March 15, 2012

Joe V. Selby, M.D., M.P.H.
Executive Director
Patient Centered Outcomes Research Institute
1701 Pennsylvania Ave. NW, Suite 300
Washington, DC 20006

[Submitted online at: http://www.pcori.org/survey/priorities-agenda/]

Re: Draft Priorities for Research and Research Agenda, Version 1

Dear Dr. Selby:

The American Pharmacists Association (APhA) appreciates the opportunity to comment on the Patient-Centered Outcomes Research Institute’s (PCORI’s) draft National Priorities for Research and Research Agenda, Version 1, published January 23, 2012. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 62,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, hospitals, long-term care facilities, community health centers, managed care organizations, hospice settings and the uniformed services. Our comments reflect the views of pharmacists practicing across the spectrum of health and patient care settings.

APhA appreciates the efforts of PCORI to fund research that offers patients and caregivers the information they need to make important health care decisions. We view the proposed national priorities for patient-centered comparative clinical effectiveness research listed below as an extremely important and positive development as pharmacists continue to become more fully integrated into the health care team.

- **Assessment of Prevention, Diagnosis, and Treatment Options** - The research goal is to determine which option(s) work best for distinct populations with specific health problems.

- **Improving Healthcare Systems** - Focuses on ways to improve healthcare services, such as the coordination of care for patients with multiple chronic conditions.

- **Communication and Dissemination** - Looks at ways to provide information to patients so that they, in turn, can make informed healthcare decisions with clinicians.

- **Addressing Disparities** - Assures that research addresses the healthcare needs of all patient populations. This is needed as treatments may not work equally well for everyone.

- **Accelerating Patient-Centered and Methodological Research** - Includes patients and caregivers in the design of research that is quick, safe, and efficient.
Similarly, we see these proposed national priorities as a positive step towards reaching PCORI’s stated statutory purpose:

…to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations.

To further improve this first set of research priorities and agenda, APhA offers specific comments on the following sections.

**Improving Healthcare Systems**

We took special notice that in the proposed research area of improving health care systems, PCORI specifically names pharmacists as a topic of interest, namely on page 17 “research that compares the effectiveness on patient outcomes of a wide range of system-level strategies to incorporate new and extended roles for allied health professionals (e.g., pharmacists, nurses, physician assistants, dentists, patient navigators, volunteers, etc.) into the healthcare team.” APhA would welcome the opportunity to assist PCORI as it finalizes its research priorities and agenda, specifically with the research area of Improving Healthcare Systems. Numerous outcomes-based studies, pilot programs, demonstration projects, and other activities document and reconfirm pharmacists’ impact on patient health and well-being, process of care delivery, and overall health care costs. We feel the public, and especially patients, would be well served through additional research specific to patient outcomes as related to system-level strategies to incorporate new and extended roles for allied team members, such as pharmacists.

Recently, the U.S. Public Health Service, Office of the Chief Pharmacist released a report, *Improving Patient and Health System Outcomes through Advanced Pharmacy Practice. A Report to the U.S. Surgeon General, 2011* 1 (report) supporting pharmacists delivering patient care services through collaborative practice agreements as an accepted model of improved health care delivery that can meet growing health care demands in the U.S. The report provides in part on page 36 “Through the delivery of patient care services, pharmacists improve outcomes, increase access to services for medically underserved and vulnerable populations, improve patient safety, shift time for physicians to focus on diagnosis and more critically ill patients, improve patient and provider satisfaction, enhance cost-effectiveness, and demonstrably improve the overall quality of health care through evidence-based practice.”

Despite federal pharmacists 49 years of collaborative disease management through appropriate medication use as well as other clinical and cognitive pharmacy services, 2 non-federal pharmacists still face numerous barriers to establishing an effective payment model. As such, we would encourage PCORI to research barriers such as pharmacist payment models that allow for the creation of a viable self-sustaining business model. This could be accomplished through researching payment methodologies via a pilot program that would recognize pharmacists as Medicare providers under Medicare Part B.

U.S. Surgeon General, Dr. Regina Benjamin, MD, MBA has publicly praised the report. Additionally, the Surgeon General’s letter of support 3 stated the report supports the following case:

Compensation models, reflective of the range of care provided by pharmacists, are needed to sustain these patient oriented, quality improvement services. This may require further

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2 *Id* at Pg. 7

evolution of legislative or policy language and additional payment reform considerations.

Beyond providing “…health leadership with evidence-based discussion about improving patient and health system outcomes through an additional paradigm of health care delivery for expanded implementation in the United States,”\(^4\) the report provides 27 pages of studies that document the value of pharmacist services.\(^5\)

Medications are often the first line of defense in fighting and preventing disease. As it stands, improper medication use costs our nation approximately $177 billion a year. Pharmacists provide cognitive services like medication therapy management (as described in the pharmacy profession’s consensus definition – see attached), care coordination, prevention and wellness, and disease management services to help patients get the best benefits from their medications by actively managing drug therapy, by identifying, preventing and resolving medication-related problems and coordinating/communicating with the physician and other members of the healthcare team. These services support prescribers in improving clinical and economic outcomes, and can help prevent costly adverse drug events, reduce hospitalizations and hospital readmissions, and improve care transitions.

Lawmakers in all 50 states have recognized the evolution of pharmacy practice. Today, it is within the scope of practice in every state for pharmacists in all practice settings to obtain medication histories, review the patient’s medications to identify medication-related problems, engage collaboratively with physicians to resolve identified problems, educate the patient about proper use of medications, encourage adherence with prescribed medications and other therapies, document and communicate information and recommendations to other providers on the patient’s health care team, and provide wellness services, including immunizations.

