GTMRx Institute™
Get the medications right™

July 29th, 2020
Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services

Dear Administrator Verma:

The Get the Medications Right Institute (GTMRx - see membership list- Addendum A) thanks the Centers for Medicare & Medicaid Services (CMS) for the interim final rule effective May 8th, 2020 regarding coverage of medication management services under Medicare Part B (the "IFC"). GTMRx is a multi-stakeholder organization of over 1000+ members of payers, providers, and consumers committed to ensuring patients have access to appropriate and personalized use of medications and gene therapies to optimize outcomes and reduce costs. We write today to request a meeting with CMS to discuss the provision of high quality, patient-centered Part B medication management services.

We were extremely pleased that the IFC clarified that "medication management is covered under both Medicare Part B and Part D." We also thank CMS for clarifying that pharmacists, as auxiliary personnel, can provide such services incident to a physician or non-physician practitioner (NPP).[1] While we applaud CMS's recognition of medication management services, we want to ensure that patients have access to the most effective interventions. To accomplish this, we recommend that CMS clarify several aspects of Part B medication management, which we highlight below.

I. CMS Should Define "Medication Management" to Mean "Comprehensive Medication Management"

We urge CMS to specifically define the term "medication management" as used in the IFC to mean "comprehensive medication management" (CMM). CMM is more rigorous in process and purpose, team-based, information-focused, and patient-centric than the Medication Therapy Management (MTM), which is typically provided under Part D. CMM provided by clinical pharmacists goes far beyond MTM which does not require a formal collaborative practice agreement between a pharmacist and a prescriber. MTM can be provided in any setting where a patient receives medications and often coincides with the dispensing of a medication.[2] CMM services require the clinical pharmacist to work in collaborative practice with physicians and other non-physician practitioners (NPP) to improve overall patient outcomes.

[1] Centers for Medicare & Medicaid Services, "Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID– 19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program: Pharmacists Providing Services Incident to A Physicians' Service," 85 Fed. Reg. 27550 (May 8, 2020).

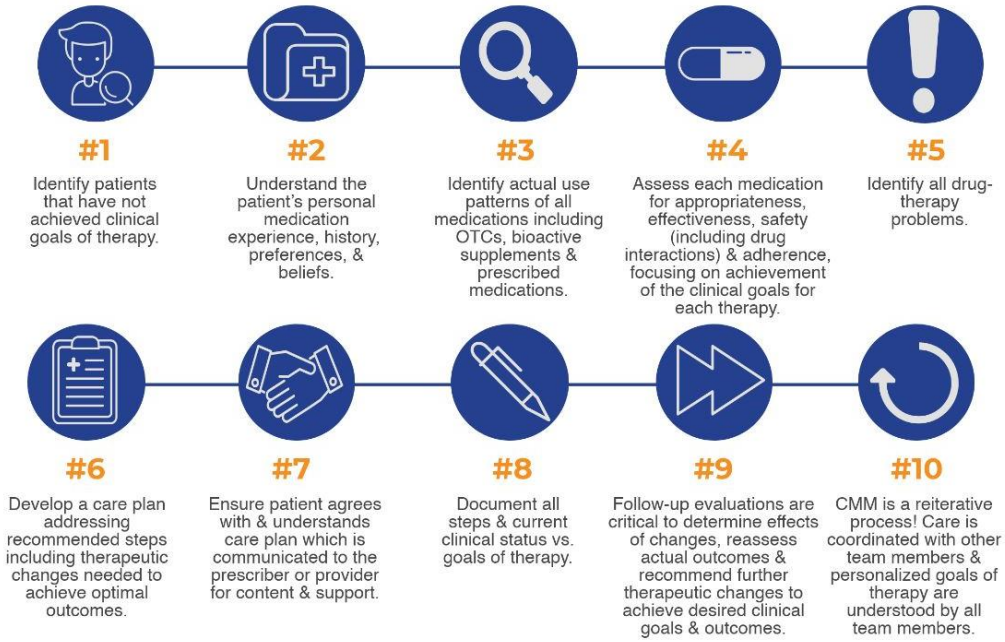
[2] An example of MTM might be to assess a medication profile to ensure a patient with coronary artery disease is prescribed a beta-blocker. CMM involves the development of a patient-centered care plan including an assessment of the patients clinical status, each medication, and health problems along with follow up evaluations.

