

PUBLIC AND SCIENCE POLICY COMMITTEES MEETING AGENDA

Thursday, June 9, 2022, 12:00 – 2:00 p.m. ET

Link to webinar:

<https://permedcoalition.webex.com/permedcoalition/onstage/g.php?MTID=eacd2d40e98f578caf0b706876cb5376d>

(passcode: pmc123)

Dial 202-800-9984 and enter meeting ID 825756.

Note: You will be muted upon entry. Please dial 4* to unmute your line.

12:00 p.m. ET **Welcome & Introduction**

Edward Abrahams

President

Personalized Medicine Coalition

12:05 p.m. ET **Exploring the Potential Impact of a Transitional Coverage for Emerging Technologies (TCET) Pathway**

- **Steven Farmer, M.D., Ph.D.**
Chief Strategy Officer for Coverage and Senior Medical Officer
Center for Clinical Standards and Quality
Centers for Medicare and Medicaid Services

12:35 p.m. ET **Business Meeting**

Daryl Pritchard, Ph.D.

Senior Vice President, Science Policy

Personalized Medicine Coalition

- **Science Policy Updates**
 - **PMC's [Research Program for Advancing Personalized Medicine in 2022](#)**
 - Study No. 8: "Addressing Practice Gaps in the Implementation of Personalized Medicine in Cancer Care"
 - Study No. 9: "Addressing Disparities in Research Advancing Personalized Medicine"

- **Working Group Updates**

- Health Data Working Group
 - *American Data Privacy and Protection Act* ([discussion draft](#) with [section-by-section summary](#))
- Pharmacogenetics Working Group

Cynthia A. Bens

Senior Vice President, Public Policy
Personalized Medicine Coalition

- **Public Policy Updates**

- **Congressional Activities**

- [Congressional Personalized Medicine Caucus](#)
- User fee program reauthorization ([House Energy and Commerce bill](#); [Senate HELP bill](#) with [section-by-section summary](#))
 - PMC [remarks](#) during FDA's *Public Meeting on the Fifth Reauthorization of the Medical Device User Fee Act* (April 21, 2022)
 - PMC [remarks](#) during FDA's *Public Workshop on the Seventh Reauthorization of the Prescription Drug User Fee Act* (September 28, 2021)
- FY 2023 appropriations for FDA and NIH
 - PMC [outside witness testimonies](#) (May 2022)

- **Regulation**

- FDA [Draft Guidance](#) on *Use of Circulating Tumor Deoxyribonucleic Acid for Early-Stage Solid Tumor Drug Development*

- **Coverage and Reimbursement**

- CMS' Transitional Coverage for Emerging Technologies (TCET) pathway
CMS' payments for CAR-T cell therapy under Inpatient Prospective Payment Systems (IPPS) [proposed rule](#) for FY 2023
- CMS' proposed discontinuation of ICD-10 "not otherwise specified" (NOS) codes for coverage of next-generation sequencing (NGS)-based genetic testing under National Coverage Determination (NCD) 90.2
 - PMC [comment letter](#) (May 5, 2022)

- **Tracking PMC members' policy issue expertise**
- **Working Group Updates**
 - Pharmaceutical & Diagnostics Working Group
 - Patient Advocacy Organization Working Group

1:50 p.m. ET New Business

2:00 p.m. ET Conclusion