally favored eligibility criteria, modes of delivery and enrollment models that are ill-suited to people with dementia. The Centers for Medicare & Medicaid Services should take a proactive stance to encourage the development of medication therapy management programs that meet the needs of people with Alzheimer's and other forms of dementia, particularly those who reside in the community.

Introduction

Every year the United States spends over \$200 billion to correct medication-related problems.¹ Some patients do not take their medicine as prescribed; some are treated with too much, too little or the wrong medicine; and some are prescribed medicines that interact dangerously with each other (Table 1). As a result, as many as 200,000 people in the United States may die from medication-related problems each year² and 16 percent of all hospital admissions are due to medication-related problems.³

The burden of advancing age and increasing incidence of chronic illness make older adults particularly vulnerable to these medication-related problems. On average, they are taking more medications and many are becoming less able to manage them. The Office of Inspector General of the Health and Human Services Department reports that 55 percent of older adults fail to comply in some way with their medication regimen.⁴ Nearly 28 percent of hospital admissions for people age 65 and older are due to medication-related problems.⁵ Moreover, medication-related problems are estimated to be one of the top five causes of death in that age group.⁶ One-quarter of all nursing home admissions result from older people being unable to take their medications properly.⁷

These challenges are amplified for people with diminished capacity to make sound health care decisions, such as those with Alzheimer's disease or dementia. Alzheimer's disease, a progressive brain disorder that results in a gradual and steady deterioration of mental ability, can make it impossible for a person to manage his or her medication. Dementia was identified by the Office of Inspector General as one of the dominant reasons older adults fail to comply with their medication regimens.⁸ Similarly, a survey commissioned by the Mental Health Foundation of the United

¹ American Society of Consultant Pharmacists, "Seniors at Risk: Designing the System to Protect America's Most Vulnerable Citizens from Medication-Related Problems," 2004.

² Simonson, W. and J.L. Feinberg. 2005. Medication-related problems in the elderly: defining the issues and identifying solutions. *Drugs & Aging* 22(11):559-569.

³ Nelson, K.M. and R.L. Talbert. 1996. Drug-related hospital admissions. *Pharmacotherapy* 16:701-707.

⁴ Office of Inspector General, "Medication Regimens: Causes of Noncompliance," June 1990.

⁵ Williams, Bradley R. "Avoiding Medication Mishaps: A Pharmacist's Perspective." *Geriatric Times*, May/June 2000.

⁶ American Society of Consultant Pharmacists, "Seniors at Risk: Designing the System to Protect America's Most Vulnerable Citizens from Medication-Related Problems," 2004.

⁷ Green, L.W., Mullen, P.D. and G.L. Stainbrook. 1986. Programs to reduce drug errors in the elderly: direct and indirect evidence from patient education. *Journal of Geriatric Drug Therapy* 1(1):3-18.

⁸ Office of Inspector General, "Medication Regimens: Causes of Noncompliance," June 1990.

Kingdom found that over 90 percent of people with dementia who were living in the community suffered from medication-related problems.⁹ The financial and social implications of this are devastating.

Table 1: Common Medication-Related Problems

Problem	Description
Untreated conditions	The patient has a medical condition that requires drug therapy but is not receiving a drug for that condition.
Drug use without indication	The patient is taking a medication for no medically valid condition or reason.
Improper drug selection	The patient's medical condition is being treated with the wrong drug or a drug that is not the most appropriate for the special needs of the patient.
Subtherapeutic dosage	The patient has a medical problem that is being treated with too little of the correct medication.
Overdosage	The patient has a medical problem that is being treated with too much of the correct medication.
Adverse drug reactions (ADRs)	The patient has a medical condition that is the result of an adverse drug reaction or adverse effect.
Drug interactions	The patient has a medical condition that is the result of a drug interacting negatively with another drug, food or laboratory.
Failure to receive medication	The patient has a medical condition that is the result of not receiving a medication due to economic, psychological, sociological or pharmaceutical reasons.

In the United States, at least \$100 billion is spent each year on Alzheimer's disease, with the average lifetime cost of care for an individual with Alzheimer's estimated at \$174,000 in 1991.¹⁰ The average annual direct cost of care in 1998 was \$19,000 per individual still in the community and \$64,000 per institutionalized individual.¹¹ Further, most individuals with Alzheimer's disease eventually spend part of their lives in a nursing home or assisted living facility.

The comprehensive approach of medication therapy management (MTM) could play a crucial role in optimizing therapeutic outcomes for people with dementia and lead to reduced overall health care expenditures. The provision of MTM services for this population could optimize the use of medicines that slow the rate of mental decline, minimize the use of drugs that worsen dementia as well as the inappropriate use of drug therapy to address behavioral symptoms of Alzheimer's disease. MTM can also help compliance with drug regimens, potentially delaying the need for long-term care services.

All Medicare Part D drug plans must by law provide MTM services, but there are special challenges that must be met in order for the Part D program to deliver high-quality MTM programs that meet the needs of people with Alzheimer's disease and other forms of dementia.

