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January 6, 2014

Richard Kronick, Ph.D.
Director, Agency for Healthcare Research and Quality
Agency for Healthcare Research and Quality (AHRQ)
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850

Re: Draft Systematic Review: Medication Therapy Management

Dear Dr. Kronick:

The American Society of Health-System Pharmacists (ASHP) is pleased to submit comments to the Agency for Healthcare Research and Quality (AHRQ) on the Draft Systematic Review: Medication Therapy Management (draft report) as published on December 3, 2013.[i] ASHP is the national professional organization whose 42,000 members include pharmacists, pharmacy technicians, and pharmacy students who provide patient care services in acute and ambulatory care settings, including hospitals, health systems, and clinics. For 70 years, the Society has been on the forefront of efforts to improve medication use and enhance patient safety.

Overall, ASHP supports the methodology of dividing measured outcomes into intermediate (e.g., drug-related problems, adherence issues) and patient-centered (e.g., morbidity, mortality, quality of life). However, it is essential the final report note that the overwhelming majority of studies evaluated were not designed to measure longer term outcomes. Study timeframes averaged three to six months, with some interventions only extending for a handful of visits. Therefore, it is not surprising the major finding is that there is insufficient evidence to determine whether or not MTM has an impact on outcomes. As currently stated, the primary study conclusion could be interpreted as medication therapy management confers no benefit. However, as described in the report a primary finding is that available evidence is limited or inconclusive in its ability to determine benefit as determined by the authors' schemata. As noted by the authors on page ES-15, "This body of evidence has significant clinical and methodological heterogeneity, which limits the ability to make any universal statements about effectiveness." This statement is in stark contrast to the statements on effectiveness included in the "Structured Abstract," which will be the most read and cited aspect of the report. ASHP strongly encourages the authors to reconcile this discrepancy.

Further, in the conclusion on page vi, the authors state that "…funders may wish to weigh the relative value of information on overall effectiveness, effectiveness of implementation features and program implementation and accountability when commissioning new research." The intent of this statement is unclear. Are the report authors recommending that future studies be structured to address limitations in the current evidence base? For example, there is a clear need to further design studies to evaluate the long-term impact of these programs. ASHP requests that the authors revise the conclusion to improve the clarity of the recommendation that is being provided.

ASHP is concerned that the exclusion of programs initiated in the inpatient setting fails to recognize some of the significant improvements that have resulted from interventions at care transitions. There is significant evidence that medication-related issues frequently arise from changes in the setting of care or a loss of disease state control that necessitates hospitalization. Therefore, medication therapy management programs are increasingly being directed at this high-impact scenario. Exclusion of these programs by the study authors overlooks programs that have resulted in improved patient outcomes and reduced overall costs. The emergence of these programs supports the need for continued study of the effectiveness of medication therapy management programs. For additional information, please see *ASHP-APhA Medication Management in Care Transitions Best Practices*.[ii] Additional reports demonstrating the effectiveness of these programs are found in the published and gray literature.

On page vi, the intent of the following sentence is unclear and likely to be misinterpreted: "Similarly, we found sufficient evidence to conclude that MTM conferred no benefit for a limited number of outcomes." As written this implies that the results of comparator groups demonstrated no improvement, yet a review of the program evaluated indicates that improvement was demonstrated by groups receiving MTM.

On page vi, fourth paragraph under "Results," ASHP requests clarification of the term "brief clinical summaries," which is used to describe the information available to pharmacists to support the medication therapy programs that are the subject of this evaluation. On page ES-13, the authors note that only one study provided pharmacist access to patient records. This fact should be highlighted given that all medical interventions, regardless of health care provider, are best implemented when the health care provider has access to complete and accurate patient information.

On page ES-5, under "Timing," the authors note that outcomes measured at the first intervention were not considered if two or more interventions (i.e., episodes of care) were provided. While this approach is consistent with achievement of long-term outcomes, it overlooks the value of intermediate outcomes such as prevention or treatment of adverse drug events and non-adherence that are identified and corrected at the first intervention. These interventions represent significant improvements in patient care and cost avoidance.

As noted previously, ASHP is concerned that the study excluded interventions initiated in the inpatient setting, as described under "Settings" on page ES-5. The Society respectfully requests that the authors provide a rationale for excluding medication management programs in the inpatient setting. Table A on pages ES-3 to ES-6 does not clearly state which criteria are inclusion criteria and which are criteria for exclusion. The table seems more of a list of what was considered when assessing each of the studies for inclusion, but does not provide specific and detailed requirements.

