PMC 2022 POLICY AGENDA

	Priority / currently engaged	*Monitor / engage if need be*	*Monitor only*
Modernizing regulatory policies	• Oversight of diagnostic tests (e.g. VALID Act, modifications)* • Engaging user fee amendments reauthorization (e.g. PDUFA, MDUFA) to advance novel clinical trial designs (e.g. decentralized, adaptive trials), patient-focused drug development, patient preferences in medical device evaluation, digital health technologies, real-world evidence, expedited approval pathways, and FDA staffing needs* • Cell- and gene-based therapies • Pharmacogenomic testing (incl. STRIPE Collaborative Community in pharmacogenomics) • Tracking FDA approvals and market authorizations	• Co-development of diagnostics and drugs* • Biomarker qualification • Genetic non-discrimination (e.g. GINA) • Artificial intelligence/machine learning-based diagnostics • Digital biomarkers • Direct-to-consumer genetic tests • Patent protection and intellectual property law • Global regulatory policies (harmonize with FDA) • Orphan Drug Designation	
Modernizing coverage and payment policies	• Genetic and genomic testing services (e.g. Sec. 407 of Cures 2.0)* • Payment models incentivizing innovation (e.g. value-based and outcomes-based payment, alternative payment models, CMMI demos impacting Part D and Part B; guardrails for CMMI; financing high-price, high-impact therapies; Oncology Care First payment model)* • Novel approaches to facilitating coverage and reimbursement (e.g. successor to MCIT pathway, parallel review) • Ensuring drug pricing proposals do not endanger access to PM (e.g. reference pricing/ “Most Favored Nation,” Part B to Part D Switch)	• Diagnostic testing (e.g. clinical lab fee schedule, laboratory date of service policy, PAMA implementation)* • Next generation sequencing diagnostic tests (e.g. NCD for NGS in Advanced Cancer)* • Preventive screening and early disease detection • Benefit design reforms (e.g. prior authorization for diagnostics, step therapy) • Cell- and gene-based therapies (e.g. CAR-T) • Telehealth and remote/home-based care	

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	Priority / currently engaged	*Monitor / engage if need be*	*Monitor only*
Advancing innovation in care delivery and value of personalized medicine	• Use of real-world evidence* • Clinical guidelines • Value assessment frameworks and methodologies • Advancing a patient-centered outcomes research agenda for PM • NAS study on use of genetic/genomic testing to improve outcomes	• Clinical trial enrollment rates; diagnostic testing treatment arms in trials • Utilization management (e.g. clinical-decision-making tools) • Quality measures • Tissue-agnostic diagnosis and treatment • De-identified data • Interoperability and data management • Access to genetic counselors (e.g. Access to Genetic Counselor Services bill)	• 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	• New initiatives in Biden administration (e.g. ARPA-H)	• Impacts of COVID-19 (reduction in preventive screening and biomarker testing, pre-submissions to FDA)

***** *an asterisk indicates PMC members rated this issue as a high priority*

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 *2022 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.