



Pharmacy Health Information Technology Collaborative

VIA Electronic Submission to: ADE@hhs.gov (Subject: Draft National ADE Action Plan)

October 4, 2013

Yael Harris, Director

Division of Health Care Quality

Department of Health and Human Services

Office of Disease Prevention and Health Promotion

1101 Wootton Parkway, Suite LL100

Rockville, MD 20852

Washington, DC 20201

Re: Draft National Action Plan for Adverse Drug Event Prevention

Dear Dr. Harris:

On behalf of the membership of the Pharmacy Health Information Technology Collaborative, we are pleased to respond to the *Request for Comments on the Draft National Action Plan for Adverse Drug Event Prevention*.

The Pharmacy HIT Collaborative is supportive of the continued use of electronic health information exchange across providers and patients, especially the integration of pharmacists in providing quality patient care and their role with regard to adverse drug event (ADE) prevention and the use of health information technology (HIT) to attain such. The Pharmacy HIT Collaborative advocates the meaningful use of HIT and the inclusion of pharmacists within a technology-enabled integrated health care system. The inclusion of pharmacy in the national action plan for ADE prevention may help in providing more robust information regarding ADE occurrences. Pharmacists are in a strong strategic position to advance ADE prevention.

The Pharmacy HIT Collaborative is actively engaged with the Office of the National Coordinator for HIT (ONC) and others in the development of a national strategy and framework for technology solutions for health information exchange, which includes ADE prevention and reporting. We are supportive of the principles of the draft national action plan to reduce ADEs and create a culture of safety around the effective use of all medications (prescription and nonprescription), particularly the use of HIT to achieve these goals.

The active participation of pharmacists in HIT and health information exchanges (HIEs) is aligned with overall HIE goals that include improving patient safety, enhancing quality of clinical care, and enhancing identification of threats to public health (e.g., ADEs). The electronic exchange of current or real-time pharmacist-provided patient

Pharmacy Health Information Technology Collaborative

| 401 Holland Lane Suite 702 | Alexandria, VA, 22314 | www.pharmacyHIT.org | 703-599-5051 |

care information using HIT, HIEs, or e-prescribing networks will ensure effective, bidirectional communication among health care team members. As you will see throughout our comments, improving bidirectional communication between pharmacists and other health care providers, which is currently not at adequate level, will be critical to the success of the proposed ADE Plan and national HIT strategy.

HIT for Adverse Drug Event Prevention (page 4)

As health care providers and users of HIT and electronic health records (EHRs) in all pharmacy practice settings, the Pharmacy HIT Collaborative and its members are in a strong strategic position to help with the national strategy design to advance ADE prevention. HIT is a critical component for all pharmacy practice settings, and it is vitally important that the national strategy for HIT, as well as the proposed ADE national strategy, includes improved linkages to pharmacists, especially with regard to incorporating bidirectional communication among multiple health care providers and settings. The proposed ADE strategy also needs to ensure pharmacists' access to critical patient health care information, including diagnosis and laboratory results/values, through an interoperable EHR system. The Collaborative is pleased to see that the proposed strategy acknowledges the need for improved linkage with pharmacy.

Pharmacists play an important role in optimizing therapeutic outcomes and promoting safe, efficacious, cost-effective medication use while providing patient-centered care that could help advance ADE prevention. Domains of the pharmacist involvement in the health delivery system include assuring the appropriate use of medications, medication safety by prevention of adverse events and medication errors, development and deployment of clinical decision support and documentation, assurance of integrity of the medication-use system, and monitoring of patient outcomes from medication therapy, which includes comprehensive medication reviews.

