

STATEMENT OF DECISION

Respondent:	Mrs Li Shen
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The Commission has removed from this Statement of Decision material which it considers to be confidential information under section 41B(5) of the *Health Care Complaints Act 1993*.

1 The Complaint

- 1.1 On 20 August 2020, the Health Care Complaints Commission (**Commission**) received a complaint from a female patient (**Patient A**) about Medsound Pty Ltd (**Medsound**), a diagnostic ultrasound practice located at Suite 15, 14 Edgeworth David Drive Hornsby NSW 2077.
- 1.2 Patient A raised concerns about unhygienic practices while undergoing a transvaginal pelvic ultrasound at Medsound, in addition to concerns regarding the qualifications of the sonographer who performed the examination.
- 1.3 The Commission identified Ms Li Shen as Medsound's current director. However, despite numerous requests and the service of a Commission Notice to Produce information and records issued under section 21A of the *Health Care Complaints Act 1993 (Act)*, Ms Shen declined to respond to the complaint, identify her role at Medsound or provide the name of the sonographer who performed the ultrasound on Patient A.
- 1.4 On 11 November 2020, the Commission received information from the Australian Health Practitioner Regulation Agency (**AHPRA**), advising that they had received a complaint about an ultrasound report issued by Medsound that had been signed by a specialist radiologist (**Dr A**) whose name did not appear on AHPRA's public register of medical practitioners.
- 1.5 On 19 November 2020, Commission officers attended Medsound's premises and exercised the power of entry, search and seizure pursuant to section 33 of the Act, in order to obtain further information relating to the qualifications of the sonographers and Dr A, in addition to assessing hygiene practices and patient records. The Commission officers interviewed Ms Shen and seized equipment. The entry, search and seizure of equipment and records was filmed by the Commission.
- 1.6 During a search of the premises, Commission Officers discovered a large box of ultrasound reports authored by Dr A dating back to 2017-2018. These reports had not been signed however, the reports contained fax number information, indicating they had been faxed to referring medical practitioners.
- 1.7 A subsequent discussion during the search with Ms Shen revealed that she worked as the principal sonographer at Medsound. She also employed a part-time sonographer and supervised a student sonographer. Ms Shen was reluctant to provide the name of the reporting radiologist for Medsound, however, ultimately admitted that she had been writing the reports under the name of Dr A based on her findings of the ultrasound examinations.
- 1.8 Further enquiries by Commission Officers determined that Ms Shen had not obtained any recognised qualifications or accreditation in sonography and although

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Ms Shen advised the Commission that she was qualified to practice as a medical practitioner in China, she admitted that she was not registered as a medical practitioner in Australia, and had not obtained any relevant specialisation in radiology.

- 1.9 On 19 November 2020, the Commission added Ms Shen as a respondent to the complaint under section 20A of the Act.
- 1.10 On 23 November 2020, the Commission made an interim prohibition order prohibiting Ms Shen from providing any health services. As a result of this order, Ms Shen closed Medsound and the practice has not reopened.

2 Issues

2.1 Notwithstanding that Ms Shen does not possess any relevant health qualifications, she has been providing health services in NSW and is considered to be an unregistered health practitioner and subject to the Code of Conduct for unregistered health practitioners (**Code of Conduct**) made under Schedule 3 of the *Public Health Regulation 2012*.

2.2 The Commission investigated:

- Whether Ms Shen breached the Code of Conduct; and
- Whether Ms Shen poses a risk to the health or safety of members of the public.

2.3 The relevant clauses of the Code of Conduct are:

- Clause 3(1): *A health practitioner must provide health services in a safe and ethical manner.*
- Clause 3(2)(a): *A health practitioner must maintain the necessary competence in his or her field of practice.*
- Clause 3(2)(b): *A health practitioner must not provide health care of a type that is outside his or her experience or training.*
- Clause 3(2)(c): *A health practitioner must not provide services that he or she is not qualified to provide.*
- Clause 6(1): *A health practitioner must adopt standard precautions for the control of infection in his or her practice.*
- Clause 12(1): *A health practitioner must not engage in any form of misinformation or misrepresentation in relation to the products or services he or she provides or as to his or her qualifications, training or professional affiliations.*
- Clause 15: *A health practitioner must maintain accurate, legible and contemporaneous clinical records for each client consultation.*
- Clause 17(1): *A health practitioner must display a copy of each of the following documents at all premises where the health practitioner carries on his or her practice:*

