PMC 2019 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) • Tracking FDA approvals and market authorizations • Educating the public about direct-to-consumer genetic tests	• Cell- and gene-based therapies • Co-development of diagnostics and drugs • Digital biomarkers • Digital health technologies • Global regulatory policies (harmonize with FDA) • Legislation impacting GINA • Orphan Drug Designation • Patient-focused drug development	• Biomarker qualification	• Patent protection and intellectual property law
Modernizing coverage and payment policies	• Next generation sequencing diagnostic tests • CAR-T and other cell- and gene-based therapies • Payment models incentivizing innovation (e.g. value-based and outcomes-based payment, alternative payment models, CMMI demos impacting Part D and Part B) • Ensuring policy proposals do not endanger access to PM (e.g. Part B to Part D Switch, IPI) • Novel approaches to facilitating coverage and reimbursement (e.g. parallel review)	• Clinical lab fee schedule • NCD on NGS for Advanced Cancer • PAMA implementation		
Advancing innovation in care delivery and value of personalized medicine	• Value assessment frameworks and methodologies • Utilization management (e.g. clinical-decision-making tools, step therapy) • Clinical guidelines • Use of real-world evidence • Setting a patient-centered outcomes research agenda for PM	• Quality measures • Related legislative initiatives (e.g. *Advancing Access to Precision Medicine*)	• De-identified data	• Health information technologies

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	Priority / actively engaged	*Monitor / engage if need be*	*Monitor only*	*Not a priority*
Cultivating support for personalized medicine	• Establishing a Congressional PM Caucus • NIH and FDA appropriations	• Collaborative communities at FDA's CDRH • PCORI re-authorization		

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 2019 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.