Organization of the National Action Plan for ADE Prevention (pages 20-21)

We agree that HIT could help in the identification of effective interventions to prevent ADEs and accelerate integration of ADE monitoring and prevention strategies into the practice of daily medicine, and pharmacists are in a strong strategic position to advance those aspects of the proposed plan. To achieve them, however, it is important that the HIT framework employ acceptable standards for data transmission; clinical decision support, including medication therapy management (MTM; see also Opioid ADE comments for more specifics about MTM); EHRs; bidirectional communication, etc., not only for computer systems that are used in HIT by providers and patients but also mobile medical applications (apps) and other internet-based health care apps that are now being developed and used in health care delivery at an astonishing rate. It is not clear in the draft strategy if the HIT recommendations include mobile devices or if the term HIT is being used in the more traditional sense. We believe the ADE strategy should address and include mobile devices and medical apps as part of ADE prevention.

On June 26, 2013, the membership of the Pharmacy HIT Collaborative submitted comments to ONC about the *Request for Comments on the Development of a Risk-*

*Based Regulatory Framework and Strategy for Health Information Technology.*¹ The Pharmacy HIT Collaborative is supportive of the continued use of electronic health information exchange across providers and patients, as well as strategies that are effective and feasible to further advance and promote interoperability and health information exchange and ensure the protection of patient data collected and shared through electronic means, including mobile devices and mobile medical apps.

We agree that a coordinated approach and oversight between the health care industry and federal regulators is critical to the successful, safe use of HIT that is being adopted.

As mentioned previously, the Pharmacy HIT Collaborative is actively engaged with the ONC and others in the development of a national strategy and framework for health information exchange. We commend the Food and Drug Administration (FDA), ONC, and Federal Communications Commission (FCC) for moving forward with the request from Congress to thoughtfully examine the regulatory framework concerning HIT and extending the opportunity to HIT stakeholders to provide comments and recommendations for creating the risk-based regulatory framework and strategy health information report.

We also recommend employing standards developed by the American National Standards Institute (ANSI), the National Council for Prescription Drug Programs (NCPDP), and Health Level Seven (HL7); platform uniformity, and applicable guidelines developed by professional health care associations for mobile devices and telehealth.

As patient-centered, health care providers, pharmacists capture and monitor their patients' health information through mobile medical devices. Examples of areas in which pharmacists and patients use mobile medical devices include: glucose monitoring/diabetes management, at home hypertension monitoring/management, medication management, and medication reconciliation at transitions of care.

In order to ensure patient safety and reduce risks, HIT, including mobile medical apps, should be subject to specific safety and technical standards to enter the market. Such risks could impact ADE prevention. Assuring that vendors developing technology and related products follow nationally recognized guidelines, such as ANSI standards, is critical. The FDA has already acknowledged some risks to patient safety and the public health in its July 2011 guidance concerning mobile medical apps.

The Pharmacy HIT Collaborative is supportive of the continued use of electronic health information exchange across providers, as well as ideas that would be effective and feasible to further advance and promote interoperability and health information exchange. In that regard, the Collaborative and its membership developed and published *The Road Map for Pharmacy Health Information Technology Integration in U.S. Health Care*².

The Roadmap is the first pharmacy HIT strategic plan. It provides guidance to provider organizations, policymakers, vendors, payers, and other stakeholders striving to integrate pharmacy HIT into the national HIT infrastructure, while promoting the meaningful use of EHRs that support safe and effective medication use, continuity of care, and access to the patient

¹ *Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology*, June 26, 2013, submitted by Pharmacy e-Health Information Technology Collaborative, Alexandria, VA.

² *The Roadmap for Pharmacy Health Information Technology Integration in U.S. Health Care*, 2010, Pharmacy e-Health Information Technology Collaborative, Alexandria, VA, 2010.

care services of pharmacists in conjunction with other members of the patient care team, of which all are applicable to the national action plan for ADE prevention.

