

# 4 How medical practice standards are set by legislation: other legislation

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Many Acts and Regulations impact on medical practice standards. The Health Practitioners Competence Assurance Act 2003 (see chapter 3), the Medicines Act 1981, the Misuse of Drugs Act 1975, and the Health Act 1956 are the most significant Acts.

Some medical legislation is complex and the wise doctor will discuss difficult issues with a senior colleague or an adviser from the indemnity insurer.

## Prescribing medicines

The Ministry of Health's Medicines Control Team (part of the Quality and Safety Group) and Medsafe are jointly responsible for the legislation governing the

prescribing and supply of medicines. The Medicines Act 1981 and the Misuse of Drugs Act 1975 set out who may prescribe medicines as well as other controls relating to medicines. Doctors have a duty of care to ensure that prescriptions are legible and unambiguous as mistakes or illegibility may have serious consequences not only for the patient, but for the doctor concerned.

Every prescribing doctor needs to have on hand the publication MIMS, New Ethicals. Subscription details are available from [www.mims.co.nz](http://www.mims.co.nz) or 0508 464 676. The Pharmac schedule lists current extra charges for different medicines. The Medsafe website may be accessed for approved data sheets [www.medsafe.govt.nz](http://www.medsafe.govt.nz).

A principal task of Medicines Control is the surveillance and administration of the Medicines Act and the Misuse of Drugs Act regarding the distribution chain of medicines. The Advisers will supply information on regulatory controls on prescription medicines and controlled drugs.

The Ministry will prosecute offences under the Medicines Act and the Misuse of Drugs Act. Doctors found guilty of such offences may be fined and imprisoned. In 2001 a doctor pleaded guilty to a number of offences under the Medicines Act and was sentenced to three months imprisonment. Convictions of any offence punishable by a term of imprisonment of 3 months or longer must be reported to the practitioner's responsible authority.

Similarly, professional disciplinary action may be taken against a doctor. A doctor whose practising certificate had been suspended was found guilty of professional misconduct and registration was cancelled for forging the signature of another doctor and ordering a number of prescription medicines from overseas.

### **Drug seekers**

Early discussion with a Medicines Control Adviser is wise if a doctor is in any doubt about the bona fides of any request for drugs, especially controlled substances.

### **Inappropriate prescribing**

Inappropriate prescribing can include activities which are not strictly illegal under the Medicines Act or the Misuse of Drugs Act, but which may be regarded as a significant deviation from good prescribing practice.

Inappropriate use of addictive drugs is detrimental to the user. It impairs both behaviour and the health of the individual, which in turn impacts on the wider community. The causes of inappropriate prescribing of addictive drugs are ignorance, irresponsibility, personal gain, and threat or intimidation. For further details see Medical Council's statement on Prescribing practice with respect to addictive drugs.

Under the Medicines Act and the Misuse of Drugs Act there is power for Medical Officer of Health to restrict the supply of a given medicine to a person, or require its supply only from a named source.

A doctor's registration was cancelled after being found guilty of professional misconduct for writing a substantial number of prescriptions for sudomyl when there was no medical/clinical justification for much of that prescribing.

### **Standing orders**

Section 105 of the Medicines Act also gives rise to the Medicines (Standing Order) Regulations 2002. The regulations allow for the administration and/or supply of specified medicines by non-prescribing health practitioners (i.e. nurses) to patients but only under specific conditions. The medicines and the conditions under which the medication can be administered or supplied to a patient, by a non-prescribing practitioner, will be outlined in the standing order by the patients' primary carer (i.e. a doctor or other appropriate practitioner with prescribing authority). If it is necessary for a non-prescribing health practitioner to administer or supply a medicine under a standing order, the primary carer is required to countersign the charted treatment or record within the required period stated in the standing order.

### **The Medicines Act 1981**

The Medicines Act covers the prescribing of registered medicines. Medicines that are controlled drugs are also covered by the Misuse of Drugs Act 1975.

The Medicines Act does, however, cover some of the major drugs of abuse, for example, chlormethiazole (Hemineurin), antidepressants and antipsychotics.

