



Australian Government
Repatriation Medical Authority

Statement of Principles
concerning
DIABETES MELLITUS
(Reasonable Hypothesis)
(No. 48 of 2020)

The Repatriation Medical Authority determines the following Statement of Principles under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

Dated 26 June 2020

The Common Seal of the
Repatriation Medical Authority
was affixed to this instrument
at the direction of:

A handwritten signature in black ink, appearing to read 'Nicholas Saunders'.

Professor Nicholas Saunders AO
Chairperson

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1 Name

This is the Statement of Principles concerning *diabetes mellitus (Reasonable Hypothesis)* (No. 48 of 2020).

2 Commencement

This instrument commences on 27 July 2020.

3 Authority

This instrument is made under subsection 196B(2) of the *Veterans' Entitlements Act 1986*.

4 Repeal

The Statement of Principles concerning diabetes mellitus No. 89 of 2011 (Federal Register of Legislation No. F2011L01448) made under subsections 196B(2) and (8) of the VEA is repealed.

5 Application

This instrument applies to a claim to which section 120A of the VEA or section 338 of the *Military Rehabilitation and Compensation Act 2004* applies.

6 Definitions

The terms defined in the Schedule 1 - Dictionary have the meaning given when used in this instrument.

7 Kind of injury, disease or death to which this Statement of Principles relates

- (1) This Statement of Principles is about diabetes mellitus and death from diabetes mellitus.

*Meaning of **diabetes mellitus***

- (2) For the purposes of this Statement of Principles, diabetes mellitus:
- (a) means persistent hyperglycaemia characterised by either:
 - (i) two positive laboratory blood tests on separate days showing:
 - A. a fasting plasma glucose concentration of at least 7.0 millimoles per litre; or
 - B. a plasma glucose concentration of at least 11.1 millimoles per litre two hours after ingestion of 75 grams of glucose on a baseline fasting state (glucose tolerance test); or
 - C. an HbA_{1c} level of at least 6.5%; or

- (ii) an episode of diabetic ketoacidosis or hyperosmolar hyperglycaemic state with a blood glucose level of at least 11.1 millimoles per litre; and
 - (b) includes:
 - (i) drug-induced diabetes mellitus;
 - (ii) gestational diabetes mellitus;
 - (iii) primary diabetes mellitus;
 - (iv) secondary diabetes mellitus;
 - (v) type 1 diabetes mellitus; and
 - (vi) type 2 diabetes mellitus; and
- Note: *type 1 diabetes mellitus* and *type 2 diabetes mellitus* are defined in the Schedule 1 – Dictionary.
- (c) excludes impaired glucose tolerance.
- (3) While diabetes mellitus attracts ICD-10-AM code E10, E11, E12, E13 or E14, in applying this Statement of Principles the meaning of diabetes mellitus is that given in subsection (2).
- (4) For subsection (3), a reference to an ICD-10-AM code is a reference to the code assigned to a particular kind of injury or disease in *The International Statistical Classification of Diseases and Related Health Problems, Tenth Revision, Australian Modification (ICD-10-AM)*, Tenth Edition, effective date of 1 July 2017, copyrighted by the Independent Hospital Pricing Authority, ISBN 978-1-76007-296-4.

Death from diabetes mellitus

- (5) For the purposes of this Statement of Principles, diabetes mellitus, in relation to a person, includes death from a terminal event or condition that was contributed to by the person's diabetes mellitus.

Note: *terminal event* is defined in the Schedule 1 – Dictionary.

8 Basis for determining the factors

The Repatriation Medical Authority is of the view that there is sound medical-scientific evidence that indicates that diabetes mellitus and death from diabetes mellitus can be related to relevant service rendered by veterans, members of Peacekeeping Forces, or members of the Forces under the VEA, or members under the MRCA.

Note: *MRCA*, *relevant service* and *VEA* are defined in the Schedule 1 – Dictionary.

