



**Australian Government**  
**Repatriation Medical Authority**

**Statement of Principles**  
**concerning**  
**CHOLELITHIASIS**  
**(Reasonable Hypothesis)**  
**(No. 51 of 2016)**

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

Dated 22 April 2016

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 'N. Saunders'.

Professor Nicholas Saunders AO  
Chairperson

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**1 Name**

This is the Statement of Principles concerning *cholelithiasis (Reasonable Hypothesis)* (No. 51 of 2016).

**2 Commencement**

This instrument commences on 23 May 2016.

**3 Authority**

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

**4 Revocation**

The Statement of Principles concerning cholelithiasis No. 7 of 2008 made under subsection 196B(2) of the VEA is revoked.

**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 cholelithiasis and death from cholelithiasis.

*Meaning of cholelithiasis*

- (2) For the purposes of this Statement of Principles, cholelithiasis means the aggregation of bile constituents into a stone or calculus with a diameter exceeding two millimetres, in the gallbladder or in the intrahepatic or extrahepatic bile ducts; and which may present as biliary colic.
- (3) While cholelithiasis attracts ICD-10-AM code K80, in applying this Statement of Principles the meaning of cholelithiasis 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)*,

*Death from cholelithiasis*

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

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 cholelithiasis and death from cholelithiasis 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: *relevant service* is 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 cholelithiasis or death from cholelithiasis with the circumstances of a person's relevant service:

- (1) being obese for at least the two years before the clinical onset of cholelithiasis;

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

- (2) having rapid and extreme weight loss within the two years before the clinical onset of cholelithiasis;

Note: *rapid and extreme weight loss* is defined in the Schedule 1 - Dictionary.

- (3) having a very low calorie diet for the six months before the clinical onset of cholelithiasis;

Note: *very low calorie diet* is defined in the Schedule 1 - Dictionary.

- (4) undergoing bariatric surgery within the five years before the clinical onset of cholelithiasis;

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

- (5) taking a drug or a drug from a class of drugs from the specified list of drugs, for a continuous period of at least three months before the clinical onset of cholelithiasis, and where treatment has ceased, the clinical onset of cholelithiasis has occurred within three months of cessation;

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

- (6) having cirrhosis of the liver at the time of the clinical onset of cholelithiasis;
- (7) having non-alcoholic fatty liver disease at the time of the clinical onset of cholelithiasis;
- Note: *non-alcoholic fatty liver disease* is defined in the Schedule 1 - Dictionary.
- (8) for males only, having hepatitis C virus infection at the time of the clinical onset of cholelithiasis;
- (9) having a haemolytic disease at the time of the clinical onset of cholelithiasis;
- Note: *haemolytic disease* is defined in the Schedule 1 - Dictionary.
- (10) having Crohn's disease at the time of the clinical onset of cholelithiasis;
- Note: *Crohn's disease* is defined in the Schedule 1 - Dictionary.
- (11) having an ileal resection or ileal bypass before the clinical onset of cholelithiasis;
- (12) having type 2 diabetes mellitus at the time of the clinical onset of cholelithiasis;
- Note: *type 2 diabetes mellitus* is defined in the Schedule 1 - Dictionary.
- (13) having total parenteral nutrition for a continuous period of at least three weeks before the clinical onset of cholelithiasis, and where total parenteral nutrition has ceased, the clinical onset of cholelithiasis has occurred within 30 days of cessation;
- Note: *total parenteral nutrition* is defined in the Schedule 1 - Dictionary.
- (14) being pregnant within the six months before the clinical onset of cholelithiasis;
- (15) having estrogen therapy for a continuous period of at least three months before the clinical onset of cholelithiasis, and where estrogen therapy has ceased, the clinical onset of cholelithiasis has occurred within six months of cessation;
- Note: *estrogen therapy* is defined in the Schedule 1 - Dictionary.
- (16) having a spinal cord injury at the time of the clinical onset of cholelithiasis;
- Note: *spinal cord injury* is defined in the Schedule 1 - Dictionary.
- (17) having a gastric or oesophageal resection, or another operation that included a vagotomy, before the clinical onset of cholelithiasis;

- (18) having a foreign body in the biliary tract, or a mechanical obstruction of the biliary tract, before the clinical onset of cholelithiasis;

Note: *foreign body* and *mechanical obstruction of the biliary tract* are defined in the Schedule 1 - Dictionary.