A. CMM Provides Tested, Holistic Interventions

CMM focuses on patients who have not achieved clinical goals of therapy. It is a systematic approach where physicians and pharmacists ensure that medications (whether they are prescription, nonprescription, alternative, traditional, vitamins, or nutritional supplements) are individually assessed to determine that each medication is appropriate for the patient, effective for the medical condition, safe given the comorbidities and other medications being taken, and able to be taken by the patient as intended.[3] It is a patient-centered approach to optimizing medication use and improving patient health.

Through CMM, care is coordinated with the other team members including the physician, and patients actively participate in the process. Clinical pharmacists provide high-level services for both acute and chronic issues that are supported by documentation.[4] CMM is a well-defined strategy for optimizing medication use, ensuring that it is consistently replicable across care settings, yields positive outcomes, and is readily scalable.[5]

As outlined in the graphic below, CMM is a multi-step rigorous process that engages all members of the health care team, assuring more effective coordination of care.



[3] McInnis, Terry, et al., editors. *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes*. 2nd ed., Patient-Centered Primary Care Collaborative, *The Patient-Centered Medical Home: Integrating Comprehensive Medication Management to Optimize Patient Outcomes*. PCPCC Medication Management Task Force collaborative document

[4] CMM visits are 30-60 minutes in duration. One example of a visit would entail a pharmacist meeting with an 80 year old patient referred by the physician with type 2 diabetes, hypertension, coronary artery disease, and chronic kidney disease taking over 10 medications. The pharmacist will take a comprehensive history of present illness, review of systems, home measurements like blood glucose, blood pressure, physical exam (if face-to-face visit) and then a medication review. Labs are reviewed, a treatment plan will be developed including modifying, discontinuing and initiating medications and comprehensive disease/medication education will be provided.

[5] McClurg, M., Sorensen, T., Carroll, J.The Patient Care Process for Delivering Comprehensive Medication Management (CMM): Optimizing Medication Use in Patient-Centered, Team-Based Care Settings. CMM in Primary Care Research Team. July 2018

B. CMM Produces Significant Patient and Systemic Benefits

We understand the hesitations CMS may have regarding additional payments with the hope that they will yield downstream savings. Unlike other interventions, there is substantial evidence that CMM will produce cost savings. Practices around the country demonstrate the value-proposition for CMM each day. The return on investment (ROI) of team-based medication management services has been well documented, as articulated by Cipolle, et al., "to average around 3:1 to 5:1 and can be as high as 12:1, resulting in a reduction in the direct mean medical cost of between $1200 and $1872 per patient per year for each of the first 5 years for those patients with chronic diseases such as diabetes, cardiovascular health issues, asthma and depression."[6] The evidence of its effectiveness continues to grow. It has been shown to improve the health of populations, enhance the experience of care for individuals, reduce per capita cost of health care and improve physician satisfaction.

Annually, over $528 billion is wasted and 275,000 lives are lost due to non-optimized medication use. In 2016, this was the equivalent of 16 percent of total U.S. health care expenditures. Misuse, overuse or underuse of medication therapy can lead to treatment failure, a new medical problem or both. In addition to the evidence on costs, data shows that CMM benefits the health care system through lower hospital readmission rates, and improved clinical outcomes.[7,8] A 2018 study including more than 43,000 patients found that patients who had received a CMM visit within 30 days post discharge had a statistically significantly lower rate of readmissions compared to the comparator cohort. The 60-day readmission rate was also lower.[9] Patients receiving pharmacist-led CMM had improved outcomes in chronic disease management including quality indicators for Type 2 diabetes, anticoagulation, hypertension, hyperlipidemia, and pain.[10]

