Agenda

Joint Commission of Pharmacy Practitioners

August 25, 2015

Location: Lorien Hotel & Spa   1600 King Street    Alexandria, Virginia
Liberty Room

8:00 AM       CEO Discussion
                 - Executive Session for CEOs
8:00 AM       Continental Breakfast
9:00 AM       Ia. Call to Order and Introductory Comments
                 Paul Abramowitz, Chairperson
Ib. “Summary of Discussion” for June 2, 2015 Meeting

II. Dates, Locations and Agenda for Future Meetings: Lorien Hotel
    Fall: Tuesday, November 17, 2015: Doug Hoey, Chair
    2016: Dates/location discussion
         o Date preferences and frequency

9:10 AM      III. Bringing the Strategic Plan to Life – Discussion 1
                 Update on JCPP Website

9:40 AM      IV. Bringing the Strategic Plan to Life – Discussion 2
                 Current State of Care Transitions: community, hospital and long term care
                 (Jim Owen, Doug Scheckelhoff, Nicki Brandt)

10:45 AM –  
11:00 AM    Break

11:00 AM      V. Bringing the Strategic Plan to Life – Discussion 3
                 - USP Update
                 - Presenter: Ronald T. Piervincenzi, Ph.D., Chief Executive Officer

Noon -  
12:50 PM    Luncheon
            Lunch for all participants, observers and guests – Brabo Back Dining Room

1:00PM-      VI. Patient Care Process and Quality – Discussion 4
                 “Engagement of Pharmacists in Chronic Disease Management”
                 Presenters: Janet Wright, Executive Director of Million Hearts, Peter Briss,
                 Medical Director for the National Center of Chronic Disease Prevention and
                 Health Promotion, and Michael Schooley, Branch Chief for the Applied
                 Research and Evaluation Branch Division for Heart Disease and Stroke
                 Prevention

2:15PM      VII. Hot Topic Discussion
                 - Opportunity for JCPP member organizations to raise issues that other
                   organizations should be aware of
                 - Future Topics

VIII. Update on JCPP Action Plan Implementation Organizations are asked to focus
        their update on activities they are doing to advance the key areas of the Vision Action
        Plan – limit 2 minutes per organization – Organizations are asked to provide hard-copy
        update as well

3:00PM      Additional Issues and Wrap Up
3:15 PM      Adjournment of Meeting
Joint Commission of Pharmacy Practitioners

Academy of Managed Care Pharmacy
703-683-8416
Edith Rosato, Chief Executive Officer

American College of Apothecaries
901-383-8119
Ed Hesterlee, Executive Vice President

American College of Clinical Pharmacy
816-531-2177
Michael S. Maddux, Executive Director

American Pharmacists Association
202-628-4410
Thomas E. Menighan, Executive Vice President

American Society of Consultant Pharmacists
703-739-1300
Frank Grosso, Chief Executive Officer

American Society of Health-System Pharmacists
301-664-8890
Paul Abramowitz, Chief Executive Officer

National Community Pharmacists Association
703-683-8200
Douglas Hoey, Chief Executive Officer

Liaison Members

Accreditation Council for Pharmacy Education
312-664-3575
Peter H. Vlasses, Executive Director

American Association of Colleges of Pharmacy
703-739-2330
Lucinda L. Maine, Executive Vice President

National Alliance of State Pharmacy Associations
804-285-4431
Rebecca P. Snead, Executive Vice President

National Association of Boards of Pharmacy
847-391-4400
Carmen A. Catizone, Executive Director

Summary of Discussion – June 2, 2015

52 Attendees

Representing member organizations: (19)

Academy of Managed Care Pharmacy
Edith Rosato, Chief Executive Officer
Raulo Frear, President

Accreditation Council for Pharmacy Education
Peter Vlasses, Executive Director
Bruce Canaday, President

American Association of Colleges of Pharmacy
Lucinda Maine, Executive Vice President
Pat Chase, President

American College of Apothecaries
Jerry Greene, President

American College of Clinical Pharmacy
Michael Maddux, Executive Director
Judith Jacobi, President

American Pharmacists Association
Thomas Menighan, Executive Vice President
Member organizations of the Joint Commission of Pharmacy Practitioners (JCPP) held their regularly scheduled quarterly meeting on Tuesday, June 2, 2015, at the Lorien Hotel, Alexandria, Virginia. Meeting participants were welcomed by Frank Grosso, ASCP CEO and Chair of this JCPP Meeting. Representatives of member organizations and guests introduced themselves.

**Opening Remarks / Administrative Activity**

Members reviewed and accepted the Summary of Discussion from the January 29, 2015, JCPP meeting. The participants then reviewed the 2015 JCPP meeting schedule and template agenda for the
August 25,, 2015 meetings. JCPP members were asked to provide feedback on agenda topics and were reminded that the registration memo was included in their meeting packets. The group decided to have a session at the August JCPP meeting on Pharmacy Technicians: What can we do collectively? The 80 minute session will include NABP, PTCB, ATI, PTAC, and PTEC. Each group will have 10 minute to provide an overview followed by 30 minutes for a group discussion. The group was also informed that the staff working group on Strategic Plan Goal 2 (Evidence) will be reconvening and will be tasked with planning for the November JCPP meeting agenda and other activities.

National Pharmacist Workforce Study

Caroline Gaither, a primary investigator of the Midwest Pharmacy Workforce Research Consortium, provided an overview of the results from the 2014 National Pharmacist Workforce Study. Results from the survey indicate that pharmacists are performing more patient care activities in a variety of healthcare settings, and spending less time in the traditional dispensing role. The survey also explored pharmacist roles in integrated care, interaction with other healthcare providers, workloads, stress level, etc. Up to 80% of pharmacists said their workload had increased (varying among practice settings). The survey indicated less part-time work for pharmacists and increased conflicts between home and worklife. Pharmacists’ workflow hasn’t changed much and unemployment rates for pharmacists is at 4%.

ACPE Standards 2016

Pete Vlasses, ACPE Executive Director, and Bruce Canaday, ACPE President, provided an overview of the ACPE 2016 Accreditation Standards on Key Elements for the Professional Programs in Pharmacy Leading to the Doctor of Pharmacy Degree. Revision of the Standards included: development of Standards and Guidelines built around 25 standards and their implementation; a philosophy and emphasis on ensuring that graduating students are “practice-ready” and “team-ready”; the importance of assessment and a means of improving the quality of pharmacy education’s restructuring; simplifying and clarification of critical areas; and the way Standards and Guidelines are organized. The Standards go into effect in July 2015 with the programs being assessed against the Standards in Fall 2016. They also informed the JCPP members of an ACPE Invitational Stakeholder Conference ("CPE 40 years later – Current and Future Opportunities and Challenges, October 29-30, 2015, in Chicago, IL)."

Pharmacist Opinions on Biosimilar Naming

Mary Jo Carden, AMCP Senior Director for Regulatory Affairs provided an overview of the results from a survey of pharmacists on their views related to biosimilar pharmaceuticals and the naming and management of those products. As the date for introduction of biosimilars in the United States approaches, questions remain regarding the naming, coding, and approval process for these agents. These questions were explored through the survey conducted by Xcendra in collaboration with AMCP, APhA, and ASHP. The survey identified concerns by pharmacists in the areas of current practices for sharing information, methods used to record dispensed products, familiarity of biosimilars, and confidence in substituting products. Key take-aways from the survey included pharmacists have greater confidence in substituting interchangeable biosimilars that share the same name; work must continue on ensuring that identifiers, such as national drug code and HCPCS are used consistently by all providers to allow for monitoring and surveillance; and the “Purple Book” and other resources must be improved to provide
better information to pharmacists about interchangeable biosimilars. Additional surveys are planned to gain additional insights.

**President Dialogue on “Bringing to Life the Pharmacists’ Patient Care Process**

Anne Burns, APhA VP External Practice Affairs, facilitated a discussion among the JCPP member Presidential Officers regarding their perspectives on implementation by their constituencies, and colleagues within their own practices, of the elements of the patient care process. Input received included the following recommendations:

- Develop presentations for delivery to pharmacists and students / faculty, as well as presentations for the public and other stakeholders
- Map current processes to the patient care process
- Help members understand how to implement the process and the impact it can have on patient care delivery and outcomes
- Target click-thru advertising focused towards pharmacists (ie web banners on google)
- Work with medicine, nursing and other stakeholders to understand the process of care and the role of pharmacists
- Have presidential officers and CEOs incorporate the process of care and collaboration to develop it into their delivered speeches throughout the year
- Create an algorithm / flow chart for each process component and the thought process they should consider
- EHR documentation
- Self-assessment form and toolkits
- Create 1-2 lines of standard language that could be published that describes the process
- Create a process button
- Conduct a competition for student pharmacists
- Include in preceptor training
- Be clear on what you do but also how you document uniformly
- Encourage student research

**Hot Topics and Organizational Updates**

The JCPP organizations discussed future meeting topics. In 2016, when it is available, demonstration of Mimyc – an interprofessional training game should be scheduled. No hot topics were identified for discussion.
Each organization reported on progress it was making in the areas of focus related to the implementation of the JCPP Vision Strategic Plan: Patient Care Process; Pharmacy Quality; Value of Pharmacists’ Patient Care Services; HIT; Provider Status Recognition, in addition to other organizational information.

A number of newsletters, journals, and other educational materials from practitioner organizations were provided so that member organizations may better serve pharmacy practitioners and coordinate future projects.

The attendees were informed of the beginning of work to develop a unique JCPP website. Each organization was asked to identify their website development staff liaison.

The next regularly scheduled meeting of JCPP is August 25, 2015; it will focus pharmacy technicians, USP Update, and engagement of pharmacists in chronic disease management.

There being no further business, the meeting was adjourned at 2:41pm.

