Testimony

of the

American Pharmacists Association

Submitted to the Senate Committee on Finance

on "The Medicare Prescription Drug Benefit: Monitoring Early Experiences"

May 2, 2007

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Before the Committee on Finance
United States Senate

Hearing on
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Good morning. Thank you for the opportunity to appear before you today and present the views of the American Pharmacists Association. I am Tim Tucker, a pharmacist and the President-elect of APhA. I have been in practice for 19 years and currently own a community pharmacy in Huntingdon, Tennessee. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 60,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings, and the military.

We appreciate the Committee's commitment to providing oversight of this important benefit. As we look to the program's future, it is important to take advantage of what we have learned from the first year's successes and failures to address the program's weaknesses. The Medicare Part D prescription drug benefit took the important step of providing Medicare beneficiaries access to prescription medications — one of the primary tools in health care's tool kit. As a result, pharmacists believe it is imperative that we make this benefit work and their efforts to date reflect this commitment. While largely a success — due to pharmacists' efforts, as well as the work of the Centers for Medicare and Medicaid Services (CMS) and other agencies — challenges continue to impact pharmacists and their ability to help patients make the best use of their medications. Because of pharmacists' critical role administering the benefit, it is essential to fix the problems that impede pharmacists' ability to work within the program.

Although my written testimony references survey results from several surveys that we conducted in 2006, my oral comments will reference results from a survey we conducted this week of our members.

Pharmacy Reimbursement: The Low and Slow of Part D

Medicare Part D has had a dramatic impact on the business of pharmacy. Contracting and reimbursement issues continue to plague pharmacy. These issues include unfair negotiation tactics, delayed updates of pricing metrics, low reimbursement levels, delayed payments, and a lack of pricing transparency. Some of these issues are amplified for the pharmacies serving low-income or uninsured patients.

Unfair "Negotiations"

The program architects assumed that providing pharmacies the authority to negotiate would provide pharmacies the opportunity to negotiate contracts that meet their individual pharmacy's needs. Unfortunately, pharmacies are often faced with two scenarios, neither of which represents the spirit of the law.

First, pharmacies are offered "take it or leave it contracts". Just as they sound, these contracts force pharmacies to accept contract terms without an opportunity to negotiate rates. Second, pharmacies are offered contracts that are "tied" with other contracts. In these cases, a Part D plan links the Part D contract to other contracts that the pharmacy may have with the Plan for other, non-Medicare Part D populations. If the pharmacy chooses to contract with the Plan to serve Part D beneficiaries, then the pharmacy can retain its other contracts with the Plan. But if the pharmacy declines the Part D contract, then the pharmacy also loses its contracts for the other, non-Medicare Part D populations.

The contracting situation is even worse for many of the pharmacies and healthcare entities that form the nation's safety net and provide care for the uninsured. Although Part D plans are encouraged to include safety net pharmacies in their networks, many part D plans have ignored or systematically excluded these pharmacies from their contracting activities.

Some safety-net entities are not able to meet the standard terms of a Part D contract due to formulary restrictions, or other constraints based on their Federal funding to care for the uninsured or specific patient groups. The Health Resources and Services Administration (HRSA) worked with CMS to develop a Model Safety Net Pharmacy Addendum to Pharmacy Contract for Part D. The Addendum was designed to bridge the standard contract terms that many safety net providers are not able to meet. APhA applauds these efforts by HRSA and CMS. Unfortunately, many Part D plans are avoiding safety-net providers, or offer severely reduced reimbursement rates. Consequently, these pharmacies and their already vulnerable patients are less able to reap the benefits of Part D. Until the business and financial incentives for the plans align with the public policy concerns of including safety net pharmacies, these pharmacies – and their patients – will continue to be excluded from meaningful participation in Part D.

At a minimum, greater oversight of plan contracting processes is required to ensure that community pharmacy can continue to serve Medicare Part D beneficiaries. Additionally, we recommend that Congress consider providing an anti-trust exemption to allow individual pharmacies to collectively negotiate with Part D plans. This step would go a long way in helping level the "negotiation" playing field.

