PMC 2020 Policy Agenda

	Priority / currently engaged	*Monitor / engage if need be*	*Monitor only*	*Not a priority*
Modernizing regulatory policies	• Oversight of diagnostic tests (e.g. VALID Act, modifications)* • Pharmacogenomic testing* • Tracking FDA approvals and market authorizations	• Co-development of diagnostics and drugs* • Cell- and gene-based therapies • Direct-to-consumer genetic tests • Patient-focused drug development • Genetic non-discrimination (e.g. GINA) • Digital biomarkers • Patent protection and intellectual property law • Biomarker qualification • Patient preferences in medical device evaluation • Digital health technologies • Orphan Drug Designation • Global regulatory policies (harmonize with FDA) • User fee amendments reauthorization (e.g. PDUFA, MDUFA, BsUFA)		
Modernizing coverage and payment policies	• Next generation sequencing diagnostic tests (e.g. NCD for NGS in Advanced Cancer)* • Cell- and gene-based therapies (e.g. CAR-T) • Novel approaches to facilitating coverage and reimbursement (e.g. parallel review) • Ensuring drug pricing proposals do not endanger access to PM (e.g. IPI, Part B to Part D Switch) • 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)	• Benefit design reforms (e.g. prior authorization for diagnostics, step therapy) • Sequencing services • Preventive screening and early disease detection • Clinical lab fee schedule • PAMA implementation	• "Surprise" medical bills	

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Advancing innovation in care delivery and value of personalized medicine	• Clinical guidelines* • Value assessment frameworks and methodologies* • NAS study on use of genetic/genomic testing to improve outcomes • Setting a patient-centered outcomes research agenda for PM • Tissue-agnostic diagnosis and treatment • Access to genetic counselors (e.g. Access to Genetic Counselor Services bill) • Use of real-world evidence	• Utilization management (e.g. clinical-decision-making tools) • Clinical trial enrollment rates; diagnostic testing treatment arms in trials • Quality measures • Interoperability and data management	• De-identified data	
Cultivating support for personalized medicine	• Congressional Personalized Medicine Caucus* • FDA appropriations • NIH appropriations	• PCORI re-authorization implementation • Collaborative community in pharmacogenomics		

***** 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. For more information about PMC's initiatives in education and evidence development, download of copy of our 2020 Strategic Plan here.
- 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 contact David Davenport at ddavenport@personalizedmedicinecoalition.org.