STATE OF MARYLAND
DHMH
Maryland Department of Health and Mental Hygiene
201 W. Preston Street • Baltimore, Maryland 21201
Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary

DEC 2 2 2009

The Honorable Martin O'Malley
Office of the Governor
State House
Annapolis, MD 21401-1925

The Honorable Thomas V. Mike Miller, Jr.
President of Senate
State House, H-107
Annapolis, MD 21401 - 1991

The Honorable Michael Erin Busch
Speaker of House of Delegates
State House, H-101
Annapolis, MD 21401 - 1991

RE: Report on a Study to Assess the Outcomes Achieved by Drug Therapy Management Agreements as Provided Under Therapy Management Contracts

Dear Governor O'Malley, President Miller and Speaker Busch:

Pursuant to Section 4, (HB 781) Chapter 249 of the Acts of 2002, the Department of Health and Mental Hygiene respectfully submits this report on the Study to Assess the Outcomes Achieved by Drug Therapy Management Agreements as provided under Health Occupations Article, Subtitle 6A, Therapy Management Contracts, Annotated Code of Maryland.

I hope this information is useful. If you have any questions regarding this report, please contact Ms. Anne Hubbard, Director of the Office of Governmental Affairs, at (410) 767-6481.

Sincerely,

John M. Colmers
Secretary

Enclosure

cc: Ms. Sarah Albert
Anne Hubbard, M.B.A.
LaVerne G. Naesea, Executive Director, Board of Pharmacy
Anna D. Jeffers, Legislation/Regulations Manager, Board of Pharmacy

MARYLAND
BOARD OF PHARMACY

DRUG THERAPY MANAGEMENT REPORT ON THE STUDY TO ACCESS THE OUTCOMES ACHIEVED BY DRUG THERAPY MANAGEMENT AGREEMENTS TO THE GENERAL ASSEMBLY

January 1, 2010

DRUG THERAPY MANAGEMENT
REPORT ON THE STUDY TO ASSESS THE OUTCOMES ACHIEVED BY DRUG THERAPY MANAGEMENT AGREEMENTS

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Joint Committee of the Board of Physicians and the Board of Pharmacy

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Executive Secretary

DRUG THERAPY MANAGEMENT
REPORT ON THE STUDY TO ASSESS THE OUTCOMES ACHIEVED BY DRUG THERAPY MANAGEMENT AGREEMENTS

EXECUTIVE SUMMARY

This report provides the General Assembly with the history of the Drug Therapy Management Program (the "Program") in Maryland, a summary of the current approved Drug Therapy Management Agreements, a summary of the pending Drug Therapy Management Agreements, the Demonstration Study Evaluation Final Report (the "Study") that assesses the outcomes achieved by drug therapy management agreements under Health Occupations Article, Subtitle 6A. Therapy Management Contracts, and the Board of Pharmacy's recommendation for the permanent continuation of this program. The history of the Program in Maryland has evolved slowly since 2002. Even with a slow implementation, the Program has provided patients, pharmacists and physicians with another option for the safe monitoring of medications prescribed for chronic disease-states. There are six active Drug Therapy Management Agreements currently active in Maryland with 195 participating patients. The Department of Health and Mental Hygiene designated the Board of Pharmacy to contract with an outside entity to conduct a study to assess the outcomes achieved by drug therapy management agreements under the Act. The Board of Pharmacy entered into a Memorandum of Understanding with the University of Maryland School of Pharmacy to conduct the study. As the Study will show, the program has been successful with no safety concerns and total patient satisfaction. There are currently three more applications for the Program that are pending. The University of Maryland School of Pharmacy monitored and studied the participants from October 1, 2007 until March 31, 2009. The objectives of the Study were twofold: 1) evaluate the short-term patient safety and clinical outcomes of drug therapy management in Maryland; and 2) to evaluate the barriers and success for implementation of the drug therapy management models. The conclusions of the Study were: 1) drug therapy management is safe; 2) it results in positive outcomes for patients; yet 3) the application process is burdensome with paperwork. The Maryland Board of Pharmacy, recognizing the national trend to embrace drug therapy management and recognizing the positive outcomes found in the Study, recommends eliminating any further sunset provision and making this program permanent in Maryland.

BACKGROUND

House Bill 781 - Physicians and Pharmacists - Therapy Management Contracts which passed during the 2002 legislative session, allows a licensed physician and a licensed pharmacist to enter into time-limited agreements to treat specific disease-states using approved protocols. HB 781 specified that the Department of Health and Mental Hygiene should conduct a study to assess the outcomes achieved by drug therapy management agreements. Section 5, chapter 249 of the 2002 Acts of the General Assembly (program enabling chapter) specified that chapter 249 "shall remain in effect for a period of five (5) years and eight (8) months, and at the end of May 31, 2008 with no further action required by the General Assembly, the Act shall be abrogated and of no further force and effect."

HB 781 specified that the Board of Physicians and the Board of Pharmacy jointly promulgate regulations to implement the legislation within 6 months of October 1, 2002. Due to unanticipated delays related to limited available staff resources during the 2003 legislative session, the regulations, COMAR 10.34.29.01 - .11, Drug Therapy Management, did not become effective until December 11, 2003.

COMAR 10.34.29.01 - .11, Drug Therapy Management, established a Joint Committee, consisting of representatives from both the Board of Physicians and the Board of Pharmacy, that would review and recommend actions by the respective Boards regarding approval of drug therapy management applications. The regulations also included guidelines and the required content of a protocol and a physician-pharmacist agreement. They set forth in detail the requirements for approval of a pharmacist to enter into drug therapy management with a physician and the overall approval process.

Following a series of initial meetings between representatives on the Joint Committee, program review procedures were implemented and acceptance of applications began in January 2005. The first application was approved in February 2006 and the University of Maryland School of Pharmacy was contracted to conduct the evaluation study beginning in April 2006.

