August 31, 2022

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-4023-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically via: http://www.regulations.gov

Re: Medicare Request for Information on Medicare Advantage program
(Document Citation 87 46918)

Dear CMS:

Thank you for the opportunity to respond to the above-referenced request for information. The GTMRx Institute (Get the Medications Right) is a non-profit coalition of 1,700 members focused on ensuring optimal use of medication and gene therapies through interprofessional and team-based care. This is done through a scientific, evidence-based, and cost-effective decision-making processes which we refer to as comprehensive medication management (CMM).[1]

GTMRx fully supports the Vision for Medicare[2,3] to advance health equity, expand access to affordable health coverage and care, drive high quality person-centered care, promote affordability and sustainability, and the intent to engage partners and communities. We believe that CMM, implemented based on a standard, evidence-based process[4], should be a central component of CMS' future program and innovation efforts. As a recent Centers for Medicare and Medicaid Innovation Center (CMMI) funded hypertension improvement project at the University of Southern California (USC) School of Pharmacy demonstrated[5], the collaborative process between clinicians and clinical pharmacists that is central to the CMM model, can generate remarkable results. 87% of enrolled patients achieved blood pressure targets within 45 days; over 67,000 medication-related problems were identified among 5,775 patients, and all involved (clinicians, patients) reported high degrees of satisfaction. Additionally, GTMRx has published multiple use cases that highlight the benefits of CMM.[6] CMM involves much more than a focus on medication adherence or traditional medication therapy management (MTM).[7] In the USC example, medication adherence represented only 20% of the medication-related issues, while 33% of the interventions related to appropriateness/effectiveness, 20% were safety-related, and 12% involved improving patient self-management.

[1] https://gtmr.org/resources/10-steps-to-achieve-cmm/
[2] https://www.cms.gov/blog/building-cms-strategic-vision-working-together-stronger-medicare
[3] https://www.healthaffairs.org/do/10.1377/forefront.20220110.198444/full/
[4] https://gtmr.org/what-is-the-comprehensive-medication-management-process/
[5] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp- content/uploads/2022/03/Hochman_Chen_GTMRx-Issue-Brief.pdf
[6] https://gtmr.org/use-cases/
[7] https://gtmr.org/blog-cmm-vs-mtm-patient-focused-process-vs-medication-focused-activity/

We believe CMM services, delivered through interprofessional teams in collaboration with primary care clinicians, can significantly contribute to the CMS Vision for Medicare through individualized and population-based approaches that improve quality and reduce unwarranted variation in cost. The opportunity for improvement is tremendous. Approximately 68.7% of clinician visits involve drug therapies[8], 275,000 people die each year due to non-optimized medications contributing to $528B in annual costs (16% of 2016 U.S. health care spend).[3] The evidence shows that CMM improves quality of care and has an average return-on-investment of 3:1[9] to 12:1[10] when applied to patients with chronic conditions. This is because CMM goes beyond medication adherence. Rather than a focus on whether a person took their medications, CMM services are more comprehensive and look at appropriateness, safety, self-management, and other patient-specific factors including social needs, social risks, financial barriers, etc.

Based on the available evidence, well-documented use cases, and alignment with the Vision for Medicare, GTMRx urges CMS to:

1. Support team-based, interprofessional care through programs, policies, and new reimbursement models.
2. Implement GTMRx payment and policy recommendations.[11]
3. Address inequities in access to high-quality medication therapy through a National Pharmacoequity Initiative.
4. Broaden access to standardized CMM services through telehealth.
5. Pilot a "gold-card" approach to reduce the burden of prior authorization for medication when CMM is in place.
6. Support value-based payment models that encourage team-based, interprofessional care across all CMS programs.
7. Include an indication of access to a clinical pharmacist and CMM in MA plan descriptions and support development of an associated, reportable quality metric to include in Medicare Star ratings.

The remainder of our comments are organized according to specific questions from the RFI.

Advance Health Equity

RFI Question: https://www.federalregister.gov/d/2022-16463/p-16
What steps should CMS take to better ensure that all MA enrollees receive the care they need, including but not limited to the following:

- Enrollees from racial and ethnic minority groups.
- Enrollees of disadvantaged socioeconomic status.
- Enrollees who live in rural or other underserved communities.