###
Agenda
Joint Commission of Pharmacy Practitioners

November 17, 2015
Location: Lorien Hotel & Spa  1600 King Street  Alexandria, Virginia
Liberty Room

8:00 AM    CEO Discussion
           - Executive Session for CEOs

8:00 AM    Continental Breakfast
9:00 AM    Ia. Call to Order and Introductory Comments
           Doug Hoey, Chairperson
           Ib. “Summary of Discussion” for June 2, 2015 Meeting
II. Dates, Locations and Agenda for Future Meetings: Lorien Hotel
     2016: Dates/location discussion

9:10 AM    III. Bringing the Strategic Plan to Life – Discussion 1
           Update

9:40 AM    IV. Bringing the Strategic Plan to Life – Discussion 2
           Proposed – Perspectives from Decision-makers – Need input

10:45 AM   Break
11:00 AM   V. Bringing the Strategic Plan to Life – Discussion 3

Noon -     Luncheon
12:50 PM   Lunch for all participants, observers and guests – Brabo Back Dining Room

1:00PM-    VI. Patient Care Process and Quality – Discussion 4

2:15PM     VII. Hot Topic Discussion
           - Opportunity for JCPP member organizations to raise issues that other
             organizations should be aware of
           - Future Topics

VIII. Update on JCPP Action Plan Implementation Organizations are asked to focus
       their update on activities they are doing to advance the key areas of the Vision Action
       Plan – limit 2 minutes per organization – Organizations are asked to provide hard-copy
       update as well

3:00PM     Additional Issues and Wrap Up
3:15 PM     Adjournment of Meeting
2016 JCPP MEETING DATES - PROPOSED

Based on the responses received on the CEO survey, below are the highest rated dates. Out of 11 organizations there were no dates where more than 9 organizations indicated they could attend. Therefore, we have indicated the dates that work best and who indicated they could not participate (CEOs - presidential officers may still be able to) We will solicit hotel bids for these dates and see what we come back with. Let me know if you have any questions.

Mitch

BEST CHOICES FOR 2016 JCPP DATES – WE WILL SOLICT HOTEL BIDS FOR THESE DATES

<table>
<thead>
<tr>
<th>Choice</th>
<th>Date</th>
<th>Who can't attend</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>January 13</td>
<td>ACA,ACPE</td>
</tr>
<tr>
<td>2</td>
<td>February 17</td>
<td>NABP,AMCP,ASHP</td>
</tr>
<tr>
<td>3</td>
<td>February 24</td>
<td>ACA,ACCP,ASHP</td>
</tr>
<tr>
<td>3</td>
<td>May 3</td>
<td>NABP, ACPE,ASHP</td>
</tr>
<tr>
<td>1</td>
<td>June 2</td>
<td>APhA</td>
</tr>
<tr>
<td>1</td>
<td>June 16</td>
<td>ASHP</td>
</tr>
<tr>
<td>1</td>
<td>August 2</td>
<td>NABP, ASCP</td>
</tr>
<tr>
<td>2</td>
<td>August 24</td>
<td>NCPA,ACPE,ASHP</td>
</tr>
<tr>
<td>3</td>
<td>November 15</td>
<td>NABP,ACPE</td>
</tr>
<tr>
<td>3</td>
<td>November 16</td>
<td>NABP,ACPE</td>
</tr>
<tr>
<td>1</td>
<td>November 29</td>
<td>NABP,ACPE</td>
</tr>
<tr>
<td>2</td>
<td>November 30</td>
<td>NABP, ASHP</td>
</tr>
<tr>
<td>4</td>
<td>December 13</td>
<td>ACPE,ASHP</td>
</tr>
</tbody>
</table>
JCPP WEBSITE DEVELOPMENT UPDATE

Below are the 2 draft logos developed by the working group. You will be asked to provide input and decision on the logo to be used.

Also provided are the draft website main pages (depending on logo):

Bowl of Hygeia / Mortar & Pestle
This design incorporates the “bowl of hygeia” symbol of pharmacy in combination with the “mortar & pestle” in the negative space of the snake’s neck.
Circle of Organizations

This design shows 11 separate organizations coming together to form one unified circle. The coloring brings in the green of pharmacy.
Pharmacists Collaborating for a Healthy America

MEMBER ORGANIZATIONS

The Pharmacists’ Patient Care Process

Developed by a group of national pharmacy organizations working under the direction of JCPP.

The process is applicable to any practice setting where pharmacists provide patient care and for any patient care service provided by pharmacists.

The patient care process is articulated in a manner aligned with the patient care processes of other health care professionals while at the same time detailing the unique medication-related aspects of pharmacists’ training.

News

Appendicitis: Are antibiotics a cut above surgery? Lorem ipsum dolor sit up.

Novel drug reverses dabigatran effect within minutes. Lorem ipsum.

Appendicitis: Are antibiotics a cut above surgery?

Events

Aug 22
NASPA Summer Meeting

Aug 28
ACA Summer Meeting

Sep 4
APHA Annual Meeting for Executive Members

Sep 16
ASHP Annual Meeting
Pharmacists Collaborating for a Healthy America

The Pharmacists’ Patient Care Process
Developed by a group of national pharmacy organizations working under the direction of JCPP.

The process is applicable to any practice setting where pharmacists provide patient care and for any patient care service provided by pharmacists.

The patient care process is articulated in a manner aligned with the patient care processes of other health care professionals while at the same time detailing the unique medication-related aspects of pharmacists' training.

ABOUT THE PROCESS & AVAILABLE RESOURCES

News
Appendicitis: Are antibiotics a cut above surgery? Lorem ipsum dolorem sit up.

Novel drug reverses dabcitrapan effect within minutes. Lorem ipsum.

Appendicitis: Are antibiotics a cut above surgery?

Events

NASPA Summer Meeting
ACA Summer Meeting
APHA Annual Meeting for Executive Members
ASHP Annual Meeting
Pharmacists Collaborating for a Healthy America

The Pharmacists' Patient Care Process

Developed by a group of national pharmacy organizations working under the direction of JCPP.

The process is applicable to any practice setting where pharmacists provide patient care and for any patient care service provided by pharmacists.

The patient care process is articulated in a manner aligned with the patient care processes of other health care professionals while at the same time detailing the unique medication-related aspects of pharmacists' training.
Ronald T. Piervincenzi, Ph.D.

Chief Executive Officer

Ronald T. Piervincenzi, Ph.D., is the Chief Executive Officer of USP.

For 12 years Dr. Piervincenzi was a partner and leader in McKinsey & Company's Global Pharmaceutical and Medical Products Practice where, among other responsibilities, he launched McKinsey's global drug safety, medical and regulatory service line. Most recently, as a VP in Development Sciences with Biogen Idec, he launched a new group (Value-Based Medicine) focused on applying tools and technologies of personalized medicine to the multiple sclerosis disease area.

Dr. Piervincenzi earned his M.S. and Ph.D. from Duke University in Biomedical Engineering, with research focused on protein engineering. He is the founder of multiple non-profits in the community service and scientific spaces including serving currently as Board Chair for the Newark Mentoring Movement and the NextStep Translational Research Foundation.
For almost two hundred years after the Pilgrims landed in Massachusetts Bay in 1620, there was no authoritative resource to ensure the quality of medicines or a system for naming them in America. In the early years of colonial America and the young republic, there were a number of apothecaries, blacksmiths, midwives, and others who “practiced medicine” by providing their own preparations or popular English medicines to treat the ill. Educated physicians from England did not come to America, America only had a few homegrown ‘practitioners’ trained through apprenticeships. There were no medical societies, hospitals, or medical schools until after the mid 1700s. Clergymen and public officials also “treated” the population under their authority, and relied on imported books and dispensatories based on the Edinburgh and London Pharmacopeias.

During the Revolutionary War a few local pharmacopeias were published. The Lititz Pharmacopoeia was the first in 1778, compiled by William Brown who was trained in Edinburgh. Another small pharmacopoeia was published for the French military hospitals in North America, the Compendium Pharmaceuticum by Jean Francois Costé. After the war ended the use of these works diminished and for the most part American physicians went back to using British pharmacopeias and dispensatories. Physicians began to emerge during these early years of the republic, and they practiced both medicine and pharmacy by diagnosing diseases, and compounded and dispensed medicines. But still there was no assurance that these medicines were composed of quality materials and even if they were potent. John Morgan, who established the first medical school in America in Philadelphia in 1765, proposed the “composing a pharmacopoeia for use by Physicians and Practitioners of Pennsylvania” at a meeting and on June 3, 1788 passed a motion to appoint a committee to “form a Pharmacopoeia for use of the College.” But by 1789, the interest in a pharmacopoeia just for Pennsylvania had dwindled. Support grew, instead, for creating a national pharmacopoeia that would bring order to these preparations.
throughout the nation. Prominent national and medical figures such as Benjamin Franklin spoke not only about a formulary but of “some Standard amongst ourselves” for America. But this goal proved to be challenging in a country that was still undeveloped and sparsely populated, pharmacy could be practiced without a license, and the joint practice of medicine and pharmacy prevailed. This effort did not come to fruition and no pharmacopoeia was published at this time to support the nationalistic fervor of some of the leading physicians of the time who wanted the “full range of truly American medicinal plants” (Sonnedecker, A National Movement Emerges 1994) to be included.

The distinction of the first American Pharmacopoeia went to the Massachusetts Pharmacopoeia, published in 1808 by the Massachusetts Medical Society (Sonnedecker, A National Movement Emerges 1994). Two young physicians, James Jackson and John Collins Warren took on the responsibility to identify those articles that cured diseases and best methods of preparation, and named them using English versus Latin names. The Massachusetts Pharmacopoeia was intended to be a standard of uniformity for medicinal articles to be adopted by all “professional men” in the United States, although compliance with it was not required. It relied on “self-government among independent and reliable practitioners, rather than government intervention” (Sonnedecker, A National Movement Emerges 1994). The New Hampshire Medical Society adopted it but South Carolina, although supportive of the idea of a national pharmacopoeia did not see it as a “national” effort representing the differences between diseases and their treatment in different parts of the country. Nonetheless, it was a significant achievement and proved to be a model for future efforts. An American New Dispensatory based on the Massachusetts Pharmacopoeia published by James Thacher, a Boston physician and Revolutionary veteran gave further credibility to the Massachusetts effort.

Ten years later, in 1816, Samuel Latham Mitchill, along with Valentine Seaman, published the Pharmacopoeia of the New York Hospital, again for the use of hospital interns. But Mitchill had greater ambitions of breaking free of the ‘colonial’ yolk of Britain. Mitchill along with Lyman Spalding and Jacob Bigelow, who later became the founders of the USP, had their own motivations to start a ‘national’ pharmacopoeia. Spalding espoused uniformity, Mitchell, nationalism, and Bigelow saw a pharmacopoeia as supporting the native materia medica.

Spalding drew the initial plan and coordinated the group. His goal was to fulfill the urgent need for uniform standards for medicines that could be utilized across the country. Mitchell used his influence
in medical and political arena (he was also a United States senator) to promote the idea. Bigelow with his expertise in plant drugs and the publication process, served as editor of the USP. On January 6, 1817, during a meeting of the New York County Medical Society, Lyman Spalding formally proposed the framework for the establishment of an American pharmacopoeia in the United States of America. It was proposed that four pharmacopeial conventions would be held in the four regional districts. Each would produce or select a pharmacopoeia, and would send delegates to the national convention in Washington, January 1, 1820. The pharmacopoeia would be revised every ten years. The state medical societies would adopt it thereby giving it authority. A committee of the State Medical Society of New York adopted the project of establishing a “uniform Pharmacopoeia throughout the United States” (Sonnedecker, A National Movement Emerges 1994) and named an influential implementation committee. The society sent a circular to other medical societies and schools around the nation marking the beginning of democratic participation in the revision of USP.

