Pharmacy e-Health Information Technology Collaborative

VIA Electronic Submission to http://www.regulations.gov

June 6, 2011

Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1345-P

Re: 42 CFR Part 425; Medicare Program; Shared Savings Program: Accountable Care Organizations and Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and Innovation Center; Proposed Rule and Notice

Dear Dr. Berwick:

Overview of the Pharmacy e-Health Information Technology Collaborative and Comments in Response to the Strategic Plan

On behalf of the membership of the Pharmacy e-Health Information Technology Collaborative (Collaborative), we are pleased to submit comments in response to the proposed rule, *Medicare Program; Shared Savings Program: Accountable Care Organizations (ACOs) and Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and Innovation Center* (42 CFR 425) published in the *Federal Register* on April 7, 2011. The Collaborative's comments focus on ensuring the HIT clinical and functionality measures necessary to ensure that pharmacists may exchange data as partners in ACOs. The Collaborative is not commenting on the Medicare Program: Waiver Designs in Connection with the Medicare Shared Savings Program and Innovation Center.

The Collaborative is concerned that many of the HIT functionalities and the 65 clinical quality metrics proposed by the ACO rule are more advanced than requirements for meaningful use (MU) and as a result, the technology standards final ACO rule may be tailored to the MU standards and impede the ability of ACOs to demonstrate administrative and claims reconciliation functions essential to ensuring real meaning in health care quality improvement. To assure success of ACOs, the government should ensure that MU HIT standards are aligned with those for ACOs. While the Collaborative supports a gradual, phased-in approach to the quality metrics, CMS should also incorporate other metrics that do not translate directly into

shared cost savings. ACO requirements place no emphasis on medication management but ACOs should be encouraged to pay attention to appropriate medication management through the incorporation of quality measures.

Formed in the fall of 2010, the Collaborative's focus is to assure the MU of standardized electronic health records (EHRs) support safe, efficient, and effective medication use, continuity of care, and provide access to the patient-care services of pharmacists with other members of the interdisciplinary patient-care team. The Collaborative's goal is to assure that the pharmacist's role of providing patient-care services is integrated into the National HIT interoperable framework. The group is pursuing EHR standards that effectively support the delivery and documentation of and billing for pharmacist-provided patient care services across all care settings.

The Collaborative seeks to ensure that pharmacist-provided patient care services in all practice settings are represented in the MU of EHRs. The 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, and a transaction processing network. The Collaborative was founded by nine pharmacy professional associations representing over 250,000 members and includes three associate members from other pharmacy related organizations. For additional information, visit www.pharmacye-hit.org.

As the comments below describe, pharmacists must be included as health care professionals to share and transmit data and information to meet the goals of ACOs for clinical integration of information and coordination of care among health care professionals, payers, and patients. Specifically the Collaborative requests that CMS:

- Allow data sharing, including claims and clinical information, by pharmacists as partners in ACOs as described in Section II.C.3, Data Sharing. The Collaborative is working to incorporate pharmacists' clinical services into MU provisions through the pharmacist PP-EHR beyond simply the exchange of e-prescribing information related to medications prescribed. This requirement should be consistent for ACOs as well.

- Ensure that ACOs provide data provisions described in Section II.E by aligning MU requirements with ACO requirements for data sharing and clinical quality metrics. ACO clinical quality metrics, as described in Table 1, are more extensive than MU quality metrics. The Collaborative has previously supported pharmacists' role in achieving clinical quality metrics for EHRs and believes that the metrics proposed in the rule would more effectively meet the needs of patients in ACOs compared to MU. However, the Collaborative cautions CMS not to implement measures that discourage participation by providers in ACOs. Rather the Collaborative suggests that CMS consider harmonizing performance measures adopted by e-prescribing, PQRI, and the EHR incentive programs. CMS should also consider incorporating pharmacy quality measures approved

by the Pharmacy Quality Alliance (PQA) into MU and ACO requirements.