Low Reimbursement

Because of the lack of opportunity for pharmacies to negotiate their contracts with Part D plans, pharmacies have been forced into contracts that do not cover their costs. To ensure that Medicare beneficiaries continue to have access to community pharmacies, additional oversight of pharmacy reimbursement must be established. This oversight would provide greater assurances that a pharmacy's costs associated with acquiring a drug product are covered, and that Part D plans provide pharmacies a "reasonable" dispensing fee to cover the pharmacy's costs associated with dispensing the product. The fee would cover salaries, overhead, and a reasonable profit and would be based on data from relevant "cost to dispense" studies. Reimbursement rates must include a fair return to the community pharmacy that has elected to participate in the program. Absent these assurances, pharmacies will continue to be asked by Plans to dispense Part D drugs at a financial loss.

Slow Reimbursement

Some Part D plans have also challenged the financial viability of pharmacies by unnecessarily delaying their payments. While we have seen some improvements in the program, some pharmacies continue to endure lengthy payment delays for medications dispensed to patients. Pharmacies cannot sustain long delays in payment particularly since those with whom pharmacy contracts, such as wholesalers, are enforcing penalties for any delayed payments from pharmacies.

In our December, 2006 survey, respondents (59) indicated that on average: none were reimbursed by the plans with whom they contract within 14 days; 14% were reimbursed by the plans with whom they contract within 15-21 days; 15% were reimbursed by the plans with whom they contract within 22-30 days; 12% were reimbursed by the plans with whom they contract within 31-60 days; and 7% reported that it took the plans longer than 60 days to reimburse the pharmacy. One respondent to the August, 2006 survey reported that their group purchaser showed about $60,000 of outstanding receipts of over 90 days from about 4 or 5 Part D Plans. The December, 2006 survey revealed the various ways pharmacies have addressed these cash flow problems. Seventeen percent of survey respondents reported negotiating extensions with wholesalers; 9% reported taking out a business loan/line of credit; 7% reported taking out a personal loan/line of credit; 10% reported laying off staff; and 3% reported reducing pharmacy hours.

Likely due to pharmacy's expressed concern regarding ongoing delays, CMS surveyed Part D plans on the frequency of their payments to pharmacies. CMS reported that their survey results indicated that of the 20 plans that responded, all reported that their contracts require them to pay pharmacies within 15 days. In a July 6, 2006 letter to the Agency, APhA disputed CMS' survey method. APhA suggested that a mere review of contract terms does not reflect actual reimbursement practices and to truly gain insight into how frequently pharmacies are paid, CMS should survey pharmacies. The weakness of CMS' survey is exemplified by the reports APhA received of pharmacists receiving multiple reimbursement checks in one envelope. Although the Part D plans may cut reimbursement checks every 14 days, as per the terms of the contract, they waited to mail the payments until multiple checks were cut. Clearly, more needs to be done ensure that plans are complying with the letter and the spirit of their contract terms. It is egregious to place this financial burden on the backs of pharmacy. In addition to increasing oversight in this process, we strongly recommend

establishing a "prompt payment" standard that would require plans to pay pharmacies every 14 days for electronic claims and every 30 days for paper claims.

Electronic Funds Transfer

As we have described, the business of pharmacy is heavily reliant on a timely cash flow and cannot sustain long delays in payment. The manner in which pharmacy claims are submitted to Part D plans should influence the timeliness of pharmacy payments. Ideally, electronically submitted claims would be paid through electronic payments to pharmacies – much like many of us do with our own personal banking. We appreciate the efforts of the Chairman, Ranking Member and Committee members to facilitate electronic transfers of funds. Despite these efforts and those of the American Health Insurance Plans (AHIP) to ensure that electronic funds transfer (EFT) is adopted by Part D plans as a payment standard, pharmacies continue to encounter issues with this method of payment. We strongly recommend requiring Part D plans that receive pharmacy claims electronically to send pharmacy payments electronically through a real-time EFT system.

Delayed Pricing Metric Updates

Even if a contract allowed for fair reimbursement and pharmacies were paid promptly, unless the payment metrics upon which a pharmacy's reimbursement is based are updated on a timely basis the pharmacy may face financial losses. APhA appreciates the efforts of the Chairman, Ranking Member, and other Committee members to address delayed pricing metric updates. Our members continue to report that prescription drug plans are delaying updates to their Average Wholesale Prices (AWPs). This practice disadvantages pharmacists by basing their reimbursement on the outdated AWPs, which are often lower than the current AWPs.