On October 1, 2006 the Board of Physicians and the Board of Pharmacy prepared a Drug Therapy Management Report to the General Assembly on the effect of the Act and their recommendations for legislative or regulatory action. The Board of Physicians and the Board of Pharmacy agree that the Drug Therapy Management Program has progressed successfully. The regulations that are in place successfully established the program and provided processes and procedures for its implementation. With the approval of the first three protocols, it was anticipated that many more physicians and pharmacists will apply to take advantage of this unique health care relationship. The first three approved protocols on Thrombosis; Tobacco Use and Dependence; and Metabolic Syndrome served as templates for future drug therapy management agreements on those specific disease-states.

The apparent intent of the 2002 Legislature was to allow sufficient time following promulgation of the program regulations, to receive and approve applications; as well as sufficient time to conduct the study to assess the outcomes achieved by drug therapy management agreements. The first drug therapy management application was not approved and forwarded to the University of Maryland School of Pharmacy until after February 2006. Consequently, the University of Maryland School of Pharmacy required an extension of time in order to collect sufficient patient outcome data and to develop its study conclusion and recommendations.

The Board of Physicians considered the Board of Pharmacy's recommendation that the program be extended through 2012 to allow time for the evaluation to be completed. However, the Board of Physicians recommended that legislation be introduced in the 2007 Legislative Session to extend the effective date of the Drug Therapy Management program to October 1, 2009.

Based on the request from the University of Maryland, and the fact that the program was delayed two years and eight months before it was fully implemented, the Board of Pharmacy changed its

recommendation and requested that legislation be introduced in the 2007 Legislative Session to extend the ending date of the Drug Therapy Management program from May 31, 2008 to October 1, 2010. The Board determined that it would be timelier to wait until the 2008 session to introduce legislation to extend the sunset date.

House Bill 233 - Physicians and Pharmacists - Therapy Management Contracts - Extension of Law, passed during the 2008 Legislative Session, taking effect on June 1, 2008 and extending the Drug Therapy Management Program until September 30, 2010. A copy of that legislation is attached as Appendix I.

This report is divided into four parts, which include: 1) *a Summary of Approved Applications; 2) a Summary of Pending Applications; 3) the Study; 4) Recommendations; and 5) Conclusion*

DRUG THERAPY MANAGEMENT REPORT

SUMMARY OF APPROVED APPLICATIONS

The Joint Committee approved the first Drug Therapy Management Agreement and Protocol for Thrombosis on February 24, 2006. Six pharmacists and 3 physicians were approved to be included in the first physician-pharmacist agreement. Two more Drug Therapy Management physician-pharmacist agreements and protocols were approved in August 2006. Both of these, Tobacco Use and Dependence; and Metabolic Syndrome, include two approved physicians and eight approved pharmacists. All three approved Drug Therapy Management agreements and protocols were submitted by various units of University of Maryland Medical Center.

Since 2007, three more Drug Therapy Management physician-pharmacist agreements and protocols have been approved and are ongoing. Two of the agreements are for Metabolic Syndrome and one is for both Metabolic Syndrome and Tobacco Use and Dependency. The clinical sites are Finks Pharmacy in Essex Maryland and People's Community Health Centers, Inc. in Baltimore. All six of the approved sites and the 195 participating patients have been part of the Study conducted by the University of Maryland School of Pharmacy under a Memorandum of Understanding between the Maryland Board of Pharmacy and the University of Maryland School of Pharmacy.

SUMMARY OF PENDING APPLICATIONS

At the present time there are three pending applications for three more drug therapy management physician-pharmacist agreements. One application was submitted by nine pharmacists and one physician practicing at Sinai Hospital and Northwest Hospital Center. The protocol is for thrombosis. Another application received is between one physician and two pharmacists and the protocol is for anticoagulation. Therapy management services will be provided at 7219 Hanover Parkway, Greenbelt, Maryland. The last application received is between two physicians and four pharmacists. Their application is not complete and they have been contacted to submit those missing items. The therapy management services will be for anticoagulation. Although a small number of applications have been received, there has been a steady stream of applications. The

Board unfortunately has learned that some pharmacists/physicians are holding off from applying for the program because they are waiting to see if the program becomes permanent.

PROGRAM STUDY

The Medication Therapy Evaluation Study and method of data collection was presented to a consortium consisting of, but not limited to, representatives from the Maryland Board of Physicians (MBP), Maryland Board of Pharmacy, Maryland Pharmacists Association (MPhA), Maryland Pharmaceutical Society (MPS), American Society of Consultant Pharmacists – Maryland (ASCP-MD), and Maryland Society of Health System Pharmacists (MSHP) before the study began. Implementation of the study and data collection began on October 1, 2007 with an extension to March 31, 2009.

The Study under Health Occupations Article, §12-6A, Annotated Code of Maryland was submitted to the Maryland Board of Pharmacy on October 4, 2009. The report includes a) an update regarding the progress of the legislation and acceptance of collaborative drug therapy by the health care community; b) a description of the protocol requirements under the legislation; and c) the results of the demonstration study under approved protocols during the 18 month period beginning October 1, 2007 and ending March 31, 2009.

The findings of the report indicated that Drug Therapy Management physician-pharmacist agreements and protocols are safe and increase clinical benefits to patients. All 195 patients involved in this program were satisfied with the care received from the pharmacists. No patient safety problems were reported. The physicians and pharmacists worked well together in caring for the patients. Improvement, however; can be made in the approval process. Many applicants found the process involved too much paperwork and too many delays. A copy of the Study is attached as Appendix II and is an integral part of this report.