[8] https://www.cdc.gov/nchs/fastats/drug-use-therapeutic.htm
[9] https://pubmed.ncbi.nlm.nih.gov/25329409/
[10] https://pubmed.ncbi.nlm.nih.gov/18359733/
[11] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2022/05/GTMRx-Payment-Policy-Recommendations-Discussion-Document_5.11.22.pdf

GTMRx Response: *Support team-based, interprofessional care through programs, policies, and new reimbursement models.*

When team-based care is supported through professional training, collaboration, infrastructure, and reimbursement models, people receive better, individualized care. This more personal, collaborative approach facilitates collection and use of appropriate information related to social risks, social needs, barriers to care, etc. which can lead to higher quality, more equitable care, especially for people with chronic conditions.[12] Here are two examples that highlight how clinical pharmacy services help address inequity and access to care for underserved populations:

- Incorporation of ambulatory care clinical pharmacists in interdisciplinary healthcare teams has helped address healthcare disparities in the Native Hawaiian population.[13]
- Use of clinical pharmacy services by American Indians and Alaska Native adults with cardiovascular disease[14] was associated with a 29% lower likelihood of having an elevated systolic blood pressure.

GTMRx has also published multiple use cases that highlight the benefits of person-centered, team based CMM.[15] Here are four representative use cases:

- Federally Qualified Urban Health Network (coalition of 8 FQHCs) under an ACO contract with the Minnesota Department of Human Services demonstrated an average Hemoglobin A1c reduction of 2.4% and estimated cost savings $950 - $1,169 per patient for those whose HbA1c decreased ≥ 1%.[16]
- Department of Veterans Affairs use of Clinical Pharmacist Practitioners (CPP) practicing CMM as part of the Patient-Aligned Care Teams (PACTs) initiative[17]:
    - In 2019, there were nearly 2.6M CMM interventions captured across 1.2M CPP face-to-face and virtual visits.
    - 27% of return appointments to primary care were avoided due to CMM interventions by CPP which opened access for Primary Care to other veterans.
    - Patient satisfaction was >90%.
- Kaiser Permanente, focused on people with poorly controlled diabetes mellitus.[18]
    - Intervention group had lower treatment costs ($35,740 versus $44,529), and more quality adjusted life years (5.51 versus 5.02 years) over a 10-year horizon using a Markov Model Analysis.
    - LDL-C, Hemoglobin A1c, and systolic blood pressure decreases were significantly greater at all time points over 12 months.

[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8275864/
[13] https://accpjournals.onlinelibrary.wiley.com/doi/10.1002/jac5.1681
[14] https://accpjournals.onlinelibrary.wiley.com/doi/full/10.1002/jac5.1651
[15] https://gtmr.org/use-cases/
[16] https://gtmr.org/resources/federally-qualified-urban-health-network-fuhn-use-case/
[17] https://gtmr.org/resources/department-of-veterans-affairs-va-primary-care-clinical-pharmacy-specialist-cps-practice/
[18] https://gtmr.org/resources/medication-optimization-use-case-kaiser-permanente-north-california-kpnc/

- University of Southern California School of Pharmacy: CMMI-funded pilot evaluated the impact of integration of clinical pharmacy teams into primary care clinics.[19]
    - Within 45 days, the program achieved target blood pressure in 90% of patients.
    - >67,000 medication-related problems identified in 5,775 patients included issues with appropriateness/effectiveness (33%), medication non-adherence (21%), safety (20%), and insufficient patient self-management (12%).
    - Patient satisfaction was 9.6 (out of 10).
    - Expansion of the program in September 2020 demonstrated continued positive benefits with blood pressure control, hemoglobin A1c reductions, and statin use.

RFI Question: https://www.federalregister.gov/d/2022-16463/p-26
What are examples of policies, programs, and innovations that can advance health equity in MA? How could CMS support the development and/or expansion of these efforts and what data could better inform this work?

GTMRx Response: *Implement GTMRx payment and policy recommendations.*

We believe that the foundation of primary care models tested by CMMI[20] were sound, but the execution and support for interprofessional team-based care that they attempted to advance was insufficient and a key reason for disappointing results.[21] Models in which interprofessional team-based care are embedded,[22] including clinical pharmacists providing CMM services, have demonstrated considerable positive clinical quality and financial benefits.[23,24,25]

However, the lack of a workable, consistent, and sufficient reimbursement for team-based care and clinical pharmacist-provided services such as CMM, is a significant barrier to broader implementation.[26] GTMRx produced a set of payment and policy recommendations[27] which include the following key points:

- All private and public medical benefit plans (e.g., commercial, Medicare, Medicaid, VA, Marketplace) should compensate interprofessional care teams for delivering CMM services.
- High quality, comprehensive and advanced primary care payment models should include payment to teams to deliver a comprehensive set of services, to include CMM.

