GUARDIANSHIP AND ADMINISTRATION AMENDMENT (MEDICAL RESEARCH) BILL 2020

Receipt and First Reading

Bill received from the Assembly; and, on motion by **Hon Sue Ellery (Leader of the House)**, read a first time.

Second Reading

HON SUE ELLERY (South Metropolitan — Leader of the House) [10.24 pm]: I move —

That the bill be now read a second time.

The government of Western Australia has declared a state of emergency and a public health emergency in response to COVID-19 and severe changes have been rolled out across the community to assist in stopping the spread of COVID-19. The state government is acting on the best medical advice in the country, but as a government we can do more to help our medical community and those patients who are suffering in their fight against COVID-19.

Currently in Western Australia, if a person has lost capacity to make his or her own decisions, even if for only a short period, medical practitioners are not authorised to seek consent for medical research from a patient's enduring guardian, guardian or next of kin. This effectively denies critically ill or otherwise incapacitated COVID-19 patients access to the cutting-edge treatments that are on trial throughout the world. If we are to provide the best health care possible for Western Australians, we must keep pace with the various treatment responses that could save our most vulnerable COVID-19 patients from serious harm or death.

The Guardianship and Administration Amendment (Medical Research) Bill 2020 provides critical legislative amendments that will enable our doctors to join the global effort to trial new and emerging treatments for COVID-19. Considerable efforts are underway worldwide to provide effective drug treatment for COVID-19. The World Health Organization is launching a multi-country clinical trial to test four drug regimens as COVID-19 therapies. A similar multi-country trial is taking place in Europe. Hundreds of other treatment trials are underway. Some COVID-19 patients are already receiving drugs that are the subject of clinical trials through compassionate-use programs. These programs allow doctors to order experimental medications in certain cases and for those medications to be used for purposes outside of what they have been approved for.

We need treatments that will slow or kill the novel coronavirus. We need to know what treatments are most effective so that we can reduce the time patients spend in hospital, particularly in intensive care. This knowledge can be gained only through medical research. Thirty-five companies and academic institutions around the world are exploring potential vaccines, including a team at the University of Queensland. One company has started human trials and another three claim to be close. However, experts are warning the population to be patient, with World Health Organization officials maintaining that a vaccine will not be available before the middle of next year. Human trials are essential to the development of a vaccine.

Last week, members would have heard Dr Andrew Miller, the president of the Australian Medical Association Western Australia, state that if Parliament does not pass amendments to the Guardianship and Administration Act 1990, our doctors and hospitals cannot offer all Western Australian COVID-19 patients a chance to benefit from the trial therapies that are being used around the world. Dr Miller is right. All Western Australians must be able to access the drugs and treatments that are being tested in other countries to give them the best chance possible for recovery. While many other Australians will benefit from rapidly advancing treatments, even cures, Western Australians under legal incapacity would be unable to do so. Currently, Western Australia legislation enables an enduring guardian, guardian or a person responsible to make a decision regarding medical treatment, but this does not extend to participation in medical research.

If a person has lost the capacity to make his or her own decision about medical treatment, even if only for a short period, the Guardianship and Administration Act 1990 authorises a person responsible to make treatment decisions on their behalf. If a person has not completed an advance health directive or appointed an enduring guardian or guardian, a person responsible is the first person in order of the priority prescribed in section 110ZD of the act who is of legal capacity, is reasonably available and is willing to make a treatment decision at the time the treatment is required. The order of priority is, first, the patient's spouse or de facto partner if that person has reached 18 years of age and is living with the patient; second, the patient's nearest relative who maintains a close personal relationship with the patient; third, the person who has reached 18 years of age and is the primary provider of care and support to the patient but is not remunerated for providing that care and support; and fourth, any other person who has reached 18 years of age and maintains a close personal relationship with the patient. This order of priority is more commonly referred to as next-of-kin consent.