RECOMMENDATIONS

The Board recommends legislation to eliminate any further sunset provision of Health Occupations Article, Subtitle 12-6A, Annotated Code of Maryland, and to make this law permanent in Maryland. The Drug Therapy Management Program offers Maryland patients a more flexible option when confronted with frequent medication changes pursuant to certain conditions. The Center of Medicare and Medicaid Services (CMS) will require Part D sponsors to incorporate Medication Therapy Management Plans into their Plans' benefit structure in 2010. Drug Therapy Management is allowed in 41 states according to the 2009 National Association of Boards of Pharmacy Survey of Pharmacy Law which was compiled in July 2009. The trend is to establish and maintain Drug Therapy Management, not to sunset these programs. Maryland should be one of the states that remain in the forefront of pharmacy practice nationwide. The Board of Pharmacy will be seeking an elimination of the sunset date for the Drug Therapy Management Program in the 2010 Session. A copy of the draft proposed legislation is attached as Appendix III.

Conclusion

Maryland pharmacists and physicians have collaborated with medication therapy management in hospitals for a long time. Extending this relationship to outpatient settings frees the physician to see more patients, without sacrificing the care of their patients with chronic conditions. Pharmacists work under a strict protocol with physicians and physicians are notified of medication changes pursuant to that protocol.

At the present time there are six drug therapy management agreements approved, with four different protocols. One hundred and ninety-five patients are presently engaged in Drug Therapy Management Agreements. Three more drug therapy management agreements are pending. If the program is ended, patients will be left with incomplete systems of care and will have to seek medication management from other places.

Interest in the program is increasing as evidenced by three new applications currently under review by the Boards. The Board has learned that some pharmacists/physicians are holding off from applying for the program because they are waiting to see if the program becomes permanent. They do not want to expend the time and expertise to prepare protocols and application materials, if the program is ended next year.

In conclusion, although Drug Therapy Management in the outpatient setting has been slow to start, it remains a valuable program. As the program grows it will provide patients with certain chronic conditions another option for management of their medications. Participating in Drug Therapy Management is much more convenient for patients since they do not have to schedule physician appointments solely for medication management. The program frees physicians to devote their time to new patients or patients with illnesses or conditions that cannot be controlled by medications with routine modifications. The program allows pharmacists to monitor conditions and alert physicians to changes in their patients. Drug Therapy Management integrates health care professions and patients and results in better patient outcomes. It is the hope of the Board of Pharmacy that the Maryland Legislature will see the value of this program, not only in its initial stages, but its potential for relieving physician shortages and an overburdened health care system in the future. Approximately forty-one states have *permanent* drug therapy management statutes. Maryland should join them.

APPENDIX I

HOUSE BILL 233

J2 8lr0111
By: **Chair, Health and Government Operations Committee (By Request – Departmental – Health and Mental Hygiene)**
Introduced and read first time: January 23, 2008
Assigned to: Health and Government Operations
Committee Report: Favorable
House action: Adopted
Read second time: February 13, 2008

CHAPTER _____

AN ACT concerning
Physicians and Pharmacists – Therapy Management Contracts – Extension of Law
FOR the purpose of extending until a certain date the termination of the provisions of law relating to certain licensed physician–pharmacist agreements and certain licensed physician–pharmacist therapy contracts; and generally relating to therapy management contracts between licensed physicians and licensed pharmacists.
BY repealing and reenacting, with amendments,
Chapter 249 of the Acts of the General Assembly of 2002
Section 5

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Chapter 249 of the Acts of 2002

SECTION 5. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2002. It shall remain effective for a period of **[**5 years and 8 months**]** **8 YEARS** and, at the end of **[**May 31, 2008**]** **SEPTEMBER 30, 2010** with no further action required by the General Assembly, this Act shall be abrogated and of no further force and effect.

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect June 1, 2008.
Approved:

_____
Governor.

_____
Speaker of the House of Delegates.

_____
President of the Senate.

APPENDIX II

STATE OF MARYLAND

DEPARTMENT OF HEALTH & MENTAL HYGIENE
OFFICE OF LICENSING & REGULATION

BOARD OF PHARMACY

DRUG THERAPY MANAGEMENT

DEMONSTRATION STUDY EVALUATION FINAL REPORT UNDER:

Health Occupations Article §12-6A

Annotated Code of Maryland

SEPTEMBER 2009

UNIVERSITY OF MARYLAND SCHOOL OF PHARMACY

DEPARTMENT OF PHARMACY PRACTICE & SCIENCE
MAGALY RODRIGUEZ DE BITTNER, PHARMD, BCPS

University of Maryland School of Pharmacy

And the Center for Innovative Pharmacy Solutions

Introduction and Overview

A. Background. In 2002, Maryland became the 31st state in the nation to enact collaborative practice legislation where licensed pharmacists and licensed physicians enter into a collaborative agreement utilizing approved protocols to provide management of drug therapy for specific diseases. House Bill 781 –Physicians and Pharmacists-Drug Therapy Management that passed was codified in July 2002, as Health Occupations Article §12-6A, Annotated Code of Maryland. On December 11, 2003, rules became effective under COMAR 10.34.29. As part of House Bill 781, a demonstration study was to be conducted to evaluate the outcomes of the agreements and protocols. In addition, the Joint Committee of the Boards of Physicians and Pharmacy was installed to oversee the approvals of collaborative protocols under the new Drug Therapy Management (DTM) regulations. On February 24, 2006, the first protocol was approved for the collaborative treatment of thrombosis at the University of Maryland Medical Center (UMMC) Anticoagulation Clinic in Baltimore, Maryland.