9 Factors that must exist

At least one of the following factors must as a minimum exist before it can be said that a reasonable hypothesis has been raised connecting diabetes mellitus or death from diabetes mellitus with the circumstances of a person's relevant service:

- (1) having an endocrine disorder from the specified list of endocrine disorders before the clinical onset of diabetes mellitus;
 Note: *specified list of endocrine disorders* is defined in the Schedule 1 - Dictionary.
- (2) having a solid organ transplant or bone marrow transplant before the clinical onset of diabetes mellitus;
- (3) having glucocorticoid therapy as specified, before the clinical onset of diabetes mellitus, and where the glucocorticoid therapy as specified has ceased or decreased, the last dose of the therapy was received within the 30 days before the clinical onset of diabetes mellitus;
 Note: *glucocorticoid therapy as specified* is defined in the Schedule 1 - Dictionary.
- (4) being treated with a drug from the Specified List 1 of drugs, which cannot be ceased or substituted, for at least the seven days before the clinical onset of diabetes mellitus;
 Note: *Specified List 1 of drugs* is defined in the Schedule 1 - Dictionary.
- (5) being treated with a drug from the antidepressant or antipsychotic classes of drugs, which cannot be ceased or substituted, for at least the six weeks before the clinical onset of diabetes mellitus;
- (6) for type 1 diabetes mellitus only:
 - (a) undergoing surgery to the pancreas before the clinical onset of diabetes mellitus;
 - (b) undergoing splenectomy for trauma before the clinical onset of diabetes mellitus;
 - (c) undergoing a course of therapeutic radiation for cancer, where the pancreas was in the field of radiation, before the clinical onset of diabetes mellitus;
 - (d) having a specified pathological condition involving the pancreas before the clinical onset of diabetes mellitus;
 Note: *specified pathological condition involving the pancreas* is defined in the Schedule 1 - Dictionary.
 - (e) having haemolytic uraemic syndrome before the clinical onset of diabetes mellitus;
 Note: *haemolytic uraemic syndrome* is defined in the Schedule 1 - Dictionary.
 - (f) ingesting N-3-pyridyl methyl-N'-p-nitrophenyl urea (Vacor) within the 30 days before the clinical onset of diabetes mellitus;
 - (g) being treated with interferon alpha within the six months before the clinical onset of diabetes mellitus; or

- (h) having infection with a Coxsackie B virus within the three years before the clinical onset of diabetes mellitus;

Note: *having infection with a Coxsackie B virus* is defined in the Schedule 1 - Dictionary.

- (7) for type 2 diabetes mellitus only:

- (a) having smoked at least five pack-years of tobacco products before the clinical onset of diabetes mellitus, and where smoking has permanently ceased, the clinical onset of diabetes mellitus has occurred within 15 years of cessation;

Note: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.

- (b) being exposed to second-hand smoke for at least 5,000 hours before the clinical onset of diabetes mellitus, and where exposure to second-hand smoke has permanently ceased, the clinical onset of diabetes mellitus has occurred within 15 years of cessation;

Note: *being exposed to second-hand smoke* is defined in the Schedule 1 - Dictionary.

- (c) being overweight or obese for at least five years before the clinical onset of diabetes mellitus;

Note: *being overweight or obese* is defined in the Schedule 1 - Dictionary.

- (d) an inability to undertake moderate physical activity of at least four METs for at least the five years before the clinical onset of diabetes mellitus;

Note: *MET* is defined in the Schedule 1 - Dictionary.

- (e) having cirrhosis of the liver at the time of the clinical onset of diabetes mellitus;

- (f) having non-alcoholic steatohepatitis at the time of the clinical onset of diabetes mellitus;

- (g) having infection with human immunodeficiency virus before the clinical onset of diabetes mellitus;

- (h) having infection with hepatitis C virus before the clinical onset of diabetes mellitus;

- (i) having hypertension at the time of the clinical onset of diabetes mellitus;

- (j) having chronic renal failure at the time of the clinical onset of diabetes mellitus;

Note: *chronic renal failure* is defined in the Schedule 1 - Dictionary.

- (k) having gout or hyperuricaemia at the time of the clinical onset of diabetes mellitus;

Note: *hyperuricaemia* is defined in the Schedule 1 - Dictionary.

