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MSIA Advice to TGA for the Development of Fit for Purpose Regulation

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MSIA Response to TGA in respect of:

Analysis of Submissions from Consultation: Scope of regulated software based products 17 Aug 2020

Brief overview: Feedback on consultation on Scope of Regulated Software based products 10 August 2020

The TGA annotation/response to MSIA suggested changes/interpretation of Schedule 2 31 July 2020.

"Health software was used by thousands of Australians during COVID to improve health in ways as small as booking a GP appointment, to those as large as ongoing management of chronic disease. During social-isolation our Daybreak app, which supports people aiming to change their relationship with alcohol, showed an increase in registrations of 52% for April and 18% for May compared to last year.

Having Government supported programs, delivered by software, was a lifeline for so many Australians and any additional regulation brought upon the sector needs to be done cautiously. We need to ensure patients get access to safe and effective services, while not reducing the ability of companies to innovate and build more effective software to help patients manage their health needs."

Jamie Moore

General Manager & Co-founder Daybreak

Hello Sunday Morning

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Executive Summary

The MSIA is the peak body for Australian health software providers and as such the member companies are the most directly affected by the legislation and proposed carve outs from that legislation.

The MSIA has lodged several submissions throughout 2019-2020 with its most recent in May 2020. Clinical safety has never been in dispute. Safety is in the DNA of health software companies. Unless it is safe it defeats the purpose of the software which is to deliver better and more efficient outcomes for all Australians – be they patients and health care providers seeking optimal health outcomes or taxpayers looking for the most effective and economical governance frameworks.

MSIA concerns included inappropriate, expensive and [1]unnecessary regulation at the cost of innovation, provider efficiency and patient safety. Whilst all of these remain valid considerations for any future industry regulation, we believe that the position in respect of what health software should be excluded or exempted is now significantly clearer.

The MSIA supports the TGA preference for leveraging regulatory frameworks adopted by comparable Jurisdictions, in this case Canada. The TGA has also sought detailed advice from MSIA members about the types of software which should be excluded and or exempted which has been invaluable for all parties.

In the current environment it is critical to support the health software systems which contribute to making Australia's health system the best in the world. This means adopting a nuanced approach which balances the risks between safety and a regulatory cost burden. The current environment has sharpened the focus on healthcare systems globally and the need for innovative new models which can be deployed at scale efficiently. This is what our members do best.

This final response to the TGA confirms the specific elements of the carve out approach where MSIA members agree the TGA has succeeded. It also highlights areas which require greater clarity. Finally, it seeks confirmation of the specific carve outs which the TGA and MSIA have scheduled.

The 48 submissions demonstrate that many parties are not clear on what "software as a medical device" is, with some confusing hardware IVD or combinations of these. The MSIA is aware that the TGA requires support of clinical users through their peak bodies. The MSIA has raised concerns in submissions directly with these vital stakeholders which represent the clients of many of our members. We are confident issues that were expressed in their submissions can be answered following preliminary discussions with the newly elected leadership teams in both entities. These discussions can now continue and the TGA will be kept informed.

The MSIA members have provided some detailed examples of how specific software works in practice to enable the TGA to comprehend its value, the limited and manageable risks as well as the unintended consequence of over-regulation impeding innovation. We hope these are useful and are happy to elaborate.

The MSIA commends the TGA interaction with industry. We welcome further involvement with the TGA which will be urgent and essential to ensure that the carve out legislation drafted is fit for purpose by February 2021.

1 Note – RACGP President announced 9 September ; AMA new leadership 1 August.

1. Canada as a model for Australia's SAMD Regulation

The Canadian approach is embodied in its Guide and Examples. The enunciated principles make sense demonstrating a deep knowledge of the complexity of health software in multiple environments and applications. Principles which enable exclusion where the software provides functionality which does not replace clinical judgement ensures that health software can use algorithms for example[2], provided that the setting is correct.