Less than three years later, on January 1, 1820, 11 of the 16 delegates - all physicians - gathered in Old Senate Chamber of the U.S. Capitol building to form the United States Pharmacopoeial Convention and create the first Pharmacopoeia of the United States. Holding the Convention at the U.S. Capitol underscored its national significance and democratic procedure although no government support or enforcement of the pharmacopoeia was expected (Sonnedecker, A National Movement Emerges 1994). The first Pharmacopoeia of the United States of America containing 221 monographs was successfully published by the end of that year. It was made up of five sections, beginning with the front matter, the historical introduction and preface, followed by the materia medica, a list of 221 drugs; a secondary list of 71 drugs for substances of “doubtful efficacy”; a section on weights and measures; and an untitled section of 329 preparations and compositions (Anderson and Higby 1995). In terms of content, the pharmacopoeia reflected the therapeutics of the time including tonics, strong laxatives, diuretics, and flavoring herbs. The preparations included cerates, confections, decoctions, extracts, honeys, infusions, liniments, mixtures, ointments, pills, plasters, powders, spirits, syrups, tinctures, troches, vinegars, washes, waters, and wines. No techniques were included, just recipes. There was nothing to address the purity of chemicals - chemical formula, identifications or assays which are hallmarks of a modern pharmacopoeia.
pharmacopeia. In 1828, a second printing of the pharmacopeia was released with corrigenda that corrected a number of errors in the first edition.

By the time the first decennial revision, a schism had developed between two of the most influential medical centers of the day, New York and Philadelphia. There were different interpretations of a section of the founding convention plans for future revisions, with Mitchill interpreting it as three delegates from each district, and the Philadelphia medical leaders thinking that the local medical societies were to send three delegates to the convention and were also late in submitting the names to Mitchill. He used this fact to keep out the Philadelphians who had been very critical of the 1820 edition. Rival conventions were held in New York and Washington. Mitchill presided over the New York Convention and two sessions were held on January 1, 1830 and June 2, 1830 as there were not many delegates in the former session.

The Washington Convention was held on January 1, 1830, as had been stipulated in the founding documents. Two separate first revisions were issued, one in 1830, the New York edition as a result of the New York Convention and the other in 1831, the Philadelphia edition out of the Washington Convention. The New York edition was revised in a hurry on the premise that if it was published earlier it would give it primacy. But there were a number of errors. The Washington Convention was more deliberate in its process. It appointed a Committee of Revision with two members from different states and once the contents were drafted, they solicited feedback from the Philadelphia College of Pharmacy thus marking the entry of organized pharmacy into the pharmacopoeial revision process. The New York edition also lacked a detailed preface, robbing it of any authority or credibility. The Philadelphia edition gave an informative preface about how choices were made with regard to nomenclature and admission of new drugs and preparation, and included “many practical suggestions” made by pharmacists. In the preface of the Philadelphia edition, George Wood stressed the need for uniformity and that it was the pharmacopoeia’s most salient contribution to medical and pharmacy practice. The Philadelphia edition survived based on it being a more thoroughly revised pharmacopeia than the New York edition and the fact that Philadelphia College of Physicians supported and publicized it with pharmacists. Bigelow also threw his weight behind the 1830 Philadelphia edition. With the death of Mitchill in 1831, the New York medical establishment withdrew from pharmacopoeial revision for the next 50 years. Throughout the nineteenth-century, members of the Convention continued to follow the guidelines laid out in the preface of the first pharmacopoeia, meeting every ten years in Washington, DC. Under
the stewardship of great leaders and physicians like George B. Wood and Franklin Bache for the next four decades, the United States Pharmacopoeia (U.S.Ph) achieved sustained prominence and gained further recognition as a national standard. Bache and Wood also authored the United States Dispensatory (USD) that provided fuller descriptions and explanations of preparations but deferred to the authority of the U.S.Ph. The 1840 U.S.Ph revision contained numerous changes and new features and was said to be a “completely revised pharmacopoeia” (Anderson and Higby 1995). In 1848, an important step toward solidifying U.S.Ph’s role as a recognized national standard came with the passage of the Drug Import Act, which mandated that drugs imported into the country must comply with USP’s quality standards for strength and purity.

Pharmacists became an integral part of pharmacopeial revision process during the 1850 revision that continues to this day along with physicians and other scientists in related disciplines. The 1860 (USP IV) and 1870 editions were not structurally any different from the earlier editions, but did include newer remedies and processes as well as technical methods. The Civil War distracted professionals responsible for its revision and did not alter the content much to meet the war time needs. USP IV for the first time included potency standards for cinchona, opium and scammony and the committee wrestled with problems in measurement science (metrology). It was the most popular edition up to that time. The 1870 edition included metric weights and measures tables, after the US Congress made the metric system legal in 1866.

At the close of the nineteenth-century, in 1880, pharmacist Charles Rice, the newly appointed Chair of the Committee of Revision, initiated a complete revision and modernization of the USP reflecting advances that had been made in pharmaceutical chemistry. Antiquated pharmaceutical recipes were replaced with specific chemical formulas and precise tests for purity. A single alphabetical listing replaced the separate lists; short descriptions of all crude drugs, common adulterants, as well as parts by weight were included in the monographs. This edition also broke free of the dominance of the nomenclature discussions in the preface and instead focused on pharmaceutical technology. There was a separate section of reagents and tables - various test solutions and volumetric solutions, specific gravity and solubility tables (Anderson and Higby 1995). In addition, Dr. Rice established the first subcommittees and pioneered the use of revision circulars to give each member of the Committee of Revision equal influence in the revision process by implementing a voting and commenting system, the framework of which is still in use today.
Dr. Rice had also served as head of the Pharmacopeia Committee at the American Pharmacists Association (APhA), that later published the National Formulary (NF) in 1888. As early as 1856, the APhA promoted the “standardization of names and formulas for dosage forms of drugs not described elsewhere” (Powers 1946). The first edition was named National Formulary of Unofficial Preparations. It included primarily formulas that pharmacist’s could compound including elixirs, emulsions, fluid extracts, tinctures, solutions, syrups, and dosage forms of the time. Over time with the emergence of pharmaceutical manufacturing in the late 1800s and the lessening of pharmacist-compounded medications, the NF began to focus on drugs that were not included in the U.S.Ph. Thus, the U.S.Ph was to include “drugs of first choice therapeutically “and NF “for other drugs whose extent of use justified development of a monograph” (Sonnedecker, Changing character of the National Formulary 1890-1970 1989). Although there was no legal recognition of the NF it was well established by the time the 1906 Federal Food and Drug Laws provided a role for both the U.S.Ph and NF in defining whether a drug should be deemed adulterated under federal law. The NF along with the U.S.Ph went a long way in establishing uniformity in drugs, nomenclature and preparations.

Once the work of NF was completed, Rice turned his attention to revising U.S.Ph for the next decennial revision in 1890. For this revision, Rice solicited the opinion of outside experts who were not members of the Committee of Revision. This has been the mainstay of USP’s revision process ever since. In 1892, the Revision Committee voted to change the abbreviation of the compendium from “U.S. Ph” to “USP.” USP VII completely switched from parts-by-weight to metric system. It also did not include patented and trademarked drugs. In Remington’s words “One of the principal objectives of a Pharmacopoeia is to establish standards, to prove the identity and purity of the substances admitted; in order to make such operative, it is necessary to have more than one source of supply or manufacture” (Anderson and Higby 1995).

This exclusion of patented drugs proved to be an ongoing matter of debate, as the changes in medicine, and pharmacy increasingly called for the scope of the pharmacopoeia also follow suit. But it wasn’t until the 1940s that they were cleared for consideration into the pharmacopoeia. Synthetic compounds began to replace “mineral and vegetable drugs.” Federal regulations started intervening in the manufacture and marketing of drugs. These developments demanded more from the USP in terms of time, expertise, and financial obligations that led to major procedural and organizational changes. The next major turning point in USP’s history was initiated during the Pharmacopeial
Convention of 1900, when then Convention President, Horatio C Wood, urged the Convention to create a written Constitution and Bylaws. “The new Constitution and Bylaws defined for the first time the institutions entitled to have representation at the Convention”, (Anderson and Higby 1995) and called for the creation of USP’s first Board of Trustees. Moreover, the members of the 1900 convention passed a resolution directing the Board of Trustees to officially incorporate the United States Pharmacopeia in the District of Columbia. The July 11, 1900 certificate of incorporation gave USP’s newly created Board of Trustees power over the “management and control of the affairs, funds, and property” of the organization.” (Anderson and Higby 1995)

*USP VIII* became official in 1905 with significant changes. Average doses, allowable percentages of impurities, specific assays for several drugs, and nomenclature of synthetic drugs and chemicals made their way into the pharmacopoeia. It included a disclaimer that the standards for purity and strength in the compendium are for substances used solely for medicinal purposes. It also included the first official biological product, diphtheria antitoxin. (Anderson and Higby 1995)

Another significant event for USP at the turn of the century was the passage of the 1906 Food, Drug, and Cosmetic Act by the federal government. Although individual states had increasingly recognized *USP*, this legislation strengthened USP’s role by mandating that drugs “sold under or by a name recognized in the *United States Pharmacopeia or National Formulary,*” must meet the standards of strength, quality, or purity stipulated in these compendia. The impact that this legislation had on the *USP* and *NF* was significant and it elevated the position of the compendia. The 4th ed. of the *NF*, the first after the Act was passed, was published in 1916. It introduced standards for identity, strength quality and purity as well as distinctive titles and formulas. Official formulas for parenteral solutions, “Ampuls,” were also included for the first time. Due to the passage of the 1906 Act, there was more scrutiny of the *USP* and more discrepancies and errors were brought to the attention of the Committee. 243 monographs were deleted; notable amongst them were standards for whiskey and brandy. Small pox vaccine was added to *USP IX*. The 9th revision of the *USP* also addressed the issue of scope. Remington remained steadfast in his stand on excluding patented drugs from *USP IX*.