⁹ The Mental Health Foundation of the United Kingdom, "Pharmaceutical Care for Older People with Mental Health Problems Living in the Community," 2001.

¹⁰ Alzheimer's Association, "Fact Sheet: Alzheimer's Disease Statistics," May 15, 2005.

¹¹ Fox, P.J., Kohatsu, N., et al. 2001. Estimating the costs of caring for people with Alzheimer's disease in California: 2000-2040. *Journal of Public Health Policy* 22(1):88-97.

1. What Is the Current Status of Medication Therapy Management Under Medicare?

Under the Medicare Modernization Act (MMA) of 2003, all Medicare prescription drug plans are required to establish MTM programs. The statutory goal of MTM programs is “to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.”¹² MTM programs must be made available at no additional cost¹³ for people with Medicare who have multiple chronic diseases,¹⁴ are taking multiple Part D drugs and have been identified as likely to incur annual drug costs¹⁵ of at least \$4,000.¹⁶

The MMA indicates that MTM services may be provided by a pharmacist. In the final rule for the Part D benefit, the Centers for Medicare & Medicaid Services (CMS) does not further specify who may provide MTM services but notes that it should be a qualified provider. CMS acknowledged the value of both face-to-face interactions and ongoing patient-provider relationships but did not mandate their integration into MTM programs.

Although the MMA does not explicitly define MTM programs, it states that MTM programs may promote

- enhanced enrollee understanding through beneficiary education and counseling on appropriate medication use and the reduction of the risk of potentially adverse events associated with the use of medication;
- increased enrollee adherence to prescription medication regimens through, for example, medication refill reminders, special packaging, compliance programs, and other appropriate means;
- detection of adverse drug events and patterns of over- and under-use of prescription drugs.

In the final rule implementing the statutory provisions on MTM, CMS elaborates, saying that MTM “services could include, but may not be limited to, performing patient health status assessments, formulating prescription drug treatment plans, managing high-cost ‘specialty’ medications, evaluating and monitoring patient response to drug therapy, providing patient education and training, coordinating medication therapy with other care management services, and participating in State-permitted collaborative drug therapy management.”¹⁷

Notwithstanding concern over potential economic disincentives for Part D plans to develop robust MTM programs or CMS’ expectation that MTM “must evolve and become a cornerstone of the Medicare Prescription Drug Benefit,” CMS declined to further define MTM program eligibility criteria, to designate specific recruitment processes for MTM program providers and patients or

¹² 1860D-4(c)(2)(A)(i)

¹³ MTM service providers are to be paid through administrative costs, according to the Centers for Medicare & Medicaid Services (CMS) final rule on the Part D drug benefit. 70 Federal Register 4297, January 18, 2005.

¹⁴ Statutory examples include diabetes, asthma, hypertension, hyperlipidemia and congestive heart failure. In the final rule, CMS recommends that plans take note of these examples in designing their programs.

¹⁵ Further clarification by CMS notes that the \$4,000 takes into account all true-out-of-pocket spending for covered Part D drugs.

¹⁶ This level was specified by the Secretary of Health and Human Services and applies only to 2006.

¹⁷ 70 Federal Register 4297, January 18, 2005.

even to establish a minimum package of services required to be offered by all plans. “We believe that insufficient standards and performance measures exist to support further specification for MTM program services and service level requirements. . . ,” CMS wrote in the preamble to the final Part D rule. As a result, plans were given significant discretion in the design of their MTM program. Many plans’ original proposals fell short of CMS’ expectations. Some drug plans submitted MTM program proposals that were considered overly restrictive in terms of program eligibility, and some were insufficient in terms of operational detail, leading CMS to ask the plans to submit new MTM proposals.¹⁸

The actual MTM programs provided by Part D plans are weighted heavily toward delivery of educational material by mail or through telephone calls from drug plans’ in-house staff. Of the five Part D plans with the highest enrollment, only Community Care Rx, a drug plan cosponsored by the National Community Pharmacists Association, has an MTM program delivered primarily through face-to-face interactions with an independent pharmacist.¹⁹ WellPoint has partnered with Walgreens’ pharmacies for its MTM services, but the remaining major plans provide MTM services exclusively or primarily through the mail or by telephone.

Few plans indicate an intention to provide a comprehensive medical review or provide follow-up. Fewer plans still define what services make up the comprehensive medical review they promise. Similarly, the vast majority of plans surveyed give no indication that they will involve primary care physicians or caregivers in MTM programs.

In addition, many Part D plans, including plans with the largest market share, used the discretion granted by CMS to set a high bar for eligibility for MTM services, requiring enrollees to take as many as 12 prescription drugs and suffer from four or more chronic conditions. A few plans did cast a wider net for MTM participants, requiring that eligible participants have only two chronic diseases and take just three or more Part D-covered medications. All participants in MTM programs, per CMS’ eligibility requirements for 2006, must have estimated annual drug costs of over \$4,000. Plans generally target potentially eligible members through drugs claims data and do not provide avenues for plan members to seek out enrollment in an MTM program.

