EXPANDING MEDICAL DEVICE E-LABELING

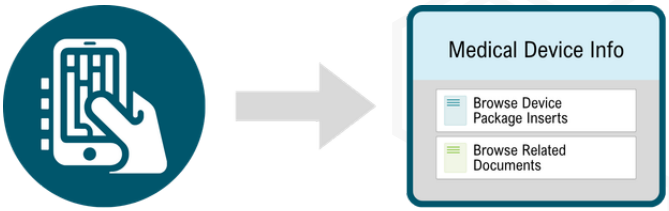
SAFER AND MORE EFFECTIVE USE OF DEVICES THROUGH NON-PHYSICAL LABELING

CALIFORNIA LIFE SCIENCES

Congress should pass the *Medical Device Electronic Labeling Act* (H.R.1539) to expand the permitted use of electronic labeling (E-labeling) for medical devices and facilitate more timely, accurate, and accessible medical device information.

EXPANDING E-LABELING

E-labeling is the electronic delivery of approved medical device labeling information (usage instructions, product information, contraindications, etc.) to support the safe and effective use of devices by patients and healthcare providers. It serves as a **more flexible and accessible alternative to paper labeling**, allowing users to retrieve current product information digitally via websites, QR codes, or downloadable files.



Current law restricts electronic labeling to prescription devices used in clinical settings, and certain in vitro diagnostics used in blood establishments or by health care professionals. **H.R.1539 addresses these limitations** by permitting directions and warning labels for all medical devices to be provided electronically, so long as:

- The **E-label is readily accessible** to intended users
- A **paper copy is available** upon request at no cost
- The label affixed to the device or its packaging **contains all information required** under current laws and regulations

ADVANTAGES OF E-LABELING OVER PAPER LABELING

H.R.1539 modernizes labeling practices and enables quicker amendments to instructions and warnings, helping patients and clinicians use medical devices as safely and effectively as possible.

Enhances access by enabling providers and patients to view labeling information anytime, anywhere.

Supports sustainability by **reducing paper waste** and environmental impact.

Allows for real time updates, which enhances compliance by helping ensure labeling is accurate and up to date.

Reduces errors by **decreasing reliance on paper labeling that may be outdated**

Misreading errors can be minimized by digital features that enable translations in most languages, text size options, and text-to-speech functions

Medical device labeling is often extensive, frequently spanning **dozens or even hundreds of pages, making digital formats far more effective for users to search, navigate, and use.**

Lowers unnecessary logistics costs by eliminating printing, shipping, and storage of voluminous physical labels.

Enables rapid updates without the need for burdensome recalls or repackaging.