APPENDIX A:

Guidelines

Guidelines for the Practice and Documentation of Comprehensive Medication Management in the Patient-Centered Medical Home

Based on Information Contained in the PCPCC Resource Guide:
"Integrating Comprehensive Medication Management to Optimize Patient Outcomes"

Background

The Patient-Centered Primary Care Collaborative (PCPCC) provides an open forum for the full range of health care stakeholders seeking to advance the quality of care for all Americans through the implementation of the patient-centered medical home (PCMH) as the principal platform for a reformed system for the delivery of primary care health services. More than 1,000 stakeholders now participate in the work of the PCPCC, representing essentially all health professions, patients and patient advocacy groups, employers, policy-makers, and public and private payers.

As part of its activities, the PCPCC develops informational materials and Resource Guides on a wide range of topics in health care (e.g., health information technology integration, payment policy reform, building and sustaining successful team-based care structures, and continuity and coordination of care) as they relate to the PCMH, Accountable Care Organizations (ACOs), and other coordinated care systems. The Resource Guides are developed with input from all interested parties who wish to engage. The goal is to promote a better understanding of how these topics relate to the broad purpose and objectives of the PCMH.

The topic of "comprehensive medication management" (CMM) within the PCMH is fully described in a Resource Guide developed by the PCPCC Medication Management Task Force and first made available by the PCPCC in 2010. The guide—*"Integrating Comprehensive Medication Management to Optimize Patient Outcomes"*—has proved to be among the most popular of all the guides developed thus far by the PCPCC. A second printing, released in 2012 with only minor editorial updates, incorporates the information presented here as an Appendix to highlight suggested guidelines for the practice and documentation of CMM services. The information is derived directly from the Resource Guide and intended to be used with it for a more complete understanding of the practice of comprehensive medication management.

As efforts to transform America's health care delivery system continue, patients must be both informed and actively engaged in decisions concerning the medications that represent the best choices for them in preventing and controlling disease. These decisions can best be made when the cultural needs and beliefs of the patient are considered and incorporated with the best knowledge and recommendations of the PCMH team members, particularly prescribers, pharmacists, care managers, and others, who provide and are responsible for the patient's medication-related care.

As outlined in the Resource Guide, a consistently delivered and validated approach to the provision of CMM services is necessary to assure appropriate and optimized medication therapy in a patient-centered fashion.[1] A consistent process of care, together with access to (and the ability of patients to afford) the "best" medications, i.e., those that best meet a patient's individual, specific needs and clinical goals of therapy, has been shown to result in vastly improved clinical outcomes and reduced overall health care costs, while also addressing "patient safety" related to adverse drug reactions, interactions, and toxicities.[2,3,4]

Patients who are at clinical goal with their medication regimens often have their therapy effectively managed by their primary care providers and will find the

application of the information found in the Resource Guide helpful in assuring clinical goals of therapy are met and maintained. For more complex regimens when patients are not at goal or are experiencing adverse medication effects, however, the primary care physician or a member of the medical home/coordinated care team may seek medication management services to achieve clinical goals and minimize adverse events. Such services optimally require a clinically oriented pharmacist trained to work directly with patients and collaboratively with other members of the PCMH team through the application of these principles.

The guidelines that follow provide more explicit explanation regarding the essential components of the practice and documentation processes that are part of the practice of CMM as described in the Resource Guide. Those seeking a more in-depth delineation and explanation of the practice of comprehensive medication management may wish to consult *Pharmaceutical Care Practice—The Clinician's Guide*[2] which served as a primary, evidence-based reference in the development of the PCPCC Resource Guide.

Health plans, government payers, employers, integrated delivery systems, medical providers, pharmacists, and patients should find this document useful as a companion document to the existing Resource Guide, upon which all the following information is based. Both documents should be considered together in seeking to better understand the practice and documentation of comprehensive medication management services.

Guidelines for the ***Practice*** of Comprehensive Medication Management in the Patient-Centered Medical Home

1) An assessment of the patient's medication-related needs

a) All medications are reviewed and documented with the patient including prescription/OTC's/herbals/etc.

b) The medication experience of the patient is discussed and recorded. (The patient's attitudes, beliefs, and preferences about drug therapy, which are shaped by experiences, culture, traditions, religious beliefs, etc., apply here).

c) The patient's medication history, including allergies/reactions is taken (include what medications have been taken for which medical conditions in the past, which have worked and not worked, which have caused the patient concerns or problems and should be avoided).

d) All current medications, their doses (the way they are actually being taken by the patient) are reviewed with the patient and documented.

