

# Principles on Facilitating Patient Access to Appropriate Health Care

Advanced Medical Technology Association (AdvaMed)

The medical device industry, at its core, exists to ensure patient access to safe, effective, and innovative medical technologies that save and improve patient lives. We are committed to ensuring that our mission is not compromised by the perpetuation of practices that create barriers to all patients' ability to experience optimal health outcomes.

All patients deserve the best possible healthcare to address their medical concerns. Clinician attitudes and behaviors, geography, economic and social factors, failure to adequately convey treatment options, and lack of insurance can impact access to appropriate care and lead to poor outcomes. These issues have deeply affected the way patients view the health care system, the way they are viewed and treated by providers, and how they are engaged in the process for developing technologies and therapies.

Access and healthcare delivery should address the specific needs of each patient. Where and how patients live, access to healthcare (including specialists), affordability of care, and underlying medical conditions contribute to disproportionate outcomes for some patients – especially those who are socioeconomically depressed and who are from vulnerable groups including ones that have historically been excluded from clinical research. Patients in certain communities also experience a greater prevalence of certain chronic illnesses leading to devastating health impacts and decreased life expectancy.

The Advanced Medical Technology Association (AdvaMed) and its members play an important role in ensuring that patients can access technologies and tests that result in the accurate diagnosis of disease and in improved patient outcomes. We are collectively engaged in efforts to ensure that our industry is doing its part to ensure that every patient gets the best care every time—especially the patients who need it the most.

AdvaMed welcomes the opportunity to be a catalyst in addressing these longstanding issues in the context of medical device development and deployment. Too many patients have experienced gaps in access to appropriate care for far too long. AdvaMed is committed to long-term action to reach real solutions. The following principles and considerations are intended as initial steps to guide industry as well as interested stakeholders including clinicians, health care providers, and health care facilities as we all embrace the long overdue call to address these access concerns.

## 1. PROMOTING INCLUSION AND ACCESS IN HEALTHCARE

**Principle:** Quality health outcomes are directly tied to access to high quality and fair healthcare that is unencumbered by stereotypes and negative/ill-informed judgments. Patients should have access to quality healthcare, regardless of their location, via physical or virtual means. All patients should be treated fairly and with dignity and respect when engaging in health encounters. Providers and care givers should be aware of the role unfounded judgments, based on lack of familiarity and/or limited exposure to different populations, can have on their interactions with patients.

**Considerations:** The association and its members should facilitate the dissemination of information and materials that promote fair treatment of patients. This work will likely require partnerships with other health providers, as well as patient and practitioner groups on various issues including educating industry and others on identifying, acknowledging, and addressing stereotypes and other factors that negatively impact the treatment of patients. AdvaMed will also work to develop and support legislation that promotes appropriate access to healthcare by every patient. AdvaMed will also work to advance efforts that improve patient access to health care facilities and providers, physically or virtually, and to improve access to health care facilities and providers in underserved communities.

## 2. PARTNERING IN EDUCATION WITH STAKEHOLDERS

**Principle:** Access to and use of innovative technologies requires knowledge of their existence. Patients who could benefit from life-saving and life-improving technologies should be aware of the innovations that are best suited to their health conditions. Medtech developers should create information and materials that increase patient awareness of innovative technologies. Any materials should present information in a clear and accessible manner, that is readily understood by a range of patients regardless of education level or country of origin. We also commit to the development of programs and pilots to ensure that clinicians are aware of the existence, use, and benefits of innovative medical technologies and offer the same range of care options to all presenting patients based on their disease state and condition and irrespective of assumptions about ability to afford, willingness to take advantage of or, ability to secure additional resources to support its use. Educational efforts should align with the promotion of appropriate care by patients and include training on the role that lack of access creates in the health outcomes for some patients. Healthcare providers should, in consultation with the patient and their caregiver where applicable, base treatment recommendations and decisions on an understanding of the patient's preference, abilities, and life circumstances.

**Considerations:** This work will require outreach to and partnership with clinicians to educate them regarding gaps in patient care, including access to technologies. Policy should account for access issues that may be tied to lack of awareness, lack of resources, or other real-world factors that may impact patient health, as well as willingness to access technologies. Efforts will require engagement and partnership with others to target outreach and education to clinicians. In addition, efforts will require engagement, regarding newly developed technologies, to clinicians treating patients who are members of marginalized, vulnerable, and/or underserved populations. This work may also involve alignment and partnership with patient and practitioner groups who represent these patient populations.

### 3. ALL PATIENTS DESERVE ACCESS TO INNOVATIVE TECHNOLOGY

**Principle:** The mission of AdvaMed is to ensure access to innovative technologies which improve patient lives. Access to technology should not be predicated upon factors such as type of insurance or insurance status, socioeconomic status, etc. Access to the best technology to support care is also predicated upon education about and awareness of options. We will advocate to ensure all patients are aware of the utility and availability of devices which best address their medical conditions. Access to technology that improves care delivery, such as telemedicine or remote patient monitoring, also depends on ensuring a robust broadband infrastructure is in place to support these technologies. Developing this infrastructure is even more critical with the high demand for options to provide patients access to safe and timely care outside of traditional settings.

**Considerations:** AdvaMed may need to develop and disseminate materials for use by patients, providers, and facilities. This policy accounts for the need to partner and work with external organizations to advance this goal. The association and its members should support legislation that promotes affordable access to care and the end of discriminatory treatment of patients linked to insurance coverage, i.e. Medicaid. The association and its members should also support legislation to incentivize the expansion of broadband or high-speed internet access to rural and underserved areas.

### 4. PROMOTING INCLUSION OF REPRESENTATIVE POPULATIONS IN MEDTECH RESEARCH

**Principle:** AdvaMed and its members promote innovation in medical technology development and design. Our methods for researching and developing these technologies should reflect the population of patients that will benefit from them. We will commit to the adoption of methods that promote improved recruitment of potential patients for clinical trials and medical device development.

**Considerations:** Policy should account for historic distrust on the part of some populations due to unfair treatment predicated upon stereotypes. Efforts will require engagement and partnership with caregivers, patient and stakeholder groups to bridge the gap and promote the need for involvement in studies and research to include clinical researchers and investigators that mirror the range of patients that will use and access the devices being studied and designed. This work may also involve alignment and partnership with groups specifically advancing the need for a more representative clinical investigator community. Policy should be reflective of the need for innovative approaches to recruit and monitor participants, including the use of primary care providers and the use of telehealth and digital medicine.