- Adopt the definition of medication reconciliation supported by members of the Collaborative, the Joint Commission, and AHRQ that is more extensive than the one proposed by CMS for ACOs in Table 1, domains 9 and 10. The definition supported by the Collaborative for incorporation into all EHRs for ACOs and MU ensures that medication reconciliation balances the use of technology with the clinical services provided by pharmacists. The Collaborative also encourages CMS to incorporate measures that support appropriate medication management as defined below into the final ACO rule.

- Mandate that aggregate data reports for data sharing requirements between CMS and ACOs under §425.19 be made obtainable, not when available, but immediately to ensure that these reports are accessible in a timely manner.

Include Pharmacists as Partners for Data Sharing in ACOs as Described in Section II.3

The Collaborative believes that the inclusion of pharmacists' clinical services is critical to achieving the goals of the ACO program to realize cost savings and improve efficiencies. This goal is consistent among all aspects of implementation of HIT provisions. The current federal HIT infrastructure limits pharmacists' exchange of information to electronic prescribing. Data elements exchanged through electronic prescribing systems generally include only information about the medications prescribed and not the full clinical information necessary for pharmacists to implement clinical recommendations. To fully achieve desired health outcomes, CMS must consider the inclusion of pharmacists as a component of electronic information exchange. Such recognition is currently lacking in the EHR incentive program and not specifically included in the ACO proposed rule.

Pharmacists providing patient care services needed a standard EHR to document and electronically exchange health information with other healthcare providers. For pharmacists to have the capability to be meaningful users of the EHR, Collaborative members worked with Standard Development Organizations (SDOs) to develop the Pharmacist/Pharmacy Provider EHR (PP-EHR) functional profile. The PP-EHR was developed by a joint Health Level Seven (HL7) and National Council for Prescription Drug Programs (NCPDP) work group and has been approved through the balloting process of both SDOs.

The Collaborative will be working with the national EHR certification organizations and pharmacy system vendors to assure that the PP-EHR functionality is adopted; including the development of certification criteria to meet the MU of EHR concepts related to pharmacists using the PP-EHR in a meaningful way. The Collaborative continues to urge, CMS and the Office of the National Coordinator (ONC) that the PP-EHR be integrated with other certified healthcare

EHRs.[1] The PP-EHR will support the exchange of clinical information (e.g., CCD); will leverage existing interoperability specifications (e.g., HITSP C83, ISO7 and ISO9); utilize existing standards (e.g. HL7 and NCPDP); and will support data flow that can be tested.

The Collaborative is prepared to assist in the healthcare industry's adoption of the PP-EHR to ensure policies and costs are addressed. The Collaborative is in the process of working with ONC and CMS to address policy, regulatory and legislative issues. For example, in March 2011, the Collaborative recommended that data requirements for medication therapy management services (MTMS) electronic transactions under Medicare Part D be incorporated into the "Standardized Format for the Comprehensive Medication Review Action Plan and Summary". This will assure that completion of the forms for the patient is driven off existing electronic data elements so that rekeying will not be necessary.

This recommendation is supported through the American National Standards Institute (ANSI), and SDOs including National Council for NCPDP, Accredited Standards Committee (ASC X12), and HL7 processes to assure MTMS electronic standard transactions are developed. The Collaborative supports and works with these organizations to make certain data elements such as those in the proposed forms are populated from the "Pharmacist EHR" and or other types of interoperable electronic systems. The Collaborative will assist the facilitation of studies to demonstrate the quality improvements and cost savings attributed to the adoption of the PP-EHR by pharmacists and its incorporation into all practice settings.

Ensure ACOs Provide Data Provisions Described in Section II.E[2] by aligning MU Requirements with ACO Requirements for Data Sharing and Clinical Quality Metrics

ACO clinical quality metrics, as described in Table 1[3], are more extensive than MU quality metrics. The Collaborative has previously supported pharmacists' role in achieving clinical quality metrics for EHRs and believes that the metrics proposed in the rule would more effectively meet the needs of patients in ACOs. However, the Collaborative cautions CMS not to implement measures that discourage participation by providers in ACOs. Rather the Collaborative suggests that CMS consider harmonizing performance measures adopted by e-prescribing, PQRI, and the EHR incentive programs.