The demonstration study evaluation design and data collection instrument was developed jointly by the University of Maryland School of Pharmacy researchers and a group of pharmacy stakeholders, and was reviewed by the Board of Pharmacy. After consultations with practitioners, the medication management study design and data collection elements were presented to a consortium of health care leaders, including the Maryland Pharmacists Association, Maryland Pharmaceutical Society, American Society of Consultant Pharmacists-Maryland Chapter, and the Maryland Society of Health System Pharmacists. Expert feedback from the consortium was integrated into the study design. The twelve-month study was initially designed to begin on January 1, 2007. However due to delays in promulgating and finalizing the regulations, and time required for submitting and approving collaborative protocols, the study began on October 1, 2007 with an extension to March 31, 2009.

B. Report Contents. The legislation and subsequent regulations, call for a report to the legislature to document the safety and health impact of the new Drug Therapy Management (DTM) activities on patient care. Patient outcomes and satisfaction with care were key elements of the evaluation. The Board of Pharmacy selected the University of Maryland School of Pharmacy to develop and conduct the demonstration study.

This report is comprised of: a) an update regarding the legislation progress and acceptance of the collaborative drug therapy by the health care community; b) a description of the protocol requirements under the legislation; c) the results of the demonstration study under approved protocols during the eighteen-month period beginning October 1, 2007 and ending March 31, 2009.

Part I: Update on the Legislation

A. Current Status of Drug Therapy Management Protocols. As of September 1, 2009, six protocols were approved and recruited 195 patients in Maryland in a variety of settings (See Table 1) . In addition to those approved, five psychiatric protocols were prepared in a partnership between the University of Maryland School of Pharmacy faculty and People's Community Health Centers, Inc., a United States (US) Health Resources and Services

Administration (HRSA) qualified organization with onsite 340B pharmacy to ensure affordable access to needed medications. These six protocols included: 1) anxiety disorder management, 2) depression management, 3) bipolar disorder management, 4) schizophrenia and psychotic disorder management, 5) ADHD management, and 6) addiction management through buprenorphine use. The only protocol approved was anxiety after many modifications; no patients have been enrolled as of this report. The Board of Pharmacy has also received other protocols for anticoagulation therapy, but these have not been evaluated by the Joint Committee of the members of the Boards of Pharmacy and Physicians. Since the data were collected for this demonstration study, the Joint Committee of the Boards of Physicians and Pharmacy has received protocols addressing the following disease states: asthma, osteoporosis, depression and anxiety.

Table 1. Number of Patients enrolled by Protocol Summary				
A. PROTOCOL	B. PHARMACISTS	C. PHYSICIANS	D. CLINICAL SITE	E. TOTAL PATIENTS
Antithrombosis Protocol	Grover and Haines	Ung, Brown, Tasker, Yim	Anticoagulation Clinic at University of Maryland Medical Center	93
Metabolic Syndrome (Rochester, Haines and Agness)	Rochester, Haines, and Agness	Donner, Lender, Shuldiner, Silver, Sheehan, Sabra, Horensten, Streeten	Joslin Diabetes Center at University of Maryland Medical Center	15
Tobacco Use and Dependence (Rochester, Haines and Agness)	Rochester, Haines, and Agness	Donner, Lender, Shuldiner, Silver, Sheehan, Sabra, Horensten, Streeten	Joslin Diabetes Center at University of Maryland Medical Center	13
Metabolic Syndrome (Fink)	Fink	Khanna	Finks Pharmacy in Essex Maryland	1
Metabolic Syndrome	Rochester	Chao, Davis, Mohiuddin, Leavitt, Bansal, Yilma	People's Community Health Centers, Inc.	8
Metabolic Syndrome & Tobacco Use and Dependence (Rochester and DiPaula)	Rochester and DiPaula	Chao, Davis, Mohiuddin, Leavitt, Bansal, Yilma	People's Community Health Centers, Inc.	65
			TOTALS	195

Six (6) licensed pharmacy practitioners were approved by the Joint Committee of the Boards of Pharmacy and Physicians as DTM providers. All of these pharmacists have their Doctorate of Pharmacy at an institution accredited by the American Council on Pharmaceutical Education and have completed a residency program.

Maryland's DTM legislation has spurred interest and action among pharmacy practitioners. The Maryland Pharmacists Association and the University of Maryland School of Pharmacy Office of Continuing Education have responded to this increased interest with continuing education workshops on collaborative practice, disease state management, and disease specific certifications.

Part II: Components of the Drug Therapy Management Defined Protocols

Drug Therapy Management (DTM) protocols are defined by the State of Maryland, as the "course of treatment predetermined by the licensed physician and licensed pharmacist according to generally accepted medical practice for the proper completion of a particular therapeutic or diagnostic intervention". The protocol defines the disease state to be treated, the treatment sites, the medications and classes of medications involved in the treatment, roles of the collaborating physicians and pharmacists, and the mode and timeframe for communications to the treating physician and the patient's medical record.

The legislation calls for a legal document, a protocol, to guide the pharmacist-physician relationship. This protocol is prepared, reviewed and approved by the Joint Committee of the Boards of Pharmacy and Physicians. It defines the responsibilities and communications between pharmacist and physician as it relates to the disease specific care to be undertaken. Patient care protocols were established using national guidelines and standards of care.

The physician must diagnose the patient prior to engaging them in a DTM protocol. The pharmacist interviews each patient referred by the physician, secures their consent, and then ascertains the patient's medical condition, prescribed pharmacotherapy and over-the-counter medications. Under certain conditions, a pharmacist may initiate, modify or continue drug therapy, and order disease-relevant laboratory tests. Qualified pharmacists monitor the outcomes of the pharmacotherapy treatment in collaboration with the patient's physician.

Treating pharmacists must be knowledgeable in the national standards for quality of care for each disease state. In addition to the 1,000 hours of clinically relevant experience. Pharmacists must document each patient's progress and must evaluate patient outcomes related to interventions defined in the protocols.