Access to CMM is particularly important for COVID-19 patients, who may require clinical testing to target correct therapies. Appropriately skilled clinical pharmacists offer a coordinated, systematic process of care in development of care plans recommending therapeutic changes needed to achieve optimal outcomes. Many patients with severe COVID-19 complications have multiple comorbidities that require expert medication management, and they may need additional treatment with antithrombotic, anticoagulant, or antiplatelet agents to combat potentially deadly inflammation and thrombosis.[11]

Because CMM follows a proven model, utilizes the entire health care team, and considers the importance of companion and complimentary diagnostics to target correct therapies, it is a far superior approach to ad hoc or scattershot medication interventions. At present, "medication management" is undefined, meaning that numerous less effective and comprehensive interventions could fall under its auspices. To realize the clinical and financial benefits of CMM, CMS must explicitly define medication management to mean CMM.

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[6] Cipolle RJ, Strand L, and Morley P. Pharmaceutical Care Practice: The Patient Centered Approach to Medication Management. Third Edition. New York, NY: McGraw-Hill Medical; 2012.

[7] Sapp E., Francis S., Hincapie, A. The American Journal of Accountable Care. 2020;8(1):8-11 https://www.ajmc.com/journals/ajac/2020/2020-vol8-n1/implementation-of-pharmacistdriven-comprehensive-medication-management-as-part-of-an-interdisciplinary-team-in-primary-care-physicians-offices

[8] CMM also provides significant benefit for chronic disease patients through improved medication adherence. Given that the vast majority of Medicare beneficiaries has one or more chronic conditions, medication adherence across multiple chronic disease medication classes would provide significant clinical and financial systemic benefits. Improved adherence among patients with diabetes, hypertension, hypercholesterolemia, and congestive heart failure reduces hospitalization rates, thereby reducing total health care costs

[9] Budlong, H., Brummel, A., Rhodes., A., Nici, H. Impact of Comprehensive Medication Management on Hospital Readmission Rates. Population Health Management. 2018.

[10] McFarland, MS, Nelson J, Ourth H, Groppi J and Morreale A. Optimizing the primary care clinical pharmacy specialist: Increasing patient access and quality of care within the Veterans Health Administration. J Am Coll Clin Pharm. 2019. https://doi.org/10.1002/jac5.1177.

[11] The most common comorbidities were hypertension (56.6%), obesity (41.7%), and diabetes (33.8%) according to an April 2020 JAMA article which included 5700 patients hospitalized with COVID-19 in the NYC area.

II. Part B Medication Management Reimbursement Must Reflect CMM's Value

To ensure patients have access to CMM, CMS must ensure that billing codes reflect the value, duration, and intensity of the services. However, at present, confusion remains regarding which codes can be billed for services provided by auxiliary personnel incident to a physician or NPP. As a result, it is unclear whether incident-to services provided by a pharmacist[12] could be billed at anything beyond the lowest level of evaluation and management codes (e.g., 99211 in person or 99441 for telehealth). If, this is the case, it will be financially unfeasible for pharmacists to provide CMM.

In 2016, the Physician Fee Schedule (PFS) Final Rule stated that eligible providers could bill for auxiliary personnel provided incident-to services "…as if they personally furnished the service."[13] However, CMS's plan to adopt the AMA CPT Codebook for determining billing levels created new confusion around incident-to services. The codebook's preamble notes that "[the] E/M services for which these guidelines apply require a face-to-face encounter with the physician or other qualified health care professional...if the physician's or other qualified health care professional's time is spent in the supervision of clinical staff who perform the face-to-face services of the encounter, use 99211."[14] The codebook further notes that "For E/M services that require prolonged clinical staff time and may include face-to-face services by the physician or other qualified health care professional, use 99415, 99416. Do not report 99354, 99355 with 99415, 99416, 99XXX."[15] Additionally, the codebook's definition of the term "medical decision making" differs from the current CMS definition, which could potentially limit the ability of auxiliary staff to participate in patient care.[16] Read together, these statements suggest that incident-to billing is limited only to codes 99211, 99415 and 99416, which is a total departure from CMS's policy as outlined in the FY 2016 PFS.

