Impact Summary: Regulation of paramedics

Section 1: General information

Purpose
The Ministry of Health (the Ministry) is solely responsible for the analysis and advice set out in this Impact Summary, except as otherwise explicitly indicated. This analysis and advice has been produced for the purpose of informing final decisions to proceed with a policy change to be taken by or on behalf of Cabinet.
Key Limitations or Constraints on Analysis
Financial The monetary benefits and costs of regulating the paramedic profession are not easily quantified. Information from some existing regulated professions provides some indicative financial costs. There may be increased costs to individuals, providers, the health system, Government and the economy. There are limitations to accurately forecasting savings that may result from avoidance of harm and increased safety to the public. *Exclusions* The Ministry has not included the regulation of the emergency medical technicians (EMT) workforce in this impact summary. Around half of EMTs are volunteers and the regulation of this group of health professionals is out of scope for this analysis. If the paramedic profession is regulated under the Health Practitioners Competence Assurance Act 2004 (the Act), the responsible authority of the paramedic profession will have the remit and power under the Act to consider regulating EMTs in the future. *Consultation* The Act requires the Minister of Health to consult with any organisation that, in the Minister's opinion, has an interest in the regulation of the profession. The former Minister, Hon Dr Jonathan Coleman, agreed to a targeted consultation process with key stakeholders. Wider public consultation has not been carried out. *Non-government funded ambulance services* Non-government funded ambulance services were invited to make submissions on the regulation of paramedics, but their low response (4) impacts on the analysis of their views. The Ministry has identified 16 non-government funded ambulance services operating in New Zealand. There is little information available about their number of vehicles and employees, and how many employees practise at the level of a paramedic.
Responsible Manager (signature and date):
Helen Wood Acting Deputy Director General Health Workforce Directorate Ministry of Health Date

Section 2: Problem definition and objectives

2.1 What is the policy problem or opportunity?

Paramedics and what they do

Paramedics (including intensive care paramedics), first responders and EMTs are health professionals working in New Zealand's ambulance services.

New Zealand currently has a paramedic workforce of approximately 1,000 individuals. The paramedic workforce is estimated to increase to 1,400 by 2020/21 to ensure all emergency road ambulances are double crewed.

The role of the paramedic includes:

- safe transport to appropriate care (such as emergency departments, after-hour clinics, general practices)
- a range of medical and surgical procedures
- administration of medicines
- treatment of patients in life-threatening situations
- clinical decision making about patient transport and referrals in emergency situations.

First responders and EMTs are the larger group of the wider ambulance workforce (representing 78 pecent of the St John and Wellington Free Ambulance workforce). They attend the lowest number of calls as they predominately work in low workload areas. They have shorter periods of training than paramedics, but they can make decisions that impact on patient health and welfare. However, their autonomy to make clinical decisions is limited by their scope of practice, which is narrower than the paramedic profession's and does not include high risk clinical interventions.

Increasing demand for ambulance services

Demand for emergency ambulance services is increasing by 4 to 5 percent a year, and a growing proportion of 111 calls for ambulance services are for non-urgent cases. To meet the needs of an increasing and ageing population, the ambulance sector its expanding its traditional ambulance transport model — this involves giving the paramedic workforce increasing responsibility to treat patients at the scene, refer patients to alternative health providers (such as after-hours clinics and general practices), or transport patients to an emergency department.

The autonomy to make clinical judgements about patient referrals, combined with situational and environmental risk factors (e.g. poor information about patient history) can increase the likelihood of paramedics causing harm to patients under this new model of care. Increasing demand for paramedics and expanded models of care have the potential to increase the incidence of harm to the public who are particularly vulnerable in an urgent situation.

Evidence of risk of harm to the public

Although the practice of the paramedic workforce has risks, there are few known events of the paramedic workforce causing significant harm. The Ministry has examined reported serious adverse events, complaints data, coroner cases and court convictions to look for evidence of harm caused by paramedics. It is not possible from these sources of evidence to distinguish paramedics from other ambulance roles, but the evidence shows that relatively few individuals from the wider ambulance workforce have harmed members of the public. There is no published information that shows whether the paramedic workforce

are incorrectly performing an invasive procedure or making an unsafe decision not to transport a patient to an emergency department.

Reported serious adverse events

St John and Wellington Free Ambulance are required to document and investigate any clinical adverse event and notify the ACC and the Ministry's National Ambulance Services Office (NASO) of events that are classified under the Severity Assessment Code (SAC) as a 1 or 2. Information about SAC 1 and 2 adverse events is published on the provider's website after the events have been investigated and the SAC classification confirmed. In the two years from July 2015 to June 2017, 147 SAC 1 and 2 reported events were closed. Of those 147 events, 51 (35 percent) were attributed to the decisions and/or actions undertaken by ambulance officers at the scene of the emergency. Other causes include issues relating to the communication centre, technology, equipment and transport.

Closed coroners cases

The website of Coronial Services of New Zealand[1] provides a searchable summary of recommendations arising from coroner cases opened after July 2007 that are now closed. A search of 'paramedic' gives 30 cases. In 18 of these cases, the person died before the paramedic arrived or was unable to be revived. Of the remaining 10 coroner cases, two mention the clinical judgement and competency of ambulance officers:

- St John's Medical Director advised the coroner that the paramedic involved did not recognise the severity of the patient's condition and the appropriate hospital for the patient to be transported to (September 2015).
- The coroner recommended that St John take steps to address failures to pass on appropriate information between ambulance crews and continue with a robust ongoing clinical competence review of staff to ensure that training and skills are not lost (July 2012).