The Pharmacy HIT Collaborative also has commented on various components of the HIT national strategy including *ONC's HIT Patient Safety Action and Surveillance Plan*³, *ONC's Advancing Interoperability and Health Information Technology*,⁴ *ONC's National Health Information Network Conditions for Trusted Exchange*,⁵ *CMS' Stage 2 and Stage 3 Meaningful Use EHR Incentive Program*,⁶ and *ARQA's Quality Measurement Enabled by Health IT*,⁷ to name a few.

We also note in the discussion of Section 1: National Action Plan Scope and Development and in Table 1, page 20, the reference to CMS' Meaningful Use (MU) EHR Incentive Program as supporting the goals of the proposed plan. Although the Pharmacy HIT Collaborative supports the meaningful use of EHRs, ONC needs to be aware that pharmacists are not eligible providers (EPs) under this program and are ineligible for EHR incentives, though they will need to exchange information with EHR systems and ensure needed bidirectional communication with EPs. Today, that exchange is not at an adequate level and is an area in which improved linkage with pharmacy is needed. The Collaborative and its members are concerned that some of the EHR incentive requirements could become unfunded mandates to pharmacists. We have commented on this throughout the EHR process, asking that pharmacists be allowed to become EPs under the program. Allowing pharmacists the opportunity to become EPs and receive EHR incentives may lead to adoption of these EHR standards at a level that may be significant.

Considerations Specific to ADE Surveillance (page 25)

Though acknowledging that some ADE surveillance is being done based on clinical documentation, the ADE draft strategy indicates that conducting national surveillance for adverse events attributable to such issues as under-treatment or medication omission is beyond the initial scope of this particular action plan. Although it is not clear in the proposed strategy if this will be considered at another time, there is currently some movement in this direction and tools that are being used could further advance ADE surveillance, intervention, and prevention.

The Pharmacy HIT Collaborative continues to take the lead on the joint project between NCPDP and HL7 to create a standard implementation guide (IG) for system vendors to use an electronic version of the MTM Part D, January 2013, take away document. This IG follows the

³ *ONC HIT Patient Safety Action & Surveillance Plan for Public Comment*, comments, Pharmacy e-Health Information Technology Collaborative, February 4, 2013.

⁴ *CMS-0038-NC Advancing Interoperability and HIT*, comments, Pharmacy e-Health Information Technology Collaborative, April 22, 2013.

⁵ *Governance RFI – 46 CFR Part 171 – National Health Information Network: Conditions for Trusted Exchange*, comments, Pharmacy e-Health Information Technology Collaborative, June 21, 2012.

⁶ *CMS-0004-P Medicare and Medicaid Programs; EHR Incentive Program Stage 2*, comments, Pharmacy e-Health Information Technology Collaborative, May 7, 2012, and *HHS-OS-0007 HIT Policy Committee: Request for Comments Regarding Stage 3 Definition of MU EHR*, January 14, 2013..

⁷ *Request for Information on Quality Measurement Enabled by HIT (FR Doc. NO.: 2012-17530)*, comments, Pharmacy e-Health Information Technology Collaborative, August 2012.

same standards all EPs receiving the incentives for the MU of EHR are mandated to use to exchange clinical documents (e.g., patient care summaries, discharge summaries and care plans).

The CMS Medicare Part D 2014 *Call Letter* encourages Part D plans to adopt the use of the electronic version take away structured document and the use of the SNOMED CT codes defined by a Pharmacy HIT Collaborative project.⁸

The Pharmacy HIT Collaborative led the work to develop this structured clinical document that will be used to electronically exchange MTM information by pharmacists providing MTM care services.

The call letter also asked for comments related to the coordination of the Comprehensive Medication Review (CMR) and the Physicians Annual Wellness Visit (AWV).

Under Part D, pharmacists providing annual CMRs are required to provide active medication lists, including contraindications to medications on the lists. This also could be a tool for ADE surveillance, intervention, and prevention. Pharmacists need to be able to share this information through consolidated Clinical Document Architecture (cCDA) structured documents. A cCDA-structured document is currently under ballot with HL7 and NCPDP.