Consistent with state law, thousands of pharmacists manage their patients’ medication therapy for a host of chronic conditions, including diabetes, asthma, high blood pressure, and high cholesterol, typically pursuant to a collaborative drug therapy management agreement with a physician. Gains through this approach are consistently demonstrated in patient adherence, safety, outcomes, and cost savings. These and other patient care activities are part of a pharmacist’s responsibility to ensure optimal therapeutic outcomes for the patients they serve. And, they are very supportive of and synergistic with physicians’ patient care and optimization of medical practice.

Furthermore, studies consistently support pharmacists’ involvement in the on-going care of patients with chronic health problems. For example, The Asheville Project\(^6\) began in 1996 as an effort by the City of Asheville, North Carolina, a self-insured employer, to provide education and pharmacist guidance for employees with chronic health problems such as diabetes, asthma, hypertension and high cholesterol. Through the Asheville Project, employees, retirees and dependents with diabetes began experiencing improved A1C levels, lower total health care costs, fewer sick days, and increased satisfaction with their pharmacist’s services. Additionally, “…total mean direct medical costs decreased by $1,200 to $1,872 per patient per year compared with base line.”\(^7\)

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\(^2\) Id. at Pg. 51-78


\(^4\) Id. at Pg. 173
The Diabetes Ten City Challenge (DTCC), another example, was a multisite community pharmacy health management program for patients with diabetes. DTCC successfully implemented an employer-funded, collaborative health management program using community-based pharmacist coaching, evidenced-based diabetes care guidelines, and self-management strategies. Positive clinical and economic outcomes were identified for the patients who participated in the program for at least one year. In fact, “…average total health care costs per patient per year were reduced by $1,079 (7.2%) compared with projected costs.”

Communication and Dissemination Research
APhA agrees with the statement on page 18 of the draft agenda that “There is a considerable barrier to the rapid transfer of evidence that could be useful in decision-making…Research is needed that compares new and alternative approaches to facilitating uptake of information by patients, caregivers, communities, and healthcare providers in timely ways…” Pharmacists, in managing the medication use process, serve an integral role in the provision of patient care that leads to improved health in patients. Pharmacists use health information technology (HIT) systems to distribute medications to patients and to work collaboratively with other members of the health care team to provide for appropriate medication use, address/prevent medication-related problems, and enhance overall health outcomes.

To provide the best care for patients, pharmacists need the ability to access information contained in patients’ electronic health record (EHR) and to be able to document care provided in the EHR through HIPAA compliant actions. APhA and other organizations, through the Pharmacy e-Health Information Technology Collaborative (launched in September 2010 by nine national pharmacy organizations, including APhA), are working together on HIT and privacy issues to help ensure that pharmacies are able to effectively contribute to and utilize the evolving HIT infrastructure. Furthermore, the Collaborative is pursuing EHR standards that effectively support the delivery, documentation of and billing for pharmacist-provided patient care services across all care settings.

APhA and our members focus on promoting optimal medication use that improves health, wellness, and quality of life. As PCORI discusses next steps for Communication and Dissemination Research, we encourage additional research on the effective integration of pharmacists’ services into the national HIT infrastructure.

Addressing Disparities
APhA shares PCORI’s concern with the persistence of disparities in health status and healthcare in this country. Our policy, as adopted by the APhA House of Delegates, supports the elimination of disparities in health care delivery. To this end, we are in support of efforts, as outlined in the Draft Priorities for Research and Research Agenda document, to explore patient-centered approaches to understanding and reducing disparities in health.

As the public’s most accessible health care provider, pharmacists can play a significant role in research that explores approaches to overcoming/eliminating a range of barriers that may lead to disparities in health status and healthcare in this country.

In conclusion, APhA thanks you for the opportunity to provide comments on the Draft Priorities for Research and Research Agenda, Version 1. APhA would welcome the opportunity to assist PCORI as it finalizes its research priorities and agenda in this area highlighted in our comments. If you have any questions or require additional information, please contact Jason Hansen, Director of Health Policy, at jhansen@aphanet.org or by phone at (202) 448-8729.

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9 Id. at Pg. e52
10 Additional information on the Pharmacy e-HIT Collaborative is available online at http://www.pharmacyhit.org/.
11 JAPhA NS49(4):493 July/August 2009
APhA Comments to PCORI on Draft Priorities for Research and Research Agenda, Version 1
March 15, 2012

Sincerely,

Thomas E. Menighan, BSPharm, MBA, ScD (Hon), FAPhA
Executive Vice President and CEO

TM/jh

cc: Brian Gallagher, BSPharm, JD, Senior Vice President, Government Affairs
Marcie Bough, PharmD, Senior Director, Government Affairs
Jason Hansen, MS, JD, Director, Health Policy
Medication Therapy Management Services
Definition and Program Criteria

Medication Therapy Management is a distinct service or group of services that optimize therapeutic outcomes for individual patients. Medication Therapy Management Services are independent of, but can occur in conjunction with, the provision of a medication product.

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

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

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

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

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

Approved July 27, 2004 by the Academy of Managed Care Pharmacy, the American Association of Colleges of Pharmacy, the American College of Apothecaries, the American College of Clinical Pharmacy, the American Society of Consultant Pharmacists, the American Pharmacists Association, the American Society of Health-System Pharmacists, the National Association of Boards of Pharmacy**, the National Association of Chain Drug Stores, the National Community Pharmacists Association and the National Council of State Pharmacy Association Executives. 

** Organization policy does not allow NABP to take a position on payment issues.