Health and Disability Commissioner (HDC)

Since 2008, the HDC has received 112 complaints about ambulance services, including four complaints about ambulance officers. Information available about HDC complaints includes the following three cases:

- Clinical decision making by a paramedic during a patient transfer that led to a patient death.
- Conflict of interest of the ambulance service and care provided. This complaint did not originate from the consumer and was not supported by the consumer. The HDC did not continue its investigation.
- Standard of care and medication administered. At the time of preparing this Impact Summary, the outcome of this investigation had not been released.

St John and Wellington Free Ambulance

St John and Wellington Free Ambulance have provided the Ministry with the type and number of complaints they received from January 2014 to September 2015. There was a total of 1,179 complaints (1,150 for St John and 29 for Wellington Free Ambulance). Each organisation has provided the data differently but, in both cases, the majority of the complaints (between 40 to 50 percent) were about the attitude and communication of ambulance officers. About 15 to 20 percent of complaints were about clinical matters and adverse events.

[1] http://coronialservices.justice.govt.nz/findings-and-recommendations/

Addressing risk of harm

There are a number of existing mechanisms to manage the risks of harm of the paramedic and wider ambulance workforce (see Appendix 1). For example, St John and Wellington Free Ambulance:

- have established clinical procedures and guidelines
- operate a clinical desk service to provide clinical advice to ambulance officers in the field
- set and restrict the procedures and medications that ambulance officers can perform according to their qualifications and delegated scope of practice.

However, there are limits with how these existing mechanisms address risks of harm (see Appendix 1). A major limit is that there is no consistent standard or independent body for monitoring the competency of the paramedic profession. Under the current regulatory environment, the onus is on the ambulance provider to ensure its workforce is competent and fit to practise. The paramedic profession may require increased oversight if they are to treat patients in the home or community under the new ambulance model of care.

Many submitters from the targeted stakeholder consultation process commented that the highest risk of harm to the public is the paramedic profession's autonomy to decide whether to transport patients to emergency departments. Submitters also considered that situational and environmental risk factors, such as poor information about patient history, can increase the likelihood of paramedics causing harm to patients. There have been documented HDC cases and submissions provided that describe errors in clinical judgement (non-transportation and missed diagnosis).

The paramedic profession's current scope of practice has severe risk of harm, such as laryngeal intubation and administration of suxamethonium (a paralysing drug) – these high risk procedures are performed without supervision. Other medications that paramedics use frequently also have the capacity to result in severe harm to patients if used inappropriately (such as pain relief medications).

There may be under-reporting of harm as:

- there is no national standard for investigating adverse events involving ambulance officers
- ambulance officers may be hesitant to self-report adverse events
- patients may not know how to make a complaint about ambulance officers
- patients are often not conscious of the care they receive from ambulance officers.

Government and non-government funded ambulance services

There are about 16 non-government funded ambulance services operating in New Zealand. Non-government providers of ambulance services are not legally required to comply with the New Zealand Standard for Ambulance and Paramedical Services NZS 8156:2008 (the Ambulance Standard) and government requirements for clinical safety and oversight. This is because they do not receive government funding. Government-funded ambulance services are contractually required to comply with the Ambulance Standard and government requirements for clinical safety and oversight.

Both government funded and non-government funded ambulance services are subject to the Health and Disability Code of Consumers Rights the same as any other health service provider (organisations and individual professionals).

There is no mandatory requirement for non-government funded ambulance services to report adverse events.

Opportunity for regulation to reduce risk of harm

There is an opportunity to reduce the potential risk of harm to the public by regulating paramedics under the Act.

Regulation would provide mandatory national standards, qualifications and competencies for all paramedics, and a mechanism to consistently monitor complaints and a paramedic's fitness to practice. This would more clearly distinguish, for the public and the sector, between the different ambulance officer roles and competencies. It would remove uncertainty about the level of service an ambulance officer was qualified to provide regardless of whether or not the ambulance service received government funding.

Regulation would also bring paramedics into line with other professions that provide similar high risk services (e.g. doctors and nurses).

2.2 Who is affected and how?

Regulation would provide additional mechanisms to reduce the risk of harm to the public from the practice of paramedicine. Regulation would ensure a consistent professional standard, qualifications and competencies across paramedic services regardless of whether they are government funded or not.

Other national consistencies would also result (e.g. a code of ethics for all paramedic services) that would benefit the public.

Targeted consultation with key stakeholders showed a high degree of support for regulation of paramedics. Most saw the benefit to public safety. Concerns about some of the detail and the costs of regulation were raised rather than concern about regulation itself. There may be some non-government funded ambulance services that do not support regulation.

Refer to Section 5 Stakeholder views for information about the consultation process and results.

2.3 Are there any constraints on the scope for decision making?

The Ministry recognises the potential for paramedics to expand their scope of practice to support acute care in primary health settings and hospitals. Barriers to enable more effective use of paramedics in this role must be reduced. The potential role of paramedics has influenced our analysis of the options.

Section 3: Options identification

3.1 What options have been considered?

Two aspects require consideration:

1. **Industry self-regulation** versus **statutory regulation of paramedics** considers the costs and benefits of each approach, primarily in terms of public safety and financial cost. Under both options, government funded ambulance services would continue to be subject to contractual requirements that aim to minimise risk and monitor performance.
2. **Governance options for regulating paramedics** if regulation is agreed by Cabinet considers the costs and benefits of different governance models, primarily in relation to financial cost and benefits for public safety.