The problem with the existing legislation as highlighted in the COVID-19 pandemic environment is that persons responsible are authorised to make only treatment decisions. For the purposes of the Guardianship and Administration Act 1990, treatment means medical or surgical treatment, including a life-sustaining measure and palliative care; dental treatment; and other health care. The act does not authorise enduring guardians, guardians or next of kin to

consent for patients to participate in medical research, including drug and treatment trials. This overlooks the continuum between treatment and research, which exists in many cases. A single patient may be treated in his or her best interests—or in a way that is, at least, not adverse to their interests—but the treatment is also part of larger research for the community's benefit.

In 2015, a statutory review of the Guardianship and Administration Act 1990 recommended that the legislation be amended to enable a person responsible to make a decision on behalf of a person, for that person to participate in medical research, including treatment that is part of research, in certain circumstances, including if it is in their best interests to do so, considering the risks involved, human research ethics, and other factors. The statutory review was tabled by the Liberal–National government in 2015, but no action was taken to implement the recommended legislative amendments to the Guardianship and Administration Act 1990. Although the McGowan government recognises the importance of implementing all the supported recommendations from the statutory review, the recommendations dealing with consent to medical research are, in the current environment, crucial. The amendments in the Guardianship and Administration Amendment (Medical Research) Bill 2020 will ensure that all Western Australians have the opportunity to participate in world-leading research and experimental treatments specifically targeted at combating the COVID-19 coronavirus.

I will outline the bill's key amendments, which will, in brief, allow enduring guardians, guardians and next of kin to consent to medical research and, in emergency circumstances, enable an independent medical practitioner to authorise research without consent, subject to strict safeguards and stringent conditions to protect the person.

The bill will insert new part 9E, which relates to medical research. Medical research is defined as research conducted with or about individuals, or their data or tissue, in the field of medicine or health. Medical research will include research activities such as the administration of pharmaceuticals or placebos, the use of equipment or a device and the provision of health care that has not yet gained the support of a substantial number of practitioners. The bill provides an order of priority of persons who will be able to make a research decision about a person. This person is referred to as the research decision-maker. The order of priority detailed in the bill will authorise a person responsible to make a research decision. If a person has not appointed an enduring guardian or a guardian, a person responsible is the first person in order of priority who is of legal capacity, is reasonably available and is willing to make a research decision at the time the research decision is required. The order of priority will mirror the current next-of-kin consent for treatment decisions.

The bill ensures that a research decision-maker cannot consent to a person participating in the medical research unless the research is in the best interests of the person or is not adverse to the interests of the person. If the research goes beyond observation or non-invasive examination, treatment or procedure, then the research decision-maker cannot consent to participation unless the research will not involve any known substantial risks to the person; any known substantial risks greater than the risks associated with existing treatment; or any substantial risk greater than if the person did not participate in the research.

The principles of the Guardianship and Administration Act 1990 revolve around best interests and respect for a person's wishes, and the bill ensures the amendments have regard to these principles. The bill inserts a new section that prescribes the factors that must be taken into account when determining whether participation in medical research is in the best interests of the person.

The bill provides that the following factors must be considered: the wishes of the person; the likely effects of participation, including the existence, likelihood and severity of any potential risks, and whether those risks are justified by any likely benefits of the research; any other consequences if the person is not involved in the research; any alternative treatments available to the person; and any other prescribed matters.

The bill clearly states that, when making a research decision, the research decision-maker must regard the wishes of the person as the paramount consideration. If a person has an advance health directive in place that specifies his or her wishes about participation in medical research, or particular types of medical research, following this directive will be mandatory.

If a person requires treatment urgently to save the person's life, prevent serious damage to the person's health, or prevent significant pain or distress, and it is not practicable to obtain a research decision from a research decision-maker within an appropriate time frame, the bill permits a researcher to carry out research approved by a human research ethics committee. However, this can occur only if an independent medical practitioner has determined that a person is incapable of making reasonable judgements about research for themselves, and if an independent medical practitioner has determined that the research is in the best interests of the patient, or is not adverse to the interests of the patient by increasing his or her medical risks.