Without regular updates to the database used to reimburse pharmacies, pharmacies are at risk for being underpaid for the prescriptions they dispense. Because pharmacies are expected to pay current 'real time' prices to manufacturers and wholesalers from which they purchase drugs, it is only fair that plans pay pharmacies based on the current prices at which pharmacies are purchasing drugs. To ensure that pharmacies are receiving appropriate compensation that reflects the latest available data, we support your recommendation to require pricing metric updates the same day that the Plan receives an AWP change. Absent this change, pharmacies will continue to be underpaid for prescriptions.

Generic Drug Pricing Transparency

Part D contracts with pharmacies often fail to include information about payment rates for generic drugs that is essential to pharmacies' ability to anticipate and plan for business costs. APhA recommends requiring plans to disclose their reimbursement terms for generic drug products. The terms should detail how the plan will reimburse pharmacies for the generic drug products they dispense to Part D beneficiaries, to which generic drug products these reimbursement rates will apply, and how frequently these rates will change. Absent this information, pharmacies enter into contracts without the access to the elements required for them to accurately predict the reimbursement they will receive from plans for generic drug products.

"Direct Negotiation"

Current "direct negotiation" proposals lack sufficient detail for APhA to take a position on them. Absent these additional details, APhA is left to hypothesize about how direct negotiation and striking the non-interference clause would impact pharmacy reimbursement for the drug product and the dispensing-related pharmacist services that are reflected in the dispensing fee.

Some argue that pharmacy could fare better because the government would be authorized to 'interfere' in the negotiations between pharmacies and prescription drug plans and/or their PBM colleagues. However, others argue that pharmacy could fare worse because of the government's track record on pharmacy reimbursement. In the Medicaid program, the average pharmacy dispensing fee is about $4 when it costs on average about $10 to dispense a medication.[1] Those who oppose direct negotiation suggest this low reimbursement would be replicated in Medicare Part D. APhA will wait to take a position on current direct negotiation proposals until greater details are available about how drug products and pharmacist services would be reimbursed.

[1] National Study to Determine the Cost of Dispensing Prescriptions in Community Retail Pharmacies, Grant Thornton LLP, January 2007

Plan-to-Plan Claim Reconciliation

When a beneficiary switches plans it isn't always clear to the pharmacist dispensing the prescription which plan, or that even a new plan, should be billed. Sometimes the information on the new plan isn't presented to the pharmacist and the pharmacist inadvertently bills the wrong plan. This situation often occurs with dual-eligibles who can switch plans at any time. When an incorrect billing occurs, pharmacies are asked to re-bill the claim to the "correct" plan. To do this requires a lot of administrative work for the pharmacy, which has no responsibility for the accuracy of the Part D database used to bill pharmacy claims. We strongly encourage the Committee to direct CMS to implement a "plan to plan" reconciliation process to eliminate the need for plans to use pharmacies as billing intermediaries. Plans could directly bill other plans, removing the need to use community pharmacies as billing arbitrators.

Formulary Management

Formularies are a common pharmacy benefit management tool that when well-designed can provide patients access to medications while balancing cost and clinical effectiveness. APhA opposes formularies that unfairly limit – through administrative, financial, or other means – patient access to necessary medications. Severely limiting patient access to necessary medications would make the Part D benefit an empty promise.

Standardization

A commonly reported administrative burden for pharmacists is the time and effort required to manage each individual plan's formulary because each formulary is different in what it requires of the pharmacist, patient, and prescriber. For example, the message the plan communicates to the pharmacist and whether it provides "actionable" information, the forms that are required to process a prior-authorization or exceptions request, how and to whom the forms must be transmitted, and the required information can differ for each plan. Because pharmacists play an integral role in implementing formulary management tools for patients, it is essential that they have the information that they need to execute a plan's processes.

The results of APhA's December, 2006 survey reflected the various ways plans are responding to claims for non-formulary drugs. The following represent what the 59 survey respondents identified as plan actions: 85% reported that plans rejected claims; 44% reported that plans provided formulary alternatives; 86% reported that plans required prior authorization; and 29% reported that plans were required an exceptions request. Such a high number of rejected claims that require prior authorization or an exceptions request demands that more be done to reduce the administrative burden on pharmacists who must take the initial step of communicating the plan's required information to the patient's prescriber to facilitate a prior-authorization or exceptions request.

