

Australian Capital Territory

# Public Health (Public Health Risk Activity Licensing Exemption) Determination 2021 (No 1)

Disallowable instrument DI2021–38

made under the

**Public Health Act 1997, s 22 (Exemption from licensing requirement—activity accreditation schemes)**

## EXPLANATORY STATEMENT

---

### **Background**

Section 21 (1) of the *Public Health Act 1997* (PHA) provides that a person must not carry on a licensable public health risk activity unless the person holds an activity licence for the activity. This does not apply to a person who is exempt under section 22.

DI2005-302 declares that it is a licensable public health risk activity to carry out a *skin penetration procedure*. A *skin penetration procedure* includes any process that involves the piercing, cutting, puncturing or tearing of a living human body.

As such, DI2005-302 requires pathology collection centres (also known as specimen collection centres) to have a public health risk activity licence because they carry out *skin penetration procedures* (e.g. collecting of blood samples).

### **Exemption from licensing requirement**

Section 22 of the PHA provides that a person who carries on a licensable public health risk activity is exempt from the requirement to be licensed if they are accredited under an activity accreditation scheme for the activity. The Minister may determine via disallowable instrument what constitutes an activity accreditation scheme for licensable public health risk activities.

This instrument exempts pathology collection centres from requiring a public health risk activity licence under DI2005-302 because they are already adequately regulated by the Commonwealth Government. Pathology collection centres are highly regulated under Commonwealth legislation to ensure that collection centres accessing Medicare benefits are of high quality and clinically relevant. This exemption is consistent with the objectives of the PHA, which include the protection of the public from public

health risks *not* adequately controlled by another law of the Territory or a law of the Commonwealth.

Part 3 of this instrument determines the following to be an activity accreditation scheme in relation to the licensable public health risk activity of carrying out a skin penetration procedure:

- being approved as an ***Approved Collection Centre*** as defined under the *Health Insurance Act 1973* (Cwth).

The regulatory controls applied by the Commonwealth Government under the *Health Insurance Act 1973* (Cwth) regarding the approval of *Approved Collection Centres* adequately address the public health risks posed by pathology collection centres in the ACT. These controls include:

- To be an *Approved Collection Centre*, a person must be a current Approved Pathology Authority (APA). To be an APA, a person must own an Accredited Pathology Laboratory (APL). The only recognised accreditor for APLs is the National Association of Testing Authorities, Australia (NATA). If an Approved Collection Centre is associated with an APL, in granting accreditation, NATA must also consider the standards and procedures in place at the Approved Collection Centre.
- *Approved Collection Centre* staff must be suitably qualified people and employed or engaged by an APA.
- An *Approved Collection Centre* must meet the National Pathology Accreditation Advisory Council (NPACC) Guidelines for Approved Pathology Collection Centres. The NPAAC is a ministerially-appointed Council established by an Order under the *National Health Act 1953* (Cwth). It is comprised of representatives from all states and territories, nominees from peak professional bodies and the Australian Government Department of Health
- A person authorised by the Commonwealth Minister for Health may at any reasonable time enter and inspect an *Approved Collection Centre*.

Consistent with the PHA objective of avoiding dual regulation of public health risks, Part 3 of this instrument exempts an *Approved Collection Centre* from the requirement to hold a public health risk activity licence to carry out a skin penetration procedure. These facilities are still required to comply with other PHA requirements (e.g. they must comply with any relevant Code of Practice, be subject to inspection by authorised public health officers, etc). As per section 22, this exemption is conditional on an *Approved Collection Centre* complying with the Health Insurance Act, the PHA, and any corresponding public health risk law.

This instrument is not associated with an increased regulatory impact as it decreases regulatory burden. As such, a regulatory impact statement is not required.

This determination does not engage with an individual's human rights within the *Human Rights Act 2004*.