- (l) having posttraumatic stress disorder at the time of the clinical onset of diabetes mellitus;
- (m) having depressive disorder at the time of the clinical onset of diabetes mellitus;
- (n) having bipolar disorder at the time of the clinical onset of diabetes mellitus;
- (o) having schizophrenia at the time of the clinical onset of diabetes mellitus;
- (p) having bilateral orchiectomy before the clinical onset of diabetes mellitus;
- (q) having anti-androgen therapy as specified for at least the one year before the clinical onset of diabetes mellitus;

Note: *anti-androgen therapy as specified* is defined in the Schedule 1 - Dictionary.

- (r) being exposed to arsenic as specified before the clinical onset of diabetes mellitus;

Note: *being exposed to arsenic as specified* is defined in the Schedule 1 - Dictionary.

- (s) inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD):
 - (i) for a cumulative period of at least 500 hours, within a consecutive period of ten years before the clinical onset of diabetes mellitus; and
 - (ii) where the first exposure occurred at least five years before the clinical onset of diabetes mellitus; and
 - (iii) where that exposure has ceased, the clinical onset of diabetes mellitus has occurred within 25 years of cessation; or

Note: *inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD)* is defined in the Schedule 1 - Dictionary.

- (t) for parous women only, inability to breast feed for a cumulative period of at least six months before the clinical onset of diabetes mellitus;

Note: The period of breastfeeding could be cumulative over a number of pregnancies.

- (8) for gestational diabetes mellitus and type 2 diabetes mellitus only, being pregnant at the time of the clinical onset of diabetes mellitus;
- (9) having an endocrine disorder from the specified list of endocrine disorders before the clinical worsening of diabetes mellitus;

Note: *specified list of endocrine disorders* is defined in the Schedule 1 - Dictionary.

- (10) having a solid organ transplant or bone marrow transplant before the clinical worsening of diabetes mellitus;
- (11) having glucocorticoid therapy as specified, before the clinical worsening of diabetes mellitus, and where the glucocorticoid therapy as specified has ceased or decreased, the last dose of the therapy was received within the 30 days before the clinical worsening of diabetes mellitus;
- Note: *glucocorticoid therapy as specified* is defined in the Schedule 1 - Dictionary.
- (12) being treated with a drug from the Specified List 1 of drugs, which cannot be ceased or substituted, for at least the seven days before the clinical worsening of diabetes mellitus;
- Note: *Specified List 1 of drugs* is defined in the Schedule 1 - Dictionary.
- (13) being treated with a drug from the antidepressant or antipsychotic classes of drugs, which cannot be ceased or substituted, for at least the six weeks before the clinical worsening of diabetes mellitus;
- (14) undergoing surgery to the pancreas before the clinical worsening of diabetes mellitus;
- (15) undergoing splenectomy for trauma before the clinical worsening of diabetes mellitus;
- (16) undergoing a course of therapeutic radiation for cancer, where the pancreas was in the field of radiation, before the clinical worsening of diabetes mellitus;
- (17) having a specified pathological condition involving the pancreas before the clinical worsening of diabetes mellitus;
- Note: *specified pathological condition involving the pancreas* is defined in the Schedule 1 - Dictionary.
- (18) having haemolytic uraemic syndrome before the clinical worsening of diabetes mellitus;
- Note: *haemolytic uraemic syndrome* is defined in the Schedule 1 - Dictionary.
- (19) ingesting N-3-pyridyl methyl-N'-p-nitrophenyl urea (Vacor) within the 30 days before the clinical worsening of diabetes mellitus;
- (20) having depressive disorder at the time of the clinical worsening of diabetes mellitus;
- (21) having bipolar disorder at the time of the clinical worsening of diabetes mellitus;
- (22) having schizophrenia at the time of the clinical worsening of diabetes mellitus;

(23) for type 2 diabetes mellitus only:

- (a) having smoked at least five pack-years of tobacco products before the clinical worsening of diabetes mellitus, and where smoking has permanently ceased, the clinical worsening of diabetes mellitus has occurred within 15 years of cessation;

Note: *pack-year of tobacco products* is defined in the Schedule 1 - Dictionary.