CMS recognized the challenges of these formulary management tools and encouraged the industry to standardize prior-authorization processes. Industry created a workgroup in which APhA participates. The workgroup has focused on creating standardized claims messaging. Two of the five messages were adopted by the National Council for Prescription Drug Programs (NCPDP), the standards development organization for transmission of pharmacy claims data. While this was an important first step, the need for the messages remains. Our December 2006 survey found that only 29% of the claims messages returned by plans provided specific, actionable information more than 50% of the time. Clearly, more needs to be done.

Prescriber Participation

Formulary management issues remain the number one complaint of APhA members regarding the administration of the Part D benefit. Some of this reflects an ongoing issue with prescriber involvement in this process. Pharmacists continue to report that a large number of physicians, frustrated by the uncompensated and burdensome work required to facilitate formulary management decisions, will not respond to formulary requests from pharmacists. This is reflected in the same APhA December 2006 survey in which 59 respondents reported on their experience with prescribers regarding prior authorization or exceptions requests: 34% reported that prescribers were very willing to complete the process; 85% reported that prescribers relied upon the pharmacist for plan and formulary alternative information; 15% reported that prescribers required patients to schedule office visits to resolve formulary issues; 63% reported that prescribers refused or delayed requests because of lack of time; and 31% reported that prescribers would not participate in the process.

Formulary Management Recommendations

Some of these issues could be resolved if plans shared their formulary information with pharmacists, prescribers and patients. Such sharing would facilitate patients making better informed plan choices, prescribers making better educated decisions about what medications to prescribe to their patients, and pharmacists better understanding their patients' options when faced with a plan rejection of a claim for a prescribed medication. Current postings are sporadic, difficult to find (nearly impossible without Internet access) and confusing.

To address remaining issues with formulary management, APhA recommends:

- Conducting outreach to the prescribing community to ensure their participation in formulary compliance.
- Requiring plans to provide "actionable" messages in formulary edits that give pharmacists the information necessary to facilitate a plan formulary decision.
- Requiring plans to standardize tier processes, to standardized electronic claims, and to use the standardized "Medicare Part D Coverage Determination Request Form".
- Requiring plans to provide easily accessible formulary information to pharmacists, preferably in a downloadable format.
- Requiring plans to share formulary-related communications with pharmacists and prescribers.
- Similar to the administrative fee CMS pays states, compensating pharmacists for their formulary compliance efforts.
- During the annual renewal process, expanding the evaluation of plans to include the plan's administration of prior authorizations and step therapy, and processing of exceptions requests.

Medication Therapy Management: Increasing Our ROI

MTM 2006: Missed Opportunities

Understandably, CMS has focused its implementation efforts on getting medications to patients. However, it is time to look comprehensively at the program and at how to improve the nation's investment in Medicare Part D by ensuring that patients make the best use of their medications. The medication therapy management (MTM) programs that Part D plans are required to provide a subset of Medicare beneficiaries were expected to generate these outcomes. Described as a "cornerstone" of the new prescription drug benefit, MTM services are an essential component of effective patient care. Generally speaking, MTM programs compensate pharmacists for providing a range of clinical services to patients, including educating patients about their medication and the conditions for which the medications are prescribed, reviewing a patient's medication regimen, developing a medication action plan to address identified issues, monitoring a patient's medication therapy over time, screening for potential adverse effects of medication, and monitoring a patient's ability to take his/her medication correctly[2].

Unfortunately, most plans have fallen short of the mark. The cost of a plan's MTM program is part of the Part D plan's administrative. Because the program does not have a separate payment for MTM services, there is little to no incentive for a stand-alone prescription drug plan (PDP) to provide a robust MTM program. MTM is seen simply as a cost to be squeezed out of their administrative fee. The MA-PD programs have a greater incentive to provide a "robust" MTM program because they will capture savings in their medical benefit from healthier patients that may experience fewer physician office and emergency department visits — a result of many well designed MTM programs.