E. Fullerton Cook took over the reins of the Committee of Revision and *USP X* replaced Part 1 and II of *USP IX* with Monographs, and General Tests, Processes and Apparatus. Only preparations that had some claim to efficacy were included. As a result many common drugs used widely by
physicians and patients ended up with no public standards. It wasn’t until the next revision that proprietary or branded drugs were admitted into *USP X*. It was included in the *USP* only if the manufacturers had provided written consent, appropriate tests and standards, and admitted only under chemical or descriptive names. This was supported by the pharmaceutical industry and a closer working relationship was established between USP and industry. They participated more actively in the revision of the *USP*. Cook also reintroduced advisory panels so the best minds in science, pharmacy and medicine could participate in the revision of the pharmacopeia. The USP Vitamin Advisory Board included leading experts Lafayette Mendel and Elmer V. McCollum, and its work led to the first vitamin standard to be included in the *USP*. This period also saw closer cooperation between USP and government agencies with the importance of bioassay methods growing as also the developments in legislative (1902 Biologics Act) and scientific areas. The assays that determined the potency of digitalis led to the Bureau of Chemistry, the predecessor to the Food and Drug Administration (FDA) providing packaged, standardized product samples, or “reference standards”, for industry to comply with methods in

*USP X*. The 1920’s marked the advent of the USP Reference Standards program with standards for Vitamin A and D content in cod liver oil. During the period 1900 and 1930, the *USP* was translated into Spanish and then Chinese, both being important contributions to international public health. There were other innovations in the publication of the *USP* such as the continuous revision in the 1930s to keep pace with rapid developments in medical and pharmaceutical science and industry. The *NF* also saw major revisions in the 1930s. The sixth edition of the *NF* included monographs on ampuls and tablets with standards for identity, strength, purity and quality and admissions into the *NF* were based on science. Obsolete drugs were discontinued and “additional chemical, biological and proximate assays were developed and introduced” (Powers 1946). The 11th revision of the *USP* in 1936 saw obsolete items such as fluidextracts and tinctures being removed. A number of biologicals were added such as the scarlet fever antitoxin, rabies and typhoid vaccines and ephedrine.

The 1938 Food, Drug & Cosmetic (FD&C Act) expanded the role of both the *USP* & *NF* in the adulteration and misbranding provisions of federal law, regarding naming, identity, and strength, quality and purity, and also provided a role for *USP*’s and *NF*’s packaging and
labeling requirements. The Act had far reaching effects on how the USP and NF worked. The USP evolved from ‘continuous revision’ to a five year publication cycle in the 1940s. The NF also included provisions to issue revision supplements and being published every five years instead of 10 years. The publication schedules were also synchronized and slowly the differences between USP and NF monographs became almost indistinguishable over the next few decades as the NF also started admitting drugs based on their therapeutic value as opposed to just extent of use. In contrast to the USP’s reluctance to set up a laboratory in earlier revision cycles, the American Pharmaceutical Association, the publishers of NF, saw the need for a well equipped laboratory to research and test new methods and procedures. A laboratory was established in 1938 at the Association’s headquarters. It also saw efforts to coordinate the scope of the two compendia. As a result of diagnostic agents being recognized as “drugs” in the 1938 Act, NF VII included a chapter on diagnostic substances.

USP XII in 1942 was the first revision published under the five year schedule and it included monographs for injections for the first time, and compressed tablets finally were included although they were in use since Charles Rice’s time. There were also some firsts for the FDA. Insulin in 1941 and increased production of Penicillin in 1944 during World War II led to the Congress of the United States adding sections to the 1938 FD&C Act requiring FDA to certify insulin and penicillin products in response to appeals from USP and AMA. USP XIII was the first revision to have monographs under English titles following the NF decision to switch to English titles earlier. Five of the oils that were official since the 1820 USP, were dropped from USP XIII and the first adrenal hormones and seven penicillin preparations were introduced. For the first time, the “unqualified admission of proprietary products without regard to patent status” (Anderson and Penningroth, Good Work and True 2000) were included.

USP XIV saw the disappearance of the diphthong, the “œ” in the word Pharmacopeia on its title page. Patented drugs were indicated with an asterisk and there was also a warning against violating property rights of the patent and trademark holders. It included five antibiotics, and the first official monograph for antihistamine. Folic acid was first included in USP XIV, as also the first two official anticoagulants, heparin andbishydroxycoumarin, and amphetamine.

With continued official legal recognition, USP grew and expanded its efforts to promote public health during the mid twentieth-century. In 1950 after years of working out of the homes of its volunteers, USP purchased its first permanent headquarters on Park Avenue in New York City, which was urgently needed to support USP’s rapid expansion. To cultivate this growth, the USP Board of Trustees appointed Lloyd Miller to serve as Director of Revision in 1949, making him USP’s first
salaried employee. USP XV released in 1955, included new steroid products, combined diphtheria and tetanus toxoids and pertussis vaccine (DTP), and excluded several older remedies such as cascara sagrada extract and fluid extract, ephedrine, and estradiol. The General Tests section was extensively revised with modern tests and assays. The General Notices section was revised collaboratively with APhA’s Revision Committee, so the two compendia were as close to conformance as possible. It also included detailed standards for official biologicals that previous revisions did not. Miller also insisted on clarity and consistency in style and a USP Style Guide provided guidelines for the publication. Dosage ranges and the classification of drugs according to pharmacological category was introduced in USP XV and XVI. Due to the rapid introduction of new drugs into the market, the USP was to a certain extent outdated when a new revision was published so the Committee of Revision decided to include a list of “provisional admissions” in the XVI revision that were worthy of admission but did not have monographs at the time of publication. These would then be elaborated through Supplements. The XVI revision most notably included the first chemical assay for vitamin D; diuretics, human blood cells, and influenza virus and poliomyelitis vaccine were some others. During Miller’s tenure the USP would also grapple with nomenclature issues, specifically in selecting nonproprietary names in the USP and the need for a USP research laboratory. In response to these challenges, USP took on its first auxiliary publication, the United States Adopted Names or USAN that was a combined effort of the AMA, USP and APhA. It also established the Drug Standards Laboratory with funding provided by the AMA, APhA, and USP in the 1960s thus supporting the expansion of the Reference Standards program.

The 1962 Kefauver-Harris amendments to the FD&C Act introduced key changes affecting USP. FDA for the first time was given authority to require GMPs (current good manufacturing practices). Also for the first time drugs were required to be cleared by FDA for both safety, and efficacy, before marketing; this obviated the need for a USP committee on scope, since all newly marketed drugs were required to be deemed both safe and effective. Beginning with the XVII revision official antibiotic monographs included “only those aspects of identity, purity, potency, and packaging and storage that are of special interest to the physician and pharmacist” (United States Pharmacopeial Convention 1965) reflecting the requirement that FDA certify all antibiotics. USP XVII and XVII included several technical innovations such as standards for plastic prescription containers, content uniformity standards for some tablets and capsules, and caution statements for few dangerous drugs such as digoxin and methotrexate. Reference Standards (there had been only 37 in 1950) grew considerably in USP XVIII but did not include narcotic agents and radioactive agents. The most challenging problem of
this time was the bioavailability of solid dosage forms and setting practical bioavailability standards proved to be elusive. As a start USP XVIII included dissolution tests for six monographs replacing the disintegration tests. Another technical advance that was anticipated, Good Manufacturing Practices (GMP), was “monitoring potentially harmful bacteria” in the production process and chose “four index organisms” to serve as a warning signal (Anderson and Higby 1995, 359). The General Tests, Processes and Apparatus section included three chapters on effectiveness of antimicrobial agents in parenterals and ophthalmic solutions. The 1960s also saw drugs in the currently official USP and NF being included in third-party health care plans and those of the federal government drug coverage (Anderson and Higby 1995, 374).

The USP maintained its headquarters in New York for nearly twenty years before relocating to Washington, DC area in 1969, a move that was prompted by the need for more space and a closer proximity to the FDA that had expanded its operations and authority as a result of the Kefauver-Harris Act. One of the major technical issues facing the Committee of Revision during the 1970s was that of bioequivalence. The OTA Drug Bioequivalence Study in 1974 criticized “current standards and regulatory practices” in assuring bioequivalence for drug products and did not spare either the FDA’s Good Manufacturing Practices or compendial standards of USP and NF. It charged that the “physical tests and assay procedures of much greater sensitivity” (Anderson and Higby 1995, 465) than those specified by the compendia existed, objected to the initial dissolution test in USP XVIII among other issues. It also called for a single compendial organization to “revise drug and drug product standards continuously on the basis of the best available technology.” (Anderson and Higby 1995, 466). William Heller, the Executive Director, responded that organizational changes were already underway with the purchase of the NF and the drug standards laboratory. He also indicated that the panel failed to differentiate between manufacturing processes that were under FDA authority and “regulatory standards and tests for raw materials and finished drug products” (Anderson and Higby 1995, 466) that were in the compendia.

After long and protracted negotiations, USP successfully purchased the NF, along with the Drug Standards Laboratory in the 1975 from the APhA. The USP released the first combined edition of the USP-NF in 1980. It also began publishing the Pharmacopeial Forum in 1975 to publicize revision proposals and to solicit public comments. The 1970s and 1980s were dominated by organizational and business issues with major reorganization of staff as well as the Committee of Revision. A major focus of the revision activity in the early 1970s was focused on drug selection and this was formally separated from standard-
setting providing expanded opportunities for USP. In 1973, the first edition of the *USP Guide to Select Drugs* was published. It was a listing of drugs admitted into *USP XIX* and arranged according to pharmacological/therapeutic categories based on the *American Hospital Formulary Service* classification. This was all in the hopes that a federal formulary would be established aimed at Medicare and Medicaid programs. This did not come to fruition due to a number of reasons such as physician opposition, drug efficacy requirement of the 1962 Act, acquisition of the *NF* and difficulty in the drug selection program, and as a result USP withdrew altogether from drug selection, which had been a part of USP’s mission since 1820.