On page ES-7, under "Data Synthesis," the authors describe using a process of meta-analysis to evaluate the results of three or more "similar" studies. However, among key findings for KQ 1 and elsewhere in the report the authors acknowledge significant variability in the structure of medication therapy management programs. ASHP requests additional information regarding the criteria for determining similarity of programs. For example, ASHP recommends that the disease state addressed should be a primary characteristic for determining similarity. The finding (low strength of evidence) that the rate of hospitalizations among heart failure patients decreased compared to usual care illustrates the importance of this stratified approach.

Further, anecdotal reports and limited evidence indicate that focusing on specific high-risk patients or disease states may demonstrate the most benefit. To further elicit these factors, the ASHP Research and Education Foundation recently awarded a grant to Almut G. Winterstein, Ph.D., Professor, Department of Pharmaceutical Outcomes and Policy in the University of Florida (UF) College of Pharmacy to develop a medication complexity index. The tool, which will be available in 2015, will prospectively identify patients at greatest need for pharmacist-provided drug therapy management. ASHP highly encourages AHRQ to schedule a re-evaluation of the impact of medication therapy management following completion and implementation of this project.

Pages ES-14 to ES-15 compare this analysis to earlier work completed by Chisholm-Burns and colleagues. The authors appropriately acknowledge the key differences in these studies, including the inclusion of studies in which pharmacists provided direct patient care services that expand beyond medication therapy management. While the authors of the Draft Report limit the studies evaluated to those focusing on MTM, the Chisholm-Burns evaluation includes studies that focus on other types of direct patient care beyond MTM. The inclusion of these studies more accurately conveys the current state of pharmacy practice.

Further, the authors note that results from a yet-to-be included study by the Centers for Medicare and Medicaid Services found improved adherence and appropriateness of therapy.[iii] Key findings from this study include:

1. MTM programs improved medication adherence and quality of prescribing for CHF, COPD, and diabetes patients particularly when comprehensive medication reviews were provided;

2. MTM programs initially improved the safety of drugs prescribed in new enrollees for the first 6 months while the effects diminished by 1 year; and
3. MTM programs decreased hospital utilization and costs in diabetes and CHF patients receiving CMR but not in COPD patients.

ASHP believes that the "Structured Summary" and "Executive Summary" will require significant revisions when these results are included in the final draft.

ASHP believes the following statement on page ES-15 is an oversimplification of the intent of medication therapy management programs, specifically their impact on resource utilization: "For example, whether one should expect the number of medications prescribed for heart failure to increase or decrease under the careful scrutiny of an MTM intervention is not clear." Similar statements are found on page ES-21 under "Research Gaps." ASHP asserts that it is not possible, and is in fact inappropriate to predetermine the desired impact based on the number of prescribed medications. Medication therapy management is intended to be a patient-centered process geared at optimizing the drug therapy regimen for the individual patient, rather than a predetermined target that may or may not meet patient-specific needs.

ASHP supports the finding under "Implications for Clinical Practice and Policymakers" that encourages that medication therapy management be positioned as contributor to overall improvement in processes of care. As we experience increases in team-based and integrated care, it will become increasingly important to identify and quantify the contributions of each member of a patient-care team in improving patient outcomes.

Under "Research Gaps" on page ES-20, ASHP agrees that the effectiveness of medication therapy management provided by pharmacists would be best measured when compared to other interventions (e.g., MTM provided by other providers) as compared to usual care. However, the ability to design studies to evaluate comparative effectiveness is limited by the absence of other caregivers with similar training and expertise to provide these interventions. This is especially true as the complexity of medication therapy increases.

The Society appreciates the opportunity to comment on the Draft Report. Please contact me if you have any questions or wish to discuss our comments further. I can be reached by telephone at 301-664-8806, or by e-mail at ctopoleski@ashp.org.

Sincerely,

Christopher J. Topoleski
Director, Federal Regulatory Affairs

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[i] http://www.effectivehealthcare.ahrq.gov/ehc/products/516/1826/medication-therapy-management-draft-131203.pdf

[ii] http://media.pharmacist.com/practice/ASHP_APhA_MedicationManagementinCareTransitionsBestPracticesReport2_2013.pdf

[iii] Medication Therapy Management in Chronically Ill Populations: Final Report (http://innovation.cms.gov/Files/reports/MTM_Final_Report.pdf)