From November 2005 to April 2006, APhA conducted a telephonic and email survey of large and national health insurance plans to learn about the construct of Part D MTM programs for 2006[3]. The method of service delivery reported by the plans was variable and ranged from mailed information (76%) to telephone call centers (90%) to face-to-face visits (19%) between a patient and clinician (primarily pharmacists). Some plans (28%) offered a "tiered" MTM benefit in which all targeted beneficiaries were eligible for "low intensity" services such as mailed educational materials, but a subset of beneficiaries meeting specified criteria were eligible for "high intensity" face-to-face consultations with a

[2] The MTM Consensus Definition is located at:
http://www.aphanet.org/AM/Template.cfm?Section=Home&CONTENTID=4577&TEMPLATE=/CM/ContentDisplay.cfm

[3] Touchette, DR, Burns, AB, Bough, MA, Blackburn, JC. Survey of Medicare Part D Plans' Medication Therapy Management Programs. *J Am Pharm Assoc*. 2006;46:683-691.

clinician, primarily pharmacists. Patient education, adherence programs, and medication reviews were the most common types of services offered by the plans. The number of chronic conditions required to receive MTM services ranged from 2-6 and the number of medications ranged from 2-24. Twelve of the 21 MTM programs further required targeted beneficiaries to have chronic diseases from a specified list. This early data suggests that more may need to be done to align the incentives to facilitate more beneficiaries receiving more robust MTM.

MTM: The Other Half of the Story

Focusing on product cost is only half of the medication use story. As more high-tech medications are developed, more patients are being asked to self-manage their diseases. In many cases, what used to be accomplished through an invasive medical procedure is now treated with medication therapy. While a positive medical advancement, these medication regimens may be more complicated for a patient to self-manage. Outside the hospital or nursing home, patients — not physicians or pharmacists — must manage their medications. And the data supports that patients are not always given the tools necessary to effectively manage their medication therapy alone.

Each year, Americans spend more than $75 billion on prescription and nonprescription drugs. Yet, a study published over a decade ago in the Archives of Internal Medicine[4] noted that more than $76 billion is spent on preventable drug-related medical problems caused by improper medication use. In a 2000 update to this study[5], the cost of drug-related morbidity and mortality in the ambulatory setting had risen to exceed $177 billion. Furthermore, an independent study[6] conducted by researchers at the David Geffen School of Medicine, University of California, Los Angeles, concluded that when initiating new medications, physicians often fail (up to 65% of the time) to communicate critical elements of medication use to the patient. And, a recent report of the Institute of Medicine (IOM) report, *Preventing Medication Errors: Quality Chasm Series* identified multiple challenges consumers face when using medications that result in billions of dollars unnecessarily being spent by patients and the healthcare system. These statistics support stepping away from our current silo approach of focusing only on product cost and looking at other factors that contribute to our rising health care budget, such as ensuring that patients are receiving the full benefit of their medications.

Provided the opportunity, pharmacists, working with patients and physicians, are the best equipped and positioned to address many medication related problems and improve medication use. The Institute of Medicine (IOM) agrees. In its recent report, *Preventing Medication Errors: Quality Chasm Series*, the IOM recommends that patients be empowered for safe and effective medication self-management. It also suggests that pharmacists address these problems by becoming the managers of patients' medication health.

MTM: Results

A few examples of MTM improving health and saving health care dollars include:

- A long term assessment of the clinical, economic, and humanistic outcomes of community pharmacists providing MTM for patients with asthma found that: all subjective and objective measures of asthma improved; emergency department visits and hospitalizations decreased; and while medication costs increased, asthma-related medical claims decreased with estimated direct cost savings of $725 per patient per year[7]
- The medication therapy management services of pharmacists in 1000 hospitals saved nearly 400 lives and $5.1 billion in health care costs[8] [9].
- Patient compliance with medication for high cholesterol improved from a national average of 40% to 90% with medication therapy management[10].

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[4] *Archives of Internal Medicine*, Vol. 155, Oct. 9, 1995, pp. 1949-1956.
[5] Ernst FR, Grizzle, AJ. Drug-Related Morbidity and Mortality: Updating the Cost-of-Illness Model. *Journal of the American Pharmaceutical Association.* 2001: Mar-Apr; 41(2):192-199
[6] *Archives of Internal Medicine.* Vol. 166, Sept. 25, 2006, pp. 1855-1862.
[7] The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community –based medication therapy management program for asthma. . *J Am Pharm Assoc.* 2006;46(2):133-47.
[8] Bond CA, Raehl CL, Pitterle ME, Franke T. Health care professional staffing, hospital characteristics, and hospital mortality rates. Pharmacotherapy 1999; 19(2):130-8.
[9] 7 Bond CA, Raehl CL, Franke T. Clinical pharmacy services, pharmacy staffing, and the total cost of care in U.S. hospitals. Pharmacotherapy 2000 June; 20(6):609-21.
[10] Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in Project ImPACT: Hyperlipidemia.