Part III: Evaluation of Drug Therapy Management Demonstration Study

A. SCOPE AND STUDY OBJECTIVES. Drug Therapy Management Demonstration Study objectives were to: 1) evaluate the short-term patient safety and clinical outcomes of collaborative practice pharmacy services in Maryland; and 2) to evaluate the barriers and success for the implementation of the Drug Therapy Management collaborative model.
This eighteen-month evaluation includes the following information:

1) A preliminary report on the communication patterns between the pharmacists, physician, and patients in the coordination of care;
2) A report on the patient perceptions of care and barriers to care;
3) A summary description of the patient population, the severity and complexity of those receiving care under the collaborative treatment protocols; and
4) A report on the short-term clinical endpoints involving patient safety and clinical outcomes for patients enrolled in DTM protocols during the study period.

B. STUDY METHODOLOGY. The prospective study design followed new patients from the point they consented and enrolled (by signing the patient/pharmacist/physician contract) under an approved Maryland collaborative DTM protocol. The study design allowed for comparison of pre- and post- clinical factors to evaluate the impact of collaborative practice on the disease management in the enrolled patients.

For each protocol, the characteristics of the patient population including demographics, disease states, and medication classes will be described. In addition, protocol-specific data on surrogate and/or clinical outcomes, appropriate monitoring of laboratory and adverse events, patient adherence to therapy, and patient satisfaction will also be presented.

Patient satisfaction data was collected through a literacy-sensitive survey instrument at the end of treatment or during the follow-up period.

Participants enrolled on a voluntary basis and could opt out or withdraw at any time. Clinical and laboratory data, prescribed drugs, and adherence to health related visits were recorded during the enrollment period.

C. DATA COLLECTION. Each practice site with an approved protocol, collected pre-determined data elements for patients at the time of enrollment and at three months post-enrollment. For each study period only newly enrolled patients were recorded in the report. In addition, specific data elements were documented for each specific disease state protocol.

1. **Protocol Specific Data- Tobacco Use and Dependence Protocols.** Data collected for patients under the Tobacco Use and Dependence Protocols included: a) the quit date and number quitting by that date; b) the class of medications prescribed for the patients undergoing pharmacist intervention; c) adverse events and barriers experienced by the patients; and d) adherence to visits with the physician and pharmacist. The age, duration and intensity of tobacco use were also recorded.

2. **Protocol Specific Data- Metabolic Syndrome Protocols.** Pharmacists operating under the collaborative Metabolic Syndrome Protocol collected baseline and three month information on a number of clinically relevant factors including: a) weight; b) clinical laboratory test results (triglycerides, high density lipoprotein (HDL), low density lipoprotein (LDL), total cholesterol, fasting glucose, and hemoglobin A1C levels); c) systolic and diastolic blood pressure; d) the number and classes of medications; and e) adverse events reported.

3. **Protocol Specific Data-Antithrombosis Protocol.** Data collected for patients enrolled in the Antithrombosis Protocol included: a) number of bleeding episodes whether minor (defined as no medical referral required) or major (defined as bleeding that requires treatment, medical evaluation, or at least two units of blood); b) the number of visits by each patient to the doctor; c) the number and adherence to pharmacist appointments; d) diagnosis or reason for referral to the Antithrombosis Protocol; and e) medication diagnoses for all patients. In addition, the protocol mandated tracking of any and all life threatening bleeding, bleeding which may lead to cardiac arrest, and surgical/angiographic intervention or irreversible sequelae.

In addition, all sites evaluated patient satisfaction with care, and reported obstacles to implementation or limitations with the current protocol that impaired pharmacist care of enrolled patients.

Pharmacists were required to submit the data elements in an excel database to the study investigator. Data was then compiled by Dr. Magaly Rodriguez de Bittner and a team at the University of Maryland School of Pharmacy, Department of Pharmacy Practice and Science. Quarterly reports were submitted to the Maryland Board of Pharmacy.

Data on provider qualifications were reviewed by the Boards of Pharmacy and Physicians when the protocol and agreement was submitted.

D. STUDY RESULTS

1. Patient Data and Characteristics. A total of 195 patients were enrolled in approved protocols during the study period. Table 1 describes the type of protocol and the number of patients enrolled in each protocol.

Table 1. Number of Patients enrolled by Protocol Summary				
A. PROTOCOL	B. PHARMACISTS	C. PHYSICIANS	D. CLINICAL SITE	E. TOTAL PATIENTS
Antithrombosis Protocol	Grover and Haines	Ung, Brown, Tasker, Yim	Anticoagulation Clinic at University of Maryland Medical Center	93
Metabolic Syndrome (Rochester, Haines and Agness)	Rochester, Haines, and Agness	Donner, Lender, Shuldiner, Silver, Sheehan, Sabra, Horensten, Streeten	Joslin Diabetes Center at University of Maryland Medical Center	15
Tobacco Use and Dependence (Rochester, Haines and Agness)	Rochester, Haines, and Agness	Donner, Lender, Shuldiner, Silver, Sheehan, Sabra, Horensten, Streeten	Joslin Diabetes Center at University of Maryland Medical Center	13
Metabolic Syndrome (Fink)	Fink	Khanna	Finks Pharmacy in Essex Maryland	1
Metabolic Syndrome	Rochester	Chao, Davis, Mohiuddin, Leavitt, Bansal, Yilma	People's Community Health Centers, Inc.	8
Metabolic Syndrome & Tobacco Use and Dependence (Rochester and DiPaula)	Rochester and DiPaula	Chao, Davis, Mohiuddin, Leavitt, Bansal, Yilma	People's Community Health Centers, Inc.	65
			TOTALS	195

Demographic data included age, gender, and disease state of patients enrolled in each protocol. Table 2 includes the age distribution of the patients. While some assumptions can be drawn from the locations at which the patient received services, additional data about income, zip code and co-morbidities was not collected.