UnitedHealthcare requires four or more chronic conditions and prescriptions for nine or more chronic medications for MTM program eligibility. Services consist primarily of educational materials delivered by mail and secondarily of telephone or face-to-face communications. UnitedHealthcare will select the beneficiaries to target for face-to-face consultation, which is conducted annually. MTM services may include doctor consultation.

PacifiCare requires that eligible participants take 10 Part D medications and have three of five chronic conditions: congestive heart failure, hyperlipidemia, coronary artery disease, hypertension or diabetes. Educational materials will be provided via mail, and plan enrollees will receive refill reminders and health status assessment forms. Doctors treating MTM enrollees will receive educational materials, special alerts and doctor-specific reports.

¹⁸ “CMS Asks Plans to Resubmit Medication Therapy Management Proposals.” *Inside CMS*, May 19, 2005.

¹⁹ Information on plan MTM programs is derived primarily from a survey conducted by the American Pharmacists Association available at <http://www.aphanet.org/AM/Template.cfm?Section=Home&Template=/TaggedPage/TaggedPageDisplay.cfm&TPLID=57&ContentID=4682>.

Together, PacifiCare and UnitedHealthcare, which merged last year, have 27 percent of the enrollees in stand-alone prescription drug plans.²⁰

Humana, with 18 percent of the stand-alone prescription drug plan market, requires only two or more chronic diseases for eligibility and eight or more unique, chronic systemic medications in order to receive mail or e-mail educational materials. Some participants, based on a proprietary scoring method, will be eligible for follow-up communications if they opt in. MTM services will be provided primarily through a Humana call center by internal staff but also through face-to-face interactions. MTM services may include one comprehensive medication review and one follow-up appointment.

The MTM programs are identical in the Medicare Advantage plans—plans that are supposed to provide coordinated medical and prescription drug coverage—and in the stand-alone drug plans offered by these companies.

There is little detailed information made available to the public, including plan members, on the MTM eligibility criteria or MTM services offered by WellPoint drug plans, which boast the third highest enrollment. According to a 2005 press release, the plans' MTM services will be provided through pharmacists at the Walgreens chain.²¹

Community Care Rx (CCRx), a Part D drug plan offered by MemberHealth, will use face-to-face interaction between community pharmacists and patients to deliver MTM services. The program's focus is on saving customers money through education on lower-cost therapeutic alternatives. Members must take 10 or more medications in four or more drug classes to qualify and must have at least one of six chronic conditions—diabetes, dyslipidemia, hypertension, congestive heart failure, chronic obstructive pulmonary disease or asthma. The plan identifies MTM-eligible patients to the pharmacist for purposes of outreach. CCRx is the fourth largest drug plan in terms of enrollment.²²

WellCare, the fifth largest plan, offers MTM services exclusively by internal staff with delivery entirely through mailed materials and over the telephone. Services include patient health education, medication adherence tools and pharmacist consultation. Drug regimen compliance and control of medication cost are the desired outcomes of the program. No information is available on eligibility requirements. Plan members must fill out an application to enroll in the MTM program.

Among the drug plans with lower enrollment, restrictive eligibility criteria are also common and there is a consistent preference for using mailed educational material as the primary delivery vehicle. For example, both the prescription drug plan (PDP) and Medicare Advantage (MA) plans offered by the BlueCross BlueShield plans in Pennsylvania and West Virginia require 12 or more Part D medications for eligibility and five or more chronic diseases. MTM services will be provided entirely by in-house staff and primarily by mail.

The restrictive criteria set for MTM eligibility by the major national plans unnecessarily limit the provision of this valuable service. Even for those who qualify, the focus on mailing educational

²⁰ CMS, Medicare Prescription Drug Plans (PDPs) by Total Enrollment in Parent Organization, April 27, 2006.

²¹ WellPoint, "WellPoint Announces Strategic Relationship with Walgreens for Medicare Part D Services," October 5, 2005.

²² Community Care Rx, "MTM by the MTM Experts: Community Pharmacists," 2006.

material and telephone communication limits the potential to reach those most in need—individuals with cognitive deficiencies or with low health literacy levels. These modes of delivery also sacrifice the potential to involve caregivers in MTM.

This focus also precludes a comprehensive medication review, which should include over-the-counter drugs, nutritional supplements and drugs excluded from Part D. Face-to-face interactions can also capture medications that patients or caregivers only know by describing the pill size and color. The use of in-house staff also impinges on the independence of the medication review.

2. The Promise of Medication Therapy Management

Results from a range of innovative approaches to providing MTM services suggest that MTM programs have the potential to improve health outcomes and reduce overall health care expenditures, especially for older adults.²³ The most robust MTM programs allow self-referral and referral from primary care physicians or specialists but also directly recruit participants. Comprehensive MTM services include in-person counseling, which is supplemented by telephone and print communication. Additionally comprehensive MTM programs provide services to caregivers as well as patients.

