

## PMC 2024 POLICY AGENDA

	<i>Priority / currently engaged</i>	<i>Monitor / engage if need be</i>	<i>Monitor only</i>
<b>Modernizing regulatory policies</b>	<ul style="list-style-type: none"> <li>• Oversight of diagnostic tests (e.g., FDA rulemaking, VALID Act, modifications)*</li> <li>• Regulatory use of real-world evidence*</li> <li>• Pharmacogenomic testing (incl. STRIPE Collaborative Community in pharmacogenomics)</li> <li>• Artificial intelligence/machine learning-based technologies</li> <li>• New user fee commitments (e.g. PDUFA, MDUFA)</li> <li>• Tracking FDA approvals and market authorizations</li> </ul>	<ul style="list-style-type: none"> <li>• Co-development of diagnostics and drugs</li> <li>• Biomarker qualification; digital biomarkers</li> <li>• Orphan Drug Designation</li> <li>• Data privacy and security; genetic non-discrimination</li> <li>• Global regulatory policies (harmonize with FDA)</li> </ul>	
<b>Modernizing coverage and payment policies</b>	<ul style="list-style-type: none"> <li>• Genetic and genomic testing services (e.g., <i>Precision Medicine Answers for Kids Today Act</i>)*</li> <li>• Ensuring drug pricing reforms/implementation do not endanger innovation and access to personalized medicine (e.g., Medicare drug price negotiation)*</li> <li>• Medicare initiatives to modernize coverage pathways and evidence review (e.g., TCET pathway, parallel review, CED)</li> <li>• Value-based and outcomes-based payment models incentivizing innovation and access to personalized medicine</li> <li>• Access to genetic counselors (e.g., <i>Access to Genetic Counselor Services Act</i>)</li> </ul>	<ul style="list-style-type: none"> <li>• Diagnostic testing (e.g., national coverage determinations, <i>PAMA</i> implementation)</li> <li>• Coverage, reimbursement, and equitable access to preventive screening, early disease detection, and other novel tools advancing personalized medicine</li> <li>• Benefit design reforms (e.g., prior authorization for diagnostics, step therapy)</li> <li>• Cell- and gene-based therapies (e.g., CAR-T)</li> <li>• Telehealth and restrictions on “high-cost laboratory tests”</li> </ul>	

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	<i>Priority / currently engaged</i>	<i>Monitor / engage if need be</i>	<i>Monitor only</i>
<b>Advancing innovation in care delivery and value of personalized medicine</b>	<ul style="list-style-type: none"> <li>• Development and use of real-world evidence</li> <li>• Value assessment frameworks and methodologies, or impact Medicare negotiation of personalized medicines</li> </ul>	<ul style="list-style-type: none"> <li>• Access to biomarker testing*</li> <li>• Clinical guidelines*</li> <li>• Quality measures</li> <li>• Patient-centered data sharing and policy incentives for equity, trust and transparency</li> </ul>	<ul style="list-style-type: none"> <li>• Interoperability standards</li> </ul>
<b>Cultivating support for personalized medicine</b>	<ul style="list-style-type: none"> <li>• Congressional Personalized Medicine Caucus*</li> <li>• FDA appropriations</li> <li>• NIH appropriations</li> </ul>	<ul style="list-style-type: none"> <li>• Diversity and inclusion in research, clinical trials and health data</li> <li>• Biden administration initiatives (e.g., ARPA-H, Cancer Moonshot)</li> </ul>	

\* 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 [2024 Strategic Plan](#).
- PMC has multiple forums convening its members to discuss policy issues and advocate for personalized medicine. This includes our 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](#) and contact David Davenport at [ddavenport@personalizedmedicinecoalition.org](mailto: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.