The 1970 convention resolution had called for including therapeutic information in the *USP. USP XIX* included brief dispensing information and expanded the dosage section but these were “nonenforceable” information in the official monographs that concerned a number of stakeholders. Most supported a separate volume clearly identified as nonofficial and the FDA wanted no distinction between approved and nonapproved uses of drugs. USP Board endorsed the separate volume but wanted it to be an extension of *USP*. This led to the birth of the *USP Dispensing Information (USP DI)* in 1980. *USP XIX* in 1975 had 1284 monographs which was a substantial increase from *USP XVIII*. It also included complex tests and methods, partly in response to the OTA report. Liquid chromatography was introduced and was increasingly used in later revisions. The first excipient monograph also made its way into the pharmacopeia. System suitability tests were introduced in *USP XIX*. *USP XX-NF XV* was the first combined volume and it discontinued dispensing information that was published in a separate publication *USP DI*. The Reference Standard program took over the distribution of reference substances of controlled drugs from NIMH in 1972 and the antibiotic reference standards from the FDA in 1975. The number of reference standards grew from about 250 in 1970 to 700 in 1975 (Anderson and Penningroth, Good Work and True 2000) and about 1200 Reference Standards were available in 1988. Most of the innovations between 1970 and 1990 were in the areas of dissolution tests, microbial limit tests, and standards for particulate matter in parenterals. Setting excipient standards was challenging as traditional parameters of strength and purity were not as important as particle size or surface area. Another major technological advance was the public offering of the sixth supplement to the *USP XXII-NF XVII* in an electronic version in 1992. The growth in the number of monographs admitted into *USP-NF* continued into the 1990s with *USP XXII-NF XVI* covering a majority of the top 2000 drug substances and products with over 3,200 monographs.
By the mid-eighties USP had once again outgrown its current space in Rockville, MD that it had purchased in 1970, and began construction on a new building for its headquarters, known today as Twinbrook II. At the time of this building’s completion in 1989, USP was increasingly making efforts to improve its international activities, and promote public health around the world. In 1989, the USP along with representatives from the Japanese and European Pharmacopoeia formed the Pharmacopeial Discussion Group to support the international harmonization of pharmaceutical monographs. Most notable of the harmonization efforts at this time was the NF monograph on ‘Lactose Monohydrate’ which was the first monograph to be harmonized.

USP 23-NF 18 published in 1995 included a new section on nutritional supplements that included four new general chapters, on disintegration-dissolution, manufacturing practices, microbial limits and weight variation. It also worked to replace, reduce and refine tests and assays that used live animals. 250 rabbit pyrogen tests were replaced by the Bacterial Endotoxin Test, an in vitro procedure. Mouse safety test was deleted from antibiotic monographs. Veterinary drugs also made their appearance in USP 23. Two new chapters dealing with bioavailability and bioequivalence were introduced. Apothecary units were deleted and metric units were used for prescription and dispensing. Computer generated graphic formulas was another first in this revision.

In 1996, USP introduced its first web site. USP 24-NF 19, published in 2000, saw the deletion of federal and other texts that were based on federal regulations as now they were freely available from government websites. Along with a GMP general chapter, two other information chapters dealing with FD&C Act requirements and Controlled Substances Act (CAS) were deleted. The 1997 FDA Modernization Act (FDAMA) provided a role for USP-NF monographs related to compounding, including the USP chapter on compounding, as part of a Congressional initiative to address pharmacy compounding. FDAMA also included a special role for USP standards related to determining when Positron Emission Tomography (PET) drugs might be deemed adulterated. PET tracers were addressed in 11 monographs and a general chapter on radiopharmaceutical in PET compounding was developed. Three radiolabeled monoclonal antibodies were introduced, the first antibodies to be included in the USP. Microbiology was another area where the standards were extensively revised. A general chapter on biocompatibility of materials, and cell permeability was introduced although standards for biomaterials themselves were deferred to later revisions. Chapters on quality of biotechnology drug products were also prepared.
The Bacterial Endotoxin test chapter was entirely harmonized and a single reference standard was developed.

*USP 25-NF 20* published in 2002 started the annual publication of the *USP-NF* and also as an online product. Two Supplements were published between annual editions. This revision created safety criteria for admission of dietary supplement monographs and classes for these monographs. In *USP 28-NF 23* published in 2005, chromatographic assays were developed for a number of drug substance monographs replacing titration assays as the FDA required stability-indicating assays for these articles. The process of continuous revision continued with standards for pharmaceutical waters, packaging and storage, labeling and of muilitdose and single dose vials, cautionary statements on ferrule and cap overseas for neuromuscular agents, control of heavy metals, medical gases, heparin, glycerin, sterile compounding, elemental impurities being some of the significant revisions. A major initiative of redesigning monographs was initiated in 2009 with “~4,000 monographs in the *USP 33–NF 28* were redesigned, encompassing more than 4,100 pages, over four million words, and many figures and tables” (United States Pharmacopoeial Convention 2010), with the intent of not changing any of the substantive monograph requirements. There were significant errors in this massive undertaking and for the first time in USP history, a revision was recalled and reissued in 2010.

USP’s international expansion and interests continued to grow into the twenty-first century, leading in 2005 to the establishment of USP’s first international office in Basel, Switzerland. This was followed by the opening of international laboratories in India in 2006 and China in 2007 and soon after in Brazil in 2008. USP has also engaged in a number of global health initiatives that help support the efforts of under-resourced countries to build capacity to combat substandard and counterfeit medicines.

During the first two decades of this century USP has also successfully launched several new publications including the *Pharmacists Pharmacopeia*; the
newly acquired *Food Chemical Codex (FCC)*; Dietary Supplements Compendium (DSC); and two online only publications *Medicines Compendium (MC)* and *Herbal Medicines Compendium (HMC)*. USP has also translated the *USP-NF* into Spanish, Russian and Chinese.

Currently, *USP-NF* remains the oldest continuously published pharmaceutical compendia, growing to include over 4000 monographs, and 3,000 reference standards which are recognized as the standard of quality in more than 140 countries around the globe.

Today, the USP continues to strive to fulfill its mission “to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods” with the active participation of its volunteers and staff.
Bibliography

7. —. USP XVII. 1965.

Acknowledgement:
This article was first published on the International Society of the History of Pharmacy Website
Peter Briss, MD MPH  
Medical Director  
National Center for Chronic Disease Prevention and Health Promotion

Dr. Peter Briss serves as the Medical Director of CDC’s National Center for Chronic Disease Prevention and Health Promotion. He has been with CDC and the US Public Health Service for 25 years. He has performed a broad range of cross-disciplinary research and service particularly involving systematic reviews, evidence-informed practice, and research translation addressing topics ranging from health care to community prevention including lead poisoning, vaccine preventable disease, tobacco, cancer, heart disease, and oral health. He has participated in public health teaching, practice, and research at state and federal levels in the U.S. and internationally.

Dr. Briss received his medical degree and training in internal medicine and pediatrics at the Ohio State University and his MPH in Health Management and Policy from the University of Michigan. He completed training in epidemiology and preventive medicine at CDC, is board certified in internal medicine and preventive medicine, and is an active clinician at Grady Memorial Hospital in Atlanta. He has authored or coauthored more than 90 professional publications and coedited the Guide to Community Preventive Services. He has served on many expert groups and committees including the board of directors of the National Quality Forum.

Michael Schooley, M.P.H.
Branch Chief for the Applied Research and Evaluation Branch  
Division for Heart Disease and Stroke Prevention

Michael Schooley is Chief of the Applied Research and Evaluation Branch at the Division for Heart Disease and Stroke Prevention, Centers for Disease Control and Prevention. Michael has been working in public health with CDC for over 20 years. His work has focused on applied research, with particular emphasis on monitoring and evaluating chronic disease prevention and control programs and policies for cardiovascular health, tobacco use prevention, and obesity prevention and control. He has expertise in program evaluation, performance measurement, policy research, research translation, and national and state surveillance. In addition to his subject matter expertise, he has strong experience and skills in management and facilitation. Michael received his Master of Public Health degree in epidemiology and international health from Emory University.

Janet S. Wright MD, FACC
Executive Director, Million Hearts®

Dr. Janet Wright is the Executive Director of Million Hearts®, an HHS national initiative, co-led by CDC and CMS, with the explicit goal to prevent 1 million heart attacks and strokes in the U.S. by 2017.

From 2008 to 2011, Dr. Wright served as Senior Vice President for Science and Quality at the American College of Cardiology. In that role, she provided medical and scientific oversight of clinical guidelines, performance measures, health policy statements, and appropriate use criteria; quality improvement projects; and the National Cardiovascular Data Registry, a suite of databases containing more than 12 million patient records in both inpatient and outpatient care settings.

Dr. Wright practiced cardiology for many years in Chico, California, and during those years, she served on ACC’s Board of Trustees, NCQA’s Physician Program Committee, and the Center for Information Therapy, a non-profit organization committed to the provision of personalized health information during each health encounter. Her primary interests are the design and implementation of systems of care to achieve optimal outcomes for patients and the full deployment of hooks, tricks, and cues that help people get and stay healthy.
A PROGRAM GUIDE FOR PUBLIC HEALTH

Partnering with Pharmacists in the Prevention and Control of Chronic Diseases

National Center for Chronic Disease Prevention and Health Promotion
Acknowledgments

Contributing Divisions
Division for Heart Disease and Stroke Prevention
Division of Diabetes Translation

Authors
Cynthia M. Morrison, MSPH
Denice Glover, MSW
Siobhan M. Gilchrist, JD, MPH
Margaret O. Casey, RN, MPH
Andrew Lanza, MPH, MSW
Rashon I. Lane, MA
Miriam Patanian, MPH

Contributors
Kristen G. Betts, RDH, BHS
Lazette Lawton, MS
Susan Ladd, MS
Mary G. George, MD, MSPH, FACS, FAHA
Sherri Yoder, PharmD, BCPS
Edward Gregg, PhD
Judy Hannan, RN, MPH

State Partners
Crystelle C. Fogle, MBA, MS, RD
Linda Krantz, MS
Teresa M. Robinson, MBA
Adelline Ntatin, MPH, MBIM, MA
Magaly Rodriguez de Bittner, PharmD, BCPS, CDE
Philip T. Rodgers, PharmD, BCPS, FCCP
Executive Summary

New ways to expand team-based health care are needed to protect the health of Americans. Many chronic diseases, which are increasing with the aging U.S. population, are preventable or manageable. The role of the pharmacist has expanded beyond just dispensing medications and is evolving into active participation in chronic disease management as a part of team-based care. Programs addressing chronic diseases in state health departments and communities can build team relationships through public and private partnerships. We intend for this guide to serve as a starting point for Centers for Disease Control and Prevention (CDC) grantees to build these relationships with pharmacists and other strategic stakeholders.

The objectives of this guide are to provide the following information:

• Basic definitions for medication therapy management, comprehensive medication management, and collaborative drug therapy management.

• A description of the role of the pharmacist in team-based health care.

• Evidence to support maximizing pharmacists’ engagement in team-based health care.

• An overview of pharmacist scope of practice policies at the federal and state levels.

• A description of how chronic diseases are addressed in community pharmacies.

• Examples of medication therapy management from state health departments.

• Strategies for working with pharmacists.
Purpose of This Guide

The National Center for Chronic Disease Prevention and Health Promotion is working to transform CDC’s chronic disease activities by focusing national and state efforts on the ‘4 Domains’ listed below:

1. **Environmental Approaches**: Make healthy behaviors easier and more convenient for more people.

