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Regulation of software, including software as a medical device

AMA submission to the TGA

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The AMA fully supports the TGA's proposals to strengthen existing, and introduce new, regulations to ensure health-related software, including software as a medical device, is adequately scrutinised and monitored for safety, quality and performance.

The enhanced regulations will improve patient safety, and help inform both patients and health practitioners about expected requirements for safety and performance.

The AMA understands that the Australian Digital Health Agency is undertaking activities related to health apps. The TGA should ensure that the Agency's related work is consistent and complementary.

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