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(a) *this code of conduct*

(b) *a document that gives information about the way in which clients may make a complaint to the Health Care Complaints Commission, being a document in a form approved by the Secretary*

- Clause 17(2): *Copies of those documents must be displayed in a position and manner that makes them easily visible to clients entering the relevant premises.*

3 Investigation

- 3.1 The Commission obtained significant evidence during its search of the Medsound premises. This included computer equipment, mobile phones and thousands of clinical records. The investigation raised several cross jurisdictional issues which required close collaboration with several state and national government bodies including the Commonwealth Department of Health, NSW Police, the Ministry of Health and AHPRA.
- 3.2 Several medical practitioners previously associated with Medsound also provided the Commission with information about the working practices of Medsound and Ms Shen.
- 3.3 Ms Shen has not responded to any Commission correspondence since 19 November 2020 and her current whereabouts are unknown.
- 3.4 A detailed summary of the evidence obtained during the Commission's investigation is set out at Sections 4 - 6 of this Statement.

4 Summary of Evidence

Medsound

- 4.1 Medsound was established on 6 February 2017 with two directors, Ms Shen and a sonographer (**Sonographer A**) who the Commission has confirmed is qualified and accredited. Ms Shen is listed as the current sole director.
- 4.2 Medsound's website, <https://www.medsoundimaging.com> advertises that it offers ultrasound examinations of the abdomen, pelvis, early pregnancy, kidneys, breast, thyroid and neck as well as doppler studies, deep vein thrombosis examinations, echocardiography and musculoskeletal (**MSK**) ultrasounds and injections.
- 4.3 It states that Medsound's sonographers have more than 15 years of practice experience in this field and that the reporting radiologists have more than 10 years' experience.
- 4.4 Enquiries by the Commission revealed that the majority of the ultrasound examinations performed at Medsound were bulk billed by Medicare using the Medicare provider number of a radiologist (**Dr B**), between March 2017 until September 2020.
- 4.5 Dr B advised the Commission that he provided remote reporting services to Medsound from March 2017 until June 2018, during which time he reported approximately 400 ultrasound examinations and attended on-site at Medsound on

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14 occasions to provide MSK supervision and perform five ultrasound-guided MSK injections.

- 4.6 Dr B stated that the majority of these ultrasound examinations were conducted by Ms Shen with some others performed by Sonographer A. Information from Medicare demonstrates that during this period, more than 1800 ultrasound examinations were billed to Dr B's provider number, more than four times the number of ultrasound reports completed by Dr B.
- 4.7 Dr B advised that he did not know that his provider number was still active and connected to Medsound until September 2020 when he received a telephone call from Medicare. Dr B stated that at this time he contacted Ms Shen who advised him that this was due to an administrative error. Dr B subsequently cancelled his provider number on 20 September 2020.
- 4.8 Sonographer A advised the Commission that Ms Shen had asked him to become a director of Medsound in March 2017. Ms Shen was solely responsible for the leasing of premises and buying of equipment, and Sonographer A would attend Medsound on Thursday evenings to perform MSK ultrasounds as Ms Shen was unable to perform these. Sonographer A confirmed that Dr B attended Medsound for the MSK ultrasound examinations as required by Medicare.
- 4.9 Sonographer A stated that he would scan patients and complete a worksheet, however, did not complete any transferring of images or facilitate the images to be reported by a radiologist as Ms Shen was responsible for these tasks. Sonographer A ceased working with Ms Shen and removed himself as a director of Medsound in September 2017 after a disagreement relating to monies owed by Ms Shen to Sonographer A.
- 4.10 The Commission is aware that Ms Shen employed at least two other qualified and accredited sonographers between 2017 and 2020, however, the Commission has been unable to contact one of these employees.
- 4.11 The other employee (**Sonographer B**), who the Commission has confirmed is a qualified and accredited sonographer, advised that she worked for Medsound temporarily in June and July 2020 during COVID-19. Sonographer B stated that she worked for two-hour shifts, one to two days per week for a few weeks. During this two-hour shift, Sonographer B states that she scanned only 1-3 patients. Sonographer B states she completed a worksheet at the end of every examination but did not transfer any images or meet the reporting radiologist.
- 4.12 During the entry, search and seizure by Commission officers on 19 November 2020, Ms Shen advised that she did not retain any of the ultrasound images or keep any patient records. No images were found stored on the ultrasound machine on the premises.