As noted in the pharmacy profession's *Improving Care Transitions: Optimizing Medication Reconciliation*⁹, the comprehensive goals of medication reconciliation are "to obtain and maintain accurate and complete medication information for a patient and use this information within and across the continuum of care to ensure safe and effective medication use," to electronically communicate accurate patient medication information, and then take appropriate actions to resolve any discrepancies. This bidirectional electronic communication concerning the movement of a patient is needed by pharmacists and may help alleviate a variety of medication-related problems, including ADEs, that may lead to hospital readmission.

Ensuring electronic bidirectional communication between pharmacists and other health care providers is a key objective of the Pharmacy HIT Collaborative and its members. Improving linkages with pharmacies in this area will further help with the integration of pharmacies and pharmacists into the national HIT strategy, as well as the proposed ADE prevention strategy.

We support the use of the NCPDP Structured and Codified SIG within the SCRIPT standard 10.6 in a manner that meets the specific needs of practice settings as part of medication-related clinical decision support. The NCPDP SCRIPT standard 10.6 contains transactions for reporting medications filled by a pharmacy (fill status notification), drug utilization review (DUR), and cancel notification of discontinued medication, which also can be used to advance ADE prevention. The NCPDP SCRIPT standards for electronic prior authorization for medications are developed and supported by the Pharmacy HIT Collaborative.

We would encourage and support the harmonization of HL7 and NCPDP (SCRIPT and

⁸ *CY 2014 Medication Therapy Management Program Guidance and Submission Instructions*, Centers for Medicare and Medicaid Services, Center for Medicare, April 5, 2103, pages 11-12. <http://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Memo-Contract-Year-2014-Medication-Therapy-Management-MTM-Program-Submission-v040513.pdf>.

⁹ *Improving Care Transitions: Optimizing Medication Reconciliation*, 2012, developed by the American Pharmacists Association, Washington, DC, and the American Society of Health-System Pharmacists, Bethesda, MD. (<http://www.ashp.org/DocLibrary/Policy/PatientSafety/Optimizing-Med-Reconciliation.aspx>)

Telecom) standards as part of the ADE prevention strategy. Such harmonization would encourage MU of EHR Incentive Program EPs, Eligible Hospitals (EHs), Critical Access Hospitals (CAHs), and others to submit electronically and uniformly.

Incentives and Oversight Opportunities (pages 38-50)

The Federal Interagency Workgroup (FIW) identified possible requirements of the EHR MU Incentive Program that could be leveraged and recommends that they be used to advance the prevention of ADEs in the three-targeted areas: anticoagulation ADE, hypoglycemic ADE, and opioid ADE. As discussed previously, although the Pharmacy HIT Collaborative supports the MU of EHRs, pharmacists are not EPs under this program and are ineligible for EHR incentives, though they will need to exchange information with EHR systems and ensure needed bidirectional communication with EPs. The Collaborative's concern is that these requirements, if implemented, could become unfunded mandates for pharmacists' inclusion in the ADE prevention strategy.

As a profession that is in a strong strategic position to help advance the ADE prevention plan, we believe pharmacists should be allowed the opportunity to become EPs.

Sections 5-7: Anticoagulation ADE, Hypoglycemia ADE, and Opioids ADE (pages 51-151)

The Pharmacy HIT Collaborative is pleased that the proposed ADE prevention plan includes a strategy for improved linkage with pharmacy for the three areas of the plan's focus: anticoagulation ADE, hypoglycemia ADE, and opioids ADE. The Collaborative supports this strategy.

As patient-centered health care providers, pharmacists have the ability to capture medication issues and problems across the patient care spectrum and reconcile contraindications for medications, medication allergies, and medication problems, which can help identify and prevent ADEs. Pharmacists have electronic capabilities to assist with care coordination in these three areas, particularly during points of transition of care where ADEs may occur (this will be discussed in more detail in Anticoagulation ADE).