2. **Health Systems**: Improve delivery and use of quality clinical services to prevent disease, detect diseases early, and manage risk factors.

3. **Community-Clinical Linkages**: Ensure those with or at high risk for chronic diseases have access to quality community resources to best manage their conditions.

4. **Epidemiology and Surveillance**: Provide data and conduct research to inform, prioritize, deliver, and monitor programs and population health.

Within the Community-Clinical Linkages domain, CDC’s Diabetes Prevention and Control Program (DPCP) and Heart Disease and Stroke Prevention (HDSP) Programs both include a focus on enhancing the role of community pharmacists in team-based care as outlined below:

- **DPCP Core Diabetes Interventions and Strategies**: “Expand the role of allied health professionals by replicating and scaling evidence-based programs founded on the principles of the Asheville Project and the Diabetes 10-City Challenge.”

- **HDSP Programs Strategies for States to Address the “ABCS” of Heart Disease and Stroke Prevention**: “Promote use of pharmacists as health care extenders to promote control of hypertension and high blood cholesterol.”

Basic Definitions

Medication Therapy Management

As defined by the American Pharmacists Association, medication therapy management (MTM) is a term used to describe a broad range of health care services provided by pharmacists, the medication experts on the health care team. A consensus definition, adopted by the pharmacy profession in 2004, defines MTM as a service or group of services that optimize therapeutic outcomes for individual patients. Pharmacists provide MTM to help patients get the best benefits from their medications by actively managing drug therapy and by identifying, preventing, and resolving medication-related problems. MTM services are independent of; but can occur in conjunction with, the provision of a medication or medical device.
Pharmacist Education

As you seek pharmacists as partners, understanding their background may be helpful. Today, pharmacists graduate with a Doctor of Pharmacy degree, commonly referred to as a “PharmD.” Some longer-practicing pharmacists may not have a PharmD but have a Bachelor of Science (BS) in pharmacy. Because the BS was more focused on drug distribution and dispensing, in 2004, the American Council of Pharmaceutical Education made the PharmD the required degree for accredited pharmacy programs in an effort to provide more clinical education.

Presently, pharmacists also have the opportunity to complete one or two years of optional residency training after graduation. Residency training can occur in hospitals, community pharmacies, or other sites and prepares the pharmacist for more advanced practice in those areas.

Additionally, pharmacists may choose to complete certificate programs focused on the management of specific disease states or other certifications that demonstrate competency and expertise in a certain area. The Board of Pharmaceutical Specialties offers certification in six areas of specialty in pharmacy, designated by credentials after the PharmD. Some pharmacists may seek credentials that cross professional boundaries to further differentiate themselves, such as becoming a Certified Diabetes Educator.

Pharmacists provide **MTM services** in all care settings in which patients take medications. Although pharmacists in different settings may provide different types of services, the goal of all pharmacists providing MTM is to make sure that the medication is right for the patient and his or her health conditions and that the best possible outcomes from treatment are achieved.

Comprehensive Medication Management

In *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes*, the Patient-Centered Primary Care Collaborative defines comprehensive medication management as the standard of care that ensures each patient’s medications—whether they are prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements—are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended. Within this system, each medication is assessed for the medical condition or indication for which it is taken. To produce clinically useful data, the indication must be electronically linked with the product, dose, duration, manner in which the medication is taken, therapy goals, clinical parameters that determine progress toward these goals, and actual outcomes. The clinical status of the patient must be determined for each drug and each condition (e.g., current blood pressure level and cholesterol levels for patients with high blood pressure and high cholesterol). Without knowledge of the current clinical status of a patient, the indication, appropriateness, and effectiveness of most medications cannot be determined.

Comprehensive medication management includes an individualized care plan that achieves the intended goals of therapy with appropriate follow-up to help the pharmacist determine actual patient outcomes. The pharmacist evaluates the outcome parameters against the patient’s individualized therapy goals and re-evaluates the patient to identify any new medication-related problems that might interfere with the safe and effective use of medications in the patient’s care plan. These follow-up evaluations occur in a time frame that is clinically appropriate for the specific patient as well as his or her medical conditions and drug therapy plan. Evaluation time frames vary with each patient and are triggered when major transitions—such as hospitalization—occur or at the request of the patient’s providers/prescribers.

Collaborative Drug Therapy Management

As defined by the [American College of Clinical Pharmacy](https://www.accp.com) (ACCP), collaborative drug therapy management (CDTM) is a “collaborative practice agreement between one or more physicians and pharmacists wherein qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility
for performing patient assessments; ordering drug therapy-related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens.” CDTM is best used when providing an advanced level of service whereby the pharmacist not only has access to a patient’s medical record but has dedicated clinical time as well.

Although MTM is often conducted through a collaborative relationship with patients and other health care professionals, it is already within the scope of pharmacy practice and does not require a formal collaborative practice agreement. CDTM laws vary by state, and pharmacists must comply with the requirements of the state in which they practice.

**Team-Based Care**

According to the proposed definition from a working group of the Institute of Medicine, team-based health care is the provision of health services to individuals, families, and/or their communities by at least two health providers who work collaboratively with patients and their caregivers—to the extent preferred by each patient—to accomplish shared goals within and across settings to achieve coordinated, high-quality, and patient-centered care.

**Self-Insured Employer**

A self-insured employer is a company that provides health, disability, and/or worker’s compensation insurance benefits to employees on its own, with claims to be paid by the company, rather than pay premiums and file claims through a third-party insurance provider. Self-insurance is also referred to as “self-funded” health care. Employers can administer insurance plans internally or hire a third-party administrator to provide assistance only.

**Role of the Pharmacist in Team-Based Care**

The role of pharmacists in providing patient care services is compatible and synergistic with the patient-centered medical home model and other innovative models of team-based care. Pharmacists extend the health care team to the local community, providing patients with the resources and care they need. In addition, pharmacists are some of the most accessible health care professionals and have a broader knowledge
of medicines (prescription and over-the-counter) than any other member of the health care team. Research shows real value in pharmacists’ management of diabetes and heart disease. For the millions of Americans with uncontrolled diabetes, the risk for heart disease, stroke, kidney failure, blindness, and amputation are significant. Engaging pharmacists as members of the health care system can significantly improve treatment of diabetes, better control high blood pressure, improve management of cholesterol, and reduce overall health care costs.

**Evidence to Support Maximizing Pharmacists’ Engagement in Team-Based Care**

The booklet, Pharmacists and the Health Care Puzzle: Improving Medication Use and Reducing Health Care Cost, developed by the American Pharmacists Association, describes how pharmacists have demonstrated value and savings to the health care system. It further explains how services such as MTM affect health outcomes and gives examples of services pharmacists provide to improve chronic care management for cardiovascular risk factors, such as diabetes and hypertension.

A recent report to the U.S. Surgeon General, entitled *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice*, uses objective data to demonstrate how models of innovative care involving pharmacists can ultimately help alleviate demands on the health care system (e.g., access, safety, quality, cost, provider shortages, etc.) and improve patient outcomes. The report describes existing, accepted, and successful models of health care delivery and patient care using pharmacists as health care providers and essential members of the health care team.

The report provides a thorough, evidence-based discussion of the comprehensive MTM services that pharmacists currently provide. For nearly 50 years, federal pharmacists have been able to practice collaboratively with physicians and other health care providers in expanded scopes, delivering comprehensive disease management, health promotion, disease prevention, MTM, and other cognitive clinical services. The report presents public- and private-sector models and calls for health leadership and policymakers to support and implement existing, evidence-based, and cost-effective pharmacist-delivered patient care models as the demands within the nation’s health care system escalate.

One way to measure the cost-efficiencies of pharmacist-delivered CDTM is to consider the calculated return on investment (ROI), which reflects the value of the service based on the cost of delivering the service. The data collected from CDTM demonstrated an ROI of as high as 12:1 and an average between 3:1 and 5:1. This value is based on the ability of medication management services to reduce hospital admissions, use of unnecessary or inappropriate medications, emergency room admissions, and overall physician visits.
For example, in the Asheville Project, employees of the city of Asheville with conditions such as diabetes, asthma, hypertension, and high cholesterol received intensive self-management education through the Mission-St. Joseph’s Diabetes and Health Education Center. The employees teamed up with their local pharmacists, who ensured they were using their medications correctly. The project found that pharmacists improved the clinical outcomes of diabetes patients and reduced overall health care costs. This MTM model provided chronic care management through ongoing education, monitoring, follow-up, and referrals for patients with diabetes. An expansion of the Asheville Project to other chronic conditions demonstrated that after six months, 69% of participants with high cholesterol achieved their cholesterol goal versus 33% at baseline, and 81% of participants with hypertension reached their blood pressure goal versus 30% at baseline. Employers who supported these projects also benefited substantially from increased productivity and fewer employee sick days.

**Pharmacist Scope of Practice Policies**

Federal and state policies have advanced the role of pharmacists in direct patient care through MTM reimbursement, pharmacy service definitions, and advanced pharmacy models to achieve optimal medication use and patient and therapeutic outcomes.

**Federal Policies**

At the federal agency level, the Indian Health Service (IHS) has been engaged in an advanced pharmacy practice model whereby pharmacists deliver direct patient care services with physician collaboration since the early 1970s. The Veterans Health Administration implemented a similar program in 1995 that updated the granting of prescribing authority for clinical pharmacy specialists. Interestingly, the basic level of pharmacy care that IHS provides falls under general MTM (medication review, counseling, and monitoring of therapeutic outcomes) that is more commonly seen in the private sector. These advanced models have increasingly diffused into the private sector over the past two decades, mainly within hospitals, clinics, and educational facilities.

On a federal policy level, the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003, Public Law 108-173, was enacted to control health care costs and improve the quality of care. This law required Medicare Part D prescription drug plan sponsors to offer pharmacist MTM services to beneficiaries with multiple chronic diseases (e.g., diabetes, hypertension). Medicare Part D plan sponsors are required to reimburse pharmacies for MTM services, but rates and eligibility criteria may vary and, in many cases, are inadequate and lack feasibility.
**State Policies**

As of January 2011, 31 states have laws that allow physicians and pharmacists to collaborate in providing advanced services (such as those outlined in the CDTM definition above) that could occur in a community pharmacy setting, for conditions such as hypertension and high cholesterol. Eleven additional states allow pharmacists to provide these CDTM-type services under limited conditions, such as for hospitalized patients only, or solely to administer vaccinations and emergency contraception. Several other states have since enacted laws authorizing CDTM.

