



## **NFHS STATEMENT ON MEDICAL DEVICES**

**National Federation of State High School Associations (NFHS)  
Sports Medicine Advisory Committee (SMAC)**

The use of medical devices by student-athletes with health conditions has become more commonplace. With the wider use of insulin pumps, as well as other medical devices such as heart monitoring equipment and prosthetics, concerns have been raised regarding the safety of the athlete wearing the device, the safety of teammates and opponents, and the risk of damages to the device itself.

A wearable medical device needs to have a medical purpose, meaning it should work in a way that is metabolic, immunological or pharmacological. Wearable medical devices have an inherent risk and as such must be regulated in order to prevent harm to the user or others. FDA approval (not clearance) is the gold standard, and companies need to do a lot of testing to receive this designation. Within this definition of medical devices, there are three categories of medical devices:

1. general medical devices (e.g. x-ray equipment, ECG monitors);
2. in vitro diagnostic medical devices (these analyse blood and body tissue, such as a finger prick glucose tests and pregnancy tests); and
3. active implantable medical devices (bodily implants, such as glucose sensors and cardiac pacemakers).

Meanwhile, software that monitors general fitness, health or wellbeing (as opposed to a specific disease) or provides reference information and recommends lifestyle treatment choices are not classified as a medical device. Wearable technology are not approved by the Food and Drug Administration (FDA) but are instead labeled as “FDA cleared.”

The NFHS SMAC has discussed these issues and recommends the following:

When it is necessary for a student-athlete to wear a medical device (such as an insulin pump, heart monitoring equipment, etc.) during athletic competitions, the device shall be padded and securely attached to the player’s body, underneath the uniform. Devices attached to the head (such as hearing aids and cochlear implants) do not need to be padded but shall be firmly secured to the body. No medical device shall pose any risk of injury or hazard to the student-athlete, teammates and/or opponents. The official has jurisdiction to disallow any medical device deemed unsafe for athletic competition. The head coach, or team personnel designated by the head coach, shall notify the official of the presence of the medical device prior to each contest. In addition, State Association approval may be required prior to a student-athlete wearing a medical device in athletic competition.

**References:**

<https://www.fda.gov/media/154866/download>

<https://www.fda.gov/industry/importing-fda-regulated-products/importing-medical-devices>

<https://www.fda.gov/consumers/consumer-updates/it-really-fda-approved>

**April 2023**

**April 2019**

**November 2018**

**April 2016**

**October 2012**

**October 2009**

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