July 26, 2022

The Office of the Assistant Secretary of Health (OASH)
Primary Health Care RFI
Via Email: OASHPrimaryHealthCare@hhs.gov
Attn: Sarah Boateng

Re: Request for Information: HHS Initiative to Strengthen Primary Health Care
(Document Citation 87 FR 38168)

Dear OASH Primary Care Team:

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 organization 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 HHS Initiative to Strengthen Primary Health Care and its aim to advance health and wellness through partnerships with patients, families/caregivers, and communities to provide whole person, comprehensive care using interprofessional teams.

We believe that clinical pharmacists providing CMM services as part of interprofessional teams in collaboration with primary care clinicians can significantly contribute to advances in quality, equity, and access through individualized and population-based approaches to care that reduce unwarranted variation in cost. The opportunity for improvement is tremendous. Approximately 75% of people leave the doctor's office with a prescription,[2] 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] and evidence shows that CMM has a ROI of at least 3:1 and as high as 12:1.[4]

The remainder of our comments are organized according to three of the four specific areas of inquiry from the RFI, specifically #'s 1, 2 and 4.

1. Successful models or innovations that help achieve the goal state for primary health care
2. Barriers to implementing successful models or innovations
3. Successful strategies to engage communities
4. Proposed HHS actions

Successful models or innovations that help achieve the goal state for primary health care

The core tenets of the medical home, as articulated the American Academy of Pediatrics (1960s)[5,6] and updated through the Joint Principles of the Patient-Centered Medical Home

[1] https://gtmr.org/resources/10-steps-to-achieve-cmm/
[2] https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2016_namcs_web_tables.pdf
[3] https://pubmed.ncbi.nlm.nih.gov/29577766/
[4] https://www.jmcp.org/doi/abs/10.18553/jmcp.2014.20.12.1152
[5] https://medicalhomeinfo.aap.org/overview/Pages/Whatisthemedicalhome.aspx
[6] https://www.pcpcc.org/about/medical-home

(PCMH) (2007),[7] align with Barbara Starfield's definition of primary care[8] and subsequent policy statements by organizations including the Primary Care Collaborative,[9] Primary Care for America,[10] and the recent NASEM report.[11] Further, the key elements of the PCMH and recommendations that followed were embedded in many Center for Medicare and Medicaid Innovation (CMMI) models including Primary Care First, Comprehensive Primary Care, Comprehensive Primary Care Plus, various ACO models, and state-based innovation model projects authorized under Section 1115A of the Social Security Act.[12] Despite the concordance in concepts, the recent Innovation Center Strategy Refresh report[13] reflected on the fact that over the last ten years, "…only six out of more than 50 models launched generated statistically significant savings to Medicare and to taxpayers and four of these met the requirements to be expanded in duration and scope." Of the six cited, only three were primary care-oriented (Maryland All-Payer Model, ACO Investment Model, and Pioneer ACO Model).

We believe that the foundation of the primary care models previously tested is sound, but the execution and support for interprofessional team-based care that they attempted to advance was insufficient and a key reason for the disappointing performance.

Models—in which interprofessional team-based care, including clinical pharmacists and other health professionals, focused on individualized care—have demonstrated considerable positive benefits[14] that likely would have contributed to better performance in several of the CMMI models. Earlier work from the Primary Care Collaborative, "Integrating Comprehensive Medication Management to Optimize Patient Outcomes," offers guidance for development of team based CMM programs.[15] Evidence supports the impact of how these programs impact achievement of the Quadruple Aim.[16,17]

GTMRx has collected examples across multiple clinical settings that demonstrate the benefits of CMM.[18] 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%.[19]
- Department of Veterans Affairs use of Clinical Pharmacist Practitioners (CPP) practicing CMM as part of the Patient-Aligned Care Teams (PACTs) initiative[20]:

[7] https://www.acponline.org/acp_policy/policies/joint_principles_pcmh_2007.pdf
[8] https://www.jhsph.edu/research/centers-and-institutes/johns-hopkins-primary-care-policy-center/Publications_PDFs/A243.pdf
[9] https://www.pcpcc.org/about/shared-principles
[10] https://www.primarycareforamerica.org/wp-content/uploads/2022/03/PCfA_PC101FactSheet_FINAL.pdf
[11] https://nap.nationalacademies.org/resource/25983/Highlights_High-Quality%20Primary%20Care-4.23.21_final.pdf
[12] https://innovation.cms.gov/innovation-models/md-tccm
[13] https://innovation.cms.gov/strategic-direction-whitepaper
[14] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2020/11/Outcomes-of-Implementing-ED.v4-1.pdf
[15] https://www.pcpcc.org/sites/default/files/media/medmanagement.pdf
[16] https://www.amjmed.com/article/S0002-9343(20)31173-6/fulltext
[17] https://www.jabfm.org/content/32/4/462
[18] https://gtmr.org/use-cases/
[19] https://gtmr.org/resources/federally-qualified-urban-health-network-fuhn-use-case/
[20] https://gtmr.org/resources/department-of-veterans-affairs-va-primary-care-clinical-pharmacy-specialist-cps-practice/

