



**3101 Broadway, Suite 650  
Kansas City, MO 64111-2446  
(816) 531-2177  
(816) 531-4990 FAX  
<http://www.accp.com>**

**President**  
Barbara G. Wells, Pharm.D., FCCP, BCPP  
University of Mississippi  
(662) 915-7265

**President Elect**  
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Medical College of Georgia  
(706) 721-6492

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Medical University of South Carolina  
(843) 792-8501

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(312) 996-7961

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(410) 706-1865

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(608) 262-5549

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(215) 596-8576

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University of Colorado HSC  
(303) 315-6993

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**Director, Government and Professional Affairs**  
C. Edwin Webb, Pharm.D., M.P.H.  
Washington, D.C.  
Office: (202) 756-2227  
Fax: (202) 756-7506

**Editor, Pharmacotherapy**  
Richard T. Scheife, Pharm.D., FCCP  
Boston, MA  
Office: (617) 636-5390  
Fax: (617) 636-5318

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Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
P.O. Box 8014  
Baltimore, MD 21244-8014

**Reference File: CMS-4068-P**

Dear Sir/Madam:

The American College of Clinical Pharmacy (ACCP) appreciates the opportunity to provide comments regarding the implementation of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). In particular, ACCP is providing comments concerning the proposed rule as published in the August 3, 2004, *Federal Register* notice concerning implementation of the outpatient prescription drug benefit (Part D benefit), with particular emphasis on medication therapy management programs (MTMP), quality assurance issues, and other provisions to improve medication use and enhance the health status and outcomes of Medicare beneficiaries.

ACCP is a national professional and scientific society that represents more than 8,000 clinical pharmacist practitioners, researchers, and educators. Our members have been the profession's leaders for almost three decades in providing professional services, consultation, cutting-edge clinical research, and educational leadership that improve the quality of medication use in the health care settings in which they practice. As a founding organization of the Pharmacist Provider Coalition, ACCP has worked diligently with Congress, the Medicare Payment Advisory Commission, and other key policymakers for more than four years to

establish the principle that pharmacists' professional services for assuring the appropriate use of medications should be integrated into the Medicare program, regardless of the source of supply, or payment, for the medications themselves. Effective implementation of the Part D benefit, including the MTMP provisions, will serve as an important initial benchmark toward the goal of making these valuable services available to all Medicare beneficiaries.

We appreciate your careful consideration of the comments that follow, and look forward to working closely and directly with CMS in the months and years ahead in assuring that the new Part D benefit not only enhances Medicare beneficiary access to needed medications, but that the program's operational and quality standards assure that therapeutic outcomes are indeed optimized because pharmacists' medication therapy management services are a substantial and integral part of the new Part D benefit.

### **General Comments:**

ACCP is pleased that the proposed rule acknowledges and reinforces in both the preamble and appropriate sections of the proposed rule the important distinctions among the various quality assurance, utilization management, and related requirements for the Part D benefit that are established by MMA. In particular, the recognition that a MTMP involves **"...targeted, direct patient care"** activities is a critical observation that should be emphasized and reinforced in standards that CMS adopts for evaluating the quality and effectiveness of a PDP's benefit design, structure, and delivery with respect to the MTMP component of the benefit. To that end, we encourage CMS to consider incorporating into the final rule language consistent with the consensus definition and program criteria for MTM services developed by eleven national pharmacy organizations, including ACCP, earlier this year (enclosed as Appendix A).

We are pleased that the proposed rule recognizes that **pharmacists "...will be the primary providers..." of MTM services.** By virtue of their professional education and training, pharmacists are uniquely qualified, positioned, and motivated to provide these services to Medicare beneficiaries. Further, the range of direct patient care activities that comprise MTM

services are those that are most consistent with the defined scope of practice of pharmacists as articulated in state pharmacy practice acts. Finally, the effectiveness of pharmacists as providers of MTM services has been documented extensively in the professional literature<sup>1</sup> – more so than for any other health care professional. We therefore encourage inclusion in the final rule of language or guidelines that would require that the PDP’s plan for provision of MTM services include and utilize only those providers whose professional knowledge, experience, skills, and defined scope of practice qualify them to provide MTM services.

We are also pleased to see the emphasis on beneficiary choice, and maintenance and support of existing beneficiary-provider relationships, in assuring both quality and continuity of care. Many Medicare beneficiaries have long-standing and effective relationships with their pharmacists, which have helped to assure the appropriateness and effectiveness of their medication use prior to the implementation of the Part D benefit. In the final rule, CMS should provide guidance to PDP’s in developing the MTMP component of their plans to assure that these important existing beneficiary-provider relationships are facilitated and encouraged to the maximum extent possible.