While pharmacists are uniquely positioned to provide MTM program services, the most comprehensive MTM programs strive to incorporate other health care professionals into their programs. For example, in the Fairview Health Services' Pharmaceutical Care Program, a Minneapolis-based program, pharmacists work with doctors and other health care providers to identify and resolve drug therapy issues. Such an interdisciplinary, team-based approach that incorporates an intervention and referral process capitalizes on different professional expertise to expand the set of services provided and their corresponding value. Similarly, it promotes the overall success of the MTM program by integrating its services within the broader context of the patient's health care experience. The Fairview program has recorded significant successes in reducing health care costs and bad drug interactions and improving attainment of patients' therapeutic goals.²⁴

Robust MTM programs offer a full spectrum of patient-centered services that accommodate a patient's social, cultural and medical status. In general, these include a thorough evaluation of a patient's current drug regimen that screens for adverse drug reactions, dangerous drug interactions, and duplicate and/or omitted therapy. The ultimate goal is the development of a comprehensive care plan for the patient. Ideally, MTM programs review the use of over-the-counter medications and herbal and nutritional supplements. Information on patient intake of these products, as well as medications excluded from Part D, such as benzodiazepines, is not available through Part D plan data. Only direct interaction with the beneficiary or caregiver allows the medication review to take account of these non-Part D-covered medicines.

Some MTM services, such as a medication review, are more effective when provided in person. This provides the opportunity for direct observation of health status and interactive discussion of the medication(s), as well as observation of the patient's use of such devices as inhalers, home blood pressure monitors, glucose monitors, etc. For example, an MTM program in Asheville, North

²³ The Lewin Group, "Medication Therapy Management Services: A Critical Review," May 17, 2005.

²⁴ University of Minnesota, "Study shows pharmacists-physician partnership reduces health care costs, bad drug interactions," August 7, 2003.

Carolina that targeted diabetes management included patient training in the correct use of glucose monitors by pharmacists. Because of the success of the diabetes initiative, the Asheville project was expanded to target asthma patients as well.²⁵ Both initiatives saw an increase in spending for disease-related medications but a decrease in spending for other medical claims.²⁶

Broad MTM programs offer educational and support services designed to enhance patient understanding and adherence with drug regimens. For instance, the Pharmacist Review to Increase Cost-Effectiveness (PRICE) Clinic in Sacramento, California, a pharmacist-directed initiative that targets low-income older adults who frequently discontinue use of medications because of their expense, considers all medically appropriate cost-cutting interventions such as generic drug use, tablet-splitting, therapeutic interchange and mail-order pharmacies and also helps patients enroll in relevant assistance programs. A preliminary review of the program in 2002 indicated a decrease in participants' out-of-pocket expenditures and improved access to needed drugs.²⁷ Similarly broad-spectrum MTM programs incorporate lifestyle education about physical activity, diet modifications and other health risks like smoking and alcohol consumption.

Comprehensive MTM programs keep careful records of the services provided and communicate essential information to the patient's primary care physician. This facilitates monitoring of patients' response to therapy to determine the safety and effectiveness of new drug regimens as well as patients' adherence to new routines. Similarly, keeping a record of medication regimens minimizes the chance of repeating past failures. Furthermore, it promotes continuity of care and assists with patient follow-up. Some programs schedule face-to-face follow-up sessions, and some provide services over the telephone. The most robust programs provide follow-up services in person on a monthly or weekly basis.

MTM programs have significant promise to improve health outcomes for people with Alzheimer's disease and other dementias. The need for comprehensive MTM programs for this population is considerable. Alzheimer's disease is a progressive, degenerative disorder that is frequently accompanied by other conditions. It affects one in 10 individuals over age 65 and nearly half of those over age 85.²⁸ An estimated 4.5 million Americans have Alzheimer's disease.²⁹ According to 1999 Medicare claims data, people with Alzheimer's disease and/or dementia are more likely than those without dementia to have certain comorbid medical conditions. Out of all people with Medicare suffering from Alzheimer's disease and/or dementia:

- 30 percent also had coronary heart disease;
- 21 percent also had diabetes;
- 28 percent also had congestive heart failure; and

²⁵ Bunting, B.A. and C.W. Cranor. 2006. The Asheville Project: Long-Term Clinical, Humanistic and Economic Outcomes of a Community-Based Medication Therapy Management Program for Asthma. *Journal of the American Pharmacists Association* 46(2):133-147.

²⁶ "Asheville Project: Medication management improves asthma outcomes, costs." *Daily Pharmacy News*, March 21, 2006.

²⁷ Stebbins, M.R., Kaufman, D.J., and H.L. Lipton. 2005. The Price Clinic for Low-Income Elderly: a Managed Care Model for Implementing Pharmacist-Directed Services. *Journal of Managed Care Pharmacy* 11(4):352-353, 356-357.

²⁸ Ibid.

²⁹ Ibid.

