PMC 2026 POLICY AGENDA

	High Priority / ongoing engagement	*Priority / engage*	*Monitor /engage if need be*
Modernizing regulatory policies	• Improving frameworks for oversight of diagnostic tests • Addressing challenges with existing regulatory pathways for cell and gene therapies • Advancing the use of real-world evidence in regulatory decision making • Shaping frameworks for federal oversight of the development and use of artificial intelligence/machine learning-based technologies • Harmonizing global regulatory policies with the US FDA's when appropriate	• Supporting improved coordination to review drugs and their companion diagnostics • Advocating PDUFA VIII/MDUFA VI priorities that support personalized medicine (e.g., increased staffing, improved consistency of review/communication, biomarker qualification, Rare Disease Hub, guidance development) • Advocating national data privacy, security, and sharing policies that promote innovation while protecting patient access and genetic non-discrimination	• Pursuing consensus and standards development for pharmacogenomic testing (e.g., STRIPE Collaborative Community)
Modernizing coverage and payment policies	• Supporting legislation to expand Medicare and Medicaid coverage of genetic testing, genomic and exome sequencing services, and biomarker testing • Ensuring drug pricing reforms/implementation do not endanger innovation and access to personalized medicine (e.g., Medicare drug price negotiation, legislative fixes to *Inflation Reduction Act*, foreign reference pricing) • Supporting expanded coverage, reimbursement, and access to preventive screening, early disease detection, and other novel tools advancing personalized medicine • Modernizing coverage and reimbursement frameworks fostering uptake of artificial intelligence/machine learning-based technologies • Addressing access barriers to personalized medicine for patients by streamlining prior authorization for diagnostics and drugs, opposing step therapy, maintaining coverage for telehealth	• Ensuring a transparent, uniform and effective process for reimbursement of diagnostic testing services including national coverage determinations and reforms to the *Protecting Access to Medicare Act* • Accelerating Medicare initiatives, coverage pathways and care models intended to improve access (e.g., value/outcomes-based payment, FDA/CMS parallel review, TCET and CED) • Weighing in on coverage and reimbursement policies for cell- and gene-based therapies that limit patient access to approved products	• Supporting reforms to the U.S. Preventive Services Task Force (USPSTF) evidence review processes

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Advancing innovation in care delivery and value of personalized medicine	• Supporting the development and use of real-world evidence in evaluations of clinical utility and cost effectiveness of personalized medicine • Advocating the update and implementation of clinical guidelines and quality measures relevant to personalized medicine • Advancing policies that improve access to genetic counselors and pharmacists who guide personalized medicine (e.g., *Access to Genetic Counselor Services Act*)	• Supporting the revision of methodologies for value assessment that account for and incorporate personalized medicine principles and practices (e.g. ICER) • Improving diversity, equity, and inclusion in research, clinical trials, and health data	• Clarifying laboratory date of service policy/14-day rule for providers
Cultivating support for personalized medicine	• Educating members of Congress and congressional staff through the Congressional Personalized Medicine Caucus	• Securing increased appropriations for research underpinning personalized medicine at the NIH • Balancing increased FDA appropriations with user fee funded activities that impact personalized medicine	• Demonstrating the impact of agency-wide initiatives on personalized medicine (e.g., NIH reform, FDA Reform, ARPA-H)

Additional Resources

- For more information on PMC's previous work on these and other related issues, please visit the "Policy" section of our website here. The topic 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 on www.personalizedmedicinecoalition.org.
- PMC has multiple forums convening its members to discuss policy issues and advocate for personalized medicine. This includes our Public and Science Policy Committees; ad hoc 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 Cynthia Bens at cbens@personalizedmedicinecoalition.org to join. We also encourage you to let us know if you have subject matter expertise on a specific policy issue above.