Through the various patient-care services that pharmacists provide, their participation in Medicare Part D and other programs, pharmacists also maintain active medication lists, active allergy lists, implement drug-drug and drug allergy interaction checks, and implement clinical support rules.

Pharmacists must be able to communicate electronically with providers to ensure the medications prescribed have appropriate problem identifications. Improvements with linkage to pharmacy and bidirectional communication are needed. Pharmacists engaging patients in their care will guarantee appropriate medication use.

Anticoagulation ADE

Three of the FIW recommendations for actions for anticoagulation ADEs are applicable to pharmacy.

- Improve access to more integrated EHR data with linked pharmacy (medication exposure)-laboratory outcomes data at national and local surveillance levels,
- Improve surveillance of anticoagulant ADEs resulting during care transitions, as well as those occurring in nursing home and home care settings and among vulnerable patient populations such as those residing in rural/remote regions, and
- Address challenges in capturing the burden of ADEs among patients who seek care for anticoagulant ADEs outside of integrated healthcare systems.

The Pharmacy HIT Collaborative supports and agrees that improved access to more integrated EHR and laboratory outcomes data, surveillance during transition of care, capturing ADE information from patients outside of integrated health care systems, and improved linkage to pharmacy, particularly, real-time integrated linkage, are needed to advance ADE prevention for anticoagulation management. Also key to this is improved bidirectional communication among health care providers using HIT and EHRs. A common, shared HIT solution with access to clinical health information available to all health care providers in need of that information is an important priority of the Collaborative.

Although pharmacists are capturing this information, they need electronic bidirectional exchange with EPs, EHs, CAHs, and other providers to share and receive problems related to patients' medications (e.g., reported ADEs), particularly at the transition of care level where a high potential of ADEs can occur. Transition of care involves more than EPs, EHs, CAHs, long-term care facilities, nursing homes, and home care settings. Pharmacists will be involved in the transition of care and medication reconciliation of these patients.

Pharmacists' unique experiences, expertise, and access to medication information that others may not have bring enormous value to physicians in their prescribing decisions, particularly, with regard to checking drug-drug and drug-allergy interactions. This is especially an important aspect in caring for patients after they are discharged from a hospital.

The Pharmacy HIT Collaborative supports the bidirectional exchange as the focal point of transition of care in all practice settings, especially with regard to problem lists, particularly more current updated problem lists, that providers (e.g., EP, EH, CAH) may not have access to. It is vitally important that pharmacists have access to current problem lists at transition of care, particularly with regard to long-term and post acute care (LTPAC) settings, to match medications for patients to use. This is important for MTM services pharmacists provide especially under Medicare Part D. Bidirectional exchange of summary of care documents will help advance ADE prevention. With frequent access to medications and patients, pharmacists are in a position to make this exchange.

Recent studies on medication errors indicate that transitions from one care setting to other settings are a time of high risks for ADEs because of prescribing or transcription errors. Evidence shows that discharge from a hospital is particularly dangerous for medication errors. In its 2006 *Preventing Medication Errors* study, the Institute of Medicine estimated that there are at least 1.5 million preventable ADEs that occur each year in the United States and the risk of medication errors is higher upon discharge from a hospital because discrepancies in medications are more common.¹⁰

¹⁰ *Preventing Medication Errors: Quality Chasm Series*, 2006, Institute of Medicine of the National Academies, Washington, DC.

In its January 14, 2013, comments to ONC about *Stage 3 Definition of Meaningful Use of EHRs*, the Collaborative proposed that the Health Information Technology Policy Committee (HITPC) recommend that certified EHRs be required to report data on the number of patients for whom a provider reviewed *all* their medications before the patient is discharged from the hospital, as well as the credential of the final reviewer.¹¹

To support this intervention, the Pharmacy HIT Collaborative also stated that certified EHRs should allow pharmacists to review medication orders before electronic prescriptions are transmitted. For example, an EHR should have an option to “hold” all e-prescriptions of discharge medications until a pharmacist is able to log on and review the orders. An EHR should also have an auto-send feature if a pharmacist is unable to review after some length of time to ensure patients are able to receive their prescriptions.