### **The Misuse of Drugs Act 1975 and the Misuse of Drugs Regulations 1977**

Drugs are classified according to the level of harm they pose. These cover class "A" (very high risk), "B", (high risk) or "C" (moderate risk) controlled drugs and various rules apply to their prescribing. Class A drugs, for example, cocaine, heroin, methamphetamine, are almost non-prescribable whereas those in class B contain some of the better known controlled drugs such as methadone, morphine and pethidine.

Doctors may not treat a drug dependent person with controlled drugs unless they have ministerial authorisation to do so. Applications for authorisation should be made to the Director-General of Health.

Class A and B controlled drugs must be kept in a cupboard or compartment, which is of metal or concrete construction. Although not a requirement for doctors to keep a controlled drug register it is good medical practice to do so particularly where the drug cabinet is jointly accessed by members of a group practice.

### **Crimes Act 1961**

Section 61 of the Crimes Act protects every one from criminal responsibility for performing with reasonable care and skill any surgical operation upon any person for that person's benefit, if the performance of the operation was reasonable, having regard to the patient's state at the time and to all the circumstances of the case. The common law may also protect a doctor performing a surgical operation in an emergency under so-called 'Good Samaritan' principles.

Section 151 of the Crimes Act places a legal duty on a person who is in charge of another person to provide the necessities of life. Although not defined, "necessaries of life" would, in appropriate circumstances, include medical and

hospital treatment. A doctor is under a legal duty to supply a sick person in his or her charge with the necessities of life. However, the law also recognises a distinction between ‘active killing’ and merely allowing someone to die by the withdrawal of life support. See for example, *Auckland Healthcare Services Ltd v L* in which the NZ Court of Appeal permitted the withdrawal of treatment in circumstances where the court was satisfied that treatment was futile and merely prolonging death.

Section 155 of the Crimes Act imposes a legal duty on those who undertake to administer surgical or medical treatment to have and to use reasonable knowledge, skill and care in doing those acts. Criminal liability does not apply where the medical or surgical treatment is a necessity. Causing death by or as a result of medical or surgical treatment may result in a conviction for murder (if deliberate) or manslaughter.

In 2001 a doctor was convicted of manslaughter of his mother who was nearing the end of her life. He injected her with a cocktail of drugs in significant quantities that she might die and he also strangled her.

### **The public health as part of medical practice**

The purpose of the Health Act 1956 is to improve, promote and protect the public health. It outlines the statutory duties and responsibilities of medical officers of health and covers other matters such as the notification of infectious and notifiable diseases.

Following a comprehensive review of this Act, it is proposed it be replaced with a Public Health Act. The Public Health Bill is currently awaiting its second reading. The Health Select Committee reported back to Parliament on 26 June and recommended the Bill pass with amendments.

The Purpose of the Public Health Bill is to improve, promote, and protect public health in order to help attain optimal and equitable health outcomes for Māori and all other population groups.

The Health (Immunisation) Regulations 1995 require that all children born from January 1995 have an immunisation certificate to show their immunisation status. There is no compulsion to have children immunised.

### **Reporting of notifiable and infectious diseases**

Under section 74 of the Health Act a medical practitioner is required to give notice of cases or suspected cases of notifiable diseases to the medical officer of health and/or the territorial authority. The First and Second Schedules to the Health Act 1956 list the infectious diseases notifiable to the medical officer of health.

Cases of tuberculosis are notifiable to the medical officer of health under the Tuberculosis Act 1949.

### **Cervical screening**

The Health (National Cervical Screening Programme) Amendment Act 2004 established a National Cervical Screening Programme. The purpose of the Act is to reduce the incidence and mortality of cervical cancer through the effective

operation of the National Cervical Screening Programme and by facilitating the process of evaluation of the Programme. The Programme is to ensure that women who have had cervical smears are followed up at regular intervals. There are strict privacy requirements on the disclosure of information on the National Cervical Screening Programme Register. As part of ensuring the performance and safety of the Programme, specially trained evaluators to access clinical information in accordance with strict confidentiality rules can be appointed.

A doctor who takes a cervical smear test is required to inform the woman that she is automatically enrolled on the Programme but that she may withdraw from the Programme at any time. The doctor must provide information to women about the cervical smear test and the Programme. If the woman withdraws from the Programme, she and her smear taker are responsible for her regular cervical screening.