The MSIA would endorse a similar approach and documentation by the TGA. This would both reduce the compliance burden on industry and the cost of the TGA developing its own framework in a complex and evolving area.

Reference to "chat-based triage"[3] was useful and demonstrative of the need for various applications to be used in virtual settings. The framework is particularly useful now that it highlights the need for regulation to be sufficiently responsive to current consumer needs whilst not over-burdening industry which could have cost ramifications and increase the number of consumers seeking free or cheap unregulated Apps online. Not good for health outcomes or innovation and productivity in Australia's health software industry.

Imaging systems are excluded[4] which we will discuss in more detail under the next section. Likewise clinical decision support systems, Electronic Health Records, care coaching and the approach taken towards Medical Device Data Systems could be usefully adopted for Australia.

Finally, given the comments during meetings, and the TGA response to the submissions and the final analysis, the MSIA have assumed that the TGA will be adopting the Canadian regime. Reliance by over 120 companies on this premise has shaped this final response.

Can the TGA please confirm that the TGA will be following the Canadian approach as detailed in its Guide and Examples?

2 P. 7 https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance/examples.html - examples in respect of algorithms.

3 Supra - P 16 in respect of chat based triage versus strong reaction to alleged "pop-ups' complained of in June which used such triaging in Australia

4 Supra - P. 8 & 16

2. Is it a Medical Device in Australia?

Detailed Review of MSIA and TGA list of Excluded and Exempted Software

At the request of the TGA, MSIA members carefully annotated the proposed list[6] of excluded and exempted software provided by the TGA. The TGA then commented on Appendix 2 to provide clarity and certainty in response. The MSIA members have relied on this response.

In most instances it is specific and clear. There are however some aspects of this Appendix which need confirmation, clarity and or explanation. For example where the TGA advises there will be boundaries, what are they? Can we co-design these? Particularly if there is to be cohesion with the preferred Canadian approach.

1. Administrative Support Systems (p.1)

Carved out by TGA but carve out to be discussed. The MSIA assumes the principles adopted and espoused by the Canadian Guide and Examples will be the basis for discussion.

Please confirm if other guidelines or rules to be considered.

2. Electronic Patient Record Keeping (p2)

Carved out by the TGA but to be discussed. Please confirm the parameters of the discussion and alignment with Canadian approach. This is a key area for primary care, now more than ever.

Additional changes or imposts would not provide additional safety but would impact providers ability to provide care efficiently.

3. Clinical workflows which use algorithms (p.2)

Clinical workflow and support are carved out in the draft but noted for discussion. The MSIA queried if the suggestions/algorithms about information displayed would affect classification. The TGA advised

"Yes – there will be criteria to define the boundary"

What will these criteria be? Will the TGA use the same approach as Canada whereby algorithms which are a part of decision making and not replacing judgement and are capable of independent review do not equal SAMD[7]. If so this would appear sensible.

If not what approach does TGA propose? Please advise.

4. Care Coaching and Self-Management p.2 and Self-Management p.5

The TGA has carved this out except if it includes diagnoses and treatments. There needs to be a very clear proposition of the boundaries in this rapidly evolving space. The Canadian approach is based on risk and oversight by a provider[8] and refers also to authoritative sources as a rationale for exclusion. If the software does not pose

6 Page 13-16 MSIA 22 May 2020 Submission https://www.tga.gov.au/sites/default/files/submissions-received-scope-regulated-software-based-medical-devices-msia.pdf

7 P. 17 https://www.canada.ca/en/health-canada/services/drugs-health-products/medical-devices/application-information/guidance-documents/software-medical-device-guidance/examples.html

8 Canadian Examples p16

harm shouldn't there be an exemption as there is under the Canadian approach?

It would be helpful if those alternative mechanisms for oversight were to be defined or listed some way. For example, some members need to meet ISO9001 requirements as well as clinical governance requirements (that do cover technical areas). If TGA imposes regulation this will create significant overlap, duplication and unnecessary cost.