Table 2. Patient Demographics			
Condition	Average Age (Mean)	Age Range	Number of Patients
Metabolic Syndrome	54.0	31 to 73	24
Smoking	48.1	19 to 70	78
Antithrombosis	54.3	21 to 91	93
All Patients	**51.6**	**19 to 91**	**195**

2. Provider Data. Data collected by the Joint Committee of the Boards of Physicians and Pharmacists prior to approval of each DTM protocol provided general characteristics of the providers in the study. Six (6) licensed pharmacist practitioners were approved by the Joint Committee of the Boards of Pharmacy and Physicians as DTM providers. Each pharmacist has his or her Doctorate of Pharmacy from an institution accredited by the American Council on Pharmaceutical Education. In addition, each has completed a residency training program. Physicians and pharmacists reported satisfaction with the program and stated that collaborative agreements met their patient care needs.

3. Communications and Collaboration Data. The frequency with each patient met with the physician and with the pharmacist for adherence-related appointments was recorded. Rapid and seamless communication between the pharmacist and physician was the goal of the protocol. The time between the pharmacist's appointment with the patient and the submission of the patient care notes to the physician was tracked. Sixty percent of patient care reporting occurred "immediately" through on-site hard copy or electronic medical records (EMR). As Table 4 illustrates a total of twelve percent of reporting took place within a week.

Table 3. Timeframe for Pharmacist Reporting Patient Status to the Collaborating Physician

	Metabolic Syndrome & Tobacco Cessation	Antithrombosis (EMR)	Total/ %
Immediately	24	93	117 60.0%
Within a Week of Patient Visit	24	NA	24 12.3%
Other	1	NA	1 0 .5%
NA	53	NA	53 27.2%
	102	93	195

In all cases, the pharmacists reported that the protocol developed for the collaborative agreement was adequate to meet the needs of the physician and pharmacist to properly treat the patient. National treatment guidelines were the basis for the processes of clinical care and for the targeted patient outcome indicators. Occasionally, medical records were not immediately available to DTM pharmacist which resulted in some self-reported information from the participating patient. Pharmacy records and medication types and dosages were often available to DTM pharmacists via pharmacy, medical records, and EMR.

4. Patient General Enrollment and Adherence. Pharmacists were asked to collect the number of times that the "patient" agreement proved problematic. One hundred percent of the patients who were informed and asked to consent to participate in the DTM protocol, agreed to do so by signing the DTM contract. None of the patients asked refused to participate.

Table 4. Patient Visits and 3-Month visit Adherences with Pharmacist & Physician

	# of Patient Appointments with Physicians	Ratio of Physician to Pharmacist Appointments	Scheduled Appointments with Pharmacist	# of Kept Appointments	Pharmacist Treatment Adherence Rate %
Antithrombosis Protocol (Grover and Haines)	Not Available		530	382	72.1%
Metabolic Syndrome	45	.65 to one	69	58	84.1%
Tobacco Use and Dependence	96	.23 to one	419	329	78.5%
TOTAL APPOINTMENTS (N=72)	141	.22 to 1	1018	769	76%

As seen in Table 4, patients' adherence to pharmacy appointments varied by protocol. Data was not available in the UMMC Anticoagulation Clinic to ascertain the patient visits with the referring physicians.

5. Patient Satisfaction. As part of the process of care in the collaborative DTM protocols, pharmacists assisted patients by coaching them and by fostering better understanding of their disease, their disease-specific health care needs, the proper use and dose of their medications, their self-care skills, behavioral changes, and prevention of side effects. Patient satisfaction was collected using a written satisfaction survey provided by the pharmacist. These key indicators included those above, and others such as self-care and decision-making regarding medications. Patients were asked to rate all of the above aspects of the care their pharmacist provided in the DTM process. Patients reported strong satisfaction with pharmacist services and stated that participation in the program improved their well-being. (See Table 5 below.)

Table 5. Patient Satisfaction with Pharmacist Care (All Sites)

Clinical site	Protocol	Survey N=	STRONGLY	AGREE	Patient Satisfaction with Pharmacist Care
Anticoagulation Clinic at UMMC	Antithrombosis Protocol	31	30	1	30 of 31 Strongly Satisfied
Joslin Diabetes Center at UMMC	Metabolic Syndrome	28	21	7	21 of 28 Strongly Satisfied
Joslin Diabetes Center at UMMC	Tobacco Use and Dependence	6	5	1	5 of 6 Strongly Satisfied
People's Community Health Centers, Inc.	Tobacco Use and Dependence	33	17	16	17 of 33 Strongly Satisfied
People's Community Health Centers, Inc. * 1 literacy issue	Metabolic Syndrome	12	12	0	12 of 12 Strongly Satisfied
Finks Pharmacy	Metabolic Syndrome	1	0	1	1 Satisfied
		111	85	26	Total

The results indicated that 100% of patients responding to the patient satisfaction survey were strongly satisfied or satisfied with the care received from the pharmacists. This includes all sub factors: the pharmacists improved their knowledge about their medications, their ability to recognize and prevent medication side effects, their self-care skills and knowledge about suggested lifestyle changes, their ability to take their medications properly, and overall improvement of their well-being. During the study period, the Boards of Pharmacy and Physicians did not received complaints from physicians, pharmacists, or patients concerning the DTM Programs that were in place.

6. Patient Safety. No patient safety problems were reported. No major bleeding or incidences of thromboembolic events were reported during the study period. Smokers prescribed Chantix experienced no unmanaged side-effects. Patients treated under the Metabolic Syndrome Protocol reported no acute events, and no medication-related complications or confusion. Diabetes patients treated under this protocol reported no acute events related to the disease or medication management, and no hospitalizations during the study period.