Policies requiring reimbursement by insurers and Medicaid for pharmacist services are not widespread. As of January 2011, only three state Medicaid programs (Minnesota, Missouri, and Oregon) reimburse for MTM services provided by a pharmacist through individual, face-to-face assessment and intervention.

**Addressing Chronic Disease in Pharmacies**

**Medication Adherence**

Medication adherence is the degree to which patients take medications as directed by their physician or licensed health professional. Medication non-adherence is the degree to which patients do not take medications as directed, which is costly and dangerous. One report estimated that 18% of unresolved drug-related issues involved medication non-adherence. Poor adherence to medications increases overall health care costs as patients become sicker faster and require more costly interventions. Data show that as many as half of all patients do not adhere to their prescription-medication regimens, and the result is more than $100 billion spent each year on avoidable hospitalizations. Non-adherence to medication regimens also affects quality and length of life; for example, one study estimated that better adherence to antihypertensive treatment alone could prevent 89,000 premature deaths in the United States annually. Patients do not adhere to medication regimens for a variety of reasons, including side effects, timing, not understanding the benefits of the medication, and not wanting to take "so many pills."

**Lifestyle Modification**

The Diabetes Prevention Program study has shown that a chronic disease such as diabetes can be prevented or managed with appropriate changes or modifications to a person’s lifestyle. For example, the risk of developing diabetes and heart disease may be reduced with good nutrition, weight loss, and regular physical activity; once diagnosed, these conditions can be managed with medication and behavior modification. A pharmacist in a community setting (e.g., the local drug store) should consider the need for an appropriate counseling area for privacy, additional personnel...
to assist with dispensary and other customer needs, time to provide counseling, professional training, and employer support.

State Health Department MTM Project Examples

Additional information for each example is provided in Appendix A.

- The Maryland P³ Program (Patients, Pharmacists, Partnerships)™ is an example of comprehensive medication management that improves chronic disease-related health outcomes. The Maryland P³ Program™ uses trained pharmacists to assist patients with proper use of medications, diagnostic testing, counseling, and overall disease management. Pharmacists work in collaboration with patients’ health care providers to improve medication adherence and clinical and economic outcomes. The program currently works with self-insured employers.
  
  **Program Contact:** Adeline Ntatin, antatin@dhmh.state.md.us

- The Montana Pharmacist Blood Pressure Management Program targets state of Montana employees, spouses, and retirees who are active health plan members. Members are offered face-to-face counseling with a pharmacist and provided blood pressure resources.
  
  **Program Contact:** Crystelle Fogle, cfogle@mt.gov

- The South Carolina Stroke Belt Project replicates the Asheville Model in counties with high rates of stroke mortality. Employees with chronic health problems, such as diabetes, hypertension, high cholesterol, and asthma, receive face-to-face coaching by a care manager who may be a community pharmacist or nurse educator.
  
  **Program Contact:** Joy Brooks, brooksf@dhec.sc.gov

Working with Pharmacists to Build Chronic Disease MTM Programs

Planning Your Project

There are many ways chronic disease prevention and control programs can work with and support pharmacists in their efforts to improve patient outcomes for heart disease and diabetes. Below are some suggestions for how you might get started in partnering with the pharmacist community.

1. **Partner** with an organization or group that understands this area well. First, look within your state health department to determine if another program is conducting a similar project. Some communicable disease, immunization, or maternal-child health programs already may be engaged with pharmacists. It might be more appropriate to add a focus area to an existing project rather than develop a new one. An ideal partner in any pharmacist-based intervention is the
state Medicaid program. This program works to reduce costs and improve access and delivery of care, and pharmacist-based programs have been shown to do that. When looking for external partners, consider a college or school of pharmacy. Management of chronic disease is an area of interest for many schools, so they may be able to offer a great deal of assistance. Another potential partner is the state pharmacy association. These groups work to improve quality of care, promote medication adherence, and enhance patient safety.

Because resources and financial support are often a barrier to successful program implementation, engaging the business community in your state is critical. For example, the Maryland P3 Program has shown that partnership with the Mid-Atlantic and the Virginia Business Groups on Health (representing self-insured companies in the region) is an important component of the program’s success. For more information on what business health coalitions exist in your state, visit the National Business Coalition on Health.

It is important to work with self-insured employers in your region because at this time, they are the leading model for supporting and sustaining the work of pharmacists in helping patients achieve blood pressure, cholesterol, and A1c management, thereby improving outcomes for heart disease and diabetes.

2. Learn what pharmacists can and cannot do in your state—what is their scope of practice? The Council on Credentialing in Pharmacy provides an overview of the topic in Scope of Contemporary Pharmacy Practice: Roles, Responsibilities, and Functions of Pharmacists and Pharmacy Technicians. This resource details the types of practices open to pharmacists and pharmacy technicians and describes the scope of each.

Before beginning a pharmacy-related intervention, be sure to know and understand the regulations for the pharmacy scope of practice within your state. This information is usually available from the state Board of Pharmacy. The regulations tend to be lengthy, and each state may limit the scope of pharmacy services by either commission or omission. MTM as defined by the Model Pharmacy Act and the MMA Act of 2003 does not require a collaborative practice agreement. In addition, pharmacists may adjust or modify drug therapy pursuant to verbal orders from the prescribing health care provider.

3. Explore model programs including those listed above and, together with partners, decide which model will work best for the program. A pilot project in a specific region or with a specific large employer may be an option to consider. Be sure to build in a rigorous evaluation for the project at the beginning of the planning stage. Demonstrating effectiveness will help scale up and spread the initiative to other regions or employers over time. Aggregate, rather than individual, health outcomes
are more easily collected. Additionally, project costs and return on investment should be included as a part of the evaluation. Issues for all parties to explore when choosing an intervention include:

a. **Recruiting and engaging participants:** Determine how to select pharmacists for the project and how to recruit employers.

b. **Informing and training pharmacists:** Determine what curriculum will be used, who will provide the training, where and how the training will be conducted, and who will pay for the training.

c. **Reimbursement:** Determine how pharmacists will be paid for their services. Is there a role for health plans or other payers in the project? Will a session with the pharmacist be a covered benefit? Will you work with community health centers where the pharmacist is a salaried employee with expanded duties?

4. **Focus** on policy and/or systems changes to support the program’s sustainability. Look for opportunities to influence or change systems or support policies as you move ahead with program development:

   a. Does the pharmacist scope of practice within the state need to be clarified to facilitate provision of chronic disease patient care services or work as part of the health care team?

   b. Can community health centers ensure that the employed pharmacists provide MTM or more advanced chronic disease management services for patients?

   c. Can these services become a routine part of the health benefits provided by health plans or large self-insured employers in the state?

5. **Design** your program with your partners. Research shows that in various sectors, pharmacists are already integrated into primary patient care as health care providers. Pharmacists may be very interested in helping state and community-based programs achieve blood pressure control and cholesterol management for participants, thereby improving outcomes for heart disease and diabetes. The goal for expanding or introducing MTM services in your state should be developing a program that is achievable, scalable, and sustainable. The science of program development and collaboration with the right partners can increase your success.

   The following resources may be useful in helping you and your partners plan and evaluate your program and its success.

   - The **State Program Evaluation Guides** are a series of technical assistance tools developed by the CDC Division for Heart Disease and Stroke Prevention for use by state HDSP programs. The guides clarify approaches to and methods of evaluation, provide examples specific to the scope and purpose of state HDSP programs, and recommend resources for additional reading.
Choosing the Right Partners

Patients (includes participants and employees): Individuals whose chronic diseases require a significant amount of self-management, such as diabetes or high blood pressure, need to understand how pharmacists can assist them in managing their conditions through coaching and MTM. For many patients, pharmacists are the easiest health care professionals to access. The opportunities to interface with community pharmacists are plentiful for most Americans. The average adult fills about 12 prescriptions, new and refills, each year; after 65 years of age, he or she fills more than 30 prescriptions annually.

Providers (includes physicians and pharmacists): Physicians and pharmacists are joining forces through a number of collaborations between some of the nation’s largest physician groups and retail drugstore chains. Similarly, Maryland’s P3 Program™ has demonstrated an effective collaboration between the Maryland Department of Health and Mental Hygiene, the University of Maryland School of Pharmacy, the Mid-Atlantic and Virginia Business Groups on Health, the Maryland Pharmacists Association, and the Maryland General Assembly. Throughout the nation, these types of collaborations and partnerships vary, but there appears to be a trend in which the pharmacist’s role is expanding from drug dispenser to medication therapy manager and chronic disease coach. Data indicate that the average person with chronic disease is taking his or her medication 60%–70% of the time. In a coordinated collaborative approach with pharmacists and physicians, many believe that this percentage can increase to about 90%.

When beginning this work, be aware of the various sectors within the pharmacist “world.” To help with orientation to these different types of pharmacists and learn about their respective roles, see Appendix B for a list of national organizations that represent various pharmacist sectors at the state and local levels. Included in this list are links to the organizations’ websites, which provide more information about different types of pharmacists, their missions, and various perspectives within the health care arena.

As part of the interdisciplinary team approach to care promoted by the patient-centered medical home model, other providers also are essential partners in preventing...
and managing chronic diseases. The key roles are that of the physician as primary care provider and the pharmacist as medication therapy manager and chronic disease coach.

**Payers (includes employers and health plans):** Until pharmacist-administered patient care services become a covered benefit, self-insured companies and employers who participate in local or regional business coalitions on health will be the primary groups currently paying for this service. In some cases, these groups also deliver services to their employees. Self-insured employers/companies are particularly interested and positioned to work with pharmacists because these employers assume much of the health risk of their employees and other beneficiaries.

Similarly, health plans are key stakeholders as they serve as pharmacy benefits managers or third-party administrators for self-insured companies. From its inception, the Asheville Project had a strong business case associated with the use of community pharmacists as chronic disease coaches. As the **Diabetes Ten City Challenge** has shown, pharmacists increase delivery of critical control measures such as A1c tests, eye and foot exams, flu shots, and lipid measurements; significantly improve patient satisfaction; and reduce health care costs overall. Members of numerous business health coalitions (e.g., Mid-Atlantic, Midwest, Pittsburgh) are committed to the support of this work, and in many cases, the worksite serves as the main location where services are delivered. For a full listing of business health coalitions throughout the United States, visit the [National Business Coalition on Health](#).
References

Alliance for Pharmaceutical Care. The pharmacist’s role in Medicare medication therapy management services. 2004.


Blake KB, Madhavan SS. Perceived barriers to provision of medication therapy management services (MTMS) and the likelihood of a pharmacist to work in a pharmacy that provides MTMS. Ann Pharmacother. 2010;44:424–31.