Can the TGA please provide further information about the intended approach and guidelines here.

5. Communication Tools p. 3

These are carved out but up for discussion. The MSIA is keen to ensure that the type of binary approach demonstrated to telehealth and Medicare rebates is not replicated in the boundaries applicable to this class of software. There is reference in the Canadian Examples[9] to chat based triage which is a useful tool with the correct settings and more particularly now in the COVID-19 era.

Will the TGA be setting boundaries or following the principles and examples of the Canadian approach?

6. Software in Hospitals and other settings to aggregate information from different systems

This is noted as a medium risk for discussion. In effect the paper records and information are being aggregated. The principle of not converting existing paper processes into SAMD when they are made electronic is expounded in the TGA and Canadian approach which enables healthcare providers to review and update patient records, place orders and view multimedia data from many specialities[10].

Can the TGA advise in what specific circumstances aggregation would result in medium risk and inclusion for regulation?

7. Software Systems proposing options to healthcare providers

This is listed as high risk and thus likely to be regulated. It includes natural language processing and clinical decision support. Provided that the algorithm can be assessed and is subject to the health care providers discretion what is the rationale for regulation given the mitigation processes in place? The Canadian examples are useful here representing a more calibrated approach whereby for example, accepted practices and authorities may be used for algorithms to improve safety and efficiency.

Further detailed explanation of the clinical decision support principles applied by our industry are provided in Section 3 below. Transparency of this process is key and mitigates risk.

9 Canadian Examples P.16
10 Canadian Examples P15 & 17.

8. Lab Information Systems- Pathology and Radiology (LIS & RIS)

It is noted that the TGA accepted the MSIA inclusion of radiology (RIS) into this exclusion. It is suggested for the sake of clarity that it be given its own line item.

The Canadian approach adopts the principle of excluding software which largely provides information rather than a decision, as well as software which is intended to administer or manage health processes or facilities[11]. Furthermore, the principle applied by Canada to Medical Device Data Systems[12] which refers to software which stores, retrieves or communicates medical images would appear to strengthen the exclusion of both RIS and LIS.

Finally, where the TGA is of the view that further discussion is required to assess this medium risk, the TGA principle of not duplicating existing regulation or imposing an unnecessary burden on industry, should come into play.

LIS and RIS are very well regulated by National Association of Testing Authorities, Australia, (NATA) which has a memorandum of understanding with the Commonwealth of Australia. NATA carries out the accreditation of pathology laboratories for the Department of Health. The NATA accreditation is to the standard "ISO 15189 Medical Laboratories - Requirements for quality and competence". The accreditation includes NPAAC publications, RCPA requirements, and other documents that cover specific areas within the laboratory, such as; ANZSBT-Australian & New Zealand Society of Blood Transfusion, British Society for Haematology and others.

The standard states that the "Laboratory Information System" is included in the definition of Laboratory equipment. 5.3.1 covers Equipment. 5.9 Release of results includes 5.9.2 which specifically includes the Automated selection and reporting of results. This is where the scientific/medical staff decide which rules/comments/reports they will 'configure' the LIS to handle. There is no AI in the LIS. There is no 'learning'. 5.10 Laboratory Information Management includes the validation and verification of the LIS and any subsequent changes. The requirement in this standard is that the Laboratory Management shall meet the requirements of the standard.

The LIS inclusion is specifically noted in the standard. The responsibilities are very well defined. Any result/comment/calculation that the LIS outputs, has been tested, verified, validated, and approved by Laboratory Management before it is implemented.

The MSIA would like your confirmation that LIS and RIS will therefore be excluded.

9. Natural Language Processing for Automation

The TGA has noted this as a high risk despite the clinical oversight as risk mitigation. Possibly the TGA needs an example to clarify the procedural flavor of this software.