### **Contraception Sterilisation and abortion**

The Contraception Sterilisation and Abortion Act 1977 sets out the procedures and requirements for an abortion, as well as the responsibilities of medical practitioners.

Section 174 of the Health Practitioners Competence Assurance Act states, however, that a health practitioner who objects on the grounds of conscience to providing advice or other service with respect to contraception, sterilisation or other reproductive health matters, must inform the person requesting the service that he or she may obtain that service from another health practitioner or a family planning clinic.

#### **Contraception**

There is no restriction on a medical practitioner giving contraceptive advice, or prescribing contraception to people under the age of 16, without consent from their parents. Minors do have the same right to privacy as any other person.

#### **Abortion**

Access to abortion is not restricted on grounds of age (Care of Children Act 2004). A child or young person must be subject to the same counselling and approval by a certifying consultant as any other woman seeking an abortion. The consent of a parent or guardian is not required in order for the young person to access abortion information or services. Under certain circumstances abortion is lawful in New Zealand.

#### **Procedure when a woman seeks an abortion**

When a woman seeks to have an abortion and sees her own doctor, that doctor, if requested, must arrange for her request to be considered and dealt with.

When the woman's own doctor considers that an abortion may be lawful and does not propose to perform the abortion, that doctor must refer the case to another registered practitioner who may be willing to perform the abortion. If, however, the woman's doctor proposes to perform the abortion the doctor must

- if a certifying consultant, refer the case to one other certifying consultant (who must be a practising obstetrician or gynaecologist if the woman's own doctor is not).
- when the woman's doctor is not a certifying consultant, refer the case to 2 certifying consultants (one of whom must be a practising obstetrician or gynaecologist).

Once the certifying consultants are of the opinion that the abortion would be lawful they must issue a certificate authorising the abortion.

Where the certifying consultants are of the contrary opinion, they may not authorise the abortion.

### **Sterilisation**

Every medical practitioner who performs an operation of sterilisation is required within one month of the operation to forward to the Director-General of Health (marked attention Private Hospitals Section, Information Directorate) a report of the operation giving the following particulars:

- (a) The reasons for the operation
- (b) The age, sex, marital status, race, and number of children of the person
- (c) Whether the person stayed in hospital for one or more nights
- (d) Whether the operation was performed postpartum.

Reports must not give the name or address of the person sterilised.

### **Assisted human reproduction**

Prior to the enactment of the Human Assisted Reproductive Technology Act 2004 there was little regulation in this area. Besides providing a framework, the key purposes of the Human Assisted Reproductive Technology Act are to regulate assisted reproductive procedures, prohibit unacceptable assisted human reproductive procedures and research as well as prohibiting commercial transactions relating to human reproduction.

The Act also establishes a comprehensive information-keeping regime to ensure that people born from donated embryos or donated cells can find out about their genetic origins.

The Act requires that the Director-General of Health certify fertility service providers (under the Health and Disability Services (Safety) Act 2001).

The Ministerial Advisory Committee on Assisted Reproductive Technologies develops guidelines for the ethics committee and advises the Minister of Health.

The Ethics Committee on Assisted Human Reproduction Technology, reviews and decides on applications for assisted reproductive procedures and reproductive research.

### **Euthanasia**

Euthanasia, or mercy killing, is the deliberate bringing about of the death of a person to end what is considered an intolerable existence. In New Zealand, euthanasia whether it is active (an active measure to cause death) or passive (the

withholding of treatment, which results in death) can amount to the crime of homicide.

This subject has become topical by an Australian doctor holding seminars in New Zealand promoting euthanasia and providing those attending information on how to end life.

### Advance directives

An advance directive is a written or oral directive

- a) by which a consumer makes a choice about a future health care procedure; and
- b) that is intended to be effective only when he or she is not competent.

*Clause 4, Code of Health and Disability Services Consumers' Rights*

This means that a person can make an advance choice about receiving or refusing services. In this latter case, it is sometimes referred to as a living will. A living will is a written declaration of the treatments and procedures that a person would accept or reject if they were in danger of death and incapable of decision-making.

