PMC 2023 POLICY AGENDA (DRAFT)

	Priority / currently engaged	*Monitor / engage if need be*	*Monitor only*
Modernizing regulatory policies	• Oversight of diagnostic tests (e.g., VALID Act, modifications)* • Post-market use of real-world evidence* • Cell- and gene-based therapies • Pharmacogenomic testing (incl. STRIPE Collaborative Community in pharmacogenomics) • Tracking FDA approvals and market authorizations	• Biomarker qualification • Co-development of diagnostics and drugs • Accelerated Approval Program • Implementation of new user fee commitments† (e.g. PDUFA, MDUFA) • Data privacy and security; genetic non-discrimination (e.g., GINA) • Artificial intelligence/machine learning-based diagnostics • Digital biomarkers • Patent protection and intellectual property law • Orphan Drug Designation • Direct-to-consumer genetic tests • Global regulatory policies (harmonize with FDA)	
Modernizing coverage and payment policies	• Genetic and genomic testing services (e.g., *Precision Medicine Answers for Kids Today Act*)* • Ensuring drug pricing reforms/implementation do not endanger innovation and access to personalized medicine (e.g., *Inflation Reduction Act*)* • Novel approaches to facilitating coverage and reimbursement (e.g., TCET pathway, parallel review) • Value-based and outcomes-based payment models incentivizing innovation and access to personalized medicine • Telehealth and restrictions on “high-cost laboratory tests”	• Diagnostic testing (e.g., national coverage determinations, laboratory date of service policy, *PAMA* implementation)* • Coverage, reimbursement, and equitable access to preventive screening, early disease detection, and other novel tools advancing personalized medicine* • Benefit design reforms (e.g., prior authorization for diagnostics/LBMs, step therapy) • Cell- and gene-based therapies (e.g., CAR-T)	

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	Priority / currently engaged	*Monitor / engage if need be*	*Monitor only*
Advancing innovation in care delivery and value of personalized medicine	• Development and use of real-world evidence* • Clinical guidelines* • Value assessment frameworks and methodologies, or impact Medicare negotiation of personalized medicines • Access to genetic counselors (e.g., *Access to Genetic Counselor Services Act*) • NAS study on use of genetic/genomic testing to improve outcomes	• Advancing a patient-centered outcomes research agenda for PM • Patient-centered data sharing • Quality measures • Clinical trial enrollment rates; diagnostic testing treatment arms in trials • Clinical-decision support tools • Interoperability standards • Tissue-agnostic diagnosis and treatment	• Expanded role for pharmacists
Cultivating support for personalized medicine	• Congressional Personalized Medicine Caucus* • Cures 2.0* • Diversity and inclusion in research, clinical trials • FDA appropriations • NIH appropriations	• Biden administration initiatives (e.g., ARPA-H, Cancer Moonshot)	

***** *an asterisk indicates PMC members rated this issue as a high priority*
† *these user fee commitments include advancing real-world evidence, novel clinical trial designs (e.g., decentralized, adaptive trials), patient-focused drug development, digital health technologies, and FDA staffing needs*

Additional Resources

- For more information on PMC's previous work on these topics, please visit the "Policy" section of our website here. The issue categories in the left sidebar will direct you to respective archives of comments.
- This policy agenda relates mainly to PMC's advocacy activities. More information about PMC's initiatives in education and evidence development, are outlined in our *2023 Strategic Plan*.
- PMC has multiple forums convening its members to discuss policy issues and advocate for personalized medicine. This includes the Public and Science Policy Committees; working groups convening patients, industry, and health care professionals; as well as working groups for special projects. For more information about these forums, please visit our website here and contact David Davenport at ddavenport@personalizedmedicinecoalition.org to join. We also encourage you to let us know if you have subject matter expertise on a specific policy issue above.