By having pharmacists review medication orders and report that the orders were reviewed at the time of transition, especially before electronic prescriptions are transmitted, would help in reducing medication errors, improve patients’ health, reduce costs, and advance ADE prevention.

Because patients are vulnerable at transitions of care, components of MTM should be utilized (see Opioid ADE below for more specific details about MTM). Medication reconciliation, which is part of MTM, should be a part of all providers’ EHR documentation in all practice settings at transitions of care. At a minimum, the Pharmacy HIT Collaborative recommends that the following information should be provided electronically to pharmacists at transitions of care: medication list and directions for use (added, changed, discontinued), medical condition (diagnosis), and allergies. For optimal MTM services at transitions of care, the full content of a Continuity of Care Document (CCD), including laboratory values, prescriber information, and medication history, should be provided electronically to pharmacists.

Pharmacists also need the ability to access laboratory outcomes data, as well as exchange laboratory test results they provide, electronically with EPs, EHs, CAHs, and other health care providers. Pharmacists providing patient care services provide maintenance laboratory tests (e.g., lipid screening and others).

Improving linkages with pharmacists may help in providing more robust information regarding anticoagulant ADEs occurring as a result of care transitions issues in nursing home or home care settings and helping to reduce hospital readmissions.

Hypoglycemia ADE

The Pharmacy HIT Collaborative supports the FIW’s recommendation to improve access to more integrated EHR data linked to pharmacy, laboratory, and outcomes data as a potential strategy for hypoglycemic ADEs. As stated previously, pharmacists also need the ability to access laboratory outcomes data, as well as exchange laboratory test results they provide, electronically with EPs, EHs, CAHs, and other health care providers. Improved bidirectional communications within HIT is critical, especially in advancing ADE prevention.

¹¹ *HHS-OS-2012-0007 HIT Policy Committee: Request for Comment Regarding Stage 3 Definition of Meaningful Use of Electronic Health Records (EHRs)*, submitted January 14, 2013, Pharmacy e-Health Information Technology Collaborative, Alexandria, VA.

The value of the pharmacist's role in health care has been established in a variety of practice settings, including diabetes management and medication therapy management. A well-documented body of clinical evidence also demonstrates that pharmacists' clinical services improve patient care outcomes and reduce morbidity and mortality, which would include ADE prevention and reduced emergency room visits.¹²

As patient-centered, health care providers, pharmacists capture and monitor their patients' health information through mobile medical devices and other EHRs. Pharmacists and patients use mobile medical devices for glucose monitoring/diabetes management. Pharmacists use this and other information to help their patients manage this disease state.

Because pharmacists are first-line-of-care providers in some settings, they are in the unique position to address patient disparities in rural health areas, the Indian Health Service, community health centers, community pharmacies, free clinics, and other health care venues. The pharmacist plays a key role in many practices as a health coach and advocate for healthy behaviors related to population and public health, which can aid in preventing ADEs.

Pharmacists are in a key position to intervene with patients in numerous population and public health issues within the community. With access to the HL7/NCPDP ANSI accredited Pharmacist/Pharmacy Provider EHR Function Profile (PP-EHR), pharmacists also can view, document, and assess trends relevant to patient glucose monitoring, obesity, blood pressure, and other health issues.

The Pharmacy HIT Collaborative and the pharmacy profession continue working with national EHR certification organizations and pharmacy system vendors to adopt certification criteria for the PP-EHR functionality to ensure that pharmacist-provided patient care service information can be exchanged with other health care providers. Development of certification criteria for PP-EHR s used by pharmacists will support several national HIT policy goals including:

- Enabling the electronic exchange and use of health information consistent with a nationwide HIT infrastructure,
- Supporting improvements in quality, clinical appropriateness, and continuity of care,
- Promoting coordination of care and patient/family engagement,
- Improving population health, and
- Improving patient safety, including medication safety.