- Pharmacists providing MTM services to patients in long-term care facilities increased the number of patients receiving optimal care by 45% - resulting in an estimated $3.7 billion in cost avoidance[11].
- Patients treated with blood thinners in a pharmacist-managed anticoagulation clinic had fewer emergency room visits, fewer hospitalizations, and showed a total cost savings of $1,621 per patient[12].

The idea of providing comprehensive pharmacist services to patients to empower them to self-manage their medication health is not new to the federal government. The Department of Veterans Affairs has provided MTM services to their patients for years. Pharmacists' services at a Veterans Administration outpatient clinic reduced the number of medications taken by an average of 2.4 prescriptions per person[13]. With such improved patient outcomes and reduced health care expenditures, there is little doubt that MTM services, given a chance, could contribute considerably to the efforts to increase the Medicare program's return on investment in pharmaceuticals. Unfortunately, these opportunities have not yet been secured within the Medicare Part D benefit.

APhA Foundation: Empowering Patients

Support for providing MTM to patients continues to grow within the private sector. The APhA Foundation's Patient Self-Management Program (PSMP) uses the accessibility and skills of community pharmacists to benefit employers and their employees with chronic illnesses. The success of this model has been replicated in communities large and small throughout the country; and it could be applied to the Medicare program.

In the Foundation's model, an employer (or a coalition of employers within a community) works with the APhA Foundation to provide this voluntary benefit to its employees. Participating employees are then matched with a pharmacist from a network of providers. The pharmacist conducts one-on-one meetings with the employee and follows a process of care established by the APhA Foundation specifically for this program. The pharmacist serves as a "coach" and provides counseling and education with regards to the patient's disease, medication therapy, and lifestyle choices. This relatively simple intervention has led to remarkable results. In the well known "Asheville Project," average net savings of $1,600-$3,200 per person with diabetes, in the program, were realized each year from year two on.[14]

More than 40 employers have recognized the value added by pharmacists as evidenced by their replication of the Asheville model for their own employees through the APhA Foundation's most recent initiative, the Diabetes Ten City Challenge. The Challenge is an innovative program that employers and communities can use to fight diabetes and reduce health care costs. Employer groups in ten communities were invited to establish a voluntary health benefit for employees and dependents. Using incentives, employers encourage people to manage their diabetes with the help of pharmacist coaches, physicians, and community health resources. Current participants include the following employers: Pittsburgh Business Group on Health; Northwest Georgia Healthcare Partnership; Hawaii Business Health Council, Honolulu; City of Milwaukee; The Charleston/Spartanburg South Carolina Area; University of Southern California; Manatee County Government and Pinellas County Sheriff's Office, Tampa Bay Area; City of Colorado Springs; Midwest Business Group on Health, Chicago, IL; and Western Maryland Health System, Cumberland, MD.

This model has proven so successful that on May 1, 2007, the non-profit National Business Coalition on Health (NBCH) announced a partnership with the American Pharmacists Association Foundation to implement a patient self-management program modeled after the Asheville Project. The NBCH has a membership of nearly 70 employer-led coalitions across the United States, representing over 10,000 employers and approximately 34 million employees and their dependents.

Journal of the American Pharmaceutical Association 2000; 40(2):157-165.

[11] The Fleetwood Project, American Society of Consultant Pharmacists.

[12] Chiquette E, Amato MG, Bussey HI. Comparison of an anticoagulation clinic with usual medical care. control, patient outcome, and health care costs. *Archives of Internal Medicine* 1998; 158: 1541-7.

[13] Galt KA. Cost avoidance acceptance, and outcomes associated wit pharmacotherapy consult clinic in a Veterans Affairs medical center. *Pharmacotherapy* 1998 Sept.-Oct.; 18(5): 1103-11

[14] Garrett DG, Bluml BM. Patient Self-Management Program for Diabetes: First-Year Clinical, Humanistic and Economic Outcomes. *Journal of the American Pharmacists Association*; 2005 March/April; 45(2): 130-137.

The newly announced project will involve developing resources and providing technical assistance to NBCH members who wish to implement a patient self-management program for their employees.