- 17 percent also had chronic obstructive pulmonary disease.³⁰

As a result, people with Alzheimer's disease and dementia have higher use of Medicare hospital and doctor services; higher Medicare costs for hospital, skilled nursing facility services and home health services; and higher total Medicare costs compared with all other people with Medicare.³¹ They also use more prescription drugs than other people with Medicare.³² Furthermore, they have a diminished capacity to make sound health care decisions.³³

In addition, there are a number of drug treatment issues that are specific to people with Alzheimer's and dementia. Recent research points to patterns of inappropriate prescribing of antipsychotics in nursing homes, including duplicative prescribing; prescribing for inappropriate indications, such as depression or memory loss; and prescribing at above-recommended dosages.³⁴ People with Alzheimer's-related dementia also have a particular sensitivity to the impairment of memory and cognition that can be triggered by anticholinergic drugs, such as medications for bladder control or over-the-counter drugs widely used for allergies or as sleep aids.³⁵ Therapeutic substitution can minimize or eliminate these effects.³⁶ Finally, people with Alzheimer's would benefit from assessments to determine appropriate dosing of cholinesterase inhibitors, which can reduce cognitive symptoms of the disease.

Studies have already indicated that coordinated-care programs can decrease the behavioral and psychological symptoms of dementia in people with Alzheimer's. Other research suggests that involvement of family caregivers can reduce nursing home admissions.³⁷ A more recent randomized controlled trial showed that involvement of family caregivers can also improve behavioral and psychological symptoms of people with Alzheimer's.³⁸ An MTM program targeted at people with Alzheimer's could address the medication-related aspects of Alzheimer's care, providing a backbone of support for caregivers. Over half of the caregivers of people with Alzheimer's or dementia responded in a 2003 telephone survey that they had to provide help with medications.³⁹ Community-

³⁰ Bynum, J.P.W., Rabins, P.V., Weller, W., Niefeld, M., Anderson, G.F. and A.W. Wu. 2004. The relationship between a dementia diagnosis, chronic illness, Medicare expenditures, and hospital use. *Journal of the American Geriatrics Society* 52(2):187-194.

³¹ Ibid.

³² Alzheimer's Association, "Comments on the Medicare Prescription Drug Program," October 4, 2004.

³³ Ibid.

³⁴ Briesacher, B.A., Limcangco, M.R., Simoni-Wastila, L., et al. 2005. The Quality of Antipsychotic Drug Prescribing in Nursing Homes. *Archives of Internal Medicine* 165(11):1280-85.

³⁵ Agnoli, A., Martucci, N., Manna, V., Conti, L. and M. Fioravanti. 1983. Effect of cholinergic and anticholinergic drugs on short-term memory in Alzheimer's dementia: a neuropsychological and computerized electroencephalographic study. *Clinical Neuropharmacology* 6(4):311-323.

³⁶ Sunderland, T., Tariot, P.N., Cohen, R.M., Weingartner, H., Mueller III, E.A. and D.L. Murphy. 1987. Anticholinergic sensitivity in patients with dementia of the Alzheimer type and age-matched controls. A dose-response study. *Archives of General Psychiatry* 44(5):418-426.

³⁷ Mittelman, M.S., Ferris, S.H., Shulman, E., Steinberg, G., and B. Levin. 1996. A family intervention to delay nursing home placement of patients with Alzheimer's disease: a randomized controlled trial. *JAMA* 276(21):1725-1731.

³⁸ Callahan, C.M., Boustani, M.A., Unverzagt, F.W., Austrom, M.G., Damush, T.M., Perkins, A.J., et al. 2006. Effectiveness of Collaborative Care for Older Adults with Alzheimer Disease in Primary Care: A Randomized Controlled Trial. *JAMA* 295(18):2148-2157.

³⁹ Alzheimer's Association, "Families Care: Alzheimer's Caregiving in the United States," 2004.

based programs show that MTM services can be a crucial component of care for people with Alzheimer's that is designed to maintain maximum functioning and forestall institutional care.

3. Elements of an MTM Program for People with Alzheimer's and Dementia

People with Alzheimer's and other forms of dementia have a particular need for MTM that is rooted in both the cognitive impairment they suffer and the behavioral manifestations of their condition. In addition, MTM can optimize drug therapies that are used to treat behaviors associated with Alzheimer's and minimize the use of medications that exacerbate those behaviors. The provision of MTM services to people with Alzheimer's or dementia living in the community can be a crucial factor in the maintenance of independence, obviating or at least delaying the need for long-term care in institutional settings.

But people with Alzheimer's disease and other forms of dementia are unlikely to be adequately served by most of the MTM programs being offered by Part D plans. Although Alzheimer's disease and dementia are among the chronic conditions that Part D plans can list as eligibility for MTM,⁴⁰ it is unclear whether any Part D plan actually targets people with Alzheimer's for MTM services.

Even if a Part D plan were to target people with Alzheimer's for its MTM program, the enrollment methods based on prescription data now favored by Part D plans are unlikely to be effective for this population. Prescriptions for cholinesterase inhibitors neither capture people with Alzheimer's not receiving these drugs nor do they capture other dementia indications. Plans targeting MTM services at enrollees with dementia would have to use additional outreach methods to encompass all those in need. Interaction with caregivers or direct observation of patients is a more effective means of identifying potential enrollees in an MTM program targeted at individuals with Alzheimer's or dementia.