Improving linkages with pharmacists may help in the development of more robust EHR systems for the identification and management of patients with diabetes/hypoglycemia.

Opioid ADEs

The rise of prescription drug misuse and abuse, particularly with regard to pain medications, is on the rise across the country. We agree that distinguishing between opioid overdoses that occur during the normal course of care versus misuse/abuse is challenging and

¹² *The Roadmap for Pharmacy Health Information Technology Integration in U.S. Health Care*, 2010, Pharmacy e-Health Information Technology Collaborative, Alexandria, VA, 2010.

important to categories adequately in efforts to prevent opioid ADEs.

The Pharmacy HIT Collaborative supports the FIW recommendation to improve access to more integrated EHR data with linked pharmacy and outcomes data. Additionally, the Collaborative and its members are supportive of the states' Prescription Drug Monitoring Programs.

As noted throughout our comments, pharmacists provide valuable services that can help prevent ADEs. One such service is MTM. The Pharmacy HIT Collaborative strongly recommends that the Action Plan, as well as the national HIT infrastructure, includes and supports MTM services. MTM is a distinct service or group of services that optimizes therapeutic outcomes for individual patients. Pharmacists are increasingly recognized as providers of MTM. MTM services are independent of but can occur in conjunction with the provision of a medication product. Pharmacists need HIT systems that have the functionality and connectivity to support provision, documentation, and billing of these services. MTM services include:

- Performing or obtaining necessary assessments of the patient's health status,
- Formulating a medication treatment plan,
- Selecting, initiating, modifying, or administering medication therapy,
- Monitoring and evaluating the patient's response to therapy, including safety and effectiveness,
- Performing a comprehensive medication review to identify, resolve, and prevent medication-related problems, including ADEs,
- Documenting the care delivered and communicating essential information to the patient's other primary care providers,
- Providing education and services to enhance patient understanding of, appropriate use of, and adherence to medication regimens, and
- Coordinating and integrating MTM services within the broader health care management services being provided to the patient.

Improving linkages with pharmacists may help in the development of improved surveillance and opioid ADE prevention.

Conclusion

The Pharmacy HIT Collaborative agrees that the success of the Action Plan is dependent upon ongoing coordination and collaboration among all stakeholders and encourages the ONC to especially work with the Collaborative and its members. As we have mentioned throughout our comments, the Collaborative and its members are in a strong strategic position to help advance ADE prevention and offer HIT solutions.

It is evident that access to HIT solutions and linkage to pharmacy can enhance the pharmacist's ability to improve the overall medication-related safety and quality of patient care in coordination with other health care providers to advance ADE prevention. Some HIT solutions are currently in use in the pharmacy but may require standardization. Others such as

bidirectional communication need improving.

We especially agree with the following statement that appears in the plan's conclusion and next steps:

Additionally, more coordinated and focused use of health information technology will have a critical role in advancing ADE prevention efforts through various mechanisms including, but not limited to, improvements in detection and monitoring of ADEs based on more integrated and accessible electronic health record (EHR) data, electronic transfer of medication information across multiple providers and multiple settings, facilitating improvements in linkages between pertinent pharmacy and laboratory data, as well as, integration of clinical decision support tools and health care quality measures targeted specifically at high-priority ADEs.

The Pharmacy HIT Collaborative, including pharmacy professional associations, MTM intermediaries, and NCPDP, are defining guidelines and standards related to the pharmacist's role in HIT. Pharmacists in all practice settings provide several patient-centered services electronically. It is evident that access to HIT solutions can enhance the pharmacist's ability to improve the overall medication-related safety and quality of patient care in coordination with other health care providers and improve patient outcomes.