  - 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 the CPP which opened access for Primary Care to other veterans.
  - Patient satisfaction was >90%.
- Kaiser Permanente, focused on people with poorly controlled diabetes mellitus.
  - 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.
- University of Southern California School of Pharmacy: CMMI-funded pilot evaluated the impact of integration of clinical pharmacy teams into primary care clinics.[21]
  - Within 45 days, the program achieved target blood pressure in 90% of patients.
  - >67,000 medication-related problems identified among 5,775 patients including issues with appropriateness/effectiveness (33%), safety (20%), medication non-adherence (21%), and insufficient patient self-management (12%).
  - Patient satisfaction as 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.

Other organizations currently taking risk under value-based contracts are demonstrating positive outcomes on quality and cost using interprofessional team-based care inclusive of clinical pharmacists and behavioral health specialists.[22] An article within the *AMA Journal of Ethics* provides an excellent example of how clinical pharmacists can contribute to health equity and reduction in health disparities, concluding, "Pharmacists' involvement in clinical preventive services, chronic disease state management, and transitions of care is vital to the elimination of health disparities."[23]

Barriers to implementing successful models or innovations

Care management in support of people with chronic, complex conditions is essential to better care, equity, and bending the cost curve. In a recent *Health Affairs* article,[24] Bodenheimer and Willard-Grace outline the case for nurses, pharmacists, and social workers to support better care for people with Type 2 diabetes mellitus. We believe the approach described for diabetes care can be generalized to other conditions, many of which are associated with a high degree of health inequities and disparities in care including but not limited to cardiovascular disease,[25] hypertension, chronic lower respiratory disease,[26] chronic pain,[27] cancer,[28] and neurologic conditions. We believe the payment regulations limiting the reimbursement options for nurse,

[21] https://16bvl028dn7zhgp35k7rzh5c-wpengine.netdna-ssl.com/wp-content/uploads/2022/03/Hochman_Chen_GTMRx-Issue-Brief.pdf
[22] https://www.ajmc.com/view/succeeding-in-value-based-payment-requires-engaging-pharmacists-from-health-plans-and-systems
[23] https://journalofethics.ama-assn.org/article/how-should-physicians-and-pharmacists-collaborate-motivate-health-equity-underserved-communities/2021-02
[24] https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2022.00227
[25] https://www.ahajournals.org/doi/10.1161/JAHA.121.023650
[26] https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2786682
[27] https://academic.oup.com/painmedicine/article/22/1/75/6046167
[28] https://www.cancer.gov/about-cancer/understanding/disparities

social worker, and pharmacist care outlined in the article are representative of key barriers to the implementation of interprofessional team-based care.

We support the full set of NASEM recommendations, with special emphasis on these implementation objectives (emphasis added):

- Pay for **primary care teams** to care for people, not doctors, to deliver services.
- Design IT that services the patient, family, **and interprofessional team.**

Proposed HHS Actions

Regulatory changes to payment and policy must be addressed before the United States can fully benefit from CMM implementation. Value-based care payment models function best when interprofessional teams are supported to deliver high-quality, comprehensive, person-centered services. We need immediate delivery system, payment, and policy transformation to enable successful interprofessional team implementation and dissemination of CMM. GTMRx recently published a paper with detailed payment policy recommendations.[29] In brief, we recommend:

1. Public medical benefit plans (Medicare, Medicaid, VA, Marketplace) should preferentially promote and compensate interprofessional care teams through value-based payment models.
2. Under fee-for-service models, allow physicians to bill for complex evaluation and management services provided by members of the interprofessional team working in a collaborative practice with the physician.
3. Implement the AMA Prior Authorization and Utilization Management Reform Principles[30] and introduce federal regulation in support of a gold-card approach[31] to eliminating prior authorization requirements for medications when clinical pharmacists are providing CMM services as part of an interprofessional team.
4. Federal and state agencies should support training programs to ensure there is a sufficient workforce of qualified interprofessional team members, including clinical pharmacists, credentialed, and privileged to provide CMM services to meet patient and population needs.

We appreciate your leadership and look forward to the HHS Action Plan. Thank you for the opportunity to respond to the Primary Health Care RFI.

Sincerely,

Katherine Herring Capps
Co-Founder & Executive Director
GTMRx Institute

[29] https://gtmr.org/wp-content/uploads/2022/05/GTMRx-Payment-Policy-Recommendations-Discussion-Document_5.11.22.pdf
[30] https://www.ama-assn.org/system/files/principles-with-signatory-page-for-slsc.pdf
[31] Gold-carding is exempting specific providers from prior authorization requirements if they have met certain performance measures.