[19] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2022/03/Hochman_Chen_GTMRx-Issue-Brief.pdf
[20] https://innovation.cms.gov/innovation-models#views=models&key=primary%20care
[21] https://innovation.cms.gov/strategic-direction-whitepaper
[22] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2022/03/Hochman_Chen_GTMRx-Issue-Brief.pdf
[23] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2020/11/Outcomes-of-Implementing-ED.v4-1.pdf
[24] https://www.amjmed.com/article/S0002-9343(20)31173-6/fulltext
[25] https://pubmed.ncbi.nlm.nih.gov/34032130/
[26] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2021/12/GTMR-DEC-IB-2021.v3.pdf
[27] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2022/05/GTMRx-Payment-Policy-Recommendations-Discussion-Document_5.11.22.pdf

- Recognition that value-based payment models are optimal for the provision and sustainability of CMM.
- Under Medicare and other fee-for-service models, allow physicians to bill for complex evaluation and management services provided by an appropriately trained clinical pharmacist, working in collaborative practice on the care team with the physician.
- Fully integrate companion and complementary diagnostic (e.g., pharmacogenomic) services into the CMM process to support useful clinical decision making and increased availability of data.[28]

RFI Question: https://www.federalregister.gov/d/2022-16463/p-27
Where are there gaps in health outcomes, quality, or access to providers and health care services due partially or fully to SDOH, and how might they be addressed? How could CMS, within the scope of applicable law, drive innovation and accountability to enable health care that is informed by SDOH?

GTMRx Response: *Introduce a National Pharmacoequity Initiative to address inequities in access to high-quality medication therapies.*

The Journal of the American College of Clinical Pharmacy (JACCP) recently published a special issue on health equity and clinical pharmacy.[29] An editorial in the issue points out that, "Pharmacotherapy is a major component of contemporary health care. Some estimates note that nearly 131 million Americans, or 70% of adults, are on at least one chronic medication and $370 billion are spent on prescription medications annually. Given the importance of pharmacotherapy in healthcare, equitable medication use is paramount to eliminating health disparities. However, high-quality medication use is not available to all."[30]

The JACCP issue also includes articles describing the "…ongoing transition of pharmacy from MTM [Medication Therapy Management] to more expansive patient-centered CMM responding to SDOH,"[31] and a description of a program for Native Hawaiians that incorporated clinical pharmacists into interdisciplinary healthcare teams to address healthcare disparities associated with type 2 diabetes mellitus and remote glucose monitoring.[32] An additional example of clinical pharmacists' potential role in an expanded effort to address health inequities include a telepharmacy program that addressed social determinants of health during the COVID-19 pandemic.[33]

Essien et al,[34] described achieving pharmacoequity as, "…ensuring that all individuals, regardless of race and ethnicity, socioeconomic status, or availability of resources, have access to the highest-quality medications required to manage their health needs…"

[28] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2021/09/GTMRx-PGx-and-CMM-Policy-Recommendations_6.21.21.pdf
[29] https://accpjournals.onlinelibrary.wiley.com/toc/25749870/2022/5/8
[30] https://accpjournals.onlinelibrary.wiley.com/doi/10.1002/jac5.1680
[31] https://accpjournals.onlinelibrary.wiley.com/doi/10.1002/jac5.1679
[32] https://accpjournals.onlinelibrary.wiley.com/doi/10.1002/jac5.1681
[33] https://www.sciencedirect.com/science/article/pii/S2667276621000329?via%3Dihub
[34] https://jamanetwork.com/journals/jama/fullarticle/2785584

The Inflation Reduction Act (IRA) signed by President Biden on August 16, 2022, addresses key issues that contribute to inequities related to medication costs. However, as Dr. Essien, the physician who coined the term, "pharmacoequity" concluded, U.S. policy should include, "…elimination of pharmacy deserts, and training a medical professional workforce that is without bias in its provision of clinical care."[35] In other words, the IRA is necessary but not sufficient to close equity and quality gaps.