In Canada there is specific legislation which sets out requirements that need to be followed and met before an advance directive is legally valid. There is no equivalent legislation in New Zealand, and the validity of an advance directive at common law is unclear.

To be regarded as valid it must be made without undue influence, by a person who is competent and fully informed about the consequences of refusing the particular future service. It must also apply to the current situation.

### Fitness to drive motor vehicles

For a number of private and commercial drivers (e.g. older drivers, taxi and bus drivers, etc) medical practitioners are currently required by law to assess whether a person is medically fit to drive a motor vehicle. Medical practitioners are also required under section 18 of the Land Transport Act 1998 to report to the Director of Land Transport New Zealand where:

- in their judgement their patient is not medically fit to drive; and
- they have advised their patient not to drive, and
- they believe or know that their patient is continuing to drive despite this advice.

A practitioner who notifies the Director of Land Transport in good faith under section 18 will not be liable to any civil or professional liability because of any disclosure of personal medical information in that notice.

Information setting out what the legal requirements, with a list of medical conditions and their potential relationships to fitness to drive is set out in the booklet *Medical aspects of fitness to drive: a guide for medical practitioners 2002*. Doctors are required to refer to this guide when making assessments of their patients for medical fitness to drive. An electronic copy of this document can be found at <http://www.landtransport.govt.nz/licensing/docs/ltsa-medical-aspects.pdf>.

### **Older drivers**

There is no longer a mandatory age-based on-road test for older drivers. General practitioners will continue to be responsible for assessing medical fitness to drive for their older patients. There will continue to be a medical certificate required at age 75, 80, 82 and two-yearly thereafter.

General practitioners would have the support of a range of referral alternatives to help them assess their patients where needed.

Further information is available on

<http://www.landtransport.govt.nz/information-for/older-drivers.html>.

### **Alcohol impaired drivers**

Medical practitioners may be called upon, under the Land Transport Act 1998, to take a blood specimen for evidential purposes from a person who has failed an evidential breath test, refused a breath test, a breath testing device is not readily available, or the person has been arrested for suspicion of an offence under the Act relating to alcohol or drug involved driving.

That Act allows a practitioner to take a blood sample without a person's consent if a person presents to a hospital or doctor's premises as a result of a motor vehicle accident, or at the request of an enforcement officer. The medical practitioner must tell the person (unless the person is unconscious) that the blood specimen is being taken for evidential purposes. If a blood specimen is taken from a person who is unconscious, the medical practitioner or medical officer who takes the specimen must, as soon as is practicable, notify the person in writing that a specimen was taken for evidential purposes. Before taking a blood sample the practitioner must be satisfied that taking a blood sample would not be prejudicial to the person's proper care and treatment. Practitioners are protected from civil or criminal action in respect of taking of blood under that section without consent.

### **Reporting of suspected child abuse**

Reporting of suspected child abuse is not mandatory. Reporting is, however, strongly recommended as part of your responsibility to the child. If a practitioner does report suspected ill treatment or neglect of a child to a social worker or the Police, the practitioner is protected from civil, criminal or disciplinary proceedings unless the information was provided in bad faith. Under section 16 of the Children, Young Persons, and their Families Act 1989 it is not essential for medical practitioners to seek authorisation from a child or parent in order to disclose information in situations where child abuse is known or suspected provided disclosure is made to appropriate authorities or persons, or for proper purpose.

### **Deaths and medical certificates as to cause of death**

From 25 January 2009 the requirements for doctors issuing medical certificates of causes of death transfer from the Births, Deaths and Relationships Registration Act 1995 to the Burial and Cremation Act 1964 which is administered in the Ministry of Health.

In general, the doctor attending a patient during any final illness signs a medical certificate of cause of death.

Under the Coroners Act 2006 a doctor is required to report a death to the Police where:

- death appears to be suicide, unnatural or violent;
- the cause of death is unknown;
- death occurs during or apparently as a result of some medical, surgical, dental or similar operation or procedure;
- death occurs while a person was affected by an anaesthetic or the result of the administration of the anaesthetic;
- death occurs while the woman was giving birth, or that appears to have been the result of the pregnancy or giving birth;
- death occurs in certain types of institutions or custody, including police or prison custody, or treatment facilities for mental illness or alcohol or drug addiction.