- (19) having a parasitic disease from the specified list of parasitic diseases of the biliary tract, at the time of the clinical onset of cholelithiasis;

Note: *specified list of parasitic diseases* is defined in the Schedule 1 - Dictionary.

- (20) having bacterial infection of the biliary tract at the time of the clinical onset of cholelithiasis;

- (21) having cholangiohepatitis or recurrent pyogenic cholangitis at the time of the clinical onset of cholelithiasis;

- (22) having a somatostatinoma at the time of the clinical onset of cholelithiasis;

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

- (23) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical onset of cholelithiasis;

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

- (24) being obese for at least the two years before the clinical worsening of cholelithiasis;

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

- (25) having rapid and extreme weight loss within the two years before the clinical worsening of cholelithiasis;

Note: *rapid and extreme weight loss* is defined in the Schedule 1 - Dictionary.

- (26) having a very low calorie diet for the six months before the clinical worsening of cholelithiasis;

Note: *very low calorie diet* is defined in the Schedule 1 - Dictionary.

- (27) undergoing bariatric surgery within the five years before the clinical worsening of cholelithiasis;

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

- (28) taking a drug or a drug from a class of drugs from the specified list of drugs, for a continuous period of at least three months before the clinical worsening of cholelithiasis, and where treatment has ceased, the clinical worsening of cholelithiasis has occurred within three months of cessation;

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

- (29) having cirrhosis of the liver at the time of the clinical worsening of cholelithiasis;

- (30) having non-alcoholic fatty liver disease at the time of the clinical worsening of cholelithiasis;  
Note: *non-alcoholic fatty liver disease* is defined in the Schedule 1 - Dictionary.
- (31) for males only, having hepatitis C virus infection at the time of the clinical worsening of cholelithiasis;
- (32) having a haemolytic disease at the time of the clinical worsening of cholelithiasis;  
Note: *haemolytic disease* is defined in the Schedule 1 - Dictionary.
- (33) having Crohn's disease at the time of the clinical worsening of cholelithiasis;  
Note: *Crohn's disease* is defined in the Schedule 1 - Dictionary.
- (34) having an ileal resection or ileal bypass before the clinical worsening of cholelithiasis;
- (35) having type 2 diabetes mellitus at the time of the clinical worsening of cholelithiasis;  
Note: *type 2 diabetes mellitus* is defined in the Schedule 1 - Dictionary.
- (36) having total parenteral nutrition for a continuous period of at least three weeks before the clinical worsening of cholelithiasis, and where total parenteral nutrition has ceased, the clinical worsening of cholelithiasis has occurred within 30 days of cessation;  
Note: *total parenteral nutrition* is defined in the Schedule 1 - Dictionary.
- (37) being pregnant within the six months before the clinical worsening of cholelithiasis;
- (38) having estrogen therapy for a continuous period of at least three months before the clinical worsening of cholelithiasis, and where estrogen therapy has ceased, the clinical worsening of cholelithiasis has occurred within six months of cessation;  
Note: *estrogen therapy* is defined in the Schedule 1 - Dictionary.
- (39) having a spinal cord injury at the time of the clinical worsening of cholelithiasis;  
Note: *spinal cord injury* is defined in the Schedule 1 - Dictionary.
- (40) having a gastric or oesophageal resection, or another operation that included a vagotomy, before the clinical worsening of cholelithiasis;
- (41) having a foreign body in the biliary tract, or a mechanical obstruction of the biliary tract, before the clinical worsening of cholelithiasis;  
Note: *foreign body* and *mechanical obstruction of the biliary tract* are defined in the Schedule 1 - Dictionary.