Ms Shen's qualifications

- 4.13 Information obtained from the Department of Home Affairs revealed that Ms Shen has lived in Australia since 2004 when she was granted a Skilled-Independent (subclass 136) visa as a dependent applicant of her partner, which allowed her to reside in Australia as a permanent resident. In 2012, Ms Shen was granted a subclass 155 visa which allowed her to remain in Australia as a permanent resident.

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- 4.14 Prior to moving to Australia, Ms Shen was a medical practitioner in China, having completed a Bachelor of Medicine from the Taishan Medical College in 1994. In 2010, Ms Shen applied to obtain the Australian Medical Council (**AMC**) Certificate, and as part of this application process, her medical qualifications were verified by the Australian Educational Commission for Foreign Medical Graduates.
- 4.15 The AMC Certificate is required by all international medical graduates seeking registration in Australia and involves the completion of a written examination (multiple choice questions) and a structured clinical examination.
- 4.16 Information obtained from the AMC revealed that Ms Shen undertook the written examination on 20 November 2010, 17 November 2011 and 19 November 2011 where she failed the examination on each occasion. She did not attempt the clinical examination and was not awarded the AMC certificate. Therefore, Ms Shen was unable to apply to the Medical Board of Australia for registration as a medical practitioner in Australia.
- 4.17 On 6 May 2012, Ms Shen applied through the South Australian Tertiary Admissions Centre for entrance into the Graduate Diploma of Medical Sonography at the University of South Australia and secured a place in this program on 23 May 2012.
- 4.18 The University of South Australia provided a copy of Ms Shen's academic transcript which revealed that in 2012 she attempted the subjects Professional Issues for Sonographers and Ultrasound Physics and Instrumentation 1 for which she received a grade of Fail Level 2. In 2013, Ms Shen repeated Professional Issues for Sonographers and again received a grade of Fail Level 2. The explanatory notes for the transcript explain that a Fail Level 2 is a grade achieved when the overall mark is below 40%.
- 4.19 The Australian Sonographer Accreditation Registry (**ASAR**) confirmed that Ms Shen joined the ASAR register on 26 November 2013 as a student sonographer. Ms Shen was then removed from the register on 5 June 2014 due to a failure to provide evidence of enrolment in a course after 31 March 2014.
- 4.20 The Commission has therefore confirmed that Ms Shen is neither qualified to be performing ultrasound examinations nor reporting on the findings of the examination.

5 Public Warning

- 5.1 On 24 November 2020, the Commission issued a Public Warning in relation to Ms Shen and Medsound pursuant to section 94A of the Act. The Public Warning expressed to the public the Commission's concerns that Ms Shen had been performing ultrasound examinations and writing and issuing reports of the ultrasound findings to referring doctors, without any recognised sonography or medical qualifications. It urged any individuals who had undergone an ultrasound examination between 31 January 2017 and 20 November 2020 to contact their referring general practitioner (**GP**) or other specialist medical practitioner to assess whether any repeat or follow up ultrasound examination would be required.

6 Other investigations

- 6.1 NSW Health concurrently conducted an investigation into the hygiene practices at Medsound and found that the equipment at Medsound was not being cleaned properly between patients.

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- 6.2 On 18 January 2021, NSW Health issued a public alert stating that while no instances of patient infection arising from procedures performed at Medsound had been identified, and the risk was considered to be low, all patients of Medsound were contacted individually advising them to consult their GP if they had undergone certain procedures.
- 6.3 These procedures were only those in which the ultrasound probe was in contact with mucous membranes or non-intact skin. This included scans in which the probe is put into the vagina or rectum (transvaginal/transrectal), scans of the eye and any scan on broken skin, such as a wound.
- 6.4 NSW Health stated that while the evidence indicated that MSK injections were performed by a qualified medical practitioner, this could not be reliably confirmed due to unsatisfactory record keeping and these patients were also advised to contact their GP.
- 6.5 The Commission has also been in close liaison with the Commonwealth Department of Health and AHPRA who are investigating allegations that Ms Shen unlawfully used Medicare provider numbers to facilitate payments for bulk-billed ultrasounds and provided radiology services without appropriate registration.