Furthermore, many Part D plans, including the PDPs with the largest enrollment, favor mail and telephone communication as the delivery vehicle for MTM services, which does not serve the population with Alzheimer's or dementia even if they are eligible for the programs because of other chronic conditions. Mail-order brochures and telephone calls are ill-suited to people with cognitive impairment.

The MTM programs currently offered by Part D plans hold little promise of meeting the needs of people with Alzheimer's or dementia. Fortunately, there are existing programs outside Part D that provide MTM services to people with Alzheimer's or dementia in community settings⁴¹ as well as programs of care for this population in skilled nursing facilities and assisted living facilities. Elements of these programs can serve as models for delivering MTM services through Part D plans to people with Alzheimer's or dementia living in the community.

In addition, a stakeholder group representing pharmacists, geriatricians, family doctors, case managers, older Americans and employers has developed a consensus document outlining the

⁴⁰ CMS, Medication Therapy Management Program Contract Year 2007, form for prescription drug plan bids.

⁴¹ Interviews with Gloria H. Doughty, R. Ph., M.S.W., Senior Care Pharmacist, Geri-Care Pharmacy, Lexington KY, and Lynn Harrelson, R. Ph., Senior Pharmacy Solutions, May 2006.

critical components of a high-quality MTM program.⁴² Stakeholders agreed that a patient-centered approach that took account of individuals' "environmental, social and medical status" was necessary, and that programs must focus on effective communication with caregivers. These and other principles developed by the stakeholder group, when applied to the development of an MTM program targeted to people with dementia, point to the key elements that will be necessary for a high-quality program.

Interaction with beneficiary caregivers is essential for medication regimen review. Many of the drug regimen issues particular to people with Alzheimer's or dementia require direct observation of behavioral patterns or cognitive functioning in order to conduct a "patient-centered" medication regimen review. Through their regular caregiving activities, family members and nursing staff have the opportunity to observe behavioral changes that may be rooted in reactions to both prescription and over-the-counter medications. Long-term caregivers can alert pharmacists or doctors if new prescriptions have a negative impact on behavioral patterns or cognitive function. In particular, caregivers can assist in ensuring that over-the-counter drugs, drugs excluded from Part D and drugs received from a range of pharmacies are included in drug regimen reviews.

Caregivers are in a position to notice if agitation or cognitive impairment seems heightened at particular times of the day, which can point to adjustment of dosing schedules or use of alternative medications, such as extended release drugs that reduce anticholinergic effects. They are also in a position to implement activities—afternoon walks, repetitive manual activities—that can release pent-up energies that otherwise can cause agitation or aggressive behaviors that are often treated with drug therapies. Direct observation in addition to clinical assessment can also serve to assess the value of continued drug therapy with cholinesterase inhibitors and to inform proper dosing.

Caregivers, sometimes with the aid of special packaging, have a central role in ensuring compliance with drug regimens. The MMA includes "refill reminders, special packaging, and other compliance programs" among the elements of MTM services. In skilled nursing facilities, nursing staff have a direct role in administering medicine, while long-term care pharmacies provide special packaging to help with compliance with daily regimens. In community-based programs, family members, nursing staff and pharmacists share the job of ensuring compliance. Medication boxes, whether filled by family members, other caregivers or pharmacists, can play a role in maintaining compliance. MTM stakeholders have emphasized that team-based approaches and effective communication with those involved in monitoring drug regimen compliance are crucial components of a quality MTM program. For dementia patients, this points to the central involvement of direct caregivers.

Despite the MMA's inclusion of special packaging among the elements of an MTM program, CMS in its final rule on the drug benefit does not mention this service among the components of an MTM program.⁴³ The definition of MTM services adopted by 11 national pharmacy organizations in 2005 also does not specifically include the provision of special packaging, although there is a reference to "support services and resources designed to enhance patient adherence" to drug

⁴² Academy of Managed Care Pharmacy, "Sound Medication Therapy Management Programs 2006 Consensus Document," 2006.

⁴³ 70 Federal Register 4297, January 18, 2005.

regimens.⁴⁴ These omissions may have their root in the overlap between MTM and the dispensing fee for long-term care pharmacies, which is supposed to cover special packaging. Plans are obligated to pay for such services for plan enrollees residing in long-term care facilities and may, at their discretion, pay for such services for enrollees who need them and who live in assisted living facilities or in the community.⁴⁵ Whether reimbursement is provided through a dispensing fee or through payment for MTM services, it is clear that special packaging by pharmacists can play a role in ensuring drug regimen compliance, one of the central goals of the MTM program.