- (b) being exposed to second-hand smoke for at least 5,000 hours before the clinical worsening of diabetes mellitus, and where exposure to second-hand smoke has permanently ceased, the clinical worsening of diabetes mellitus has occurred within 15 years of cessation;

Note: *being exposed to second-hand smoke* is defined in the Schedule 1 - Dictionary.

- (c) being overweight or obese for at least five years before the clinical worsening of diabetes mellitus;

Note: *being overweight or obese* is defined in the Schedule 1 - Dictionary.

- (d) an inability to undertake moderate physical activity of at least four METs for at least the five years before the clinical worsening of diabetes mellitus;

Note: *MET* is defined in the Schedule 1 - Dictionary.

- (e) having cirrhosis of the liver at the time of the clinical worsening of diabetes mellitus;

- (f) having non-alcoholic steatohepatitis at the time of the clinical worsening of diabetes mellitus;

- (g) having infection with human immunodeficiency virus before the clinical worsening of diabetes mellitus;

- (h) having infection with hepatitis C virus before the clinical worsening of diabetes mellitus;

- (i) having hypertension at the time of the clinical worsening of diabetes mellitus;

- (j) having chronic renal failure at the time of the clinical worsening of diabetes mellitus;

Note: *chronic renal failure* is defined in the Schedule 1 - Dictionary.

- (k) having gout or hyperuricaemia at the time of the clinical worsening of diabetes mellitus;

Note: *hyperuricaemia* is defined in the Schedule 1 - Dictionary.

- (l) having posttraumatic stress disorder at the time of the clinical worsening of diabetes mellitus;

- (m) having bilateral orchiectomy before the clinical worsening of diabetes mellitus;
- (n) having anti-androgen therapy as specified for at least the one year before the clinical worsening of diabetes mellitus;

Note: *anti-androgen therapy as specified* is defined in the Schedule 1 - Dictionary.

- (o) being exposed to arsenic as specified before the clinical worsening of diabetes mellitus; or

Note: *being exposed to arsenic as specified* is defined in the Schedule 1 - Dictionary.

- (p) inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD):
 - (i) for a cumulative period of at least 500 hours, within a consecutive period of ten years before the clinical worsening of diabetes mellitus; and
 - (ii) where the first exposure occurred at least five years before the clinical worsening of diabetes mellitus; and
 - (iii) where that exposure has ceased, the clinical worsening of diabetes mellitus has occurred within 25 years of cessation;

Note: *inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD)* is defined in the Schedule 1 - Dictionary.

- (24) for gestational diabetes mellitus and type 2 diabetes mellitus only, being pregnant at the time of the clinical worsening of diabetes mellitus;
- (25) inability to obtain appropriate clinical management for diabetes mellitus.

10 Relationship to service

- (1) The existence in a person of any factor referred to in section 9, must be related to the relevant service rendered by the person.
- (2) The factors set out in subsections 9(9) to 9(25) apply only to material contribution to, or aggravation of, diabetes mellitus where the person's diabetes mellitus was suffered or contracted before or during (but did not arise out of) the person's relevant service.

11 Factors referring to an injury or disease covered by another Statement of Principles

In this Statement of Principles:

- (1) if a factor referred to in section 9 applies in relation to a person; and

- (2) that factor refers to an injury or disease in respect of which a Statement of Principles has been determined under subsection 196B(2) of the VEA;

then the factors in that Statement of Principles apply in accordance with the terms of that Statement of Principles as in force from time to time.

Schedule 1 - Dictionary

Note: See Section 6

1 Definitions

In this instrument:

anti-androgen therapy as specified means taking a drug from one of the following classes of drugs:

- (a) androgen receptor blockers, including cyproterone acetate, flutamide and bicalutamide; or
- (b) gonadotrophin releasing hormone agonists, including goserelin and leuprorelin.

being exposed to arsenic as specified means:

- (a) consuming drinking water with an average arsenic concentration of at least 50 micrograms per litre for a cumulative period of at least ten years; or
- (b) consuming drinking water resulting in a cumulative total arsenic exposure equivalent to having consumed drinking water containing at least 50 micrograms per litre for at least ten years; or
- (c) having clinical evidence of chronic arsenic toxicity.

being exposed to second-hand smoke means being in an enclosed space and inhaling smoke from burning tobacco products or smoke that has been exhaled by another person who is smoking.

being overweight or obese means:

- (a) having a Body Mass Index (BMI) of 25 or greater; or
- (b) having a waist circumference of greater than 80 centimetres in women or greater than 94 centimetres in men.

