Principles for Enhancing Patient and Provider Access to Digital Health Technologies

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We are in the midst of one of the greatest technological advances in history, with rapid, widespread adoption of digital technologies, including the use of Artificial Intelligence and Machine Learning (AI/ML), across industries. Continued advancements in the healthcare sector will depend on comprehensive reimbursement policy that supports adoption of innovative Food and Drug Administration (FDA)-regulated digital health technologies, which the FDA describes as technologies and devices using computing platforms, connectivity, software, and sensors for health care and related uses. Digital health technologies may include technologies intended for use as a medical device or product (e.g., Software as a Medicare Device), in a medical product, as companion diagnostics, or as an adjunct to other medical products.

In healthcare, the increasing number of FDA-regulated digital health technologies and devices are changing how and where care is provided, unlocking value for clinicians and patients. These technologies empower a better understanding of diseases, help clinicians achieve more accurate diagnostic results, leverage large data sets to inform care, and improve patient outcomes. Realization of the full potential of these technologies will depend on a clear recognition of their value through predictable and consistent reimbursement policy frameworks.

Despite the Centers for Medicare & Medicaid Services' (CMS') progress to date in extending reimbursement for some FDA-regulated digital health technologies, outdated laws and regulations, and inadequate resources, including needed technical expertise, slow down patient access to many technologies. The principles below were developed in response to these limitations in the current reimbursement landscape for digital health technologies and reflect our priorities for action to expand patient access to these technologies.

Principle: Unlock digital health technologies' potential to address access disparities and improve patient outcomes.
Considerations: Expanding patient access to FDA-regulated digital health technologies can improve care delivery and enable improved and expedited access to care, particularly in rural and underserved patient communities. Expanded use of, and equitable access to, these technologies could bring otherwise inaccessible clinical expertise to underserved patients, while enabling more efficient clinician workload management—including the ability to engage, diagnose, and treat larger populations outside of the clinical setting.

Principle: Remove deterrents to leveraging digital health technologies to advance value-based health care.
Considerations: FDA-regulated digital health technologies can assist clinicians and hospitals in meeting the triple aim—better clinical outcomes, lower cost, and improved patient experiences. However, developers of these technologies are deterred from participation in value-based arrangements (VBAs).

To fully transition to value-based care, compensation models and the associated regulatory framework must evolve.
An efficient and effective payer reimbursement framework would enable developers to be paid based on the actual results their solutions achieve, while allowing for shared accountability in reaching clinical outcome targets and managing total care costs for patients and/or populations.

Principle: Promote transparent and predictable reimbursement policies for FDA-regulated digital health technologies.

Considerations: Patients and healthcare providers will benefit greatly from gaining access to innovative FDA-regulated digital health technologies. In addition to eliminating barriers in the context of value-based payment arrangements, as noted above, CMS should do everything within its authority to expand patient access to these technologies under fee-for-service (FFS) payment systems, including the creation of new benefit categories and establishment of appropriate reimbursement frameworks to support adoption. It is critical that FDA-regulated digital health technologies are covered and have appropriate payment under Medicare and Medicaid, as these payers frequently inform private payer decision making. Further, Medicare reimbursement frameworks for FDA-regulated digital health technologies should be clear and consistent.

There can be no "one size fits all" reimbursement policy for every FDA-regulated digital health technology. Instead, appropriate payment mechanisms will vary depending on the technology in question and the setting in which it is used. In all cases, accurately capturing the cost and value of these technologies will be critical to ensuring appropriate reimbursement. At a minimum, FFS reimbursement policies for FDA-regulated digital health technologies should adhere to the following:

- **Technologies impacting individual patient care must be valued and separately reimbursed.** Considerations: FDA-regulated digital health technologies providing clinical outputs that are distinct from an underlying or associated service or procedure have separate direct costs associated with the use and acquisition of the technology, warranting separate payment. Additionally, these services, which are commonly ordered by a patient's treating physician, often involve additional clinician work and time associated with interpretation and reporting of the clinical outputs produced by the technology. To ensure access to these innovative services, Medicare must separately pay for them, and payment rates must be adequate and appropriate across Medicare payment systems.
- **Ensure payment stability to promote patient access and accelerate innovation.** Considerations: Like all new technologies, FDA-regulated digital health technologies undergo an adoption curve where widespread adoption is preceded by gradually increasing use. The adoption curve for many of these digital health technologies may be even longer due to additional complexities associated with infrastructure, information technology, and cybersecurity requirements. Stable, predictable payer payment rates throughout the adoption curve and specifically defined coverage timetables will give healthcare providers confidence to adopt these technologies into clinical practice without the threat of reimbursement volatility.