Direct interaction with people with Alzheimer’s or their caregivers can play a key role in enrollment for MTM services. The cognitive limitations associated with Alzheimer’s and the stigma often associated with the disease make it crucial to involve caregivers in identifying individuals who could benefit from MTM. Support groups for family members of people with Alzheimer’s can provide crucial points of contact, as can visits by family members and patients to the pharmacy. By contrast, data mining of prescription patterns is unlikely to identify all those in need, while mailing and cold calls are unlikely to enroll people with Alzheimer’s in MTM programs.

Educational components of MTM services must also take account of the cognitive limitations of people with Alzheimer’s. One-on-one communication with beneficiaries and inclusion of caregivers in education efforts are necessary because mailings and cold calling are unlikely to be effective.

Clinical judgment rooted in direct observation of people with Alzheimer’s is critical to a successful MTM program. The important role of caregivers in a successful MTM program for people with Alzheimer’s or dementia must rest on a foundation of clinical judgment of pharmacists and other providers. A consultant pharmacist working in a skilled nursing facility can play that role, as can pharmacists associated with home care agencies, assisted living facilities or adult day care centers. In community settings, community pharmacists can serve as the linchpin for MTM services as can geriatricians or other doctors specializing in the treatment of people with Alzheimer’s. Stakeholders have emphasized the centrality of evidence-based medicine, as well as an interdisciplinary approach that brings a breadth of health care expertise to the drug regimen review.

4. Providing MTM Services for People with Alzheimer’s Through Part D: The Challenges Ahead

The structure of the Medicare drug benefit creates special challenges for the delivery of MTM services by Part D plans, as envisioned by the MMA.

Part D plans are paid on a capitated basis, providing them an incentive to minimize per-beneficiary drug costs. Those incentives may influence the degree of independent clinical judgment that informs the MTM program, in particular the drug regimen review that a Part D plan provides. MTM programs provided by Part D plan pharmacists can be geared toward minimizing drug costs through generic substitution. MTM services provided by independent, community pharmacists can also provide such savings, but they also hold a greater potential for identifying under use of prescription

⁴⁴ 2005. Summary of the Executive Sessions on Medication Therapy Management Programs. *American Journal of Health-System Pharmacy* 62(6):585-592.

⁴⁵ American Society of Consultant Pharmacists, “Medication Therapy Management Services—Status Update,” August 2005.

drugs or promoting substitution of more expensive alternatives. An MTM program for people with Alzheimer's has the potential to increase use of cholinesterase inhibitors, for example, or substitution of extended release anticholinergic drugs. Independent pharmacists providing MTM might also see a role for themselves in helping clients overcome restrictions on Part D plan formularies, including providing help with prior authorization or appeals procedures.

The efforts of CMS and the Pharmacy Quality Alliance to develop quality measures for MTM services could create a means for measuring the clinical efficacy of MTM programs⁴⁶ and thereby counteract the incentive of Part D plans to focus exclusively on cost-saving clinical interventions.

The payment structure for Part D plans also creates incentives for plans to discourage enrollment by high-cost beneficiaries, which CMS has sought to prevent through minimum requirements for formulary coverage. These incentives could also discourage plans from developing or promoting robust MTM services that are specifically designed to service beneficiaries with high drug costs. A robust MTM program that met the needs of people with Alzheimer's could be especially attractive for those striving to keep loved ones in community settings. But for the plans, it would increase enrollment of higher-cost MTM-eligible beneficiaries while potentially raising plan outlays for cholinesterase inhibitors and antipsychotics. The risk adjustment of Part D plan payments has the potential to mitigate the disincentive to enroll beneficiaries with multiple chronic conditions, although the history of risk adjustment of Medicare Advantage plans suggests that the incentive to steer clear of high-cost beneficiaries is not eliminated by risk-adjusting payments.

CMS rightly recognizes that plans should not charge beneficiaries additional fees for enrolling in an MTM program. Instead, MTM services are paid directly out of administrative costs, which are funded by premiums jointly paid by Medicare and people with Medicare. As a result, however, the cost of plans that provide more robust MTM services may have higher premiums. This could discourage enrollment by much of the target population. If plan premiums are above the low-income subsidy benchmark, then low-income people with Alzheimer's diseases or dementia will effectively be priced out of participation.

Part D plans could benefit from an MTM program that reduces the inappropriate prescribing of antipsychotics to people with Alzheimer's. But the principal cost savings from an MTM program targeted at people with Alzheimer's and dementia—the reduction in outlays for nursing home care—do not benefit Part D plans financially. In fact, Part D plans receive a bump in payment to account for the higher dispensing fees and drug costs of patients in long-term care. Medicare Advantage plans could benefit to the extent that their MTM programs reduced acute care episodes—for example, hospitalizations due to falls caused by drug-induced dizziness, but long-term care is not a Medicare benefit. The great bulk of costs for long-term care is borne by Medicaid.

The development of MTM services targeting people with Alzheimer's and dementia would benefit from CMS guidance on how plans can distinguish between MTM services in ambulatory and institutional settings. CMS regulations and guidance have been silent on this, even though the MMA specifically allows plans to make this important distinction.

