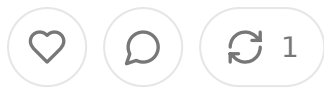


HHS's legislative agenda over the next 6-12 months and the opportunities for healthcare product leaders

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The regulatory agenda from the U.S. Department of Health and Human Services outlines key priorities for the healthcare sector. Here is HHS's legislative agenda for the next 6-12 months and the opportunities for healthcare product leaders in this space:

Understanding HHS's Regulatory Agenda

The Department of Health and Human Services (HHS) serves as the federal government's primary entity for promoting public health and advancing the development of healthcare products and services. HHS's regulatory agenda provides crucial insights into forthcoming changes in healthcare policies, payment systems, and compliance standards. These regulations affect stakeholders across the healthcare continuum, including payers, providers, pharmaceutical companies, and medical device manufacturers.

Key HHS Regulatory Proposals

Based on the agenda and priorities laid out, here are the most impactful potential regulatory actions for healthcare product leaders:

1. Nondiscrimination in Health Programs or Activities

HHS intends to expand protections under Section 1557 of the Affordable Care Act, which prohibits discrimination in healthcare based on race, color, national origin,

age, or disability. This initiative emphasizes improving access and equity in health systems.

- **Implications for Healthcare Product Leaders:**

- Vendors developing health IT or patient engagement tools must ensure their platforms comply with accessibility and non-discrimination standards, particularly for individuals with disabilities or limited English proficiency.
- Diversity and inclusivity must be prioritized in clinical trials and product design.

2. 21st Century Cures Act Implementation

The Office of the National Coordinator for Health Information Technology (ONC) is advancing interoperability rules and addressing information blocking. These rules will likely modify certification requirements for health IT developers and promote better data sharing across platforms.

- **Opportunities:**

- Health IT developers should prepare for expanded requirements under the ONC **Health IT Certification Program**, ensuring their systems align with interoperability standards.
- Vendors offering patient data-sharing solutions can capitalize on increased demand for secure, compliant technologies that enhance information flow.

3. Changes to HIPAA Privacy Rules

HHS is revisiting provisions related to the Health Insurance Portability and Accountability Act (HIPAA), potentially easing the acknowledgment requirements for providers and enhancing data-sharing for care coordination.

- **Key Actions for Leaders:**

- Assess your organization's data privacy protocols to remain compliant with evolving standards.

- Innovations that simplify data-sharing workflows while safeguarding privacy can find competitive advantage.

4. FDA Regulatory Actions

The Food and Drug Administration (FDA), operating under HHS, is prioritizing several initiatives:

- **Over-the-Counter (OTC) Drug Modernization:** Rules revising safety and effectiveness standards for OTC drug categories like antihistamines and analgesics.
- **Labeling for Gluten-Free Foods:** Establishing clearer labeling requirements for specific food types to protect vulnerable populations, such as those with celiac disease.
- **Device Regulations:** New performance standards for sunlamp products and enhancements in mammography quality standards.
- **Strategic Considerations:**
 - Pharmaceutical and food product leaders should prepare for increased scrutiny around safety and efficacy standards.
 - Device manufacturers must focus on meeting new safety benchmarks while investing in evidence generation to comply with post-market surveillance.

5. Medicare Payment and Innovation

Centers for Medicare & Medicaid Services (CMS) propose adjustments to reimbursement models and reporting requirements:

- Expansion of value-based payment initiatives, including the Home Health Value-Based Purchasing (HHVBP) program.
- Updated payment policies for long-term care facilities and hospital outpatient services.

- **Opportunities:**

- Companies offering products for post-acute or home-based care can position themselves as key players in cost-effective care delivery.
- Digital health platforms focusing on remote monitoring and quality reporting gain traction under value-based frameworks.

Strategic Imperatives for Healthcare Product Leaders

Given this agenda, healthcare product leaders must adopt a proactive approach to align their strategies with regulatory developments:

1. Innovate for Compliance

Develop solutions that not only meet but exceed new regulatory standards. Anticipate the needs of stakeholders by incorporating regulatory foresight into product development cycles.

2. Foster Interoperability

Regulatory efforts around the 21st Century Cures Act and HIPAA privacy rules underscore the importance of interoperability. Leaders should:

- Invest in scalable, standards-based data exchange solutions.
- Ensure products support FHIR-based APIs to enable seamless integration into broader health ecosystems.

3. Emphasize Patient-Centricity

Whether designing medical devices, therapeutic products, or digital tools, patient-centricity must remain central. For example:

- Enhance accessibility for diverse populations.
- Address health equity through inclusive product design and targeted outreach

4. Stay Ahead of Value-Based Trends

CMS's ongoing transition to value-based care means healthcare product leaders should:

- Develop outcomes-driven innovations that address cost-effectiveness.
- Collaborate with providers and payers to design bundled solutions tailored to based payment models.

5. Proactively Engage in Policymaking

Public comment periods are critical opportunities to shape regulatory outcomes Leaders should:

- Actively participate in stakeholder engagements and advocacy efforts.
- Build relationships with industry groups that influence policymaking.

Conclusion

HHS's regulatory agenda presents both challenges and opportunities for healthcare product leaders. By staying informed and aligning innovations with emerging standards, organizations can position themselves as leaders in a rapidly evolving healthcare landscape. The next 6-12 months will be pivotal for regulatory alignment and innovation, offering a chance to shape the future of health technologies, devices and services for greater equity, access, and patient benefit.

<https://www.federalregister.gov/documents/2018/11/16/2018-24151/regulatory-ag>

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