GTMRx supports the goal to improve the quality of and access to optimal therapeutic care. Clinical pharmacists are *specialists in medicines.* CMM includes an intentional, sequential patient assessment (i.e., indication, effectiveness, safety, adherence)[36] designed to identify and help people optimize their medication regimens. Unlike MTM, CMM is a holistic approach applicable to any patient.[37] "Pharmacy deserts" referred to by Dr. Essien can be created by the physical absence of access to pharmaceuticals, but also limited accessibility to the important services that clinical pharmacists are trained to address through in-person and virtual methods (i.e., telehealth).[38,39]

GTMRx therefore supports the concept of a National Pharmacoequity Initiative which includes regulatory changes that acknowledge these issues and promote pharmacoequity through value-based care payment models that support person-centered interprofessional teams and CMM as part of delivering high-quality, comprehensive, person-centered services, equitable care.

Expand Access: Coverage and Care

RFI Question: https://www.federalregister.gov/d/2022-16463/p-39
What additional information is or could be most helpful to beneficiaries who are choosing whether to enroll in an MA plan or Traditional Medicare and Medigap?

GTMRx Response: *When presenting Medicare Advantage health plan options, indicate whether CMM services are provided through the plan and/or supported through the provider network.*

RFI Question: https://www.federalregister.gov/d/2022-16463/p-42
What role does telehealth play in providing access to care in MA? How could CMS advance equitable access to telehealth in MA?

GTMRx Response: *Broaden access to CMM services through telehealth.*

[35] https://www.statnews.com/2022/08/19/the-inflation-reduction-act-one-step-closer-to-pharmacoequity/
[36] http://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2019/06/CMM_Care_Process.pdf
[37] https://www.sciencedirect.com/science/article/abs/pii/S0002934320311736
[38] https://gtmr.org/resources/the-integration-of-telehealth-delivery-within-a-comprehensive-medication-management-practice/
[39] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8426730/

The literature supports the effectiveness CMM services via telehealth and, as noted previously, this could be part of a broader pharmacoequity initiative to address the issue of "pharmacy deserts" and suboptimal access for underserved communities to optimal medication management.

A retrospective, quality-improvement review of CMM services within the VA Healthcare System was conducted during the COVID-19 pandemic. The Patient-Aligned Care Teams (PACT) utilized telephone, VA Video Connect (VVC), and Clinical Video Telehealth (CVT) to provide services.[40] Total number of visits increased by 32% in the telehealth timeframe and no-show rate decreased by 2% with a reduction in the cancellation rate of 5% during the same timeframe. The quality of care based on A1c and blood pressure measurements was comparable to in-person encounters. Another study demonstrated the feasibility of telepharmacy services in rural and underserved communities for people with diabetes mellitus.[41] 88% of medication therapy problems were resolved; treatment intensification was the most frequent intervention recommended.

RFI Question: https://www.federalregister.gov/d/2022-16463/p-47
How do MA plans use utilization management techniques, such as prior authorization? What approaches do MA plans use to exempt certain clinicians or items and services from prior authorization requirements? What steps could CMS take to ensure utilization management does not adversely affect enrollees' access to medically necessary care?

GTMRx Response: *Pilot a "gold-card" approach to reduce the burden of prior authorization for medication when CMM is in place.*

Implement the AMA Prior Authorization and Utilization Management Reform Principles[42] and introduce federal regulation in support of a gold-card approach[43] to eliminate prior authorization requirements for a defined list of medications when clinical pharmacists are providing CMM services as part of an interprofessional team.

Drive Innovation to Promote Person-Centered Care

RFI Question: https://www.federalregister.gov/d/2022-16463/p-51
What are the experiences of providers and MA plans in value-based contracting in MA? Are there ways that CMS may better align policy between MA and value-based care programs in Traditional Medicare (for example, Medicare Shared Savings Program Accountable Care Organizations) to expand value-based arrangements?

GTMRx Response: *Support value-based payment models that encourage team-based, interprofessional care across all CMS programs.*

[40] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8426730/
[41] https://accpjournals.onlinelibrary.wiley.com/doi/abs/10.1002/jac5.1493
[42] https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf
[43] Gold-carding is exempting specific providers from prior authorization requirements if they have met certain performance measures.

Team-based care is widely recognized as the optimal approach to delivery of healthcare. It can help reduce clinician burnout, improve patient experiences[44] and quality of care.[45] The concept is hardly new—yet despite the research and literature supporting positive experiences for clinical teams and patients, the current payment models do not recognize its value or provide sufficient incentives to support its broad implementation. The important role of clinical pharmacists[46,47] on interprofessional teams is also widely acknowledged yet poorly supported by current payment models.[48]

CMS should also support training for health professionals aligned with the concept of team-based care.[49]

RFI Question: https://www.federalregister.gov/d/2022-16463/p-58
How do beneficiaries use the MA Star Ratings? Do the MA Star Ratings quality measures accurately reflect quality of care that enrollees receive? If not, how could CMS improve the MA Star Ratings measure set to accurately reflect care and outcomes?