### **Comments on Medication Therapy Management Program (MTMP) Provisions:**

#### **(1) General Rule:**

The stated objective for a MTMP is to “...assure appropriate use of medications in targeted beneficiaries to optimize therapeutic outcomes through improved medication use.” Thus, the benefits of an effective MTMP accrue, importantly, not only to the patient but also to the Medicare program by helping to avoid or reduce expenditures for (1) preventable hospitalizations due to medication-related problems, (2) unnecessary physician office visits or other Part B services that may arise due to medication-related problems, or (3) additional expenditures for medications that may not be needed.

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<sup>1</sup> Schumock GT, Butler MG, et al. “Evidence of the economic benefit of clinical pharmacy services – 1996-2000.” *Pharmacotherapy*. 2003 Jan; 23(1):113-32.

MTM services and their beneficial effects have been particularly embraced in health care systems, managed care organizations, and similar entities that are at financial risk for overall health care costs for their clients, or which have other incentives to improve quality and/or manage overall health care costs for patients. Experience in such programs has shown that, in some patients, high quality MTM services result in changes to the medication regimen, including additions to or changes in the medications used, that may actually result in an increase in spending for the medications themselves. These increases are frequently more than offset by the avoidance of expenditures for more expensive services as the quality objectives described above are achieved.

However, under the Part D benefit, “stand-alone” PDPs may have insufficient incentives to implement comprehensive MTM programs because they may focus their efforts only on reducing the cost of medications used by beneficiaries – because they have no financial risk exposure to beneficiaries’ consumption of other health care services.

Consequently, ACCP urges CMS to develop guidelines that assure that PDPs develop MTMPs that are structured to achieve the full range of quality outcomes that will benefit both Medicare patients and the Medicare program itself. This will also allow for more effective comparison of the effectiveness of MTMPs established by PDPs and those established by MA-PD programs.

ACCP further urges CMS to provide guidance to PDPs to establish one or more core measures of MTMP effectiveness for targeted beneficiaries that could be evaluated in a longitudinal manner. This would provide information that could facilitate evaluation of MTMPs of the PDPs by CMS, Medicare beneficiaries, and health care providers. Examples of measures that could be considered include rates of hospitalization (compared to beneficiaries with similar disease and medication use profiles who are not enrolled in the Part D benefit) and frequency of emergency room or unscheduled physician office visits. Experience gained with these fundamental measures of performance could then guide the development and implementation of further, perhaps more targeted, measures of quality as PDPs, CMS, and providers gain additional experience with the new benefit.

**(2) Targeted Beneficiaries:**

ACCP understands the rationale in both the legislation and proposed regulations for targeting MTM services to patients with multiple chronic diseases, who are taking multiple medications, and who are likely to incur substantial costs for medications. Both logic and experience suggest that such patients will clearly derive substantial benefit from MTM services.

Nevertheless, since the language links those three criteria together rather than allowing any one of the three criteria to trigger the delivery of MTM services, ACCP encourages CMS to provide guidance to plans that the threshold within each of the three categories be conservative (i.e., low). It is certainly conceivable that a particular patient on only two medications, having only two chronic diseases (thus satisfying the common definition of “multiple”), could benefit substantially from an MTM intervention if either of the diseases is uncontrolled or if the medication-related problems the patient is experiencing can be effectively addressed by the pharmacist’s services. An inappropriately high threshold in these categories could result in patients not receiving a service that could clearly be beneficial to them.

With regard to the specific question of whether or not CMS should allow PDPs to determine the annual drug expenditures that would trigger the delivery of MTM services, ACCP believes that this is a reasonable approach at this initial stage of the implementation of the benefit. Perhaps, given the issue raised earlier regarding PDPs potentially narrow “drug expenditure only” perspective, such programs will consider establishing a relatively low threshold for spending to trigger delivery of at least some MTM services. As with many aspects of this new program, time and experience will likely be needed to determine the best approach to achieve the desired policy objective. The issue should be subject to regular review by CMS, with opportunity for future comments to be provided by interested and concerned parties.

Finally, although not specifically authorized by the statute, ACCP encourages CMS to consider providing guidance to the PDPs and MA-PDs that would allow for referral by a patient's primary care provider(s) or self-referral by the beneficiary (or caregiver) as additional points of access for MTM services if the provider or beneficiary believes such services will be of particular value. Such referral, of course, would need to avoid conflicts of financial interest on the part of any provider making such a referral.