⁴⁶ Testimony of CMS Administrator Mark McClellan Before the House Committee on Ways and Means Subcommittee on Health, May 3, 2006.

In the institutional setting, such as a nursing home, there is the potential for overlap between an MTM program and the services the nursing facility's long-term care facility already provides. Monthly drug regimen reviews by pharmacists are already required under the conditions of participation in Medicare and are paid for by the nursing facility. Specialized packaging is also a requirement and is reimbursed through the dispensing fee paid by Part D plans.

This is not to say that there is no need for MTM services to be provided in institutional settings. For example, the American Society of Consultant Pharmacists holds that "consultation on residents with severe behavioral symptoms associated with Alzheimer's disease or other dementias and recommending strategies to reduce these symptoms and minimize adverse effects from drug therapy" should be a part of MTM services paid by Part D plans.⁴⁷

But MTM services targeted to people with Alzheimer's in a community setting would require a different protocol that could potentially include services that would be duplicative in an institutional setting. At the same time, MTM services for people with Alzheimer's in the community need to be designed with sufficient flexibility to account for different modes of care and different levels of cognitive impairment. When family members are the caregivers, extra time for instruction in filling medication boxes may be required. For patients already receiving home care paid by Medicare or Medicaid, the compliance portion of MTM may already be in place; the Part D plan would pay for the drug regimen review and interaction with caregivers. In other situations, compliance may be best ensured by the pharmacy's provision of special packaging, whether that service is reimbursed through MTM payments or through a dispensing fee.

Finally, the fragmented nature of Part D creates additional barriers to the provision of Part D services. Pharmacists and doctors serving retirement communities, including both assisted and independent living arrangements, are ideally situated to provide MTM services. They have direct contact with beneficiaries for enrollment in an MTM program and can directly observe their response to drug therapy and aid in the compliance with drug regimens. However, they are likely to be dealing with a range of Part D plans, each with a different MTM program and each with different formularies that would impact MTM protocols.

5. Conclusion and Recommendations

Care coordination is increasingly recognized as a necessary tool in improving health and quality of life as well as in lowering overall health care costs. Congress recognized that when it included medication therapy management in the Medicare drug benefit. However, the obstacles to a robust MTM program that serves those who may need the program most—people with Alzheimer's and dementia—are inherent in the structure of Part D and should point policymakers toward provision of both the drug benefit and MTM services directly through Medicare.

As Congress considers Part D reforms, it should move toward providing MTM under Part B. This would ensure that the economic incentives of Part D plans do not impinge on the quality of MTM programs, for example, by tying payment solely to reduced costs or by discouraging regimen reviews that raise outlays. An MTM program that improves health outcomes could generate savings for both

⁴⁷ American Society of Consultant Pharmacists, "Medication Therapy Management Services—Status Update," August 2005.

Medicare and Medicaid. MTM programs under Part B could be targeted at those twin goals, rather at the narrower financial goals of the Part D plans.

However, the immediate challenge before CMS is to fulfill its own goal of making MTM a “cornerstone” of the Part D program and delivering robust MTM services to people with Medicare, particularly those suffering from Alzheimer’s and other forms of dementia.

First, CMS must ensure that all Part D plans provide robust MTM services that are widely available to the population targeted in the statutory language. CMS should not approve MTM programs that have overly restrictive criteria. Plans should be required to prominently promote their programs in their marketing materials and use outreach techniques that result in robust enrollment. CMS should continue its collaborative efforts to develop measures on the clinical efficacy of MTM programs and require plans to report this data. Current reporting requirements focus solely on enrollment statistics and the MTM programs’ impact on drug costs, although in 2007, CMS will also require reporting on MTM programs’ impact number of prescriptions per beneficiary enrolled in the programs.

If all plans are required across-the-board to provide robust MTM programs, there is minimal competitive disadvantage for plans that target the most difficult populations, such as people with Alzheimer’s and dementia, who may need more costly interventions, such as special packaging.

Second, CMS should take an active role in promoting pilot projects that would allow “best practices” to emerge. The anemic state of most existing Part D MTM programs argues for a more proactive approach. Through its demonstration authority, in conjunction with the Part D plans and separately under Part B, CMS should allow a range of providers to pilot MTM programs that will provide lessons in both the delivery of MTM services and the clinical protocols that should underlie them. Pilot programs targeting individuals with Alzheimer’s and other forms of dementia should be a major part of this effort.

Third, CMS should encourage states with state pharmaceutical assistance programs (SPAPs) that coordinate with Part D plans to use their leverage with Part D plans to encourage the development of MTM programs designed to maintain independent living for people with Alzheimer’s or dementia. States with SPAPs have the right incentives: their SPAPs bear the risk of higher drug costs and their Medicaid programs bear the cost of long-term institutional care. CMS, on a case-by-case basis, allowed SPAPs to use formulary and other criteria to channel enrollment of their members, and has allowed states to set thresholds for the premiums they will subsidize. States should have the ability to use quality criteria, such as the provision of MTM services, to decide which Part D plans will receive premium subsidies or coordination of benefits.