City of Asheville. The Asheville Project.


Patient-Centered Primary Care Collaborative. The patient-centered medical home: integrating comprehensive medication management to optimize patient outcomes. 2010.

Voluntary Medicare Prescription Drug Benefit, Cost Control and Quality Improvement Requirements, 42 C.F.R. Sect. 423, Subpart D.

## APPENDIX A

### Summary of Three State Health Departments’ Work with Pharmacists

<table>
<thead>
<tr>
<th>Program</th>
<th>Maryland P3 Program (Patients, Pharmacists, Partnerships)™</th>
<th>Montana Pharmacist Blood Pressure Management Program</th>
<th>South Carolina Stroke Belt Project</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Scope of the Practice</strong></td>
<td>By statute, Maryland authorizes a licensed physician and pharmacist to enter into a written physician-pharmacist agreement (CPA) that specifies the disease states and treatment protocols the pharmacist may use to provide patient drug therapy management (MTM).</td>
<td>Pursuant to Mont. Code Ann. §37-7-101, the scope of pharmacy practice in Montana through a written collaborative pharmacy practice agreement with one or more providers allows pharmacists to initiate, monitor, and modify drug therapy; administer vaccines; and provide patient care as defined by protocol.</td>
<td>South Carolina Code of Laws §40-43-10 states “the practice of pharmacy shall center around the provision of pharmacy care services and assisting the patient to achieve optimal therapeutic outcomes.”</td>
</tr>
<tr>
<td><strong>Partners</strong></td>
<td>University of Maryland School of Pharmacy, business community, local pharmacies, Maryland Pharmacists Association, and Mid-Atlantic and Virginia Business Groups on Health.</td>
<td>State of Montana Health Care and Benefits Division, University of Montana Skaggs School of Pharmacy, Montana Association of Health Care Purchasers, It Starts With Me (ISWM)—health screening vendor for state of Montana.</td>
<td>Municipal Association of South Carolina, South Carolina Pharmacy Association, pharmaceutical representatives, South Carolina Hospital Association, South Carolina Public Health Regions, South Carolina Department of Health and Environmental Control’s Bureau of Community Health and Chronic Disease Prevention.</td>
</tr>
<tr>
<td><strong>Method of Reimbursement</strong></td>
<td>Self-insured businesses; also looking for third-party payers, Medicaid, and state employees.</td>
<td>Pharmacists are given a one-time participation incentive of $800.</td>
<td>Self-insured businesses.</td>
</tr>
</tbody>
</table>
| **State Responsibility** | • Fund pharmacists training and education programs.  
• Support program infrastructure at the University of Maryland School of Pharmacy.  
• Strategic planning, technical assistance, and guidance.  
• Marketing and promotion to businesses and other public health stakeholders. | • Fund pharmacists training.  
• Provide blood pressure kits consisting of educational materials on blood pressure management/lifestyle, a pillbox, pedometer, and an electronic blood pressure cuff for eligible employees.  
• Enroll participants in the pharmacy program.  
• Contract with a health screening vendor who customizes lab reports and provides screening data. | • Identify fiscal and human resources.  
• Recruit stakeholders and worksites.  
• Procure vendor/contract management and technical support to administer project.  
• Collaborate, develop, and market project and evaluation expertise. |
<p>| <strong>Incentive Programs</strong> | Participants receive reduction or elimination of co-payments on medication. There is no cost to participants. | There is no cost to participants. | Participants receive waived medication co-payments, waived laboratory co-pays, and free care management. There is no cost to participants. |</p>
<table>
<thead>
<tr>
<th>Program</th>
<th>Maryland P3 Program (Patients, Pharmacists, Partnerships)™</th>
<th>Montana Pharmacist Blood Pressure Management Program</th>
<th>South Carolina Stroke Belt Project</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaborative Practice Agreement (CPA)</td>
<td>The CPA covers medication therapy management (MTM), diagnostic testing, counseling, and overall disease management. After entering into a CPA, a licensed pharmacist with a PharmD or equivalent training may provide MTM to an individual patient as specified in a therapy management contract.</td>
<td>Pharmacists currently are not using a collaborative practice agreement.</td>
<td>N/A</td>
</tr>
<tr>
<td>Linkage with Physicians</td>
<td>The pharmacist communicates verbally or in writing to the primary care provider and health care team. In addition, pharmacists document care notes in a Health Information Portability and Accountability Act–compliant web-based documentation system.</td>
<td>The pharmacist communicates in writing to the primary care provider after each interaction with the participant.</td>
<td>The pharmacist/care manager communicates verbally or in writing to the primary care provider and health care team. The care manager documents care notes in a Health Information Portability and Accountability Act–compliant Digital Outcomes Communication System.</td>
</tr>
<tr>
<td>Barriers</td>
<td>• Initial resistance from medical community.</td>
<td>• Lack of reimbursement for consults affects pharmacist recruitment.</td>
<td>• State procurement process.</td>
</tr>
<tr>
<td></td>
<td>• Low recruitment of businesses.</td>
<td>• Lack of direct access to employee data, such as screening data and medical/pharmaceutical claims.</td>
<td>• Low recruitment of businesses with small- and medium-sized budgets.</td>
</tr>
<tr>
<td></td>
<td>• Lack of third-party reimbursement, which prevents program expansion into the larger communities.</td>
<td>• Most self-insured employers are national in scope and require the program to be offered to other out-of-state locations.</td>
<td>• Locating an experienced vendor.</td>
</tr>
<tr>
<td></td>
<td>• Most self-insured employers are national in scope and require the program to be offered to other out-of-state locations.</td>
<td>• Maryland Collaborative Practice Law.</td>
<td>• Most self-insured employers are national in scope and require the program to be offered to other out-of-state locations.</td>
</tr>
<tr>
<td>Outcomes</td>
<td>The core success of the Maryland P3 Program™ is the patient’s improved health and clinical outcomes through better self-management and reduced overall costs of health care. The program has shown cost savings of $918 per employee annually, a reduction in absenteeism, and employee savings of $400–$600 per year on average through incentives.</td>
<td>Less than one year in implementation.</td>
<td>Less than one year in implementation.</td>
</tr>
</tbody>
</table>
APPENDIX B

National Organizations Representing Various Pharmacist Sectors at the State and Local Levels

Academy of Managed Care Pharmacy (AMCP) is a national professional association of pharmacists and other health care practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy’s more than 6,000 members develop and provide a diversified range of clinical, educational, and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit. The Academy observed its 20th anniversary in 2009.

American Association of Colleges of Pharmacy (AACP) is a national organization representing the interests of pharmacy education and educators. Comprising 120 accredited colleges and schools of pharmacy, including more than 6,096 faculty, 54,700 students enrolled in professional programs, and 5,400 individuals pursuing graduate study, AACP is committed to excellence in pharmacy education.

American College of Clinical Pharmacy (ACCP) is a professional and scientific society that provides leadership, education, advocacy, and resources enabling clinical pharmacists to achieve excellence in practice and research. ACCP’s membership is composed of practitioners, scientists, educators, administrators, students, residents, fellows, and others committed to excellence in clinical pharmacy and patient pharmacotherapy.

American Pharmacists Association (APhA), founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 practicing pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession. APhA, dedicated to helping all pharmacists improve medication use and advance patient care, is the first-established and largest association of pharmacists in the United States. APhA members provide care in all practice settings, including community pharmacies, health systems, long-term care facilities, managed care organizations, hospice settings, and the uniformed services.

American Pharmacists Association (APhA) Foundation is a not-for-profit 501(c)(3) organization headquartered in Washington, DC, and is affiliated with APhA, the oldest and largest national professional society of pharmacists in the United States. The APhA Foundation looks to create a new medication use system in which patients, pharmacists, physicians, and other health care professionals collaborate to dramatically improve the cost-effectiveness and quality of consumer health outcomes. The mission of the APhA Foundation is to optimize the role of pharmacists in improving people’s health. The APhA Foundation will accomplish this through research, recognition, and resources.
American Society of Health-System Pharmacists (ASHP) believes that the mission of pharmacists is to help people make the best use of medications. The mission of ASHP is to advance and support the professional practice of pharmacists in hospitals and health systems and serve as their collective voice on issues related to medication use and public health.

National Alliance of State Pharmacy Associations (NASPA) promotes leadership, sharing, learning, and policy exchange among pharmacy leaders nationwide and provides education and advocacy to support pharmacists, patients, and communities working together to improve public health. NASPA was founded in 1927 as the National Council of State Pharmacy Association Executives.

National Community Pharmacists Association (NCPA) represents America's community pharmacists, including the owners of more than 23,000 independent community pharmacies, pharmacy franchises, and chains. Together, they represent an $93 billion health care marketplace, employ more than 62,400 pharmacists, and dispense more than 40% of all retail prescriptions.

U.S. Public Health Service (PHS) Pharmacist Professional Advisory Committee (Pharm PAC) provides advice and consultation to the U.S. Surgeon General and Pharmacy Chief Professional Officer on issues related to the professional practice of pharmacy and the personnel activities of the more than 200 Civil Service and more than 1,000 Commissioned Corps pharmacists. Pharmacists have played a vital role in the PHS during the last 100 years. Although most pharmacists have been clinicians, many also have served in regulatory, administrative, or research roles.

For more information please contact Centers for Disease Control and Prevention
1600 Clifton Road NE, Atlanta, GA 30333
Telephone: 1-800-CDC-INFO (232-4636)/TTY: 1-888-232-6348
E-mail: cdcinfo@cdc.gov Web: www.cdc.gov

Publication date: 08/2012
MEMBER ORGANIZATION
UPDATES

During this portion of the meeting each organization is provided an opportunity to provide an update on activities. We ask that organizations providing updates focus their brief discussions on activities being undertaken that advance progress in one or more of JCPP’s Vision Action Plan (Patient Care Process, Pharmacy Quality, Value of Pharmacists’ Patient Care Services, HIT, Provider Status Recognition). This discussion will serve as JCPP’s process for monitoring the progression of its Action Plan. Please bring hard-copies of this form for meeting attendees and include within the form links to material vs bringing hard copies to meeting.

ORGANIZATION: ____________________________________________

• Action Plan Implementation Activity
  o Pharmacists’ Patient Care Process
    •
    •
    •
  o Pharmacy Quality
    •
    •
    •
  o Value of Pharmacists’ Patient Care Services
    •
    •
    •
  o HIT
    •
    •
    •
  o Provider Status Recognition
    •
    •
    •
• Organization Update (other information):
  •