Industry self-regulation (the status quo)

Benefit of continued self-regulation

The primary benefit of maintaining the status quo is that there would be no increased regulatory costs for either government or non-government funded ambulance services/paramedics.

Disadvantages of continued self-regulation

Under this option, paramedics would continue to provide services that pose a risk of harm to the public, with no legislative mandate that requires them to maintain their competencies and fitness to practise. Under the current regulatory framework, employers would remain responsible for ensuring the safety and competency of the paramedic workforce. Paramedics would continue to:

- perform medical and surgical procedures, administer medicines and treat patients in life-threatening situations
- undertake clinical decision-making about patient transport in emergency situations and referrals with limited clinical supervision
- operate with expanded models of care (i.e. primary care).

Under self-regulation, the Medicines (Standing Order) Regulations 2002 would continue to operate. Under these regulations, Medical Directors have legal responsibility to ensure ambulance officers are competent to safely administer and supply medications to patients under Standing Orders. This is not always ideal in situations where complex decisions are needed urgently and a Medical Director is not present.

Without regulation paramedics are not able to apply to become authorised or delegated prescribers under the Medicines Act 1981 and Misuse of Drugs Regulations. This would be a more effective and efficient use of paramedics and help support timely treatment to the public without compromising safety and quality.

Voluntary self-regulation limits the opportunities to monitor the safety of ambulance services, particularly those that are not government funded and are not subject to performance management contracts with the Ministry and ACC.

Self-regulation does not prevent a paramedic who has left one employer for reasons linked to public safety from continuing to work as a paramedic under a different employer.

Statutory regulation of the paramedic profession

Benefits of regulating paramedics under the Act

Regulating the paramedic profession under the Act will provide a greater assurance of public safety and reduce the risk of harm to the public by implementing a mandatory national set of standards, qualifications and competencies for the profession.

The main providers, St John and Wellington Free Ambulance, agree on many of the key components for regulation: qualifications, standards and competencies required for paramedics that mitigate the risk of harm to the public. Under statutory regulation, the proposed Paramedic Council would be charged with consulting on and establishing professional standards, qualifications and competencies, which would then be mandatory for paramedics wishing to practise in New Zealand.

The Act (section 118) also sets out other mechanisms that are not possible without regulation, by which public safety may be protected. For example, regulation will enable a responsible authority to:

- accredit paramedic education programmes/providers
- maintain a publicly available register of registered practitioners and any conditions on their practice (this would be a more significant benefit to the public as paramedics move further into primary care services)
- require practitioners to participate in a continuing professional development programme
- notify employers, ACC, the Director-General of Health, and the HDC that the practice of a health practitioner may pose a risk of harm to the public.

Regulation would allow the profession to apply for suitably trained paramedics to prescribe and/or administer certain medications without relying on Standing Orders. This could be a more effective and efficient use of paramedics and offer more timely treatment to the public without compromising safety and quality.

The use of the term paramedic would also be restricted. Non-government funded ambulance providers that provide paramedic-level services would be required under the Act to have registered paramedics with a valid annual practising certificate. This would provide the public with increased assurance over the safety of ambulance services and avoid confusion over who is qualified and competent to practise as a paramedic.

Paramedics would also have increased recognition of their role in multidisciplinary primary health care through agreed scopes of practice. Regulation will also mean quality and safety assurance for other health professions, district health boards, primary health organisations and private industries employing paramedics that the paramedic workforce is fit to practise.

Regulation will support greater workforce mobility internationally, where standardised entry requirements for paramedics into the profession will also mean that overseas paramedics will have a clear pathway to seek employment in New Zealand.

Regulating paramedics would also bring New Zealand in line with other countries. Other 'peer' jurisdictions that have regulated the paramedic profession include the UK, Canada, Ireland, South Africa and, from 2018, Australia.

Mobility between New Zealand and Australia is supported in the Trans-Tasman Mutual Recognition Arrangement (TTMRA). The TTMRA allows for people who are registered in an occupation in Australia to apply to be registered for that same occupation in New Zealand

(and vice versa) without having to undergo any further testing requirements. This only applies when there is a requirement to be registered in an occupation in both countries. Therefore, if New Zealand and Australia both require registration of the same profession, it makes it easier for professionals to move between the two countries.

Disadvantages of regulation under the Act

Regulation comes at a cost. The financial costs of regulation and how those costs would be met is outlined at the end of this section of the Impact Summary. The cost sharing approach outlined will minimise the cost of regulation, particularly for individual paramedics.

Regulation under the Act will not apply to EMTs and non-government funded ambulance providers who practise below the level of a paramedic. These ambulance officers will continue to be regulated under industry and employer self-regulation, Medicines (Standing Order) Regulations 2002, and the Health and Disability Code of Consumers Rights.

However, in the future, the responsible authority that regulates the paramedic profession would have authority under the Act to regulate other parts of the ambulance workforce, such as EMTs, after consulting with affected parties. This will result in additional regulatory cost on emergency ambulance road services.

Regulation under the Health and Disability Services (Safety) Act 2001 (Health Services Safety Act)

Regulating ambulance services through the Health Services Safety Act, either in addition to or instead of regulation under the Act, was also considered.

The purpose of the Health Services Safety Act is to:

a) promote the safe provision of health and disability services to the public

b) enable the establishment of consistent and reasonable standards for providing health and disability services to the public safely

c) encourage providers of health and disability services to take responsibility for providing those services to the public safely

d) encourage providers of health and disability services to continuously improve the quality of those services.