On occasion the coroner may discuss the death with the doctor in charge of the patient, who may then issue a medical certificate of causes of death.

An after hours number has been set up for duty coroners. This will give police, doctors, pathologists and other key people access to a coroner 24/7. The number is: (04) 910 4482 and will be answered by the coroner that is on duty for the entire country over the specific after hours period.

Doctors need to be as precise and specific as possible when completing the certificate of causes of death. The information provided by doctors not only appears on the official death certificate issued by the Births, Deaths, Marriages and Relationships Registration Office, but is also used in the collation of national cause of death statistics that are reported to the World Health Organization. Particular attention should be taken in selecting the underlying cause of death. Often it is a combination of a number of serious conditions that leads to the death of the person. In such cases the condition considered by the certifying doctor to most likely have “initiated the train of morbid events leading directly to death” is entered as the underlying condition on the certificate.

For further information refer to the booklet *A guide to certifying causes of death* (available in electronic format from [www.nzhis.govt.nz/publications/deathcerts.html](http://www.nzhis.govt.nz/publications/deathcerts.html)).

## Clinical coding in New Zealand public hospitals

Medical practitioners working in hospitals have a responsibility to document legible, specific, accurate and complete clinical information in the clinical record. Accurate and complete clinical information in the clinical record enables clinical coders to abstract the required information for coding and provide quality coded data. A clinical coder’s primary responsibility is to translate text descriptions of diseases, injuries and procedures into alphanumeric codes. The clinical coding classification used in New Zealand hospitals is the International Statistical Classification of Diseases and Related Health Problems (ICD), Tenth Revision, Australian Modification (ICD-10-AM). All inpatient and day-patient events are

coded and recorded in the hospital's patient management system (PMS). Electronic files of coded inpatient and day patient events are then forwarded to the Information Directorate in the Ministry of Health.

### **Why inpatient and day patient events are coded**

The coding of inpatient and day patient events transforms clinical information into a consistent terminology and format that allows for easy storage, retrieval and analysis of the data. In New Zealand inpatient and day patient event data is the basis for:

- national and regional morbidity and mortality analysis;
- contract monitoring and reimbursements;
- research into diseases, injuries and patient outcomes;
- benchmarking of clinical practice between hospitals;
- informing the NZ Cancer Registry of clinical diagnoses of cancers;
- improving patient care; and
- improving hospital practices and resource allocation.
- Patient notes are the foundation information for all of this work.

### **Advice**

There are a number of sources for advice. They are

- The Medical Protection Society, the NZ Medical Professionals' Medical Indemnity Insurance Company, or the NZ Resident Doctors' Association professional liability insurance programme for legal advice.
- Medical Officers of Health in relation to public health issues (located in each public health service, usually attached to the District Health Boards)
- Medicines Control advisers in relation to prescribing. Located in Auckland, phone (09) 580 9088 or 0800 248 671), Wellington (04) 496 2437 or 0800 163 060, and Dunedin (03) 474 8592 or 0800 248 674.

### **References**

1. Medicines Act 1981 and its Regulations
2. Misuse of Drugs Act 1975 and its Regulations
3. Improper prescribing practice with respect to addictive drugs. Medical Council of New Zealand, Wellington, 2001.
4. Medsafe website [www.medsafe.govt.nz](http://www.medsafe.govt.nz). Ministry of Health.
5. Drug abuse containment newsletters (including lists of abusers). Ministry of Health, Wellington.
6. Consent in child and youth health. Ministry of Health, Wellington, 1998.
7. Medical aspects of fitness to drive: a guide for medical practitioners. Land Transport Safety Authority. [www.landtransport.govt.nz](http://www.landtransport.govt.nz). Wellington, 2002
8. A guide to certifying causes of death. Ministry of Health, Wellington, 2001.
9. NZHIS website [www.nzhis.govt.nz](http://www.nzhis.govt.nz). Ministry of Health
10. *Health Care and the Law*, Ed Johnson, Sue. 2004. Brookers Ltd, Wellington