In order to access these provisions and make a research decision without consent, the medical research must meet the following stringent conditions: the research must have been approved by a human research ethics committee; the human research ethics committee approval must have been provided with the requirement for prior consent; and

the research must be in the context of urgent care. In addition, to make a research decision without consent, the person must be unable to make reasonable judgements about their participation in the research; in an independent medical practitioner's opinion, the person is not likely to regain capacity to give consent within a time frame specified by the human research ethics committee; it is not practicable to obtain consent from a person responsible; and participation in the research does not involve any known substantial risks to the candidate, or any substantial risk greater than the risks associated with existing treatment.

Critically, in addition to these factors, an independent medical practitioner must confirm that the person's participation in the research is in the person's best interests or is not adverse to their interests. As is required for medical research with consent, the bill clearly states that when making a research decision in an emergency situation, an independent medical practitioner must regard the wishes of the person as the paramount consideration.

The State Administrative Tribunal is to be vested with additional powers to ensure that a person may apply to the tribunal for review of a decision made under the medical research provisions. The review process will engage the various powers of the tribunal contained in the State Administrative Tribunal Act 2004. The policy is that the tribunal may review a decision about whether research is in the best interests of a candidate, or whether a candidate is able to make reasonable judgements about undertaking the research. If the tribunal considers that a review is warranted, it may, effectively, set aside a decision made by a research decision-maker or a researcher, but only with prospective effect, and without affecting the validity of anything done by a researcher in reliance upon the decision prior to the tribunal's decision. That protects the researcher acting upon the basis of a research decision, but allows the prospect of the tribunal intervening to correct research decisions that ought not to have been made. Obviously, this will be important for research that has yet to be carried out, or has been only partially carried out.

The right of review will be of less utility in cases if the research has been wholly carried out in urgent circumstances prior to the opportunity for a review application to be made. However, in the last case, the policy balance between the need for an urgent decision and urgent action, and any need for review of that decision by the tribunal, falls upon the side of allowing the urgent decision to be made and implemented in accordance with the safeguards that are already provided in part 9E.

Finally, a review clause has been included that requires that the operation and effectiveness of the amendments made by the bill be reviewed after one year, with the resulting report to be tabled in Parliament. The state government recognises that due to the urgency presented by the coronavirus, consultation on the bill has not been as comprehensive as we would like. Consequently, the review clause will enable amendments to be reviewed, with any wide input from medical and consumer stakeholders, to ensure that the policy intent of the amendments is workable on an operational level.

The bill does not enable participation in medical research as a general blanket provision but, rather, ensures specific consideration of a number of factors relevant to each individual situation. The bill maintains a balance between the considerations of the best interests of the person, while at the same time ensuring that our medical practitioners can make research decisions in time-critical emergency situations. It is supported by significant safeguards to uphold the rights and protections of the person, it contains an avenue for review by the State Administrative Tribunal, and requires a comprehensive statutory review of the amendments after one year.

Most critically, the bill authorises a person responsible to make a research decision on behalf of a person who is under legal incapacity. We need to make these amendments our highest priority to ensure that our most vulnerable Western Australians have the opportunity to access the experimental treatments being trialled to combat COVID-19. To delay these amendments any further will only deny Western Australians the opportunity to receive potentially lifesaving treatment during this pandemic.

Pursuant to standing order 126(1), I advise that this bill is not a uniform legislation bill. It does not ratify or give effect to an intergovernmental or multilateral agreement to which the government of the state is a party; nor does this bill, by reason of its subject matter, introduce a uniform scheme or uniform laws throughout the commonwealth.

I commend the bill to the house and table the explanatory memorandum.

[See paper 3758.]

Debate adjourned, pursuant to standing orders.

Made Order of the Day — Motion

On motion by **Hon Sue Ellery (Leader of the House)**, resolved —

That the second reading of this bill be made an order of the day for the next day's sitting.

House adjourned at 10.40 pm