To meet the purposes of the Health Services Safety Act, providers of health and disability services recognised under the Act[2] must be certified against relevant service standards. If they operate without certification, they must pay a fine of no more than $50,000.

There is no contractual or legal obligation for non-government funded ambulance providers to comply with the voluntary Ambulance Standard. Regulating ambulance service providers under the Health Services Safety Act would ensure that all ambulance providers complied with the same standard of service, including standards for managing clinical risk and competency of their workforce.

The Ministry does not propose that ambulance service standards be made mandatory under the Health Services Safety Act at this time as there are a number of factors that still require consideration.

- There must be a clear case that making ambulance service standards mandatory under the Health Services Safety Act is in the interests of public safety.

[2] Hospitals, rest homes, providers of residential disability care and fertility service providers must meet relevant approved standards under the HDSS Act.

- A decision will be required from the Minister of Health about whether to recommend to the Governor-General to issue an Order in Council for ambulance services to be included in the Health Services Safety Act.
- It is not clear whether non-emergency medical transport and/or first-aid level care at events and industry settings are considered 'ambulance services'.
- Regulating ambulance services under the Health Services Safety Act is permanent as an Order in Council issued under the Health Services Safety Act cannot be revoked.
- The Minister would need to consult on, then approve, a new standard for ambulance services under the Health Services Safety Act.
- The cost of compliance for some service providers could be prohibitive
- Service standards consider the whole of service, with less direct emphasis on the competency of a particular profession within the service.

The Health Services Safety Act requires services to be audited by an auditing agency designated by the Ministry. Auditing agencies would need to apply to the Ministry to be designated the role of auditing ambulance providers. Auditing agencies and ambulance services would need to regularly apply to the Ministry to be re-designated (in the case of auditing agencies) or certified (in the case of service providers).

Governance options for regulating paramedics – if regulation is agreed

Under the Act, health professions are regulated by an independent responsible authority, with members appointed by the Minister. The Act sets out the functions of responsible authorities and requires operating costs to be funded from their registrants on a cost recovery basis. Actual costs vary according to factors such as the number of registrants, the size of responsible authorities and the number of disciplinary proceedings.

Establishing a new responsible authority – the Paramedic Council

Establishing a new responsible authority, the Paramedic Council, would provide governance arrangements that enable the regulation of the paramedic profession and support the further progression of the health profession.

The Ministry, Ambulance New Zealand and the Nursing Council of New Zealand (Nursing Council) agree that establishing the Paramedic Council, with secretariat support from the Nursing Council, is the simplest and most cost effective governance option.

To comply with the Act, the Paramedic Council would require a minimum of five members and the Ministry and profession do not see the need for more than five members. This number is low compared to most other responsible authorities. For example, the Nursing Council currently has eight members, the Medical Council has ten members and the Optometrists and Dispensing Opticians Board (with 900-1000 practising registrants across two professions) has eight members.

Establishing the Paramedic Council would also ensure that the regulatory body would be governed largely by its own profession, with 1-2 lay members (depending on the size of the responsible authority). While this is generally considered a positive by the health sector, it can raise concerns for the public about conflict of interest when it comes to addressing complaints about practitioners. The Health Practitioners Competence Assurance Amendment Bill (the Bill) includes provisions to increase public, and government, confidence in responsible authorities and their focus on public safety. The Bill has had its second reading (8 November 2018) and is progressing towards its third reading in the House of Representatives.

A dedicated responsible authority for the paramedic profession would improve the health system's ability to collect workforce data to support the future planning of the paramedic

profession. The Bill has provisions requiring responsible authorities to collect workforce data and provide that data to the Ministry.

Joining the paramedic profession to an existing responsible authority – the Nursing Council of New Zealand

Other options for governance included joining the paramedic profession to an existing responsible authority by either:

- blending the Paramedic Council with the Nursing Council. This would require Paramedic Council members to be added to the Nursing Council (indicative costing of [redacted] It may also require a change of name to better reflect that it encompasses two distinct professions.
- the Nursing Council providing governance for the paramedic profession, assisted by a paramedic advisory committee (costing about [redacted]

Both of these options would mean higher governance costs than for a separate Paramedic Council due to increased Nursing Council members to include adequate paramedic representation and to cover increased governance related expenses. Appendix 2 sets out cost implications under three options: establishing a Paramedic Council, establishing a blended Council with the existing Nursing Council, and placing paramedics within the Nursing Council.

The proposed APC fee of [redacted] under a Paramedic Council is lower than the APC fees of 11 of the 14 allied health responsible authorities. The proposed APC fee increases by [redacted] under option 2 and [redacted] under option 3 to recover the cost of supporting a nine- to eleven-member Nursing Council.

It is likely that APC fees under any of the three governance options will fluctuate in the future. The APC fee may decrease as more paramedics are registered. On the other hand, the disciplinary levy included in the APC fee may increase if there are a high number of competency and disciplinary hearings. Responsible authorities are obliged to remove or reduce their disciplinary levies once they have accumulated sufficient reserve funds [3].

Financial cost of regulation and meeting the cost

The Nursing Council has estimated that the costs per individual practitioner will include:

- a one-off registration fee ($0 in the first year, and an estimated [redacted]-per registering paramedic in subsequent years), assuming that, at some point in the future, the Paramedic Council may set a registration fee
- an annual practising certificate (APC; an estimated [redacted]-per paramedic).