### **(3) Use of Experts:**

Both the statute and the proposed rule require the development of the MTMP in cooperation with licensed and practicing pharmacists and physicians. To help assure the development of programs that are of high quality and contemporary in their scope of services, CMS should provide guidance to PDPs and MA-PDs to utilize pharmacists and physicians with both expertise and professional experience in the use and delivery of MTM programs. Practitioners of both professions who have experience working under formal collaborative practice/drug therapy management agreements, as are now authorized in forty states, would be able to provide particularly valuable guidance to plans in the development of the MTMP.

ACCP also recommends that CMS establish its own expert advisory panel on MTM services, consisting of pharmacists and physicians with substantial practice experience in contemporary pharmacotherapy and MTM services. Such a panel could be especially valuable in assisting CMS in both its initial and ongoing assessment of the performance of the PDPs in the design, implementation, and evaluation of MTMPs. ACCP would welcome the opportunity to work with CMS in identifying qualified pharmacist and physician practitioners to serve on such a panel.

### **(4) Coordination with Care Management and Chronic Care Improvement Programs:**

As noted in the proposed rule's preamble, the mechanisms by which coordination of MTMP activities with the newly established chronic care improvement programs (CCIP) under Part B of Medicare could or should occur are mostly speculative at this point.

Nevertheless, from the perspective of ACCP, an effective program of medication therapy management should always be a primary component of any broader program designed to provide overall coordination and care improvement for chronic diseases, whether or not the beneficiary opts for outpatient prescription drug coverage under Part D. CMS guidance should provide that beneficiaries having Part D coverage who also are receiving services under the CCIP should have MTM services provided under the Part D benefit structure. For such individuals receiving care under both programs, it would be both logical and appropriate to allow a waiver of the requirements for “multiple medications/multiple diseases” that is found in the statute and the proposed regulations.

**(5) Considerations in Pharmacy Fees:**

ACCP strongly supports the intent of the legislation and the principle outlined in the proposed rule that fees associated with provision of medication therapy management services are separate and distinct from dispensing fees, and that the time and resources necessary to implement and deliver MTM services must be taken into account when establishing fees for the services. CMS guidance to PDP and MA-PD plans on this matter must be unequivocal.

These distinctions are critical to assuring that the services are comprehensive and appropriately compensated. Furthermore, such a separation helps to assure the appropriate avoidance of potential conflicts of interest between the prescribing/dispensing processes and the provision of MTM services, which if co-mingled financially could present potential conflicts of interest not unlike the potential conflict of interest that exists for a physician who both prescribes a medication and dispenses/sells that medication to a patient.

CMS should consider requiring PDPs to structure their contracts with pharmacy services providers in a way that would assure that any providers who are seeking to and are capable of providing both medication dispensing services and MTM services to Medicare beneficiaries have an operational and financial structure that appropriately segregates these activities to reduce real or perceived conflicts of interest.

The failure of MMA to specify how fees should be paid (and not incidentally how the delivery of services might be documented) represents an important opportunity for CMS to provide leadership in furthering the goals contained in HIPAA requirements for use of the CPT coding system for electronic claims processing for the services of health professionals, including pharmacists (*Federal Register*, 8/17/2000, Part III, 45 CFR Parts 16 & 162, p. 50331). This final rule clearly contemplates that pharmacists' professional services would be documented and billed using the CPT coding system as the recognized electronic standard.

ACCP is very concerned with the inclusion of MTM services as a component of the "administrative costs" of the PDP plan, along with drug utilization management and quality assurance measures, and believes that this is inconsistent with the clear differences between MTM services and these other types of activities as articulated throughout the statute and other sections of the proposed rule. Even if CMS does not view MTM services as a distinct "benefit" subject to beneficiary copayment or other cost-sharing provisions of Medicare, it should nevertheless insist on procedures for quality assurance and auditing purposes that conform to agreed-upon standards and, equally importantly, assure that services are indeed being provided. This approach is particularly appropriate given the stated expectations of CMS that the nature, scope, and intensity of MTM services will vary substantially based on the individual needs and clinical status of the beneficiary.