Another aspect of patient safety measured was the number of medications patients were prescribed for their condition. The Metabolic Syndrome patient population under the DTM-approved protocol was prescribed an average of 5.4 medications related to this specific condition. Patients may also have been prescribed additional medications or they may select over-the-counter therapies for other symptoms or conditions not recorded in this evaluation. The 31 patients enrolled in the protocol were currently taking between zero and eight types of medications as noted in Table 6. The pharmacists' role in collaborative practice was to monitor drug treatments for drug interactions, side-effects, and dosage. Through collaborative practice protocols, pharmacists guided enrolled patients to learn more about their disease, their symptoms, their self-care behaviors, and the proper administration of their multiple medications. Patients attending the Anticoagulation Clinic at the UMMC were all treated with a Vitamin K Antagonist.

Table 6. Metabolic Syndrome Patient Medications

Patients	# of Drugs	Statins	ACE/ARB	ASA	Biguanides	TZD	SU	Insulin	Exenatide	Symlin	DPP-IV	Beta Block	CCB	Other
24	167	20	26	22	15	9	10	35	5	0	0	12	11	2

An average 5.4 medications were prescribed and managed per patient for treatment of Metabolic Syndrome (only).

7. Clinical Outcomes and Improvements. Improvement in the clinical outcomes related to each specific disease state was observed in DTM patients. In the area of tobacco cessation, a 32.1% quit rate was recorded at three months and a reduction in adverse events was reported by the patients when compared to baseline. The baseline average number of cigarettes post-protocol enrollment was reported as 19.5 a day. The mean number of years patients smoked prior to enrollment was 26.5 years.

Nicotine replacement therapy was the most common therapy option in 43 patients, followed by Chantix therapy. The patients receiving Chantix had a 44% quit rate as compared to those receiving nicotine replacement therapies (41.9%).

Table 7. Clinical Outcomes in Tobacco Cessation Protocols						
		Nicotine Replacement Therapy	Chantix	Behavioral Only No Treatment	% of Protocol (78)	Outcome Total #
Quit Smoking						
	Number of Patients	18	4	3		25
	% of Treated	41.90%	44.40%	11.50%	**32.10%**	
Reduced to 1-10 Cig/day						
	Number of Patients	9	4	3		16
	% of Treated	20.90%	44.40%	11.50%	**20.80%**	
No change						
	Number of Patients	15	1	20		36
	% of Treated	34.90%	11.10%	76.90%	**46.10%**	
	TOTAL % Column	100%	100%	100%	100%	
	Total # of Patients	43	9	26		78

The antithrombosis protocol addressed a number of diagnoses requiring anticoagulation therapy at the UMMC. These indications are summarized in Table 8.

Table 8. Reasons for Treatment Antithrombosis Protocol				
	Number	Mean Age	%	Adverse Event
Deep Vein Thrombosis	25	51.4	26.8%	none reported
Stroke	8	54.3	8.6%	none reported
Hypercoagulability	4	31.75	4.3%	none reported
Pulmonary Embolism	17	54.0	18.3%	none reported
Mitral Valve Replacement	4	63.3	4.3%	none reported
Atrial Fibrillation	14	65.3	15.1%	none reported
Two or More Events	18	48.6	19.4%	none reported
Pulmonary Hypertension	2	25	2.2%	none reported
Thrombus	1	36	1.1%	none reported
	93		100%	

Of the ninety–three new patients who enrolled in the protocol, more than a quarter of the patients (27%) were being monitored related to a single event, or a repeat occurrence of deep vein thrombosis (DVT). Nineteen percent of those treated under the DTM protocol experienced multiple serious health conditions including pulmonary embolism in combination with stroke, stroke prevention, mitral valve replacement and hypercoagulability. No minor or major bleeds were reported by any DTM participants.

In the Metabolic Syndrome Protocol, patients demonstrated improvements in A1C levels with a reduction of 2.25 % in A1C levels and reduction in blood pressure measurements for patients who were not controlled as defined by the American Diabetes Association Standards of Care. (See Table 9).

Table 9. Clinical Outcomes in Metabolic Syndrome Protocols

N=17	Baseline (mean)	3 mo	% change	Real change in 3 months
Weight	223.2	204	-6.10%	19.2 lb reduction (mean)
Blood Pressure-Systolic				
Over 130*	138.5	132.2	-4.50%	6.3 mm/Hg reduction
All Patients	122.1	118.1	-3.30%	4.0 mm/Hg reduction
Blood Pressure-Diastolic				
Diastolic over 80*	82	77.2	-5.90%	4.8 mm/Hg reduction
All Patients	70.5	71.9	2.10%	1.5 mm/Hg increase
Hemoglobin A1c				
Over 7.0*	9.9	6.4	-35.40%	3.5 % reduction
All Patients	8.5	7.1	-15.30%	1.3 % reduction

8. Payment for Advanced Clinical Pharmacist Services. At Fink's Pharmacy, pharmacists were not billing for the services initially since these services were part of the value-added services provided to patients. Their current plan is to pursue contracts with health plans for reimbursement of these services.

In all other settings, pharmacist services were billed as part of the clinical practice. In the case of the Metabolic Syndrome DTM protocol, the Joslin Center at UMMC billed patients for services as part of the usual billing mechanism employed by the clinic. The patients at People's Community Health Centers, Inc., a HRSA qualified clinic serving Baltimore's low-income communities, were not charged for DTM services although the charge mechanisms are in place to do so.