Formed in the fall of 2010, the Pharmacy HIT Collaborative's vision and mission are to assure the nation's healthcare system is supported by meaningful use of HIT, the integration of pharmacists for the provision of quality patient care, and to advocate and educate key stakeholders regarding the meaningful use of HIT and the inclusion of pharmacists within a technology-enabled integrated health care system. The Collaborative's goals seeks to ensure HIT supports pharmacists in health care service delivery, achieve integration of pharmacists and pharmacies into HIEs, and advocates pharmacist recognition in HIT programs and policies.

The Pharmacy HIT Collaborative's founding organizations represent pharmacists in all patient care settings and other facets of pharmacy, including pharmacy education and pharmacy education accreditation. The Collaborative's Associate Members represent e-prescribing networks, a standards development organization, transaction processing networks, pharmacy companies, system vendors and other organizations that support pharmacists' services. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes seven associate members from other pharmacy related organizations. For additional information, visit www.pharmacyhit.org

On behalf of the Pharmacy HIT Collaborative, thank you again for the opportunity to comment on *the Draft National Action Plan for Adverse Drug Event Prevention*. For more information, contact Shelly Spiro, Executive Director, Pharmacy HIT Collaborative, at shelly@pharmacyhit.org.

Respectfully submitted,



Shelly Spiro
Executive Director, Pharmacy HIT Collaborative

Shelly Spiro, RPh, FASCP
Executive Director
Pharmacy HIT Collaborative
shelly@pharmacyhit.org

Mary Jo Carden, RPh, JD
Director, Regulatory Affairs
Academy of Managed Care Pharmacy
mcarden@amcp.org

Peter H. Vlasses, PharmD, DSc (Hon), BCPS,
FCCP
Executive Director
Accreditation Council for Pharmacy
Education (ACPE)
pvllasses@acpe-accredit.org

William Lang, MPH
VP Policy and Advocacy
American Association of Colleges of
Pharmacy wlang@aacp.org

C. Edwin Webb, Pharm.D., MPH
Associate Executive Director
Director, Government & Professional Affairs
American College of Clinical Pharmacy
ewebb@accp.com

Stacie S. Maass, B S Pharm, JD
Senior Vice President, Pharmacy Practice
and Government Affairs
American Pharmacists Association (APhA)
smaass@aphanet.org

Lynne Batshon
Director, Policy & Advocacy
American Society of Consultant Pharmacists
Lbatshon@ascp.com

Christopher J. Topoleski
Director, Federal Regulatory Affairs
American Society of Health-System
Pharmacists
ctopoleski@ashp.org

Thomas Felix, MD
Director, Regulatory Affairs, R&D Policy, and
Global Regulatory Affairs and Safety
Amgen, Inc.
thfelix@amgen.com

Kim Swiger, RPh
Vice President, Pharmacy Services
Mirixa Corporation
kswiger@mirixa.com

Rebecca Snead
Executive Vice President and CEO
National Alliance of State Pharmacy
Associations
rsnead@naspa.us

Ronna B. Hauser, PharmD
VP Policy and Regulatory Affairs
National Community Pharmacists
Association (NCPA)
ronna.hauser@ncpanet.org

Lynne Gilbertson
VP Standards Development
National Council for Prescription Drug
Programs (NCPDP)
lgilbertson@ncpdp.org

Stephen Mullenix, RPh
Sr VP, Communications & Industry Relations
National Council for Prescription Drug
Programs (NCPDP)
smullenix@ncpdp.org

Patty Kumbera, RPh
Chief Operating Officer
OutcomesMTM
pkumbera@outcomesmtm.com

Roger Pinsonneault, R.Ph.
Vice President, Business Development
RelayHealth – Pharmacy
Roger.Pinsonneault@RelayHealth.com

Michael E. Coughlin
President, CEO and CFO
ScriptPro
mike@scriptpro.com