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HHS announces public meeting on ways to accelerate clinical innovation

Government seeks industry comment on expediting medical product development

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The U.S. Department of Health and Human Services' (HHS) Immediate Office of the Secretary (IOS) has announced it will hold a public meeting June 20-21 to seek public input and comment on ways the department can help shorten the time needed for safe and effective medical products to go from discovery to patient use. For example, pharmaceutical companies and medical device manufacturers may want to encourage HHS to develop a database of clinical evidence for newly cleared or approved products, which commercial payers can reference when making coverage decisions. This meeting is part of the ReImagine HHS: Accelerate Clinical Innovation (ACI) initiative, which is examining the entire medical innovation process at an enterprise level to identify new ways for patients to have timely access to new medical products.

Specifically, HHS seeks industry input regarding:

- **Coverage decision process facilitation:** The appropriate federal role, if any, in connecting medical product developers with payers, commercial plan carriers, and/or Medicaid managed care plans for purposes of making the coverage decision process more efficient.
- **Knowledge sharing:** Enhanced knowledge sharing to assist in the innovation enterprise stakeholder's decision-making processes.
- **Enterprise-level biomedical innovation metrics:** Metrics for the overall innovation system to assess the viability of the system and measure the impact of procedural and policy changes.
- **Identification and prioritization of areas of focus:** Procedures, methods, and data for the identification and prioritization of diseases or conditions that would benefit from enhanced focus.

The deadline to submit comments and to register for the meeting is June 12, and HHS has specifically requested comments on:

- What existing resources can HHS leverage to provide the biomedical innovation community with timely, meaningful information to promote product development, while promoting competition and maintaining commercial confidential information?
- Which aspects of the regulatory framework for biomedical product development marketing are the most unclear to your stakeholder community, and how could HHS act to clarify processes?
- What additional information or data would be helpful to your stakeholder sector (e.g., patients, physicians, private insurance, product developers, private investors, etc.) to improve decision-making and efficiency of product development?
- Are there specific metrics for the overall biomedical innovation enterprise across public and nonpublic sectors that HHS could use to track and measure results of process changes?
- What metrics, data sources, procedures, or other factors should be considered in the identification and prioritization of diseases or conditions that would receive the most impact from enhanced HHS-wide focus?

There has always been tension between permitting developers to rely on existing sources of knowledge while at the same time protecting investments in innovation. There needs to be a calibrated line between publicly available information relating to research and development tools on the one hand, and on the other, knowledge, expertise, and data that have been generated as part of a specific development program. Anyone with a stake in medical product development will have an interest in how this line is drawn.

If you have any questions about the meeting or may be interested in submitting comments for discussion at the meeting, please contact any of the authors of this blog or the Hogan Lovells lawyer with whom you regularly work.

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