9. Obstacles to DTM. Pharmacists and physicians reported a variety of barriers to the implementation of the DTM programs. Barriers included delays in finalization of the regulations which took a period of two years to be published. In addition, the review and approval of protocols and physician-pharmacists agreements by the Joint Committee of the Boards of Pharmacy and Physicians took six to eight months. In some instances follow up communications between the Joint Committee and the Pharmacists submitting the protocols were not explicit and, at times, conflicting, making it difficult to modify protocols to address the Joint Committee's concerns. The cumbersome paperwork involved with DTM submissions (as dictated by the

regulations) was cited by pharmacists and physicians as a limiting step for broad acceptance and implementation of the program. Physicians at the Joslin Diabetes Center and People's Community Health Centers, thought it unnecessary to sign off on pharmacist SOAP notes and Physician/Pharmacist/Patient Therapy Management Contracts. These reported barriers to implementation, caused frustration among the pharmacists and may be a contributing factor in the limited number of protocols finalized during the study period. Anticipated revisions to state regulation may streamline the documents required for the DTM Collaborative Agreements and may increase the number of protocols submitted by pharmacists and physicians.

Part IV: Conclusions and Recommendations

The data collected and cited in this report indicates that patients receiving care under a DTM Collaborative Agreement during the study period benefitted from improved clinical outcomes in the Tobacco Cessation, Metabolic Syndrome and Antithrombosis programs. In addition no major complications or hospitalizations were reported for the patients in these DTM programs. Physicians and pharmacists reported that the collaborative practice protocols were adequate to meet the needs of their patients. In all cases, physicians received documentation from the pharmacist within a week of the patient-pharmacist visit. Patients reported being strongly satisfied or satisfied with the care provided by the pharmacist. There were no formal complaints received by the Boards of Pharmacy or Physicians by practitioners or patients during the study period concerning DTM.

Current practice sites in Maryland which have implemented DTM Collaborative Agreements have demonstrated improved safety and increased clinical benefit to patients. During the study period, there were a limited number of sites actively participating in the DTM collaborative programs, yet the benefits observed allowed this report to suggest future directions in evaluation which include opportunities for data collection, analysis and expansion of DTM Collaborative Agreements.

This sample included 195 patients with chronic diseases treated in six collaborative practice sites in Maryland. The data presented in this report serves as a pilot study to demonstrate trends in the outcomes related to drug therapy management collaborative practices. Additional sites and increased numbers of enrolled patients could have added strength to the data presented in this report. This was outside the control of the investigator. Several barriers to implementation of the collaborative practice were reported in the results section which included cumbersome requirements of the legislation and delays in protocol review and approval which caused frustration and challenges amongst the practitioners. All of the approved protocols empowered the pharmacist to effectively address the patients' medication and disease management concerns at the time of the visit.

The pioneering nature of the Maryland collaborative practice initiative suggest changes in traditional practice of patient care, including: a) additional information to patients regarding the availability of DTM services by pharmacists; b) physicians must be knowledgeable and interested in developing a collaborative practice with an experienced pharmacist; and c) pharmacists must be well-trained and highly experienced in patient care, as well as medication and disease management, in order to apply as providers under collaborative practice regulations.

During the study period, only highly trained and experienced pharmacists sought to partner with physicians and to pioneer Maryland's new model of collaborative care. To improve upon this model, additional continuing education and other advanced training programs for pharmacists are necessary. In addition, outreach to physicians in certain fields of practice is needed. Evidence such as the data provided in this report will better inform health care providers of the potential benefits of DTM collaborative practice.

Formal and cooperative arrangements defined under this legislation target the optimal, safe use of medication by adding highly skilled pharmacists as the medication expert on the health care team. Prescribing physicians benefit from the increased input of the collaborating pharmacist. Peer review literature has shown that patient safety in drug therapy can be improved by reducing multi-drug complications and decreasing side effects, both areas of expertise for pharmacists. Other research has found that patients with chronic disease have better medication adherence through pharmacist involvement. Improved adherence further translates into improved health outcomes, prevention of acute episodes, and reduction in medical care costs. In other studies, chronic disease management has demonstrated cost savings to the patient, the payer, the state, and the health system as a whole.

The data contained in this report examines the collaborative role of pharmacists in the medication and disease management of their patients. Collaborative practice increases the consistency of treatments for patients with chronic disease and life threatening conditions. In many cases, collaborative practice increases access to pharmacists and physician services for indigent patients and underserved patients as seen in the case of the People's Community Health Centers in Baltimore. Pharmacists provided access to care by serving as physicians' extenders under a collaborative protocol without compromising patients' health care, outcomes or safety. In addition to formalizing the process of care, the treatment strategies evaluated in this report demonstrate short-term effectiveness which could in turn, minimize health risks related to medication, prevent costly acute episodes, and avoid drug related complications.

Forty-six states in the US have *permanent* legislation that allows pharmacists and physicians to enter into collaborative agreements to provide care to patients with chronic or in some cases episodic minor conditions. Enacting permanent legislation for DTM in Maryland will allow pharmacists and physicians to continue to offer and facilitate initiatives that are consistent with the provisions (chronic disease management and medication therapy management) included in most of the health care reform legislation currently before Congress.

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APPENDIX III

A BILL ENTITLED

AN ACT concerning

Physicians and Pharmacists – Therapy Management Contracts –Sunset Repeal

FOR the purpose of repealing the termination provision for the Therapy Management Contracts program; and generally relating to the Therapy Management Contracts program.

BY repealing and reenacting, with amendments,
Chapter 249 of the Acts of the General Assembly of 2002, as amended by Chapter 650 of the Acts of the General Assembly of 2008
Section 5

SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF MARYLAND, That the Laws of Maryland read as follows:

Chapter 249 of the Acts of 2002, as amended by Chapter 650 of the Acts of 2008

SECTION 5. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2002. [It shall remain effective for a period of 8 years and, at the end of September 30, 2010 with no further action required by the General Assembly, this Act shall be abrogated and of no further force and effect.]

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2010.