ACCP therefore urges CMS to require the use of a coding and billing infrastructure for MTM services that uses CPT coding architecture consistent with HIPAA standards. Such a requirement would be fully consistent with current activities of a consortium of pharmacy organizations (the Pharmacist Services Technical Advisory Coalition) that is working with the AMA's CPT Editorial Process to support pharmacists' use of existing and potentially newly developed CPT codes in the delivery of MTM services. Without such an approach, ACCP believes it will be practically impossible for CMS to assure that MTM services are actually being delivered, are achieving the desired objectives of improving therapeutic outcomes, and are being properly compensated by the PDP.



**Comments on Other Provisions of the Proposed Rule:**

ACCP offers the following perspectives on other aspects of the proposed rule as related to the Part D benefit, on which CMS has invited comment:

1. ACCP believes that the definition of “medication error” (i.e., that used by the National Coordinating Council for Medication Error Reporting and Prevention) found in the proposed rule is an appropriate one for initial use in interpretive guidance in evaluating quality assurance and MTMP efforts of the PDPs and their providers.
2. ACCP encourages CMS to provide guidance to PDPs that would strongly encourage the active involvement of a pharmacy and therapeutics committee, with active pharmacist and physician involvement, to provide consultation and assistance to the PDP for all drug utilization management and quality assurance activities.
3. ACCP supports the view of CMS that the most appropriate proposed definition for “dispensing fee” is that outlined in “Option 1” of the three options found in the proposed rule. This definition would limit the dispensing fee to applying only to those activities associated with the preparation and transfer of the medication from the dispensing pharmacy to the beneficiary. However, even within this narrow definition, ACCP believes it is appropriate for CMS to authorize PDPs to pay different dispensing fees based on the complexity of the process that is needed to appropriately prepare the medication for effective use by the patient. Such activities could include procedures and costs associated with intravenous admixture preparation, resources or tools to assist patients in improving adherence to the medication regimen, and appropriate compounding of non-commercially available dosage forms.

ACCP looks forward to continuing to work with CMS staff as the implementation of the Medicare Part D benefit proceeds. We applaud the work of the CMS staff and stand ready to assist in any way we can to help assure that the new benefit succeeds in its goal of improving

Medicare beneficiaries' access to and improved therapeutic outcomes from the medications that they need.

Sincerely,

Handwritten signature of Michael S. Maddux in black ink.

Michael S. Maddux, Pharm.D., FCCP  
Executive Director

Handwritten signature of C. Edwin Webb in black ink.

C. Edwin Webb, Pharm.D., M.P.H.  
Director, Government and Professional Affairs

**Appendix A****Pharmacy Profession Stakeholders Consensus Document  
July 7, 2004****Medication Therapy Management Services --  
Definition and Program Criteria**

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients.

Medication Therapy Management Services are independent of, but can occur in conjunction with, the provision of a medication product.

Medication Therapy Management encompasses a broad range of professional activities and responsibilities within the licensed pharmacist's, or other qualified health care provider's, scope of practice. These services include but are not limited to the following, according to the individual needs of the patient:

- a. Performing or obtaining necessary assessments of the patient's health status;
- b. Formulating a medication treatment plan;
- c. Selecting, initiating, modifying, or administering medication therapy;
- d. Monitoring and evaluating the patient's response to therapy, including safety and effectiveness;
- e. Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events;
- f. Documenting the care delivered and communicating essential information to the patient's other primary care providers;
- g. Providing verbal education and training designed to enhance patient understanding and appropriate use of his/her medications;
- h. Providing information, support services and resources designed to enhance patient adherence with his/her therapeutic regimens;
- i. Coordinating and integrating medication therapy management services within the broader health care-management services being provided to the patient.

A program that provides coverage for Medication Therapy Management services shall include:

- a. Patient-specific and individualized services or sets of services provided directly by a pharmacist to the patient\*. These services are distinct from formulary development and use, generalized patient education and information activities, and other population-focused quality assurance measures for medication use.
- b. Face-to-face interaction between the patient\* and the pharmacist as the preferred method of delivery. When patient-specific barriers to face-to-face communication exist, patients shall have equal access to appropriate alternative delivery methods. MTM programs shall include structures supporting the establishment and maintenance of the patient\*-pharmacist relationship.
- c. Opportunities for pharmacists and other qualified health care providers to identify patients who should receive medication therapy management services.
- d. Payment for Medication Therapy Management Services consistent with contemporary provider payment rates that are based on the time, clinical intensity, and resources required to provide services (e.g., Medicare Part A and/or Part B for CPT & RBRVS).
- e. Processes to improve continuity of care, outcomes, and outcome measures.

\* In some situations, Medication Therapy Management Services may be provided to the caregiver or other persons involved in the care of the patient.