For example, a doctor enters a clinical note (e.g. Patient with COPD presents with cough and fever". The NLP system picks up the mention of an existing condition (COPD), the **doctor confirms that the concept detected is correct,** the CDS then presents the hospital defined COPD management plan. **The doctor confirms the elements of the plan they want to action**, and the tasks are activated. In accordance with the principles of the Canadian Guidance and Examples, NLP should be excluded. The MSIA would be happy to elaborate on this aspect of SAMD.

11 Canadian Guidance p.9 & 14; Canadian Examples p.16
12 P.16

10. Confirmation that the TGA has accepted all of the additions and amendments from MSIA to Appendix 2

The MSIA and TGA have jointly created the final Carve Out Schedule Appendix 2. The MSIA has relied on the comments and acceptance of tracked changes by the TGA in its further consideration of the carve outs with its members.

Can the TGA please confirm that the draft schedule as annotated by the TGA is the proposed final version and if not what changes, deletions and additions are not going to be adopted?

3. Specific examples to support exclusion of software from regulation and to assist the TGA in understanding the level of risk:

a. Clinical Risk Detection Implementation

A hospital wants to set thresholds to detect patient deterioration due to sepsis in the CDS. The hospital presents us with an algorithm for implementation usually based on the published literature, but it may be extended with local expertise. The algorithm is provided by recognised authorities. This will include thresholds for vital signs (BP, Pulse, Respiration, etc.), but also may include a blood test (e.g. Lactate). The hospital specifies the escalation policy (i.e. who is to be notified) and may include recommended tasks to be presented to the clinician for their consideration. The tasks are presented to the user who has to confirm them e.g. call or page the infectious diseases specialist.

b. Monitoring Changes in Value

A hospital would like to identify patients that are at risk of kidney injury, so they ask to implement a CDS monitor that checks if a patient's kidney function (e.g. Creatinine value) falls by some percentage, e.g. 20%, over some period of time. Again, the hospital specifies the notification and any tasks to be presented. In this case the hospital decided that the renal unit should be notified automatically of any patient with impending kidney injury. In this case the hospital wants the CDS to generate the consult to the renal unit without a doctor's intervention. Note that the CDS is improving safety by increasing clinician oversight through automation of the consult, not activating any therapy.

Can the TGA confirm that based on the Canadian principles, the following software functions which all undergo clinical oversight after calculation would be exempted :

- Algorithms that calculate the dose, depending on the weight, height and gender entered as well as pathology results imported or manually entered into the EMR. e.g. calculation of Carboplatin dose, BSA.
- Ceased medication carrying forward to future protocols for clinical decision on whether to re-prescribe
- Dose reduction by percentage
- Carry forward dose change to future days/cycles
- Out of expected human range alert for manually entered patient weight, height etc.
- Alert on weight change >10% from baseline weight
- Calculation of expiry date of unused medication from manually entered compounded duration
- Risk assessment: calculation of Norton pressure risk score from manually entered parameters.
- HADS score calculation from manually selected parameters. (Hospital Anxiety and Depression score)

c. Automation of Hospital Protocols

The surgical unit within a hospital wants to improve compliance with pre-operative patient management by automating best practice protocols they have chosen from the evidence or developed locally through committees and the hospital governance processes. The protocol is based on the patient's co-morbidities as well as the operation type. When a patient is admitted to hospital for an operation, the CDS is triggered by the admission and operation booking and presents the tasks to the junior doctor as specified in the hospital's best practice plan, this may include recommended laboratory tests that must be ordered by the admitting doctor. The CDS will then monitor the lab results and notify the doctor if further attention is needed to avoid potential problems during surgery (e.g. due to blood thinners, bad renal function, etc.)

d. Best Practice Compliance Monitoring

Similar to the automation of hospital protocols, the hospital wants the CDS to ensure that anyone on a particular type of antibiotic (Aminoglycosides) for more than 2 days has their kidney function checked (e.g. on days 2, 4, 6, etc.) to avoid kidney damage. When a patient is prescribed these drugs the CDS will set a timer for 2 days to check if the patient is still on the drug, and if a kidney function has been ordered. If not, a reminder to order a kidney function or drug level is sent to the doctor in charge. If no further action is taken a pharmacist is notified of a high risk drug patient that requires further monitoring and oversight due to lack of compliance to hospital safety protocols by the doctor.

