Private Healthcare Australia
Better Cover. Better Access. Better Care.

Review of draft guidance - Complying with the Unique Device Identification regulations for medical devices

January 2025

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About Private Healthcare Australia

Private Healthcare Australia (PHA) is the Australian private health insurance industry's peak representative body. We have 21 registered health funds throughout Australia as members and collectively represent 98% of people covered by private health insurance. PHA member funds provide healthcare benefits for over 14.4 million Australians.

1. Was the content relevant to your needs?

Private Healthcare Australia (PHA) supports the regulatory changes being proposed for UDI to help improve patient safety and provide faster identification of devices implanted into patients in the event of an adverse event, safety alert or recall. But PHA recommends an additional requirement be placed on sponsors to require any device that has a Prescribed List (PL) billing code associated with it have this code also documented on the registry.

This simple addition is something that all sponsors will already be familiar with as they require PL codes to invoice hospitals at the correct rate. Having this data readily available on the registry would dramatically improve the efficiency and speed of any product recalls or safety warnings for devices that have been implanted or used on patients who have utilised their private health insurance for the procedure.

Currently, almost 15 million Australians have private health insurance, and health funds collect detailed records of all medical procedures. In addition, all PL listed devices associated with each procedure are also recorded by health insurers, including the date of implantation, surgeon and hospital. Therefore, patients, hospitals and medical practitioners could be quickly notified about any issues with any medical devices.

2. Did the document content address all the questions you had about the topic?

Yes.

3. What additional information would you like to see, if any?

PHA recommends PL billing codes be linked to the UDI for all medical devices on the registry.

4. Did you find it easy to navigate the document?

Yes.

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5. Was the document well organised and logically structured?

Yes.

6. Did you find any sections difficult to understand? If so, what were they?

No.

Did the document help you understand how to comply with UDI requirements?

Yes

7. Did you find the examples and scenarios useful?

Yes.

8. How likely are you to refer to this document in the future?

Very likely.

9. Was the language and terminology appropriate for your level of experience?

Yes.

10. Did you encounter any issues with accessibility, for example, clarity of alternative text?

No.

11. Are there any additional topics you would like to see covered in this document?

As explained above, PHA recommends that all medical devices listed on the PL be required to have the associated billing codes linked to the products UDI on the registry.

12. Do you have any suggestions for improvement?

As explained above, PHA recommends that all medical devices listed on the PL be required to have the associated billing codes linked to the products UDI on the registry.

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