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Australia's new ad guidelines cause concern

A new version of the 'Medical guidelines for advertising regulated health services' introduced by the Medical Board of Australia, which will take effect on 17 March, has caused concern over requirements that practitioners actively pursue the removal of unsolicited testimonials online.

"The controversy centres on the requirement that health practitioners actively pursue the removal of comments posted online that are of a clinical nature, even unsolicited testimonials," said Alec Christie, Partner at DLA Piper. In an attempt to clarify some of the concerns raised the Medical Board released statements in March attempting to clarify that it does not expect practitioners to 'actively monitor internet sites.'

"There remain outstanding issues," adds Christie. "For e.g., the guidelines still require practitioners to actively pursue the removal of 'unsolicited testimonials' and place monitoring responsibilities on practitioners in relation to websites that are not directly under the control of, or directly associated with, a practitioner. The Medical Board's statement thus appears to conflict with its guidelines."

IN THIS ISSUE

HSCIC tries to build trust after NHS data sharing revelations

Following revelations that Hospital Episode Statistics (HES) data has been sold to an insurers' body and PA Consulting by its predecessor the NHS Information Centre (NHS IC), the Health and Social Care Information Centre (HSCIC) outlined on 6 March how it will 'improve the transparency of its decision-making and build public trust in its actions' in regards to the care.data programme.

"The revelations that have come to light over the past couple of weeks have put the HSCIC on the back foot, forcing it to clarify and bolster its data disclosure safeguards both in relation to the care.data initiative and more generally," said Matthew Godfrey-Faussett, Partner at Pinsent Masons. "The four measures listed in the HSCIC's 6 March press release should have been implemented well in advance of the original care.data launch date."

HES will form the basis of the data released under the care.data programme, which will be combined with GP data and other datasets, and sold to organisations in a pseudonymised and anonymised form.

The measures put forward by HSCIC include: an audit of all data releases made by the NHS IC; the publication of a report on 2 April detailing all data releases under the HSCIC including the purpose and legal basis for release; and the HSCIC will write to all recipients of data informing them of the HSCIC's right to audit their use of the data and the intention to publish details of their access.

"It certainly makes sense for the HSCIC to publish a report of the releases made by the NHS IC," adds Bridget Hughes, Senior Associate at Kingsley Napley LLP. "I would go further, however, and suggest that there should be an ongoing statutory duty on the HSCIC to disclose details of the companies to whom access to data is being given and the reasons behind the decisions."

"If the atmosphere of mistrust that now surrounds the HSCIC is to be dissipated before a care.data launch in autumn, three things are needed," thinks Godfrey-Faussett, "firstly, real transparency in relation to the data privacy safeguards that will be employed; secondly some form of compliance tick in the box from a trusted and independent third party, ideally the ICO; and thirdly, a public debate that has been allowed to run its full course, so that a balance can be struck between the benefits of the care.data programme and the risk of personal data disclosure."

The UK Government tabled amendments to the Care Bill on 3 March that would place additional restrictions on the dissemination of information by the HSCIC.

PROTECT health IT bill looks to reduce regulatory scope of FDA

Senators D. Fischer and A. King introduced the Preventing Regulatory Overreach To Enhance Care Technology Act 2014 ('PROTECT') on 10 February, aimed at creating a more specific regulatory framework for health IT and clarifying the regulatory focus of the Food and Drug Administration (FDA) to include only 'high-risk' products.

"Some believe that there is too much uncertainty with the recent FDA guidance in this area, and FDA regulation of clinical software and health software will stifle development and competition," said Paul DeMuro, Special Counsel at Schwabe, Williamson & Wyatt.

PROTECT's critics argue that deregulating some aspects of the health IT sector through overly broad definitions of risk, and limiting FDA oversight on clinical decision support software, may impair patient safety. "PROTECT would largely codify the FDA's current practice of enforcement discretion for health IT," said Kevin Madagan, Associate at Reed Smith. "Such codification would undermine the FDA's ability to remain flexible in light of evolving health IT."

"It would be beneficial if we could come up with a more refined approach that distinguishes high-risk health IT products (including mHealth apps) from low-risk products, allowing the FDA to better define which types it will definitively regulate in the future," said Sonali Gunawardhana and Scott Delacourt at Wiley Rein.