e. Risk Prediction

The hospital works with researchers to develop an algorithm that detects surgical patients at high risk of re-admission within 30 days of discharge. The CDS is used to invoke the algorithm and automate a workflow as defined by the hospital (e.g. notify a physician to oversee the medical problems of the surgical patient).

f. Patient Flow

The hospital works with researchers to predict if the Emergency Department is at risk of blockage due to patient demand overwhelming available resources, which may lead to ambulance ramping. A deep learning model is used to impending ED block and notifies an administrator to work with ED doctors to mitigate the risk.

g. Patient Home Monitoring

A patient takes their blood pressure and other biometrics, and also completes a symptom survey in a mobile app. The result demonstrates that the decrease in Sp02 (blood oxygen) and the symptom survey. Based on the virtual care and GPs specified criteria the CDS detects an increased risk of deterioration. The virtual care staff are notified of the change

in the patient's state and are requested to call the patient to (a) activate the action plan pre-specified by their GP and agreed to by the patient (e.g. take an additional dose of their medication) (b) ask them to repeat the test in an hour. The CDS reminds the patient to repeat the home monitoring and survey in an hour to track progress and possibly notify the GP. The system also reminds the virtual care staff to contact the patient if no call or contact is detected within a specified time.

h. Clinical Decision Principles

- CDS is not a single technology, and different forms and uses of CDS will require different levels of oversight.
- In particular we propose a that a carve out is important for the automation of **existing protocols** and **risk detection** using **explainable CDS** (e.g. rules and simple statistical models).
- The hospitals are required to validate the CDS, test scenarios, monitor the performance before invoking notifications and recommendations. For example, in Alcidion's Miya Precision, CDS cannot be deployed into production unless there is hospital governance sign-off. The performance of the algorithms is monitored to ensure that they continue to perform as expected over time.
- A full audit trail of all CDS activity must be available to understand why recommendations were made.
- CDS outputs are defined by the hospital and are all open-loop (i.e. require approval from a clinician to activate) except when requesting for additional clinical oversight (e.g. automatically notifying the renal unit for high risk kidney failure patients). CDS outputs may include:
  - Notifications to draw attention to clinical risk;
  - Hospital specified actions such as tasks (e.g. check BP), recommended orders (e.g. repeat kidney function test), actions to consider (e.g. a medication change), and recommendation for consults to other services (e.g. pharmacy, infectious diseases);
  - Automated consults to specialty units (the only closed-loop action).
- In the home monitoring example (7), the CDS does not generate a new plan, but notifies health care providers (virtual care, GPs), and reminds the patient to activate a pre-arranged plan and escalation policy they have agreed to with their doctor.

Regulating this form of CDS could in fact have the perverse effect of creating a dramatic increase in patient harm through preventable errors and reduction in best practice. Already in Australia over 25% of multi-day hospital patients suffer an adverse event in hospitals. One of our biggest demands is not for diagnostic systems, but assistance in implementing existing safety and best practice protocols.

One of the main barriers to improved safety and best practice is the sheer complexity of remembering all the different protocols and then manually entering them into ordering systems.

Certain CDS methods are not explainable, so called ‘black box’ algorithms (e.g. deep learning) — usual policy is to use these for patient flow or risk prediction, not for clinical management as they cannot be easily localised to individual hospitals, they are hard to test, and hard for clinicians to verify.

Finally, there is an increase is use of CDS for patient monitoring in the home. This largely follows the principles above of monitoring for changes or new symptoms. However, in the consumer case we believe a carve out is required for any CDS that recommends the patient (a) seeks medical advice, (b) implements agreed actions, and (c) digitises established practices and/or is based on medical authorities.