State-based Medicaid MTM Programs

Several states, including Iowa, Minnesota, Missouri, and North Carolina are currently offering MTM services to Medicaid beneficiaries, and more state**s** are considering adding an MTM benefit. The Iowa Medicaid Pharmaceutical Case Management (PCM) Program, implemented in 2000, targets high risk patients who take four or more regularly scheduled non-topical medications, are not nursing home residents, and who have at least one of twelve select disease states. Pharmacists perform face-to-face comprehensive medication reviews with the patient, then conduct ongoing patient monitoring to address medication problems. An evaluation of the initial phase of this program found that patients receiving PCM services had a statistically significant improvement in the Medication Appropriateness Index (MAI), and the percentage of PCM patients using high-risk medications decreased significantly.[15] A similar program was initiated in Minnesota in April 2006.

Barriers to "Robust" MTM

The results of the APhA Foundation projects are remarkable and replicable. It is time to provide Medicare beneficiaries the opportunity to share in these successes. MTM will remain a missed opportunity if improvements are not made to the current Medicare MTM benefit. To further the development of and patient access to robust MTM programs, APhA recommends removing current barriers to robust MTM, which include:

- Lack of standardization in MTM service design.
- Variability in how patients are targeted.
- Lack of standardized documentation and billing requirements for MTM services.
- Inconsistent contracting processes that do not ensure patients' ability to receive MTM from their pharmacist of choice.
- Disruption in continuity of patient access to MTM services. Each year plans must re-determine which of their enrollees are eligible for MTM. This results in a lag time where patients do not receive MTM services.
- Inadequate promotion (via the Plan Finder) of MTM service benefits to patients.
- Lack of access to important health care information, such as the diagnosis and laboratory data, needed to perform comprehensive medication therapy management.
- Deficiencies in required "robust" outcomes measures for the MTM benefit. PQA, a pharmacy quality alliance, is working in collaboration with CMS to develop performance measures to measure pharmacy and pharmacist performance.
- Inappropriate plan incentives, such as requiring that MTM be part of a plan's administrative fee
- Absence of links between Part D and Parts A and B data hampers abilities to evaluate overall impact of MTM services.

APhA is working diligently to make MTM a reality for Medicare patients. In addition to various products to prepare pharmacists, APhA is also working to establish policies to advance MTM. These efforts involve collaboration with other colleague national pharmacy organizations[16] to make MTM a reality for Medicare patients. This coalition is currently developing policy proposals that will advance the quality and effectiveness of MTM provided to Medicare beneficiaries.

Patient Access to Pharmacist of Choice

Ensuring Patient Access to Community Pharmacies

Under the "any willing pharmacy" provision of the Medicare Modernization Act, plans are required to allow any pharmacy that is willing to accept the plan's terms and conditions to participate in the plan's pharmacy network.

[15] Chrischilles EA, Carter BL, Lund BC, et al. Evaluation of the Iowa Medicaid pharmaceutical case management program. *J Am Pharm Assoc.* 2004;44(3):337-49.

[16] Academy of Managed Care Pharmacy, American Association of Colleges of Pharmacy, American College of Clinical Pharmacy, American Pharmacists Association, American Society of Consultant Pharmacists, American Society of Health-System Pharmacists, and the College of Psychiatric and Neurologic Pharmacists

However, we received numerous reports of plans that informed pharmacies that they must join the plan's pharmacy network by a specific date or they would be locked out from the plan's pharmacy network. To address these issues, APhA recommends:

- Requiring plans to allow any pharmacy willing to accept the plan's terms and conditions to participate in the plan's pharmacy network at any time – preventing plans from establishing arbitrary deadlines to lock pharmacies out of the plan's network.
- Providing incentives to Part D plans to have safety-net pharmacies participate in the program while not permitting plans to penalize these pharmacies with reduced reimbursement rates.

90-Day "Extended" Supplies

As you know, the Medicare Part D program was designed to allow Medicare beneficiaries to access a 90-day supply of their medications at their pharmacy of choice. The intent of this provision was to "level the playing field" between retail and mail-service pharmacies and give community pharmacies the same opportunity to provide a 90-day supply of medications under the same terms and conditions as a mail-service pharmacy; any differential in charge (between the community and mail-service) is paid by the beneficiary.