Note: ***BMI*** is also defined in the Schedule 1 - Dictionary.

BMI means W/H^2 where:

- (a) W is the person's weight in kilograms; and
- (b) H is the person's height in metres.

chronic renal failure means having a glomerular filtration rate of less than 15 mL/min/1.73 m² for a period of at least three months.

diabetes mellitus—see subsection 7(2).

equivalent glucocorticoid therapy means a glucocorticoid in the following table, at the doses specified in the table, or a therapeutically equivalent dose of another glucocorticoid:

Glucocorticoid	Minimum cumulative dose (milligrams)	Minimum average rate (milligrams/day)
betamethasone	60	2
cortisone	1,875	62.5
dexamethasone	50	1.67
methylprednisolone	300	10
paramethasone	150	5
prednisone	375	12.5
prednisolone	375	12.5
triamcinolone	300	10

equivalent inhaled glucocorticoid means:

- (a) 8,000 micrograms of triamcinolone;
- (b) 1,600 micrograms of budesonide;
- (c) 1,000 micrograms of fluticasone; or
- (d) a therapeutically equivalent dose of another inhaled glucocorticoid.

glucocorticoid therapy as specified means:

- (a) taking:
 - (i) hydrocortisone, orally, by injection, or per rectum:
 - A. to a cumulative dose of at least 1,500 milligrams; and
 - B. at a minimum dose rate averaging 50 milligrams per day; or
 - (ii) equivalent glucocorticoid therapy, orally, by injection, or per rectum; or
- (b) inhaling at least 1,600 micrograms of beclomethasone, or equivalent inhaled glucocorticoid, daily, for at least six months; or
- (c) using an ocular or intranasal glucocorticoid at above the maximum therapeutic dosage level, daily, for at least six months; or
- (d) applying a high or very high potency topical glucocorticoid to at least 20% of total skin surface area, daily, for at least six months; or
- (e) using a glucocorticoid concurrently with a drug from the Specified List 2 of drugs, daily, for at least 30 days.

Note: **equivalent glucocorticoid therapy**, **equivalent inhaled glucocorticoid**, **high or very high potency topical glucocorticoid** and **Specified List 2 of drugs** are also defined in the Schedule 1 – Dictionary.

haemolytic uraemic syndrome means a clinical syndrome characterised by renal failure, microangiopathic haemolytic anaemia and thrombocytopenia.

having infection with a Coxsackie B virus means having laboratory evidence of a Coxsackie B virus infection.

high or very high potency topical glucocorticoid means:

- (a) betamethasone dipropionate 0.05%;
- (b) betamethasone valerate 0.1%;
- (c) clobetasol propionate 0.05%;
- (d) diflucortolone valerate 0.1%;

- (e) fluocinolone acetonide 0.025%; or
- (f) another topical glucocorticoid of equivalent potency.

hyperuricaemia means having a serum urate level persistently greater than 0.40 millimoles per litre.

inhaling, ingesting or having cutaneous contact with a chemical agent contaminated by 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD) means:

- (a) decanting or spraying;
- (b) cleaning or maintaining equipment used to apply;
- (c) being sprayed with;
- (d) handling or sawing timber treated with;
- (e) being in an environment shrouded in dust from timber treated with; or
- (f) using cutting oils contaminated with;

one of the following chemicals:

- (i) 2,4,5-trichlorophenoxyacetic acid;
- (ii) 2,4,5-trichlorophenoxypropionic acid;
- (iii) 2,4,5-trichlorophenol;
- (iv) 2-(2,4,5-trichlorophenoxy)-ethyl 2,2-dichloropropionate;
- (v) o,o-dimethyl-o-(2,4,5-trichlorophenyl)-phosphorothioate;
- (vi) pentachlorophenol;
- (vii) 2,3,4,6-tetrachlorophenol;
- (viii) 2,4,6-trichlorophenol;
- (ix) 1,3,5-trichloro-2-(4-nitrophenoxy)benzene;
- (x) 2,4-dichloro-1-(4-nitrophenoxy)benzene; or
- (xi) 2,4-dichloro-1-(3-methoxy-4-nitrophenoxy)-benzene.