e) Each medication is assessed for the medical condition or indication for which it is taken. (To produce clinically useful data, the indication for the medication must be electronically linked with the product being used, dose, duration, manner in which the medication is being taken, therapy goals, clinical parameters that will determine progress toward these goals, and actual outcomes.)

f) The clinical status of the patient is assessed/determined for each drug/condition treated/prevented (e.g., current BP level and cholesterol levels for hypertensive and hyperlipidemic patients, respectively). Without a determination of the current clinical status of a patient, the indication, appropriateness, and effectiveness of most medications **cannot** be determined.

g) The clinical goals of therapy for each medication—national guidelines, prescriber goals, and whenever applicable, patient goals are ascertained and documented.

2) Identification of the patient's medication-related problems

All drug therapy problems (DTPs) related to indication, effectiveness, safety, and adherence are determined and documented for each medical condition or preventive therapy, based on the accepted clinical pharmaceutical taxonomy of drug therapy problems. The following questions serve to determine if any of the seven major categories of drug therapy problems are identified:

a) Appropriateness of the medication
   1) Is the medication appropriate for the medical condition being treated?
   2) Does the patient have an indication for a medication that is not being treated or prevented?

b) Effectiveness of the medication
   3) Is the most effective drug product being used for the medical condition?
   4) Is the dose appropriate and able to achieve the intended goals of therapy?

c) Safety of the medication
   5) Is the patient experiencing an adverse event from the medication?
   6) Is the dose so high it could cause toxicity in the patient?

d) Adherence to the medication
   7) Is the patient able and willing to take the medication as intended?

Significant drug therapy problems identified from the preceding questions are systematically documented in the same framework:

INDICATION:
(1) The drug therapy is unnecessary because the patient does not have a clinical indication at this time.
(2) Additional drug therapy is required to treat or prevent a medical condition in the patient.

EFFECTIVENESS:
(3) The drug product is not being effective at producing the desired response in the patient.
(4) The dosage is too low to produce the desired response in the patient.

SAFETY:
(5) The drug is causing an adverse reaction in the patient.
(6) The dosage is too high, resulting in undesirable effects experienced by the patient.

COMPLIANCE/ADHERENCE:
(7) The patient is not able or willing to take the drug therapy as intended.

3) Develop a Care Plan with individualized therapy goals and personalized interventions

The medication care plan is developed by the pharmaceutical care practitioner directly with the patient and in collaboration with the PCMH team or the patient's other health care providers. The care plan allows a provider to do the following:

a) Intervene to solve the patient's medication-related problems (interventions include initiating needed drug therapy, changing drug products or doses, discontinuing medications, and educating the patient).

b) Establish individualized therapy goals for each medical condition. Although national guidelines dictate population-level goals, each therapy goal must be individualized for each patient based on risk, co-morbidities, other drug therapies, patient preferences, and physician/PCMH team intentions.

c) Design personalized education and interventions that will optimize each patient's medication experience.

d) Establish measurable outcome parameters that can be monitored and evaluated at follow-up to determine the impact of the therapies and the service.

e) Determine appropriate follow-up time frames to ensure the interventions were effective and determine if any safety issues have developed since the last evaluation.

4) Follow-up evaluation to determine actual patient outcomes

The follow-up evaluations allow the pharmaceutical care practitioner in collaboration with the PCMH team to determine the actual outcomes resulting from the recommended interventions. The outcome parameters are evaluated against the intended outcomes (individualized therapy goals) and the patient is reassessed to determine if any new medication-related problems have developed that might interfere with the safe and effective use of the medications. These follow-up evaluations occur in a time frame that is clinically appropriate for the specific patient, the medical conditions being monitored, and the drug therapy being taken. They may well vary with each patient, but should be coordinated with the PCMH team to minimize interference with other care activities, and are particularly important when major care transitions (such as hospitalization admission/discharge) occur.

Guidelines for the ***Documentation*** of Comprehensive Medication Management in the Patient-Centered Medical Home

Background

This section outlines the essential components of documentation that support the practice of comprehensive medication management in the PCMH. The information is drawn from various PCPCC sources, primarily the *PCPCC CMM Resource Guide* (pp 11-12) and the PCPCC Meaningful Connections Resource Document[5], as well as the Minnesota MTM Medicaid Law provisions.[6]

A discussion of the relationship of these documentation parameters to the evolving development of standards for electronic health records (EHR), HIT meaningful use criteria, e-prescribing standards, clinical data exchange/integration, and related technological issues that impact the PCMH and pharmacists' practice is beyond the scope of the Resource Guide. However, as these systems continue to evolve, the effective integration of CMM-related data and documentation parameters will be an important and ongoing objective for the PCPCC and its Medication Management Task Force.