The Act allows responsible authorities to set fees and levies on a cost recovery basis. The APC may increase if the Paramedic Council has to deal with a higher than expected regulatory costs, such as an increased number of competency and disciplinary hearings. The Paramedic Council would be required to consult with relevant stakeholders on any changes to its regulatory fees.

Fees and levies must be developed in accordance with the principles and guidelines published by the Office of the Auditor-General (*Guidelines on Charging Fees for Public Sector Goods and Services*), Parliament's Regulations Review Committee, and the New Zealand Treasury (*Good Practice Guideline for Setting Charges in the Public Sector*). The Board must ensure it takes into account (for example) the principles of efficiency,

[3] The Auditor-General and The Treasury's guidelines for charging public sector services state that regulatory fees must be based on cost recovery purposes and kept as low as possible.

accountability, cost-recovery, and consultation with registrants and other relevant stakeholders.

In addition to the regulatory fees, paramedics will have the choice of obtaining professional indemnity insurance to cover the potential costs of legal representation during competency and disciplinary hearings and claims of negligence. The professional indemnity insurance premium is estimated to cost between [redacted] and [redacted] per paramedic, to be paid to the insurance provider. The Act does not require registered practitioners to have professional indemnity insurance. It will be up to employers, unions, and registered practitioners to:

- arrange for indemnity cover and negotiate its cost
- consider whether indemnity insurance is included in union or professional membership fees and reimbursed under employment agreements.

In total, it will cost between [redacted] to regulate 1,400 ambulance officers practising as front line paramedics at St John and Wellington Free Ambulance in the first year of implementation. This cost [redacted] and comprises of:

- a one-off cost of [redacted] to establish the regulatory framework
- an annual cost of [redacted] for APC fees
- an estimated annual cost of [redacted] to [redacted] for professional indemnity insurance.

Ambulance New Zealand has committed to contributing financially to the establishment of the Paramedic Council. The Auckland University of Technology, and St John have also agreed to provide administrative support to register the first intake of paramedics. This will enable registration of paramedics to be free for the first year of implementation.

From the second year onwards, regulating front line paramedics is [redacted] per annum
. This cost comprises of:

- an annual cost of [redacted] for APC fees
- an estimated annual cost of [redacted] to [redacted] for professional indemnity insurance
- an estimated [redacted] for 100 New Zealand paramedic graduates to apply to the Paramedic Council for registration.

The Ministry and ACC have agreed to provide emergency ambulance services with additional funding of up to [redacted] to contribute to the cost of implementing paramedic regulation. This funding would come the Ministry and ACC's existing baselines and should be sufficient to cover the APC fees for up to [redacted]

This is in acknowledgement of increasing expectations from the health sector, including the Ministry, that paramedics will increasingly deliver an expanded model of care (such as after-hours home visits to prevent hospitalisation) and that the paramedic profession will provide a highly specialised health service in the health system. It also recognises that APC fees for most other regulated health practitioners are paid by their employers. DHBs, for example, routinely pay employee APCs under multi collective employment agreements.

There is a risk that the funding increase will be seen as a precedent for other health professions that apply to become regulated under the Act. However, the Ministry believes that an exception should be made for paramedics as emergency road ambulance services

are partly funded by the Ministry and ACC. Additionally, ACC already considers the cost of regulation as part of overheads when determining prices for services.

The potential risk of harm from the practice of paramedicine makes it necessary to regulate paramedics and, given the nature of ambulance service funding, it is reasonable for the Ministry and ACC to increase the baseline funding to contribute to the cost of regulation for contracted ambulance services.

3.2 Which of these options is the proposed approach?

The preferred option is to regulate the paramedic profession under the Act and establish a new responsible authority, the Paramedic Council, with secretariat support from the existing Nursing Council.

Regulating paramedics under the Act will provide mandatory national standards, qualifications and competencies to reduce the risk of harm from paramedic services. Regulation will also provide mechanisms to better monitor and manage concerns/complaints about a paramedic's fitness to practice.

Establishing the Paramedic Council with secretariat support provides the most cost-effective way to achieve regulation without compromising professional clinical expertise or public safety.

Section 4: Impact Analysis (Proposed approach)

4.1 Summary table of costs and benefits

Affected parties *(identify)*	**Comment**: nature of cost or benefit (eg ongoing, one-off), evidence and assumption (eg compliance rates), risks	**Impact** *$m present value, for monetised impacts; high, medium or low for non-monetised impacts*	
Additional costs of proposed approach, compared to taking no action		*Year 1*	*Year 2 onwards*
Ambulance New Zealand	Ambulance New Zealand, the representative body of aeromedical and ambulance services, has agreed to contribute to the one-off costs of establishing the paramedic regulatory framework and registering the first intake of paramedics. Estimated establishment costs involve utilising the Nursing Council's resources and expertise, and appointing a fixed-term paramedic advisory group.	[redacted]	[redacted]
Ministry of Health and ACC	The Ministry and ACC will each provide up to [redacted] a year to St John and Wellington Free Ambulance's contract for emergency road ambulance services in the 2020/21 financial year. Funding from the Ministry would come from the Vote Health National Emergency Services appropriation. The additional funding will assist publicly funded ambulance service providers in reimbursing the [redacted] Paramedics will be responsible for paying the APC fees to the Paramedic Council, which will use the funds to support the governance and administrative costs of regulating the paramedic profession.	[redacted]	[redacted]
Publicly funded ambulance service providers, unions, and employees	St John, Wellington Free Ambulance, air ambulance providers, unions and individual paramedics will be responsible for negotiating: • the annual costs of professional indemnity insurance [redacted] • how to pay for any future increase in APC fees set by the Paramedic Council.	[redacted]	[redacted]
New Zealand-trained Paramedic graduates	Approximately 70 to 100 students graduate from the New Zealand paramedic degree programmes each year. After the first year of implementation, Graduates applying for registration with the Paramedic Council will be	[redacted]	[redacted]