PQA is an organization committed to improving health care quality and patient safety through a collaborative process aimed at defining pharmacy performance measures to improve medication use and medication-related services across the health care system.[4] PQA has approved several pharmacy specific quality metrics for pharmacies and then measures are

[1] Although not certified at the present time, the Collaborative is working with the listed organizations to define certification criteria and have the PP-EHR certified by the recognized EHR certification organizations.

[2] Medicare Program; Medicare Shared Savings Program: Accountable Care Orgniazations. 67 Fed. Reg. 19568 (April 7, 2011).

[3] *Ibid*, 19571-1959.

[4] Pharmacy Quality Alliance available at http://www.pqaalliance.org/. Accessed April 10, 2011.

integrated into electronic systems to provide outcomes data. These measures should also be considered for both MU and ACOs and be harmonized with others to ensure standard quality metrics in all programs.

In previous comments related to the ONC Federal HIT Strategic Plan released March 25, 2011, the Collaborative described pharmacists' clinical services as a means to improve outcomes and reduce morbidity and mortality and thus be included as providers of services, including sharing of HIT information and as partners in ACOs. One such study examines pharmacists' services to hyperlipidemia patients as an example of the impact that pharmacists can have on outcomes and reduction in morbidity and mortality

A key study demonstrating the positive benefit of pharmacists in preventing heart attacks is shown in the results from *ProjectImPACT: Hyperlipidemia* (Improve Persistence and Compliance with Therapy) sponsored by the American Pharmacists Association Foundation. This study demonstrates the positive outcomes associated with pharmacists' clinical interventions working in collaboration with physicians to achieve the goals of the National Cholesterol Education Program (NCEP) in 397 patients in 12 states with hyperlipidemia over the period of 1996-1999.[5] Patients enrolled in the study who received pharmacists' intervention showed a level of persistence and compliance with medication therapy of approximately 90% and by the end of the 24.6 month observation period, 62.5% of patients reached and maintained the NCEP lipid goals.[6] Overall, patients experienced reduced LDL levels of 22.1% and HDL levels improved by 14%, resulting in a potential reduction in CAD of nearly 30-40% and thus an overall reduction in the potential for a heart attack requiring hospitalization.[7]

ProjectIMPACT and other studies suggest that the use of pharmacists' clinical interventions may help prevent unnecessary hospitalizations for heart attack. Pharmacists' clinical services have also been shown to be effective for other chronic conditions and disease states. However, as suggested above, without incorporation as meaningful users of EHRs and the ability to fully share the benefits of HIT, the ability of pharmacists to make a true impact is greatly limited.

Additional research demonstrating the value of the pharmacist's role in health care shows the need for pharmacists to share electronic clinical information with other health care providers in all settings. This should increase the value of the overall medication related safety and quality of patient care.

[5] Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical Care Svcs and Results in ProjectImPACT: Hyperlipidemia. J Am Pharm Assoc 2000; 40:157-65.
[6] *Ibid.*
[7] *Ibid*.

Some examples of publications, including peer-reviewed studies, that demonstrate the value of the pharmacist's role in health care can be categorized in the following topic areas:

- Disease state management models (e.g. Diabetes Management, Ashville project)[8,9,10,11,12,13,14]
- Medication therapy management and care coordination[15,16,17,18,19,20,21,22]
- Team-based care[23,24,25,26]
- Outcomes research[27,28,29]

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[8] Finley PR, Bluml BM, Bunting BA, Kiser SN. Clinical and economic outcomes of a pilot project examining pharmacist-focused collaborative care treatment for depression. J Am Pharm Assoc 2011 Jan-Feb;51(1):40-9.

