



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

March 15, 2010

Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

David Blumenthal, MD, MPP
National Coordinator for Health Information
Technology
Department of Health and Human Services
Hubert Humphrey Building, Room 509F
200 Independence Avenue SW
Washington, DC 20201

Re: Docket No. CMS-0033-P. Centers for Medicare and Medicaid Services. *Medicare and Medicaid Programs; Electronic Health Records Incentive Program; Proposed Rule* (42 CFR 412 *et al*) Document ID: RIN-0991-AB58. 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)

Dear Acting Administrator Frizzera and Dr. Blumenthal:

In 42 CFR Parts 412, *et al*. Medicare and Medicaid Programs, Electronic Health Record (EHR) Incentive Program, Proposed Rule, the Centers for Medicare & Medicaid Services (CMS) describes medication reconciliation as “the process of identifying the most accurate list of all medications that the patient is taking, including name, dosage, frequency and route, by comparing the medical record to an external list of medications obtained from a patient, hospital or other provider.” The Office of the National Coordinator (ONC) interim final rule (IFR) (45 CFR Part 170) describes medication reconciliation as “electronically complete medication

reconciliation of two or more medication lists by comparing and merging into a single medication list that can be electronically displayed in real-time,” in relation to functions complete EHRs or EHR modules must include.

The Academy of Managed Care Pharmacy, American Pharmacists Association, American Society of Health-System Pharmacists, American Society of Consultant Pharmacists, and the National Community Pharmacists Association propose the following collective recommendations to assist in providing greater clarification of medication reconciliation, while improving the quality and safety of the medication use process for patients.

The collective recommendations of our individual organizations are based on established guidelines and the work of organizations both within the pharmacy profession and by outside stakeholders who have identified problems associated with transition of care of patients and who have made specific recommendations on improving medication reconciliation as part of a quality improvement process.

As CMS and ONC seek to further define the process of medication reconciliation and its application to the meaningful use of electronic health records (EHR), the pharmacy professional organizations representing pharmacists in different practice settings recommend:

- The definition of medication reconciliation be expanded to include requirements for the clinical decision making of the pharmacist, the health care provider with the most extensive knowledge, training and expertise on medication therapy in addition to the automated process of compiling information for a medication list.
- Standard data elements be developed for the medication reconciliation process that includes prescription medications, non-prescription medications, herbal products and dietary supplements.
- The process of medication reconciliation includes the verification with the patient of the accuracy of medication lists contained within automated databases and verification of the medications that are actually being taken and how often they are taken.
- The process of medication reconciliation includes aspects of information transfer (i.e. counseling and education) from a pharmacist to the patient or their representative in a format that is most convenient and understandable to the patient.

The recommendations provided above are supported by numerous groups and initiatives that have sought solutions and issued guidance to address this complex issue and improve the quality of care for patients. In 2005, The Joint Commission named medication reconciliation as “national patient safety goal #8”.¹

The Joint Commission defined medication reconciliation as a five step process that includes:

- Developing a list of current medications,
- Developing a list of medications to be prescribed,
- Comparing the medications on the two lists,

¹ <http://www.jointcommission.org/>

- Making clinical decisions based on the comparison, and
- Communicating the new list to appropriate caregivers and the patient.

As defined by The Joint Commission, the process of medication reconciliation is the comparison of medication lists and the application of knowledge, skills and abilities on medication therapies to make clinical decisions relevant to patient care based on the comparison. Pharmacists, as the health care provider with the most extensive training and expertise in medication therapy, therefore should be an integral part of this process.

Recognizing the importance of medication reconciliation and the specific role of the pharmacist in this process, the American Society of Health-System Pharmacists and the American Pharmacists Association, convened a workgroup to address this issue in 2007. This workgroup developed a shared vision of medication reconciliation as a responsibility of pharmacists caring for patients who transition from one sector of health care to another. Aspects of this definition were inspired by definitions published by The Joint Commission and the Agency for Healthcare Research and Quality.

The shared medication reconciliation definition that resulted from the pharmacy profession workgroup states:^{2[1]}

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 process should include a comparison of the existing and previous medication regimens and should occur at every transition of care (1) 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.

