



NATIONAL HEALTH COUNCIL

**Statement by
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National Health Council
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Thank you for the opportunity to be here today. The National Health Council (NHC) appreciates the opportunity to provide feedback on the Food and Drug Administration's (FDA's) draft performance goals for the Medical Device User Fee Amendments from fiscal years 2023-2027 (MDUFA V). This process and its outcome are incredibly important to patients, and this opportunity, along with the stakeholder meetings held throughout this process, will help make sure the outcome meets the needs of patients.

Created by and for patient organizations over 100 years ago, the NHC brings diverse organizations together to forge consensus and drive patient-centered health policy. Made up of more than 145 national health-related organizations and businesses, the NHC's core membership includes the nation's leading patient organizations. Other members include health-related associations and nonprofit organizations including the provider, research, and family caregiver communities; and businesses representing biopharmaceutical, device, diagnostic, generic, and payer organizations.

The MDUFA V draft goals letter demonstrates FDA's commitment to modernizing its regulatory frameworks and activities to meet the demands of 21st Century technologies. The NHC appreciates the hard work that went into negotiating the aspects of this agreement that will ensure that the FDA and industry work together to make sure that the process of approving or clearing new medical device innovations is efficient, properly resourced, and focused on getting innovative products out to patients quickly and safely.

Importantly, we are pleased to see there are several aspects of the agreement that are focused on infusing the voices of patients into the process and making sure that the real needs and goals of patients are considered by FDA and manufacturers. I would like to specifically comment on those today.

Enhancing the Incorporation of the Patient's Voice in Device Development and Decision-Making

The NHC applauds the FDA for continuing its crucial work to evolve the science of patient engagement through MDUFA V. Specifically, we applaud the inclusion of the following:

- Expanded clinical, statistical, and other scientific expertise and staff capacity to respond to submissions containing applicant-proposed use of voluntary patient preference information (PPI), voluntary patient reported outcomes (PROs), and/or patient generated health data (PGHD).
- Issuing guidance on best practices on incorporating clinical outcome assessments in premarket studies.
- Updating existing guidance on Patient Preference Information.

- Support for the use of innovative technologies to capture patient input and reduce patient burden to inform clinical study design and conduct, with a goal of reducing barriers to patient participation and facilitating recruitment and retention.
- A public meeting to explore ways to use patient-generated health data to help advance remote clinical trial data collection and support clinical outcome assessments.
- Activities to improve the regulatory predictability and impact of patient science.
- Patient-friendly educational modules on device trials, real-world data, device development tools, and regulatory frameworks.

Together these initiatives will help assure that the medical device approval process better incorporates the input of patients and drives equity. The multi-tiered approach of making sure that FDA has the expertise and capacity to utilize many types of data, including patient-generated data, identifying high-impact opportunities to incorporate patient perspectives, and creating tools and resources to educate the general public on the device development process is effective and will lead to better end results.

While the aspects of the agreement that address patient engagement are very positive steps, it will be critical that the details of these processes are developed correctly from the beginning. It is imperative that at every step of the way, patients and patient organizations are engaged in implementation. The NHC has a long history of helping manufacturers and regulators create quality patient engagement processes. We stand ready to assist as this agreement is codified and implemented.

Advancing Real-World Evidence for Use in Regulatory Decision-Making

The NHC supports leveraging real-world evidence (RWE) to inform FDA's decision-making. The proposed provisions for MDUFA V are a common-sense approach to furthering the science of RWE. We support updating of the Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices guidance. We believe if appropriately crafted, the proposed updated guidance can lead to a better and more consistent collection of data and best practices.

Digital Health

The NHC understands the importance of increasing timely access to existing and innovative digital health tools to both help patients access care and to assist in the effective and equitable development of new treatments. We appreciate the attention in the agreement to growing FDA's ability to quickly evaluate digital health tools and provide needed clarity on the process of evaluating digital health tools. I note the PDUFA VII agreement also has a significant commitment in the area of using digital health technologies in drug development, and I encourage FDA to work across the Centers to ensure these workstreams are coordinated.

Thank you for this opportunity today, and we look forward to working with you as we proceed to implementation.