MET means a unit of measurement of the level of physical exertion. 1 MET = 3.5 ml of oxygen/kg of body weight per minute, 1.0 kcal/kg of body weight per hour, or resting metabolic rate.

MRCA means the *Military Rehabilitation and Compensation Act 2004*.

pack-year of tobacco products means:

- (a) 20 cigarettes per day for a period of one calendar year; or
- (b) 7,300 cigarettes in a period of one calendar year; or
- (c) 7,300 grams of smoking tobacco by weight, either in cigarettes, pipe tobacco or cigars, or a combination of same, in a period of one calendar year.

relevant service means:

- (a) operational service under the VEA;
- (b) peacekeeping service under the VEA;
- (c) hazardous service under the VEA;
- (d) British nuclear test defence service under the VEA;
- (e) warlike service under the MRCA; or
- (f) non-warlike service under the MRCA.

Note: **MRCA** and **VEA** are also defined in the Schedule 1 - Dictionary.

Specified List 1 of drugs means:

- (a) abacavir;
- (b) alpha and beta agonists, including adrenaline and noradrenaline;
- (c) amiodarone;
- (d) beta-blockers;
- (e) bortezomib;
- (f) cyclophosphamide;
- (g) cyclosporine;
- (h) decitabine;
- (i) diadanosine;
- (j) diazoxide;
- (k) docetaxel;
- (l) emtricitabine;
- (m) everolimus;
- (n) gatifloxacin;
- (o) growth hormone;
- (p) imatinib;
- (q) isoniazid;
- (r) L-asparaginase;
- (s) lamivudine;
- (t) levofloxacin;
- (u) moxifloxacin;
- (v) nicotinic acid for the treatment of dyslipidaemia;
- (w) nilotinib;
- (x) pentamidine;
- (y) phenytoin;
- (z) protease inhibitors;
- (aa) rifampicin;
- (bb) sirolimus;
- (cc) sodium valproate;
- (dd) somatostatin analogues;
- (ee) statins;
- (ff) stavudine;
- (gg) streptozotocin;
- (hh) tacrolimus;
- (ii) temsirolimus;
- (jj) temzolomibe;
- (kk) theophylline;
- (ll) thiazide diuretics;
- (mm) thyroid hormones;
- (nn) vorinostat; or
- (oo) zidovudine.

Specified List 2 of drugs means:

- (a) amprenavir;
- (b) atazanavir;
- (c) darunavir;
- (d) fosamprenavir;

- (e) indinavir;
- (f) itraconazole;
- (g) ketoconazole;
- (h) lopinavir;
- (i) nelfinavir;
- (j) ritonavir;
- (k) saquinavir; or
- (l) tipranavir.

specified list of endocrine disorders means:

- (a) acromegaly;
- (b) Cushing syndrome;
- (c) glucagonoma;
- (d) hyperthyroidism;
- (e) pheochromocytoma;
- (f) primary hyperaldosteronism; or
- (g) somatostatinoma.

specified pathological condition involving the pancreas means:

- (a) acute pancreatitis;
- (b) chronic pancreatitis;
- (c) cystic fibrosis;
- (d) haemochromatosis; or
- (e) malignant neoplasm of the pancreas.

terminal event means the proximate or ultimate cause of death and includes the following:

- (a) pneumonia;
- (b) respiratory failure;
- (c) cardiac arrest;
- (d) circulatory failure; or
- (e) cessation of brain function.

type 1 diabetes mellitus means a form of diabetes mellitus caused by complete or near-total insulin deficiency and requiring daily administration of insulin.

type 2 diabetes mellitus means a form of diabetes mellitus caused by variable degrees of insulin resistance and impaired insulin secretion.

VEA means the *Veterans' Entitlements Act 1986*.