January 26th, 2022

Honorable Congressman Rep. Tom Emmer (R-MN)
Honorable Congressman Rep. Eric Swalwell (D-CA)
Personalized Medicine Caucus
United States Congress
Attn: Right Drug Dose Now Act

Dear Congressmen Emmer and Swalwell:

We are members of the Get the Medications Right Institute (GTMRx), a multi-stakeholder organization of over 1,575+ members and 975+ companies 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 appreciate Ryan Altman, Legislative Assistant and Sarah Shapiro, Legislative Director from your respective offices for presenting to the GTMRx Precision Medicine Enablement via Advanced Diagnostics Workgroup on July 9, 2021 from 11:30-12:30 pm EST and January 10, 2022 from 3:00-4:00 pm EST. Thank you for giving us the chance to offer back recommendations.

Below you will find our comments and suggestions in order to clarify and enhance the legislation:

Section 4: Adverse Drug Event and Pharmacogenomic Testing Awareness

- Page 4, Line 6: We suggestion that you direct CMS to develop a quality measurement plan to measure the value of these services. Ideally the bill would focus on reimbursement for team-based activities for the delivery of these services.
- Page 5, Line 18: Replace "medication management" with "comprehensive medication management". Include comprehensive medication management (CMM) definition: *A systematic approach to medications where physicians and pharmacists ensure that medications (e.g., prescription, nonprescription, alternative, traditional, vitamins, 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.*[1]

CMM is much more rigorous in process and purpose, team-based, information-focused, and patient-centric than medication therapy management (MTM), which is a discrete activity typically provided under Part D. CMM is an enhanced level of service that is provided through team-based care supported

[1] 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.

via collaborative practice agreements[2] and/or credentialing, and privileging procedures to allow clinical pharmacists or other non-physicians to be officially designated as members of the medical staff. Working in collaborative practice with physicians, the medication specialist educates patients and their caregivers about medications, monitor drug therapy, and coordinate communication between patients, insurers, and interdisciplinary specialty providers.

When PGx is integrated within a CMM program, it offers interpretation of findings at the point-of-care to the prescriber. In addition, it allows for precisely fitted and delivered interprofessional medical care based on the unique characteristics of an individual patient's genetic profile plus their lifestyle and environment. As PGx testing allows for a better selection of individualized drugs, CMM as a patient-care process allows for the determination of better drug combination and proper ways to administer drugs as part of a drug regimen, in high-risk patients (e.g., multiple chronic diseases, polypharmacy).

- Page 5, Lines 16-19: Add evidence-based education to increase the public's awareness regarding comprehensive medication management (CMM).
- Page 5, Lines 20-23: Add evidence-based education to increase the public's awareness on the role of the healthcare team, using pharmacogenomics (PGx) as a patient-specific tool.
- Pages 4-6, Section 399V-7 (a/b): Although important, evidence shows that education dwindles over time unless reinforced. Include concrete action for implementation and responsibility.
- Page 8, Line 17: Include specific target populations that would be considered for these grants.
- Page 9, Line 24 to Page 10, Line 7: This section already details what the CMM process is, qualify that. P9, Line 24 could be re-worded to say "(I) when a patient is eligible for CMM and PGx testing in accordance with their healthcare team and drug product's label or professional clinical guidelines." PGx is one element for medication optimization and reducing adverse drug events.
- Section 4 overall: Because of the desire to update the National Action Plan for Adverse Drug Event Prevention, we suggest not limiting this to just PGx but clearly stating that this is for updating the ADE plan more globally beyond 4 classes of medications. Although the 4 drug classes are the major contributors, they are a small piece of the overall problem. Even within a drug class, major differences exist in the pharmacokinetics of each of these drugs, and therefore, there are major differences in drug-gene interactions. Other elements to reduce ADEs is assessment of patient characteristics and social determinants of health, concurrent medications, and medical conditions to optimize medications to improve outcomes of both safety and efficacy.

Section 5: Improving EHR Systems to Improve the Use of Pharmacogenomic Information

- Page 12, Lines 15-23 to Page 13, Lines 1-8: The guidelines to certification criteria for improving EHR systems are unclear, please expand.
- Page 13, Line 9: Consider making the reporting the responsibility of those providing CMM
- Section 5 overall: CMS should identify groups to determine appropriate and valuable PGx testing and ensure reimbursement.

[2] Under collaborative practice agreements (CPAs), clinical pharmacists are able to add, modify, and discontinue medications; order lab tests; and monitor medication regimes.

- Section 5 overall: Include the ability to access discrete PGx results via EHR. This information must be available at the point-of-care in a searchable and usable format. Medication optimization relies on comprehensive and validated data. Current health information technology systems do not capture the appropriate data needed to comprehensively manage a patient's medication regimen or evaluate whether clinical goals of therapy have been met.

Section 7: Definition

- Section 7 overall: Consider using this definition of "adverse drug event" as an injury resulting from medical interventions related to a drug.[3]

Sincerely,

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[3] Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA*. 1995:274(1):29-34. https://pubmed.ncbi.nlm.nih.gov/7791255/.