These contradictory statements have generated uncertainty among provider compliance officers and Medicare Administrative Contractors (MACs). Some MACs have indicated that medication management services provided by pharmacists cannot be billed higher than 99211, even when a physician is involved, despite the complexity, decision making and time necessary to provide CMM services. Limiting providers to billing 99211 will not support the provision of appropriate medication management services.

To ensure that patients can assess appropriate medication management services, we respectfully request that CMS confirm that physicians can bill the following codes for medication management services, including when provided by a pharmacist, if the incident-to requirements are met:

- Evaluation and management (E/M) codes for established patients
  - 99211-99215
- Telehealth codes (telephonic equivalent to E/M codes)
  - 99441- 99443

[12] Note that as members of the health care team, clinical pharmacists practice under formally granted clinical privileges from the medical staff or credentialing system of the organization in which they practice or under written collaborative practice agreements (CPA) with individual physicians or medical groups. CDC has found "strong evidence that when pharmacists are part of the health care team, outcomes related to preventing or managing chronic diseases and adherence to medication improve." These outcomes include clinical and behavioral health indicators including lowering blood pressure, HbA1c, and LDL cholesterol levels.

[13] Medicare program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to part B for CY2016. (Final rule). Federal Registrar. 80: 220. (November 16, 2015) p. 71066 https://www.federalregister.gov/d/2015-28005/p-1578. Accessed June 22 2020.

[14] AMA CPT Editorial Panel (2019) at 1-2.

[15] AMA CPT Codebook, p. 14.

[16] Id. At 6; CMS definition in MLN matters.

Conclusion

Adverse drug reactions (ADR's) are the 4th leading cause of death in the US. We believe a well-defined strategy, such as CMM is needed.[17] CMM provides value in improving patient outcomes and reducing the total cost of health care. We share CMS's view, as stated in the IFC, that "…pharmacists [should] work with physicians and NPPs in new ways that expand the availability of health care services during the COVID-19 PHE, and increase access to medication management of individuals with substance/opioid use disorder."[1] However, this is possible only if services are well-defined and providers are able to bill at a financially-sustainable level that reflects the value and intensity of the services provided.

We thank the agency for its consideration of our recommendations, and we look forward to meeting with you to discuss our shared goals higher of quality care and improved patient outcomes. Please do not hesitate to contact me if you have any questions or we can provide additional information. In the meantime, we will reach to your office to coordinate a meeting.

Sincerely,

Katherine Herring Capps
Co-Founder & Executive Director
GTMRx Institute
8230 Old Courthouse Road
Suite 420
Vienna, VA 22182
Office: 703-394-5398

CC:
Brady Brookes, Deputy Administrator and Chief of Staff
Demetrios Kouzoukas, Principal Deputy Administrator for Medicare, Director of Center for Medicare
Kimberly Brandt, Principal Deputy Administrator for Policy and Operations
Brad Smith, Deputy Administrator & Director
Michael Lipp, Chief Medical Officer, Center for Medicare and Medicaid Innovation

[17] FDA. Preventable Adverse Drug Reactions: A Focus on Drug Interactions. 2018 March 06.

Addendum A.

The GTMRx Institute is a catalyst for change that brings critical stakeholders together, bound by the urgent need to get the medications right. We are physicians, pharmacists, nurses, patients, health IT innovators, drug and diagnostics companies, consumer groups, employers, payers—aligned to save lives and save money through comprehensive medication management. By showcasing evidence and innovation, we motivate practice transformation and push payment and policy reform. Together, we ACT to champion appropriate, effective, safe, and precise use of medication and gene therapies. Learn more at **gtmr.org**.

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