We appreciate the efforts of the Chairman, Ranking member, and Committee members to ensure patient access to extended (90-day) supplies of Part D drugs at community pharmacies. Unfortunately, despite these efforts, it does not appear that this "level playing field" provision is being implemented as intended. Our members report that the reimbursement rates that are being offered to them are too low for them to accept and pharmacist attempts to negotiate with the plans are rejected. Therefore, we strongly recommend additional oversight of this provision to ensure that the practical application of the law meets Congress' intent to provide patients access to extended medication supplies at their pharmacy of choice.

Enrollment/Eligibility

An ongoing challenge with the program is the lack of a monthly enrollment deadline. Although CMS encourages beneficiaries to enroll or switch plans before the 15th of any month, nothing prevents beneficiaries from enrolling or switching plans at any time. When a data lag occurs, pharmacists are faced with angry and confused patients and insufficient information to process the claim. While some systems have been implemented to try to help pharmacists manage this situation, we strongly recommend changing the enrollment requirements to avert the data lag issue. APhA recommends:

- Setting a date certain, such as the 15th of the month, by which a beneficiary must enroll in a plan in order for their benefits to "kick in" by the first of the next month.
- Limiting dual-eligible plan switches to quarterly deadlines.
- Compensating pharmacists for their enrollment and eligibility verification efforts. Ninety percent of respondents to a December 2006 APhA survey reported that they were helping patients compare and evaluate Medicare Part D plans for the 2007 benefit.

Part B vs. Part D Payment

The addition of the Part D benefit to the Medicare program created confusion with regard to how to bill certain medications that had previously been covered by Medicare Part B. The decision of whether Part B or D pays depends on where the drug is administered or dispensed and for what condition the drug is being used. CMS has provided guidance to prescribers, pharmacists, and plans on when a medication should be billed to Medicare Part D or Medicare Part B.

Unfortunately, despite CMS' efforts to rectify this situation, this B versus D situation remains an administrative burden for pharmacists. Our members have reported that plans are unnecessarily delaying payments — and therefore, potentially, patient care — by requiring proof for these medications above and beyond what should be necessary to process the claim. While we support efforts by plans to ensure they pay only legitimate claims, these delay tactics must be stopped. Results of a September, 2006 APhA survey (77 respondents) provides some insight: 74% responded that plans were requiring a diagnosis; 16% were requiring an indication; 31% were requiring a statement from the prescriber; and 32% were requiring proof of denial from Part B.

It is very difficult and sometimes impossible to get a paper claim rejecting a Part B claim. In most cases, the Part B claim would be rejected via an electronic message, therefore obtaining a paper copy of the claims rejection forces the pharmacist to call Medicare Part B administrators. This effort delays patients receiving their medication unless they are willing to pay out-of-pocket, which is not an option for many beneficiaries particularly those taking expensive medications, such as medications for organ transplants. To address these concerns, APhA recommends:

- Providing plans additional information on what medications should be covered by Medicare Part B versus Medicare Part D.
- Monitoring plan compliance with B/D directives to ensure only minimally necessary procedures are required of pharmacists and prescribers and that coverage decisions are not unnecessarily delayed.
- Requiring prescribers to include the indication for the medication on all prescriptions.

Other Operational Issues

While we have provided details on many issues that continue to impact pharmacists and patients, a few more operational issues remain. We encourage the Committee to consider these as they work to improve the Medicare Part D prescription drug benefit:

- Provide additional oversight of plans
- Secure the current co-branding exemption, which was done through Agency guidance, in federal law and extend the co-branding exemption to all marketing materials.
- Educate beneficiaries about the gap in coverage, the "donut hole" to avoid patient confusion.

Conclusion

A medication's value cannot be measured simply by cost; it must include its effect on a patient's health. An improperly used or unused medication is, ultimately, the most expensive medication. While we seek ways to improve the return on investment in our health care system, we must look beyond medication cost and focus on improving medication use. This is where we can create the real value. Improving medication use requires that patients understand their medications and how to use them. Pharmacists are best equipped to help them accomplish this. The benefits of MTM are clear both financially and clinically. As a result, APhA strongly encourages the Committee to include in its review of Medicare Part D the prospect of expanding access to pharmacist-provided MTM to Medicare beneficiaries and to limit the administrative burdens we have outlined that impact the pharmacist's ability to provide patient care services.

Thank you for your consideration of the views of the nation's pharmacists. APhA looks forward to working with the Committee to improve the program through a more effective system of providing prescription medications to Medicare beneficiaries.