In addition, documentation activities should be supportable through electronic billing functions consistent with current CPT codes established for Pharmacists' Medication Management Services, Evaluation and Management (E&M) CPT Codes, and other widely utilized codes, such as the *Minnesota DHS, MHCP Provider Manual, Medication Management Therapy Services, HIPAA—Compliant MTMS CPT Codes, Revised 1/5/2010,* in settings that require fee-for-service billing.[6]

1. A record of the patient's medication experience (understanding, concerns, preferences, beliefs, behavior)

2. Medication allergies (along with a description of the allergy, time frame, and severity) and adverse reactions (separated into dose-related and preventable)

3. Medication history (including immunizations), complete with dates, effectiveness information, record of issues, problems, etc.

4. Current medication record (including all medications regardless of source, mode of administration, or prescriber), indication for use, product, dose, duration, and how the medication is actually being taken

5. Active drug therapy problem list, complete with the cause of each problem (associated with the medical condition and medications relating to the drug therapy problem)

6. Therapeutic treatment plans for the patient and practitioner (a patient and prescriber version of the treatment plan needs to be available and provided/communicated). The following specific functionality must be available in the electronic therapeutic record to provide medication management services:

   (a) Connect indication for medication (reason for use) to specific drug product, dose, duration, and actual outcomes for each medical condition.

   (b) Identify, resolve, and prevent drug therapy problems:

   APPROPRIATENESS:
   - Eliminate unnecessary medications
   - Initiate necessary medications not being taken.

   EFFECTIVENESS:
   - Identify most effective medication in specific patient.
   - Increase dosages to effective levels.

   SAFETY:
   - Eliminate toxicities.
   - Identify adverse reactions.

   ADHERENCE:
   - Increase patient's willingness to adhere to medication regimen.

   The cause of each of the drug therapy problems described above also needs to be documented.

   (c) Record and evaluate actual outcomes from drug therapy.
   - Record personalized therapy goals and evaluate against outcome measures for each medical condition.
   - Graph laboratory levels against changes in drug therapy and doses.
   - Record outcome changes with changes in medication details.

(d) Provide post-marketing surveillance on appropriateness, effectiveness, safety, and adherence variables.

(e) Record drug therapy problems specific to drug product, medical condition, and patient parameters.

(f) Offer clinical decision support and analysis.

(g) Support patient participation and decision making in drug therapy (adherence tools, recordkeeping, etc.).

(h) Provide patients with medication information that is individualized and complements the therapeutic care plan.

References:

1. Isetts, B.; Brown, L.; Schondelmeyer S. Quality Assessment of a Collaborative Approach for Decreasing Drug-Related Morbidity and Achieving Therapeutic Goals. Arch. Intern Med 2003; 163; 1813-20.

2. Cipolle, R., Strand, L., Morley, P. *Pharmaceutical Care Practice—The Clinician's Guide,* 2004–2nd edition. McGraw-Hill; Cipolle RJ, Strand LM, Morley PC. *Pharmaceutical Care Practice: The Patient-centered Approach to Medication Management.* McGraw Hill, 2012 is the 3rd revised edition (in press).

3. "The Opportunity for Comprehensive Medication Management Within the Patient-Centered Medical Home Structure" http://www.pcpcc.net/files/medication_management_in_pcmh_with_practice_profiles.pdf.

4. Isetts, B. et al. Clinical and economic outcomes of medication therapy management services: The Minnesota experience- J Am Pharm Assoc. 2008;48(2):203-211.

5. PCPCC Resource Document, Meaningful Connections—A Resource Guide for using health IT to support the patient centered medical home. http://pcpcc.net/files/cehia_mc.pdf.

6. Minn. Stat. §256B.0625, subd. 13h in 2005 https://www.revisor.mn.gov/statutes/?id=256b.0625.

This document (Appendix A) has been prepared with the input and endorsement of the PCPCC Medication Management Taskforce representing a broad range of stakeholders dedicated to the advancement of patient care by assuring the medications that are taken represent the most appropriate and safest available to improve clinical outcomes and patient self-care. As with all other PCPCC resource guides and documents, this document is intended as a guidance document to assist interested readers and others in better understanding the issues surrounding the topic of comprehensive medication management as it relates to the advancement of principles of the PCMH. The PCPCC and its resource documents do not have the purpose of defining a "professional standard of practice" for any health profession or organization.