	responsible for paying the registration fee, which is estimated to cost [redacted]		
Other parties	An unknown but small number of paramedics will be working for non-Government funded ambulance providers and other employers (such as industrial sites, primary health care providers, DHBs). These paramedics will be responsible for negotiating with their employer on who pays the registration fee, APC fee and professional indemnity insurance premium.	Unknown	Unknown
Total Monetised Cost		[redacted]	[redacted]
Non-monetised costs	Non-government funded ambulance providers may be unable or unwilling to meet regulatory costs and cease to operate ambulance services. The impact of this on remaining ambulance services is difficult to quantify.	Low	Low

Expected benefits of proposed approach, compared to taking no action		
Regulated parties	Consistent standards of training, scopes of practice, code of conduct and ongoing competencies.	High
	Provides an opportunity for a regulated paramedic profession to apply for prescribing rights.	Medium
	Positive change in ambulance culture to enhance professional attitude.	High
	Increased recognition of paramedics' role in the multidisciplinary primary health care team, improving care coordination and development of new models of care.	High
	Increased employment opportunities for paramedics to work in other health care settings (e.g. emergency departments and urgent care clinics)	Medium
	Allows for a Quality Assurance Activity under the Act to be undertaken to assess and improve the health services provided by the paramedic workforce	Medium
Employers	Provides the employers and employees with an independent body to assess issues of professional behaviour and competence.	High
	Provides standardised entry requirements for overseas Paramedics seeking employment in New Zealand.	High

Regulators	Allow the Coroner to delegate paramedics to declare patients deceased at the scene of an accident. Paramedics could be considered to become registered health professionals under the Accident Compensation Act 2003. This would mean that claims for injuries caused by, or at the direction of, paramedics would be assessed as a treatment injury. Data collected on treatment injuries would then provide a full picture and allow prevention strategies to be developed.	High High
Wider government	Quality and safety assurance for other health professions, district health boards and primary health organisations that registered paramedics are meeting appropriate standards of competence	High
Other parties	Restriction of the use of the paramedic title, which will provide the public with increased assurance over the safety of ambulance services and avoid confusion over who is qualified and competent to practise as a paramedic. Consumers will have the choice to inspect the register to ensure the paramedic is registered and competent to practise, should Paramedics play a role in primary health care. Reduces barriers to early treatment and rehabilitation by improving paramedic workforce access, such as making direct referrals to X-ray. Facilitating paramedics practising overseas in search and rescue or disaster operations.	High High High High
Total Monetised Benefit		
Non-monetised benefits		High

4.2 What other impacts is this approach likely to have?
Refer 4.1.

Section 5: Stakeholder views

5.1 What do stakeholders think about the problem and the proposed solution?

On behalf of the Minister, the Ministry carried out a targeted consultation process (in May 2016) on whether or not paramedics meet the criteria for regulation under the Act (the criteria are available on the Ministry's website (www.health.govt.nz/our-work/regulation-health-and-disability-system/health-practitioners-competence-assurance-act/regulating-new-profession).

Panel of experts

The panel members were (positions as at the time of the panel):

- Helen Pocknall, Executive Director of Nursing at Wairarapa and Hutt Valley DHBs; Health Workforce New Zealand Board member
- Kathryn Holloway, Director of the Graduate School of Nursing, Midwifery and Health, Victoria University
- Dr Iwona Stolerak, Clinical Lead at the Health Quality and Safety Commission

The panel agree that paramedic services are a health service under the Act, that they pose a risk of harm to the public, and that the status quo arrangements are not sufficient to address the level of risk of harm. Paramedics should be regulated in line with other health professions that pose a similar risk (eg doctors and nurses).

The Health and Disability Commissioner

The HDC supports regulation to create a mandatory consistent standard and independent body for monitoring the competency of the paramedic workforce. Establishing a Paramedic Council provides for the HDC to recommend a review of competence for practitioners and is a mechanism for follow-up once the HDC has completed its investigations, including ensuring the education and ongoing competency of the paramedic profession.

The health sector

The Ministry received submissions from 37 organisations and 45 individuals about whether to regulate paramedics under the Act. There was wide agreement from 92 percent of submitters that the paramedic profession meets the Act's definition of a health service, poses a risk of harm to the public, and that the paramedic profession be regulated under the Act on the basis of public interest. Only six submitters considered it was not in the public interest to regulate the paramedic profession as they considered the ambulance sector was appropriately managing the risks of harm of the profession.

Thirteen organisations and four individual submissions advised that EMTs should be regulated under the Act. These submitters were concerned that EMTs pose a risk of harm as they can decide whether to transport patients to emergency departments or leave them at home. The organisations that raised concern about EMTs included two non-government funded ambulance providers, three ambulance unions, Paramedics Australasia, the NZ Defence Force, Australasian College for Emergency Medicine, College of Emergency Nursing New Zealand, New Zealand Nurses Organisation, Auckland University of Technology, and Whitireia School of Health. However, St John considered it could manage the risks of harm of its EMT workforce through its clinical governance frameworks and new Continuing Clinical Education programme for maintaining clinical competencies. St John expressed concern that regulating EMTs under the HPCA Act would reduce the retention of its volunteer EMT workforce, which would then impact on the provision of ambulance services.

