Advancing Prescription Drug Use-Related Software: Priorities for Updated FDA Guidance

Patients and caregivers are increasingly seeking reliable digital health information to empower better-informed medical decisions. At the same time, innovative pharmaceutical companies are actively developing software and mobile applications designed to be used in conjunction with prescription medicines to enhance clinical benefit, promote safety, and optimize the patient experience.

As these software-enabled approaches continue to evolve, clear regulatory pathways are needed to ensure that clinically validated digital tools can be appropriately integrated with prescription medicines and that their benefits can be communicated transparently to patients and healthcare providers.

In 2023, the Food and Drug Administration (FDA) published draft guidance for Prescription Drug Use-Related Software (PDURS), describing how the Agency intends to apply its drug labeling authorities to certain software outputs disseminated by or on behalf of a drug sponsor for use with a prescription drug or biologic product. The PDURS framework builds upon FDA's original 2018 proposal, which was intended to promote the development of digital technologies that can help guide the safe and effective use of medicines, help patients improve their health, and modernize FDA's approach to overseeing software designed to be used in conjunction with prescription drugs. As the framework moves toward finalization, ensuring clarity, predictability, and alignment with this original intent will be critical to enabling responsible innovation and patient benefit.

Potential PDURS products could include software that supports medication adherence, delivers behavioral or cognitive interventions that enhance treatment effectiveness, monitors symptoms or side effects, or provides dosing and administration guidance tied to a specific therapy. In some cases, PDURS may also incorporate digital biomarkers, remote monitoring, or AI-enabled decision support to help clinicians and patients optimize treatment over time.

The Opportunity Presented by PDURS

PDURS has the potential to transform healthcare delivery by aligning the interests of all stakeholders around what matters most: patient outcomes. By enabling digital solutions tailored to specific medications, PDURS creates optimized treatment experiences that directly improve patient health and wellbeing. It provides pharmaceutical companies with an opportunity to differentiate their products by pairing medicines with clinically validated software that can improve adherence, strengthen therapeutic outcomes, and support patient engagement with treatment. Importantly, PDURS also empowers providers to, at their discretion, deploy these solutions to patients who need them most, without adding cost or administrative burden.

The PDURS framework is also notable for its deregulatory nature. By allowing certain software outputs to be included in drug labeling and providing more flexibility than the traditional combination product framework, PDURS supports innovation while maintaining appropriate FDA oversight.

This approach recognizes the favorable benefit-risk profile of many software-based interventions and avoids imposing unnecessary regulatory burden on low-risk digital solutions.

The Policy Challenge

While the PDURS framework enjoys broad support, several provisions of the FDA's 2023 draft guidance introduce ambiguity that could stifle innovation and depart from the original vision and intent of the 2018 PDURS draft guidance.

Recent public comments submitted to FDA have emphasized that most PDURS solutions currently under development are standalone software functions that achieve their intended purpose without connection to medical device hardware or to a device constituent part of a combination product. These solutions may provide, for example, behavioral and cognitive interventions, psychoeducation, adherence support, symptom tracking, personalized dosing support, and other approaches that can provide clinically meaningful benefit when used alongside prescription drugs. PDURS may include well established types of software including digital therapeutics, clinical decision support, predictive algorithms, remote monitoring, and digital biomarkers,

However, the 2023 draft guidance places disproportionate emphasis on device-connected software and introduces concepts, such as suggesting software be “essential for the safe and effective use” of a drug, that were not central to the original PDURS framework. This shift risks overlooking the very categories of software that are of greatest interest to pharmaceutical manufacturers and that hold the most immediate promise for improving patient outcomes.

In addition, the draft guidance leaves critical questions unanswered with respect to evidence generation, regulatory pathways, and early engagement with FDA. This lack of clarity creates uncertainty that will slow adoption, discourage investment, and delay patient access to innovative PDURS solutions. Pharmaceutical companies are highly enthusiastic about the PDURS framework and its potential to improve patient outcomes; however, regulatory certainty is essential for sponsors to justify the significant investments required to develop PDURS solutions and to conduct the clinical studies needed to validate them.