[9] Bunting BA, Smith BH, Sutherland SE. The Asheville Project: clinical and economic outcomes of a community-based long-term medication therapy management program for hypertension and dyslipidemia. J Am Pharm Assoc 2008 Jan-Feb;48(1):23-31.

[10] Bunting BA, Cranor CW. The Asheville Project: long-term clinical, humanistic, and economic outcomes of a community-based medication therapy management program for asthma.
J Am Pharm Assoc 2006 Mar-Apr;46(2):133-47.

[11] Garrett DG, Martin LA. The Asheville Project: participants' perceptions of factors contributing to the success of a patient self-management diabetes program. J Am Pharm Assoc. 2003 Mar-Apr;43(2):185-90.

[12] Cranor CW, Bunting BA, Christensen DB. The Asheville Project: long-term clinical and economic outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc.. 2003 Mar-Apr;43(2):173-84.

[13] Cranor CW, Christensen DB. The Asheville Project: factors associated with outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc 2003 Mar-Apr;43(2):160-72.

[14] Cranor CW, Christensen DB. The Asheville Project: short-term outcomes of a community pharmacy diabetes care program. J Am Pharm Assoc (Wash). 2003 Mar-Apr;43(2):149-59.

[15] Steinman, MA, Hanlon, JT. Managing medications in clinically complex elders. "There's got to be a happy medium." JAMA, 2010;304(14):1592-1601. (October 13, 2010)

[16] Avorn, J. Medication use in older patients – better policy could encourage better practice. JAMA, 2010;304(14):1606-1607. (October 13, 2010)

[17] Weber, CA, Ernst, ME, Sezate, GS, Zheng, S, Carter, BL. Pharmacist-physician co-management of hypertension and reduction in 24-hour ambulatory blood pressures. Arch Intern Med. 2010;170(18):1634-1639. (October 11, 2010)

[18] Smith, MA, Bates, DW, Bodenheimer, T, Cleary, PD. Why pharmacists belong in the medical home. Health Affairs, 2010;29(5):906-913. (May 2010)

[19] Cutler, DM, Everett, W. Thinking outside the pillbox – medication adherence as a priority for healthcare reform. N Engl J Med, 2010;362(17):1553-1555. (April 29, 2010)

[20] Smith M, Giuliano MR, Starkowski MP. In Connecticut: improving patient medication management in primary care. Health Affairs, 2011; 30(4): 646-54

[21] De Oliveira, DR, Brummel, AR, Miller DB. Medication therapy management: 10 years experience in a large integrated healthcare system. J Manag Care Pharm. 2010:16(3):185-195. (April 2010)

[22] Porcelli, PJ, Waitman, LR, Brown, SH. A review of medication reconciliation issues and experiences with clinical staff and information systems. Appl Clin Inf 2010; 1: 442–461. (December 1, 2010)

[23] Chisholm-Burns, MA, Lee, JK, Spivey, CA, Slack, M, et.al. US Pharmacists' Effect as Team Members on Patient Care: Systematic Review and Meta-Analyses. Med Care, 2010;48:923-933. (October 2010).

[24] Weber, CA, Ernst, ME, Sezate, GS, Zheng, S, Carter, BL. Pharmacist-physician co-management of hypertension and reduction in 24-hour ambulatory blood pressures. Arch Intern Med. 2010;170(18):1634-1639. (October 11, 2010)

[25] Smith, MA, Bates, DW, Bodenheimer, T, Cleary, PD. Why pharmacists belong in the medical home. Health Affairs, 2010;29(5):906-913. (May 2010)

[26] Carter, BL, Rogers, M, Daly, J, Zheng, S, James, PA. The potency of team-based care interventions for hypertension – a meta analysis. Arch Intern Med; 169(19):1748-1755. (October 2009)

The Collaborative believes that pharmacists as full partners in ACOs could have similar positive benefits for the health care system. For example, pharmacist-led programs have been developed to assist in the management of chronic conditions, to manage patients' medication regimens, to improve formulary compliance, to reduce drug costs, to both patients and the health care system, while improving outcomes and decreasing the number of hospitalizations. Often, these programs are affiliated directly or indirectly with physician offices with the goals of helping physicians to better manage patient outcomes through pharmacists' interventions.[30] As the health care system moves to a system of rewarding value, the number of pharmacist-managed programs should grow because of the proven ability to improve health care outcomes and manage costs.