The Ministry's view is that the regulation of EMTs requires further consideration that can be done at a later date.

Section 6: Implementation and operation

6.1 How will the new arrangements be given effect?

Regulation under the Act is achieved by an Order in Council that sets out the profession to be regulated and the responsible authority that will regulate the profession.

Once established, the Paramedic Council will be responsible for the functions set out in the Act, including ongoing operation, monitoring practitioner competence and qualifications. A shared arrangement is agreed between the Paramedic Council (governance) and Nursing Council (secretariat support) and the details of this agreement in practice would need to be developed.

We would expect the Paramedic Council to be established within 12 to 18 months of the signing of the Order in Council. During this period:

- the Ministry will call for nominations for five members to be on the Paramedic Council
- the Minister will appoint Paramedic Council members after obtaining agreement from the Appointments and Honours Cabinet Committee
- a Paramedic Advisory Group will develop the regulatory framework, communicate with stakeholders, and establish the registration process
- Staff from Ambulance New Zealand, Auckland University of Technology and St John have agreed to provide staff to help register the first intake of paramedics.

After that time:

- it will be illegal for anyone not registered with the Paramedic Council to call or hold themselves out to be a paramedic
- it will be illegal for anyone to practise as a paramedic in New Zealand without being registered with the Paramedic Council and holding a current APC.

Information about the regulation of paramedics will be publicly available on websites of relevant government agencies, responsible authorities, and Ambulance New Zealand (St John and Wellington Free Ambulance). Information will also be provided, through Ambulance New Zealand, to individual paramedics (where known), paramedic education providers and paramedic students.

The Ministry will work with ambulance stakeholders to implement regulation, identify potential risks early and, collectively, determine how to mitigate those risks.

Section 7: Monitoring, evaluation and review

7.1 How will the impact of the new arrangements be monitored?

The primary purpose for regulation under the Act is to protect the public from risk of harm. The proposed Paramedic Council will be required to address complaints/concerns it receives about registered paramedics. The complaints/concerns can come from any source and may relate to competence, fitness to practice, and compliance with the Paramedic Council's codes of conduct and ethics. The Paramedic Council will be expected to keep records of complaints/concerns and the outcomes. This information will provide a more complete picture of safety across the paramedic workforce regardless of the employer or funding source.

The Health Practitioners Competence Assurance Amendment Bill, currently awaiting its third reading, will require all responsible authorities to be audited against an agreed set of performance standards/indicators at least every five years. Responsible authorities must publish the audits and report on actions to address any issues. The Ministry will monitor the audit reports and recommendations for improvement. The Paramedic Council would also be subject to this requirement.

7.2 When and how will the new arrangements be reviewed?

There are no specific plans to review the impact of the regulation of paramedics. Government funded ambulance services will continue to be monitored via contract arrangements.

The performance reviews of each responsible authority proposed in the Amendment Bill will provide a mechanism to better monitor each responsible authority's performance. The Ministry will monitor a responsible authority's progress in addressing recommended actions for improvement that result from the performance reviews.

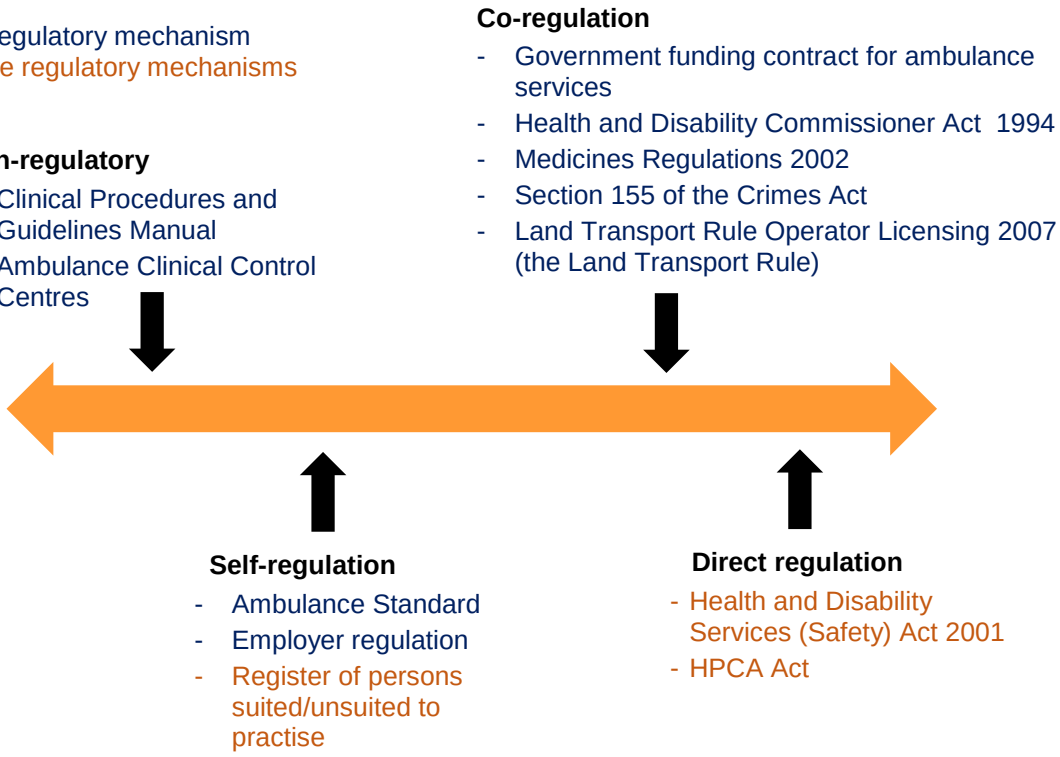
Stakeholders will continue to be able to raise concerns with, for example, the Ministry, an individual ambulance service/employer and the HDC. Once in operation, the Paramedic Council will be another avenue to address concerns about paramedics and/or their regulation.