- (42) having a parasitic disease from the specified list of parasitic diseases of the biliary tract, at the time of the clinical worsening of cholelithiasis;

Note: *specified list of parasitic diseases* is defined in the Schedule 1 - Dictionary.

- (43) having bacterial infection of the biliary tract at the time of the clinical worsening of cholelithiasis;
- (44) having cholangiohepatitis or recurrent pyogenic cholangitis at the time of the clinical worsening of cholelithiasis;
- (45) having a somatostatinoma at the time of the clinical worsening of cholelithiasis;

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

- (46) an inability to undertake any physical activity greater than three METs for at least the five years before the clinical worsening of cholelithiasis;

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

- (47) inability to obtain appropriate clinical management for cholelithiasis.

## **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(24) to 9(47) apply only to material contribution to, or aggravation of, cholelithiasis where the person's cholelithiasis 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:

***bariatric surgery*** means weight reduction surgical procedures including gastrojejunostomy, gastric stapling, vertical banded gastroplasty and gastrectomy with Roux-en-Y anastomosis.

***being obese*** means:

- (a) having a Body Mass Index (BMI) of 30 or greater; or
- (b) for males, having a waist circumference exceeding 102 centimetres; or
- (c) for females, having a waist circumference exceeding 88 centimetres.

***BMI*** means  $W/H^2$  and where:

W is the person's weight in kilograms; and

H is the person's height in metres.

***cholelithiasis***—see subsection 7(2).

***Crohn's disease*** means a type of inflammatory bowel disease that can affect any part of the gastrointestinal tract from the mouth to the anus, particularly the small bowel, with patchy areas of transmural inflammation, and usually with prominent extraintestinal manifestations.

***estrogen therapy*** means the continuous, cyclical or intermittent administration of estrogen contained in medications, including the oral contraceptive pill and post-menopausal hormone replacement therapy.

***foreign body*** means the presence of exogenous material, including a surgical clip or stent or nonabsorbable suture, a missile fragment or shrapnel, or a fish bone.

***haemolytic disease*** means an acquired or inherited disorder characterised by red cell defects and breakdown with bilirubin overproduction, including thalassaemia, hereditary spherocytosis, sickle cell anaemia or haemolytic uraemic syndrome.

***mechanical obstruction of the biliary tract*** means a structural or disease process, including benign or malignant stricture, sclerosing cholangitis, or choledochal cyst, which narrows the lumen of the biliary tract.

***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*.

***non-alcoholic fatty liver disease*** means non-alcoholic steatohepatitis, or fatty liver or hepatic fibrosis not associated with a significant intake of ethanol.

***rapid and extreme weight loss*** means total weight loss of at least 15 percent of initial body weight:

- (a) within a continuous six month period; or
- (b) at an average rate of at least 1.5 kilograms per week.

***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.

***somatostatinoma*** means a neuroendocrine neoplasm characterised by excessive secretion of somatostatin hormone by tumour cells of D-cell origin.

***specified list of drugs*** means:

- (a) atazanavir;
- (b) cyclosporine A;
- (c) fibrates;
- (d) somatostatin analogues;
- (e) tacrolimus; or
- (f) tamoxifen.

***specified list of parasitic diseases*** means:

- (a) ascariasis;
- (b) clonorchiasis;
- (c) dicrocoeliasis;
- (d) fascioliasis;
- (e) opisthorchiasis; or
- (f) trypanosomiasis.

***spinal cord injury*** means an injury to the long tracts of the spinal cord resulting in permanent motor or sensory deficits below the level of the lesion.

***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.

***total parenteral nutrition*** means continuous intravenous drip feeding with no feeding via mouth or gut.

***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*.

*very low calorie diet* means having an energy intake of less than 800 kilocalories per day.