



Can an mHealth app be liable for malpractice?

By Kirsten Beasley, Head of Healthcare Broking, North America

Mobile health apps are proliferating and becoming increasingly integrated into healthcare. So how is regulation responding and who is liable if things go wrong?

What is mHealth?

mHealth, or mobile health, is the use of digital health apps with mobile technology, such as phones, tablets, smart watches and other wearables.

How is mHealth used?

As well as everyday wellness and fitness monitoring, mHealth is increasingly used in patient care, including apps that:

- Help people to monitor and manage chronic diseases, such as diabetes.
- Track mother and baby health during pregnancy.
- Support mental health therapies and self-management.

mHealth apps are also used for public health and healthcare management purposes, such as:¹

- Education and behaviour change communication.
- Disease surveillance through data collection and reporting.
- Population health tracking through records of births, deaths and major health events.
- Electronic health records (EHRs).
- Communication between providers, for example to co-ordinate care.

How big is the market for mHealth?

The global mHealth market is currently estimated to be worth over USD 50 billion and is projected to increase in value to more than USD 800 billion by 2030.²

With their wide availability, mobile technologies have huge potential to support healthcare in developing countries with limited resources and infrastructure.

¹Labrique et al, Global Health: Science and Practice August 2013, 1(2):160-171; <https://doi.org/10.9745/GHSP-D-13-00031>

²Global Market Insights, 2021 mHealth Market Growth Statistics 2021-2030 | Global Projections Report (gminsights.com)

How is mHealth regulated?

Regulation varies between jurisdictions: not all countries have regulation and not all apps are regulated. Regulation largely depends on what an app claims to do.

Apps that meet the definition of a medical device – typically, those that diagnose, treat or mitigate disease or health conditions – are always likely to be subject to regulatory scrutiny. Areas of regulation can include:

- Medical device safety.
- Information security and governance (including privacy).
- Usability and accessibility.
- Interoperability.

Current regulatory frameworks in major markets include:

U.S.

- Food and Drug Administration – regulation of medical software before release.
- Federal Trade Commission – regulation of claims about products that are unsupported by evidence.

UK

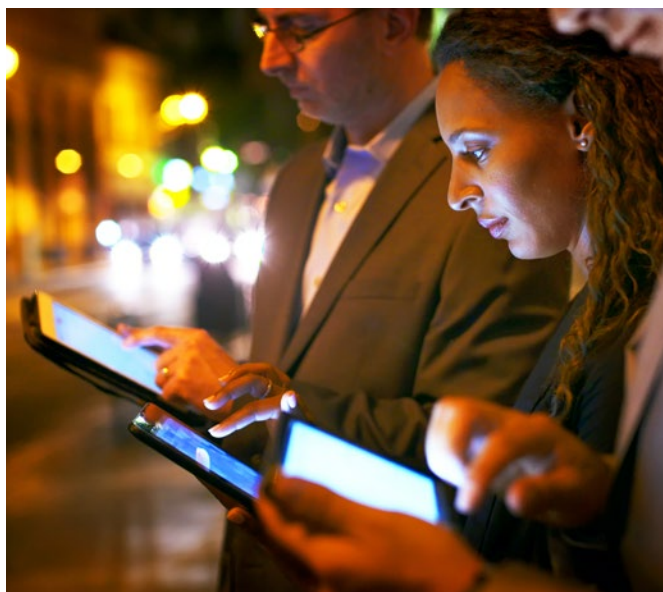
- Medicines and Healthcare Products Regulatory Agency (MHRA) – UK safety certification.
- Care Quality Commission (CQC) registration.
- NHSX's Digital Technology Assessment Criteria (DTAC).

EU/EEA

- Medical Device Regulation (MDR) – CE mark product safety certification.

Australia

- Therapeutic Goods Administration – regulation based on the Therapeutic Goods Act 1989 (overarching legislation) and subsequent regulations.



Is regulation keeping pace with mHealth technology?

The regulatory environment is struggling to keep up with the speed of change. One example of this is the UK NHS Health Apps library, which was launched in 2013 to guide patients and providers to safe and effective mHealth applications. The library was plagued by criticisms about the NHS's ability to screen mHealth apps, particularly on safety and efficacy. It was shut down after two years and only relaunched in 2017 once rigorous testing and screening had been put in place.

What kind of liabilities could mHealth app providers face?

Claims to date have focused on apps not performing as promised, especially where they have made inaccurate claims about their capabilities, such as advertising to protect against cognitive impairments, or claiming to detect symptoms of certain types of cancer.

Where an mHealth application is used as part of an intervention, it's possible that it could result in bodily injury or physical harm to a patient.

This raises the possibility of liability for medical malpractice. There is also the potential for product liability exposures as the boundaries between digital and physical healthcare blur and apps become redefined as products.

What insurance do mHealth app providers need?

App-related exposures are currently typically covered by an errors and omissions policy designed to pick up the economic losses resulting from the failure of a technological service or product.

However, as discussed above, app providers need to consider that they may also be open to claims for medical malpractice and product liability claims as the technology evolves. Some product liability policies already accept tech in their product definitions.

Fully understanding the evolving coverage needs for mHealth apps requires several different areas of underwriting expertise.

Since underwriters tend to specialise in one area, app providers need to consider brokers and insurers that can combine the different sets of knowledge required.

Key considerations for app providers and their insurers

Does the app do what it is claimed to do?

Is there robust clinical evidence to support the claims? If an app claims to improve a disease or condition, it must be able to prove it.

Is the due diligence complete?

Due diligence needs to cover the level and nature of any applicable regulatory oversight. App providers need to keep up with the latest legislative changes, decisions and approvals.

Is a clinical provider involved?

If the app provider has no medical credentials, or the medical provider is unlicensed, they may be more exposed to liability if things go wrong.

Is the app providing a medical opinion, advice or diagnosis?

If patients come to rely on information and advice from the app, and act on it to their detriment, app providers could be held liable.

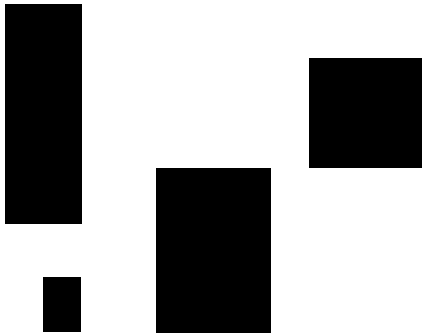




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