^{2[1]} ASHP-APhA Medication Reconciliation Initiative Workgroup Meeting, February 12, 2007, Summary and Recommendations. Accessed March 4, 2010: http://www.ashp.org/s_ashp/docs/files/MedRec_ASHP_APhA_Wkgrp_MtgSummary.pdf

In the last two years, the Pharmacy Quality Alliance (PQA) has also recognized the role of the pharmacist in the medication reconciliation process and has undertaken work to develop quality measures around this role. As a part of this work the PQA developed a definition of medication reconciliation.

The PQA medication reconciliation definition states:

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 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.

Most recently, the National Transitions of Care Coalition (NTOCC), a broad based stakeholder coalition of organizations seeking to improve the quality of care during periods of transition has published recommendations in regard to medication reconciliation.

In regards to medication reconciliation, NTOCC recommends that:

- *Standard medication reconciliation elements be developed*
- *Medication reconciliation be performed every time a patient is exposed to a new care setting or level of care*
- *Each time a patient is transitioned to a new setting, that the new setting receive key information about the patient's medication regimen that includes prescription and non-prescription remedies, a record of when the medication was taken and its route and frequency of administration, indication for use, patient allergies, and other medication-related information*
- *The role of the pharmacist should be expanded in transitions of care to include pharmacist provided medication reconciliation. Specifically that pharmacists be used to identify medication safety concerns and to prevent morbidity associated with improper drug selection, sub-therapeutic dosage, failure to receive medication, excessive dosage, drug interactions, and drug use without indication and treatment failures.*
- *Pharmacists have direct contact with patients and other health care providers to ensure medication information is transferred accurately and completely.*
- *Pharmacists educate the patient and caregiver during the patient's discharge from one health care setting to another*
- *Pharmacists be responsible for overseeing the patient's medications, including all over-the-counter drugs, prescription drugs, vitamins, and herbal medications, and ensure that new orders are made and filled properly.*

It is clear that both within and outside of the pharmacy profession, there is a clear understanding that medication reconciliation is a complex clinical process where the knowledge and skill of a trained health care professional must be utilized to produce optimized care and improved health

outcomes. While health information technology may facilitate the gathering of needed data for this process and may aid in clinical decision support, the inclusion of the pharmacist, the medication therapy expert, is crucial to this process.

For the meaningful use of EHRs to be effectively achieved, and for the quality of care for patients to be improved, the complex process of medication reconciliation must include the clinical decision making and expertise of the pharmacist. Additionally, while automated data systems can compile merged lists of medications, the process of medication reconciliation will not be effective without the verification of such information with the patient or his/her caregiver and the confirmation of the medications that are currently being taken by the patient, and the frequency with which they are taken. The process must include the transfer of information in the form of education and counseling by the pharmacist to the end user, the patient, in a format that is both understandable by and effective for the patient.

Thank you for the opportunity to provide comments and our recommendations related to medication reconciliation. Our organizations encourage you to include pharmacists by name as an integral part of the medication reconciliation process. We look forward to continue working with public and private stakeholders to develop a nationwide interoperable HIT infrastructure recognizing the important role of proper medication management and the integral role of the pharmacist.

Sincerely,

Academy of Managed Care Pharmacy
American Pharmacists Association
American Society of Consultant Pharmacists
American Society of Health-System Pharmacists
National Community Pharmacists Association

For additional information please contact:

Mark N. Brueckl, RPh, MBA
Assistant Director, Pharmacy Affairs
Academy of Managed Care Pharmacy
mbrueckl@amcp.org

Marcie Bough, PharmD
Director, Federal Regulatory Affairs
American Pharmacists Association
mbough@aphanet.org

Carla McSpadden, RPh, CGP
Director, Professional Affairs
American Society of Consultant Pharmacists
cmcspadden@ascp.com

Justine Coffey, JD, LLM
Director, Federal Regulatory Affairs
American Society of Health-System
Pharmacists
Government Affairs Division
JCoffey@ashp.org

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