

ASX RELEASE

US to introduce mandatory reporting of breast density under proposed new regulations

Wellington, NZ, 28th March 2019: [Volpara Health Technologies](#) ("Volpara"; ASX: VHT), a medical technology company whose AI imaging algorithms assist the early detection of breast cancer, has advised that the United States Food and Drug Administration (FDA) has released a proposal to amend the Mammography Quality Standards Act (MQSA) to include a requirement that all US screening facilities provide information on breast density to women and their healthcare providers after a mammogram.

The MQSA authorizes FDA oversight over mammography facilities, including their accreditation, certification, annual inspections, and enforcement of standards to help ensure mammography facilities provide quality care.

In its [press release](#) the FDA described the proposed changes as a "landmark policy to modernise mammography services . . . and help empower patients with more information." The proposed regulations are open to comment for a three-month period before being finalised.

In summary, the FDA is proposing language that would outline how breast density can influence the accuracy of mammography and recommend that patients with dense breasts talk to their healthcare provider about their breast cancer risk. The list of changes can be found [here](#).

The proposed rule would establish four categories for reporting density, with specific language to be included in notification letters:

- "The breasts are almost entirely fatty."
- "There are scattered areas of fibroglandular density."
- "The breasts are heterogeneously dense, which may obscure small masses."
- "The breasts are extremely dense, which lowers the sensitivity of mammography."

"The notification language would be general enough to be readily interpretable by women receiving the letters, but the report sent to the referring physician will be more detailed," said Dr. Jeff Shuren, director of the FDA's Center for Devices and Radiological Health, in a press conference on 27th March. "We're trying to facilitate a conversation about breast cancer screening between the patient and their healthcare professional."

Dr Ralph Highnam, CEO of Volpara, said: "This is a major step forward for the women of the United States. No matter where they live, they are about to receive information regarding an important part of their breast health for them to monitor and act on with their healthcare professionals. This will lead to increased commercial opportunity for the Volpara®Density™ clinical application, the world's most validated automated breast density solution. We look forward to talking more about this at the forthcoming Independent Investment Research meeting in Sydney on Tuesday, 11th April, along with an update on our Q4 results.

ENDS.

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About Volpara Health Technologies Limited (ASX: VHT)

VHT is a MedTech SaaS company founded in 2009 on research originally conducted at Oxford University. VHT's clinical applications for screening clinics provide feedback on breast density, compression, dose and quality, while its enterprise-wide software, VolparaEnterprise, provides role specific dashboards and wide-ranging benchmarking analytics to help clinics manage their business more efficiently.

VHT's technology and services have been used by customers and/or research projects in 37 countries and are supported by numerous patents, trademarks and regulatory clearances, including FDA clearance and CE marking. Since its listing on the ASX in April 2016, VHT has raised A\$40 million, including A\$20 million in April and May 2018. VHT is based in Wellington, New Zealand.

For more information, visit www.volparasolutions.com