7 Submissions

- 7.1 The Commission wrote to Ms Shen on 19 April 2021 proposing to take action under sections 41A and 41B of the Act and inviting submission under section 40 of the Act. Ms Shen was provided with a draft copy of the Statement of Decision in this matter.
- 7.2 No submissions were received from Ms Shen in relation to the proposed action within the 28-day statutory timeframe. Accordingly, the Commission determined to proceed with the action proposed.

8 Findings

- 8.1 The Commission's investigation found that between March 2017 and November 2020 Ms Shen performed ultrasound examinations at Medsound without holding any of the required qualifications or accreditation. She additionally reported on the findings of the ultrasound examinations and provided these reports to patients' referring GPs without being a registered medical practitioner in Australia and without any specialist training in radiology.
- 8.2 Based on all the evidence and findings set out in this Statement of Decision, the Commission finds that Ms Shen has breached the following clauses of the Code of Conduct:
 - Clause 3(1): *A health practitioner must provide health services in a safe and ethical manner.*
 - Clause 3(2)(a): *A health practitioner must maintain the necessary competence in his or her field of practice.*
 - Clause 3(2)(b): *A health practitioner must not provide health care of a type that is outside his or her experience or training.*

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- Clause 3(2)(c): *A health practitioner must not provide services that he or she is not qualified to provide.*
- Clause 6(1): *A health practitioner must adopt standard precautions for the control of infection in his or her practice.*
- Clause 12(1): *A health practitioner must not engage in any form of misinformation or misrepresentation in relation to the products or services he or she provides or as to his or her qualifications, training or professional affiliations.*
- Clause 15: *A health practitioner must maintain accurate, legible and contemporaneous clinical records for each client consultation.*
- Clause 17(1): *A health practitioner must display a copy of each of the following documents at all premises where the health practitioner carries on his or her practice:*
 - (a) this code of conduct*
 - (b) a document that gives information about the way in which clients may make a complaint to the Health Care Complaints Commission, being a document in a form approved by the Secretary*
- Clause 17(2): *Copies of those documents must be displayed in a position and manner that makes them easily visible to clients entering the relevant premises.*

8.3 In light of the circumstances of these breaches, the Commission considers that Ms Shen poses a significant risk to the health or safety of members of the public as she has wilfully disregarded the health and wellbeing of her patients for her own financial gain. She has undermined the trust that members of the public have placed in her to perform diagnostic examinations and have the findings reported on by an appropriately qualified and registered radiologist.

9 Decision

9.1 Based on the evidence and findings outline above, the Commission makes the following prohibition order under section 41A(2)(a) of the Act:

Ms Li Shen is permanently prohibited from providing any health services in any capacity, either paid or voluntary.

9.2 For the purposes of this order, a health service carries the same meaning as defined under section 4 of the Act.

9.3 The Commission also issues the following public statement under section 41(2)(b) of the Act:

The NSW Health Care Complaints Commission (Commission) conducted an investigation into Ms Li Shen, an unregistered health practitioner and director of Medsound Pty Ltd (Medsound), a diagnostic ultrasound practice located at Suite 15, 14 Edgeworth David Drive Hornsby NSW 2077.

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The Commission's investigation found that between March 2017 and November 2020, Ms Shen performed ultrasound examinations at Medsound without holding any recognised qualifications or accreditation in sonography.

Additionally, while some of the ultrasound examinations at Medsound had been reviewed and reported by a qualified and registered specialist radiologist, the Commission's investigation found that Ms Shen had authored the majority of the ultrasound reports between March 2017 and November 2020, without being a registered medical practitioner in Australia and without any specialist training in radiology.

The Commission has determined that Ms Shen has breached the Code of Conduct for unregistered health practitioners set out in Schedule 3 of the Public Health Regulation 2012 and poses a significant risk to public health and safety as she has wilfully disregarded the health and wellbeing of her patients for her own financial gain.

Accordingly, the Commission has made a public warning pursuant to section 94A of the Health Care Complaints Act 1993 (Act), and makes the following permanent prohibition order under section 41A of the Act:

Ms Li Shen is permanently prohibited from providing any health services in any capacity, either paid or voluntary.

For the purposes of this order, a health service carries the same meaning as defined under section 4 of the Act.

- 9.4 Under section 41D of the Act, the Commission will provide a copy of this Statement of Decision to the Australian Health Practitioners Regulation Agency (AHPRA) and each professional Council in NSW.



Tony Kofkin
Executive Director, Complaints Operations
27 May 2021