Adopt the Definition of Medication Reconciliation Supported by the Collaborative, the Joint Commission, and AHRQ as an Alternative to CMS' Definition in Section II.A.9[31] and Table 1[32]

Section II.A.9 and Table 1 identify medication reconciliation for transitions of care. Several members of the Collaborative have previously submitted recommendations regarding comprehensive medication reconciliation in response to the Centers for Medicare & Medicaid Services; *Medicare and Medicaid Programs; Electronic Health Records Incentive Program*; *Proposed Rule* (42 CFR 412 *et al*) and the Department of Health and Human Services. *Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology; Interim Final Rule* (45 CFR Part 170) in March 2010. The Collaborative continues to support these recommendations which also include components defined by the Joint Commission national patient safety objective goal #8 in 2005[33] and AHRQ. The definition proposed by several pharmacy organizations and supported by the Collaborative is:

> Medication reconciliation is the comprehensive evaluation of a patient's medication regimen any time there is a change in therapy in an effort to avoid medication errors such as omissions, duplications, dosing errors, or drug interactions, as well as to observe compliance and adherence patterns. This

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[27] Chisholm-Burns, MA, Zivin, JS, Lee, JK, Spivey, CA et.al. Economic effects of pharmacists on health outcomes in the US: a systematic review. Am J Health-Syst Pharm, 2010;67:1624-1634. (October 15, 2010)

[28] Nkansah N, Mostovetsky O, Yu C, Chheng T, Beney J, Bond CM, Bero L. Effect of outpatient pharmacists' non-dispensing roles on patient outcomes and prescribing patterns (Review). The Cochrane Collaboration. Issue # 7 2010. www.thecochranlibrary.com. Accessed April 29, 2011

[29] Isetts, BJ, Schondelmeyer, SW, Artz, MB, Lenarz, LA, et.al. Clinical and economic outcomes of medication therapy management services: the Minnesota experience. J Am Pharm Assoc 2008; 48(2):203-211. (March/April 2008)

[30] Smith M, Guliano MR, Starowski MP. In Connecticut: improving patient medication management in primary care. Health Aff. 2011; 30:646-654. *See also* Snella KA, Sachdev GP. A primer for developing pharmacist-managed clinics. Pharmacotherapy 2003; 23(9).

[31] *Ibid*. at 1(19546).

[32] *Ibid at 2.*

[33] Joint Commission website. Available at http://www.jointcommission.org/. Accessed April 11, 2011.

process should include a comparison of the existing and previous medication regimens and should occur at every transition of care in which new medications are ordered, existing orders are rewritten or adjusted, or if the patient has added non-prescription medications to their self-care.

Medication reconciliation should be a patient-centered process, taking into account the patient's level of health literacy, cognitive and physical ability, and willingness to engage in his or her personal health care. The goal of medication reconciliation is improvement in patient well-being through education, empowerment, and active involvement in the accurate transfer of medication information throughout transitions along the healthcare continuum. By promoting communication among patients and healthcare providers, medication reconciliation can resolve discrepancies in medication regimens and improve patient safety.

Medication reconciliation should be standardized across the continuum with a common set of data elements; such as prescriber, drug name, regimen, and allergies; that facilitate the efficient transfer of information among providers and patients. This data set should be established by an interdisciplinary group of practitioners, with the pharmacist serving as a key contributor in implementing medication reconciliation in the healthcare system.

The Collaborative encourages CMS to ensure that pharmacists may participate fully in this information exchange for purposes of medication reconciliation in ACOs. The Collaborative urges CMS and ONC to adopt this definition for incorporation into EHRs used by ACOs and MU. This definition ensures that medication reconciliation balances the use of technology with the clinical services provided by pharmacists.

