



Digital Health Policy Principles

About Biocom: Biocom represents the Southern California life science industry, which includes biopharmaceutical, medical device, and diagnostic companies, universities and research institutions, as well as service providers and patient groups. With more than 600 members dedicated to developing life-enhancing and life-saving drugs, medical devices, and biologics for patients in need, Biocom leads advocacy efforts to positively influence the region's life science community in the development and delivery of innovative products.

About Digital Health Technologies: Health care is at the cusp of a sector-wide transformation due in large part to the development of digital health technologies, from genomic testing to mobile applications to remote patient monitoring. Advances in digital health improve the efficiency of health care delivery and enable better health care resource utilization, such as pre-crisis intervention, which lead to cost containment and improved patient outcomes across a wide spectrum of disease conditions.

Digital health technologies often reduce the need to physically visit a doctor's office or hospital, allowing patients to communicate with their physicians and receive and transmit health care information instantly in a home setting, thus containing costs, preventing the deterioration of conditions, reducing the frequency of visits to medical institutions, and ensuring the continuity of care. Digital health also empowers patients to be active participants in their health care decision-making process.

Ensuring Appropriate Reimbursement of Digital Health Technologies

The lack of reimbursement opportunities is indisputably one of the major barriers to the development of digital health technologies. Coverage and coding limitations, outdated Medicare regulations, restrictive formularies, and increased cost-sharing such as specialty tiers, among others, continue to inhibit the development of digital health technologies. Such restrictions deter providers from utilizing advanced information communications technologies in their practices, which in turn limits patient access to these life-enhancing technologies and discourages investors from further financing innovative solutions. Reimbursement systems should reward innovative modes of health care delivery that result in quality improvement and cost reduction.

Principle: Biocom supports reimbursement policies that provide appropriate and inclusive coverage, coding, and payment for new digital health technologies.

Increasing NIH Funding and Expanding SBIR/STTR Opportunities

By supporting basic research, the National Institutes of Health (NIH) provides a critical foundation of knowledge and technologies that drive private biomedical investment and innovation across the country, and especially in California. In Fiscal Year 2013, California received \$3.3 billion from NIH, which has funded 7,700 grants. Among those, Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) grants have allowed small businesses and start-up companies to bring innovative ideas to commercialization. However, over the past decade, NIH funding has been flat or declining in real-dollar terms and remains below pre-sequestration levels.

Principle: Biocom supports increasing NIH funding to at least \$32 billion annually and expanding the set-asides for SBIR/STTR grants to continue driving private biomedical research and development.

Streamlining Regulations

Innovators continue to face hurdles dealing with the lack of a well-defined framework for the regulation of certain digital health technologies. As an example, unclear regulations about the direct delivery of genomic data to patients have slowed down the entire genomic space. Regulating agencies, such as the Food and Drug Administration (FDA), the Office of the National Coordinator for Health Information Technology (ONC), the Federal Communications Commission (FCC), and the Centers for Medicare and Medicaid Services (CMS) should collaborate and coordinate policies more closely, when appropriate, and establish comprehensive guidance documents for industry, payers, and providers.

Principle: Biocom supports platform-agnostic regulations of digital health technologies and believes that products with medical intended uses should be regulated by the FDA, while those representing a lower risk for patients could benefit from a less stringent set of regulations.

Developing the Use of EHRs

The increased use of Electronic Health Records (EHRs) and other online platforms holds the potential to modernize both the collection of clinical trial data and the delivery of care. For example, instead of requiring investigators to complete traditional case report forms, clinical trial data could be obtained directly from EHRs or other online platforms, which are routinely completed by treating physicians as part of patients' care. This approach would enable the study to be conducted more efficiently, alongside the delivery of care. However, because it is unclear if regulators will accept data generated using these methods, clinical trial sponsors have been reluctant to fully incorporate these technologies into registrational studies.

Principle: Biocom supports developing standards for the use of EHRs in clinical research.

Utilizing Patient Generated Data

Remote patient monitoring technologies such as telemedicine, telehealth and mobile health are increasingly playing a vital role capturing patient generated health data (PGHD). However, there is a lack of references to remote patient monitoring technologies and PGHD as criteria in the Centers for Medicare and Medicaid Services EHR incentive payment program, popularly referred to as the “Meaningful Use” rules. To date, meaningful use has focused on Certified EHRs, EHR modules, and EHR systems, but has yet to fully encourage the involvement of patients and families in their care. Doing so would encourage patients to use these cost-saving technologies, especially the most chronically ill, who can be monitored in their homes and outside of healthcare institutions.

Principle: Biocom supports including the ability to upload PGHD into certified EHRs in future stages of meaningful use as criteria to incentivize eligible providers to embrace the use of remote monitoring technologies.

Ensuring Robust Health Data Protections

Biocom recognizes the challenge of protecting patients’ information while allowing physicians and providers to access personal data to better coordinate care. With the rapid development of digital care, it has become increasingly difficult for patients to control who has access to their information, which is often captured by institutions and commercial entities without clear consent or understanding from individuals. In addition, patients experience tremendous difficulties accessing their own personal data, which include lengthy processes and deterrent costs. As a result, there is no clear ownership of data in the health information space, including the data generated by these new digital health technologies.

Principle: Biocom supports strengthening health data ownership by giving patients more control over the data generated by these new technologies to ensure both the safety and confidentiality of patient information, and updating outdated HIPAA regulations to reflect the changing health care landscape resulting from the growing use of digital health technologies.

Educating Physicians and Patients about Digital Health Technologies

The incorporation of researchers, clinicians, patients, and policy makers in the implementation stages of digital health technology use is essential to efficiently navigating the technical challenges that hinder pragmatic digital health utilization. Physician coaching is of utmost importance to ensure that doctors are aware of the benefits of these technologies and properly trained to prescribe and use them, and appropriately counsel patients. The use of these technologies to encourage and manage wellness is not difficult if given the proper educational, regulatory, and reimbursement environments.

Principle: Biocom supports educational efforts to help patients, physicians, providers, and care-givers better understand the benefits and usage of digital health devices and technologies.