Appendix 1: Existing and alternative mechanisms for addressing the risks of harm of the paramedic profession and wider ambulance workforce

Adapted from The Treasury's Regulatory Impact Analysis Handbook[4]

Key

- existing regulatory mechanism
- alternative regulatory mechanisms



Existing mechanism	Limit
Non-regulatory – Clinical Procedures and Guidelines Manual St John and Wellington Free Ambulance have developed a Clinical Procedures and Guidelines Manual for ambulance officers to follow. The manual is updated regularly and provides guidance on treatment and referral decisions.	A limit with the Clinical Procedures and Guidelines Manual is that it is not able to provide guidance on every condition and circumstance.
Non-regulatory – Ambulance Clinical Control Centres The Ambulance Clinical Control Centres at St John and Wellington Free operate a Clinical Desk Service that provides clinical advice to call takers, dispatchers, and ambulance officers in the field.	The availability of Clinical Desks limits when ambulance officers can seek clinical advice.
Self-regulation - the Ambulance Standard Under the New Zealand Standard for Ambulance and Paramedical Services NZS 8156:2008 (the Ambulance Standard), ambulance providers should: • ensure ambulance officers are appropriately qualified and trained to work within their delegated scope of practice • review ambulance officer's core competencies at least every two years and specific competencies under Medicines (Standing Order) Regulations every year	A limit of this industry regulatory mechanism is that non-government funded ambulance providers do not have to comply with the Ambulance Standard. Another limit is that the Ambulance Standard places responsibility on the ambulance provider to maintain the clinical competencies of the paramedic workforce. This can create inconsistencies with how continuing competencies are assessed and how clinical education is provided amongst ambulance providers.

[4] http://www.treasury.govt.nz/regulation/regulatoryproposal/ria/handbook

• have a continuing clinical education programme to ensure that ambulance officers maintain clinical competence.	
Self-regulation - employer regulation St John and Wellington Free Ambulance fulfil similar functions to an RA in that they regulate their workforce by: • setting the minimum qualification required for entry into the paramedic workforce • setting and restricting the procedures and medications that ambulance officers can perform according to their delegated scope of practice • undertaking pre-employment criminal, driving and medical checks of ambulance officers • investigating and acting upon reported issues of misconduct and clinical competence.	A limit of employer regulation is that it relies on employers to ensure their ambulance workforce is competent and fit to practise. There is a risk under this regulatory environment that employees are not provided with, or choose not to complete, continuing clinical education programmes. Another limit is that ambulance providers and the ambulance workforce do not have an independent body to refer to for support when there issues concerning the competence and professional conduct of individuals.
Co-regulation - Government funding contract for emergency road ambulance services Under the Government contract for funding, St John and Wellington Free Ambulance are required to: • be certified as compliant against the Ambulance Standard • inform NASO of adverse events that result in harm or death to a patient • have clinical governance systems to oversee the safety and competency of their ambulance workforce.	A limit with this regulatory mechanism is that it only applies to ambulance services that have a funding contract with the Government. There are a number of smaller ambulance providers that do not receive Government funding and are not obliged to comply with the industry and Government requirements for clinical safety and oversight.
Co-regulation - Health and Disability Commissioner (HDC) Act 1994 Ambulance officers must uphold the Code of Health and Disability Service Consumers' Rights (the Code) in their capacity as health providers, including the duty to provide consumers with services of an appropriate standard of care (Right 4 of the Code).	The HDC Act can only provide retrospective protection to the public from ambulance officers that do not meet the Code.
Co-regulation - Medicines (Standing Order) Regulations 2002. Medical Practitioners who act as Medical Directors have legal responsibility to ensure ambulance officers are competent to safely administer and supply medications to patients under Standing Orders.	A limit with this legislative mechanism is that it is not practical for Medical Directors to immediately provide all ambulance officers with advice about complex decisions.
Co-regulation – Land Transport Rule Operator Licensing 2007 (the Land Transport Rule) The Rule references the Ambulance Standard and details the requirements for gaining and keeping a licence to operate a vehicle to take passengers	The Land Transport Rule does not place conditions or standards on the provision of ambulance services.

Appendix 2: Estimated cost of governance options – establishment and annual practising certificate (APC) fees

Source: Nursing Council of New Zealand

	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	[redacted]	[redacted]	[redacted]

Option 1: A stand-alone Paramedic Council is established, with secretariat support from the Nursing Council.

Option 2: The paramedic and nursing professions are regulated under a blended responsible authority. Each profession would require a minimum of five responsible authority members appointed.

Option3: The paramedic profession is regulated by the existing Nursing Council. This would require additional Nursing Council appointments to represent the paramedic profession and add additional committee costs for the Nursing Council.