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Women's Health at a Turning Point: What Federal Policy Changes Mean for the FemTech Industry

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VIEWPOINT TOPICS

- Health Care

For decades women's health has too often been treated as a narrow policy category, despite affecting roughly half the population.

That is changing. There is now an emerging category of medicine built around regulated software, biomarker-based decision-making, and new regulatory and reimbursement pathways. FemTech now spans menstrual health, fertility, pregnancy and postpartum care, pelvic and sexual health, menopause, contraception, and conditions that affect women differently or disproportionately. As apps, wearables, connected devices, and digital platforms move health data and clinical decisions closer to users, they also raise new questions about protecting sensitive reproductive and women's health data. The industry is no longer a niche; it now intersects directly with federal executive action and congressional work. For founders, investors, and health systems, fertility policy offers the clearest early signal of where Washington may shape the broader FemTech market first.

Fertility Policy as an Early Signal for the Broader FemTech Market

In February 2025, the President signed **Executive Order 14216**, directing the Domestic Policy Council to recommend ways to expand access to in vitro fertilization and reduce out-of-pocket costs within 90 days. The order did not create new coverage mandates or legal rights on its own; it directed a policy review.

Implementation has unfolded in stages. In October 2025, the administration announced a most-favored-nation pricing agreement with EMD Serono for common IVF medications, with reported discounts of up to 84 percent off list prices for drugs such as Gonal-f, Ovidrel, and Cetrotide. The Department of Labor (DOL) has also proposed a new “excepted benefit” category that would allow employers to offer standalone fertility benefits outside a group health plan, including a capped contribution model reportedly set at $2,150 for 2025. The structure is similar to the way dental, or vision coverage is often offered. The administration has described TrumpRx, a direct-to-consumer drug-pricing platform launched in February 2026, as part of the same affordability effort.

Congressional responses to these actions have been mixed. Some members, including Sen. Katie Britt, have **publicly supported** the executive order as a step toward expanding IVF access. Others, including Sens. **Patty Murray** and **Tammy Duckworth**, have said the order does not go far enough without accompanying legislation requiring insurance coverage. The American Society for Reproductive Medicine has published **its own analysis** noting open questions about how the excepted-benefit proposal will be implemented and what it will mean for equitable access.

For companies building fertility tracking, cycle prediction, or fertility-benefits navigation tools, these changes are worth tracking closely: lower drug costs and a new employer benefits pathway both have the potential to expand the addressable population for these products, though the practical effect will depend on final rulemaking and employer uptake.

While IVF and fertility policy are currently receiving the most visible federal attention, the implications extend well beyond fertility alone. Companies working in menopause, pelvic health, maternal mental health, contraception, diagnostics, benefits navigation, and longitudinal women's health data will face many of the same questions around Food and Drug Administration (FDA) review, reimbursement, employer adoption, privacy, and congressional engagement.

Congress Holds the Pen on the Issues That Matter Most for Scaling This Industry

Executive action can move quickly, but many of the issues most important to FemTech's long-term growth remain with Congress. IVF and fertility-benefit bills have drawn both Republican and Democratic sponsors, though none has passed both chambers. The Senate HELP Committee's work on 340B reform and ongoing congressional interest in FDA digital health authorities, rooted in the 21st Century Cures Act, will directly affect how FemTech products are reviewed, reimbursed, and brought to market. Companies that make congressional engagement a core part of their strategy — not an afterthought to executive branch advocacy — will be better positioned as these authorities evolve.

Data Privacy Remains This Industry's Largest Unresolved Regulatory Risk

The federal outlook for this industry cannot be understood without addressing its largest unresolved regulatory gap: most consumer-facing fertility and cycle-tracking apps are not subject to HIPAA because they are not considered covered entities or business associates under the law. That gap has already led to enforcement activity under the Federal Trade Commission's Health Breach Notification Rule and the widely cited **$200,000 penalty** against the Premom app for sharing fertility data with Google and Chinese analytics firms. Since the *Dobbs* decision, state attorneys general and plaintiffs' firms have paid closer attention to reproductive health data. Although HIPAA updates finalized in April 2024 (and subject to subsequent litigation) added new protections for reproductive health information held by covered entities, those safeguards do not reach most consumer-facing apps. Companies that treat privacy architecture and data minimization as core design principles — not compliance afterthoughts — will be better positioned across administrations, especially if Congress or the Department of Health & Human Services (HHS) acts to close the HIPAA gap through legislation or rulemaking.

Shaping the Next Phase of Women's Health Innovation

Federal policy is no longer a backdrop for women's health innovation; it is becoming one of the forces that will define how the market grows. Executive action on fertility access and drug costs, together with bipartisan congressional attention to FDA digital health authority, benefits design, privacy, reimbursement, and drug pricing, is beginning to shape the operating environment for the broader FemTech market. Fertility policy may be the leading edge, but the same questions will increasingly affect companies in menopause, pelvic health, maternal mental health, contraception, diagnostics, benefits navigation, and other women's health categories.

For women's health innovators, investors, and health systems, the imperative is clear: do not wait for federal policy to settle before engaging. The rules now taking shape at HHS, DOL, FDA, the FTC, and in Congress will influence access, adoption, trust, reimbursement, and scale. Companies that engage early can help shape those rules, anticipate risk, and turn policy into a competitive advantage. For the next generation of women's health companies, federal engagement should not sit at the edge of the business strategy; it should be part of how the market is built.

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