Incorporate the Pharmacist-Specific Measures in the Final ACO Rule

The Collaborative is concerned with the impact the number of measures in the initial year could have on ACO formation. The proposed rule requires ACOs to report on 65 measures in the first year of the program (in five key domains). As such, the Collaborative recommend CMS consider gradually phasing-in these quality measures. We also recommend that CMS continue to recognize the importance of incorporating quality measures that will encourage ACOs to focus on areas that may not directly translate to shared savings. Moreover, the measures related to medications that are identified in the proposal are essential to promote the provision of quality care to Medicare beneficiaries. Should CMS develop a phased in approach to implementation of quality measures, we recommend CMS consider initially including the measures for Better Care for Individuals as it phases-in other quality measures. The Collaborative is pleased to see the measures related to medication management included in the proposed regulation as identified below:

- Better Care for Individuals:

- Care Coordination/Transition
  - Measure Number 10: Medication reconciliation after discharge from an inpatient facility
  - Measure Number 11: Care transition measurement (including the medication therapy management component)
- Care Coordination/Information Systems
  - Measure Number 22: Percentage of primary care physicians who are successful electronic prescribers under the eRx incentive program
- Patient Safety
  - Measure Number 24: Health care acquired conditions composite

- Better Health for Populations:
  - Preventive health
    - Measure Number 26: Influenza immunization
    - Measure Number 27: Pneumococcal vaccination
    - Measure Number 30: Cholesterol Management for Patients with Cardiovascular Conditions
    - Measure Number 33: Tobacco use assessment and tobacco cessation intervention
    - Measure Number 34: Depression screening
  - At Risk Population – Diabetes
    - Measure Number 35: Diabetes composite
    - Measure Number 39: Diabetes Mellitus aspirin use (measure 39)
  - At Risk Population - Heart Failure
    - Measure Number 49: Beta-Blockers Therapy
    - Measure Number 50: Angiotensin-Converting Enzyme (ACE) inhibitor or Angiotensin Receptor Blocker (ARB) therapy
    - Measure Number 51: Warfarin therapy for patients with atrial fibrillation
  - At Risk Population - Coronary Artery Disease (CAD)
    - Measure Number 52: Coronary Artery Disease (CAD) Composite
    - Measure Number 53: Oral antiplatelet therapy prescribed for patients with CAD
    - Measure Number 54: Drug therapy for lowering LDL-Cholesterol
    - Measure Number 55: Beta-blocker therapy for CAD patients with prior myocardial infarction (MI)
  - At Risk Population - Chronic Obstructive Pulmonary Disease (COPD)
    - Measure Number 62: Bronchodilator therapy based on FEV1
  - At Risk Population – Frail Elderly
    - Measure Number 64: Osteoporosis Management in Women Who had a Fracture
    - Measure Number 65: Monthly International Normalized Ratio (INR) for beneficiaries on Warfarin

Revisions to Aggregate Data Elements between CMS and ACOs under §425.19

The Collaborative suggests that §425.19(b)(2) be revised to read the following:

These aggregate data reports will ***contain the most current data and contain*** ~~*when available,*~~ *the following information:*

(i) Financial performance.
(ii) Quality performance scores.
(iii) Aggregated metrics on the assigned beneficiary population.
(iv) Utilization data at the start for the agreement period based on historical beneficiaries used to calculate the benchmark.

This change would implement more stringent requirement for producing these reports.

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On behalf of the Pharmacy e-HIT Collaborative, thank you again for the opportunity to comment on the proposed ACO rule and the work of CMS to implement new and innovative strategies that reward performance while implementing cost savings. As the process moves forward, the Collaborative urges you to consider the important role pharmacists play in achieving the clinical and functional objectives that result in improvement in patient care and outcomes. For more information, contact Shelly Spiro, Director, Pharmacy e-HIT Collaborative at shelly@pharmacye-hit.org.

Respectfully submitted,

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