The Need for Updated Guidance

ATA Action encourages FDA to publish updated PDURS guidance that reflects the recent industry consensus informed by public comments to the draft framework. These comments consistently called for:

- Regulatory flexibility with respect to requirements for evidence generation, consistent with FDA’s risk-based approach to digital health;
- Clear recognition that standalone software can provide a clinically meaningful benefit to a prescription drug and be appropriately included in FDA-required labeling; and
- Greater clarity regarding terminology, submission options, and regulatory expectations to encourage high-quality, innovative submissions.

Separately, FDA's draft guidance explains that, where a generic or biosimilar sponsor proposes prescription drug use-related software, FDA will evaluate the proposed product and labeling under the existing statutory and regulatory frameworks governing abbreviated new drug applications and biosimilar licensure.

We agree that PDURS should not in any way stifle follow-on competition and welcome FDA's further clarification in updated guidance to ensure that established pathways for generics and biosimilars are preserved, while enabling outcomes-based differentiation through clinically validated software.

With these clarifications in place, updating the PDURS guidance in a manner that restores the deregulatory intent of the 2018 framework will provide a consistent, predictable, and innovation-friendly regulatory environment while maintaining FDA's high standards for safety and effectiveness. ATA Action submitted a comprehensive public comment in October 2025 that captures the specific changes recommended by pharmaceutical manufacturers and digital health companies that are members of ATA.

PDURS Policy Principles

As digital health technologies continue to evolve, PDURS has emerged as a transformative force in modern healthcare. These tools represent a new frontier in personalized medicine, clinical decision support, and patient engagement. The ATA and ATA Action support a policy environment that fosters innovation, ensures patient safety, and promotes access to high-quality care through the use of PDURS. Our guiding policy principles, summarized below, ensure that software-based solutions are integrated responsibly, effectively, and with a patient-first approach.

1. **Make Medicine Personal** — Prioritize patient-centered care through personalized treatments, better data integration, and tools that address whole-person health.
2. **Empower Stakeholders** — Improve clinical decision-making, support patient autonomy, enhance provider capabilities, and align with healthcare organizations' goals.
3. **Improve Clinical Outcomes** — Ground innovations in evidence to enhance safety, efficacy, chronic disease management, preventive care, and support for clinical trials.
4. **Increase Care Value** — Optimize care delivery, ensure access in underserved communities, and reduce preventable complications and hospitalizations.
5. **Establish a New Innovation Category** — Build supportive regulatory frameworks, complement traditional therapeutics, and align with national AI strategies.
6. **Support Holistic and Preventive Care** — Integrate lifestyle medicine, mental health support, and behavioral interventions across the care continuum.

Read the full ATA Policy Principles for Prescription Drug Use-Related Software (PDURS)

Conclusion

PDURS represents a timely opportunity to modernize how prescription medicines and software are regulated in a way that improves patient outcomes, supports responsible innovation, and avoids unnecessary regulatory burden.

There is growing alignment across patient advocacy organizations, provider groups, policymakers, pharmaceutical manufacturers, and software developers that clinically validated software can play an important role in improving the safety and effectiveness of drug therapy when paired appropriately with prescription medicines.

With this momentum in place, the next step is clear. FDA, in coordination with the Department of Health and Human Services (HHS), is well positioned to update the PDURS guidance in a manner that reflects the current Administration's stated priorities focused on removing unnecessary regulatory barriers, promoting innovation, and improving patient access to effective health technologies. Updated guidance that realigns with the original vision articulated in the 2018 PDURS framework -- enabling software to help guide the safe and effective use of medicines while providing sponsors flexibility under appropriate FDA oversight -- will allow evidence-based software to be responsibly integrated with prescription medicines and translated into real-world patient benefit.