GTMRx Response: *Include an indication of access to a clinical pharmacist and CMM in MA plan descriptions and support development of an associated, reportable quality metric to include in Medicare Star ratings.*

CMM can drive improvements in a wide range of quality metrics used to support value-based payment (VBP) models for organizations currently operating under or preparing to engage in performance-based compensation arrangements. CMM can also have a significant effect on CAHPS measures, some of which carry greater weight, including customer services, care coordination, rating of healthcare quality, achieving timely appointments, care, and information.

Given the positive effects CMM can have on clinical quality through medication optimization, CMS should include an indication of a health plan's support for CMM, and that it subsequently supports the development of metrics through which the effectiveness of CMM and contributions of clinical pharmacists are assessed and reflected as part of the MA Stars measurement set.

RFI Question: https://www.federalregister.gov/d/2022-16463/p-59
What payment or service delivery models could CMMI test to further support MA benefit design and care delivery innovations to achieve higher quality, equitable, and more person-centered care? Are there specific innovations CMMI should consider testing to address the medical and non-medical needs of enrollees with serious illness through the full spectrum of the care continuum?

GTMRx Response: *As noted previously, CMS should support value-based payment models that incentivize team-based, interprofessional care that includes CMM services provided by clinical pharmacists working in collaboration with clinicians.*

[44] https://nam.edu/implementing-optimal-team-based-care-to-reduce-clinician-burnout/
[45] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2011.0931
[46] https://www.healthaffairs.org/doi/10.1377/hlthaff.2010.0209
[47] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2012.0201
[48] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.1225
[49] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2010.0052

Support Affordability and Sustainability

RFI Question: https://www.federalregister.gov/d/2022-16463/p-64
What policies could CMS explore to ensure MA payment optimally promotes high quality care for enrollees?

GTMRx Response:

- *Support team-based, interprofessional care through programs, policies, and new reimbursement models.*
- *Implement GTMRx payment and policy recommendations.*

Please see prior responses and recommendations here and here.

RFI Question: https://www.federalregister.gov/d/2022-16463/p-66
As MA enrollment approaches half of the Medicare beneficiary population, how does that impact MA and Medicare writ large and where should CMS direct its focus?

GTMRx Response: *CMS should continue to encourage beneficiaries to move into MA and VBPM.*

However, CMS needs to support better access to care in rural communities through incentives to build rural-based clinical networks supported by advanced technology, telehealth, and interprofessional team-based care including clinical pharmacists. As a recent Health Affairs article[50] concluded, switching from Medicare Advantage to traditional Medicare was more common among rural enrollees (10.5%) compared with nonrural enrollees (5.0%), and even higher among rural enrollees who were high cost or high need. Access to care—in particular restrictive provider networks—was a key issue among beneficiaries.

Engage Partners

RFI Question: https://www.federalregister.gov/d/2022-16463/p-74
How could CMS promote collaboration amongst MA stakeholders, including MA enrollees, MA plans, providers, advocacy groups, trade and professional associations, community leaders, academics, employers and unions, and researchers?

GTMRx Response:
As noted in responses to prior questions, GTMRx firmly believes in person-centered team-based care. To that end, CMS should develop payment models that support person-centered team-based, interprofessional care and the associated educational programs to train health care professionals how to practice as teams considering the knowledge, attitude, cultural beliefs and preferences of patients.

[50] https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01435

In addition, CMS should support the development of better, person-centered, clinical quality process and outcome measures to provide better indicators through which beneficiaries can truly discern higher versus lower quality of care. In addition, CMS should differentiate measures to be used for improvement (and reporting) from measures that are linked to accountability for payment. The former category could leverage patient-reported outcomes to drive quality improvement (i.e., not for accountability); the latter, could leverage new digital quality measures to help differentiate performance on measures that matter to people and upon which CMS could build more robust value-based payment models.

In summary, CMM is part of a team-based approach in which all members of the team acknowledge and respect each other's role and unique ability to contribute to the benefits of the people who place their trust in the team. GTMRx believes that clinical pharmacists providing CMM services, in collaboration with primary care clinicians and other team members, can significantly contribute to the CMS Vision for Medicare.

We appreciate your leadership and the opportunity to comment on these important issues.

Sincerely,

Katherine Herring Capps
Co-Founder & Executive Director
GTMRx Institute