



Removal of prescriber accreditation requirements for medicines for the treatment of hepatitis B and hepatitis C under the PBS Section 100 Highly Specialised Drugs Program

1 September 2026

Overview

As of 1 September 2026, prescriber accreditation requirements previously applying to medicines for the treatment of hepatitis B and hepatitis C under the Pharmaceutical Benefits Scheme (PBS) Section 100 (s100) Highly Specialised Drugs (HSD) Program have been removed.

This change follows stakeholder consultation and is expected to improve timely patient access to these PBS-subsidised medicines by expanding the cohort of health practitioners authorised to prescribe them.

What is changing?

Effective 1 September 2026, the *National Health (Highly Specialised Drugs Program) Special Arrangement 2021* (HSD Special Arrangement) has been amended to remove the legislated prescriber accreditation requirements previously applying to medicines for the treatment of hepatitis B and hepatitis C under the PBS s100 HSD Program.

The HSD Special Arrangement is made under s100 of the *National Health Act 1953* and forms the legislative basis for the s100 HSD Program. It specifies the requirements for the legal prescription and supply of s100 HSD pharmaceutical benefits.

Medicines for the treatment of hepatitis B

Prior to 1 September 2026, medical practitioners and authorised nurse practitioners (NPs) were required to be 'accredited prescribers' of medication for the treatment of hepatitis B to prescribe these medicines under the s100 HSD Program (i.e. with PBS subsidy). The term 'accredited prescriber' referred to a prescriber approved by a state or territory to prescribe medication for the treatment of hepatitis B in accordance with the HSD Special Arrangement (an accredited s100 hepatitis B prescriber).

From 1 September 2026, any medical practitioner or authorised NP is authorised to prescribe PBS-subsidised hepatitis B medicines under the s100 HSD Program, providing that the patient eligibility criteria set out in the PBS restrictions for the relevant medicine/s (as published on [PBS Online](#)) are met.

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Medicines for the treatment of hepatitis C

Prior to 1 September 2026, authorised NPs were required to be 'accredited prescribers' of medication for the treatment of hepatitis C to prescribe these medicines with PBS subsidy under the s100 HSD Program. The term 'accredited prescriber' similarly referred to a prescriber approved by a state or territory to prescribe medication for the treatment of hepatitis C in accordance with the HSD Special Arrangement (an accredited s100 hepatitis C prescriber). This was a residual legislative requirement applying only to authorised NPs prescribing PBS-subsidised hepatitis C medicines under s100 HSD Program arrangements.

From 1 September 2026, any authorised NP is authorised to prescribe PBS-subsidised hepatitis C medicines under the s100 HSD Program (as well as under the section 85 (s85) PBS General Schedule), providing that the patient/prescriber eligibility criteria set out in the [General Statement for Drugs for the Treatment of Hepatitis C](#) (General Statement) are met. Subject to the same General Statement criteria, medical practitioners continue to be authorised prescribers for these medicines under both the PBS General Schedule and the s100 HSD Program irrespective of accreditation status.

Why have these changes been made?

The Department has implemented these changes following stakeholder consultation indicating that removal of the prescriber accreditation requirement previously applying to hepatitis B medicines under the s100 HSD Program will improve timely patient access to PBS-subsidised hepatitis B treatment, particularly in regional, rural and remote areas where access to accredited s100 hepatitis B prescribers is most limited. The removal of this requirement also better aligns legislative requirements with the contemporary clinical landscape for hepatitis B treatment in Australia.

Removal of the prescriber accreditation requirement previously applying to hepatitis C medicines under the s100 HSD Program aligns PBS prescribing requirements for hepatitis C medicines across the s85 General Schedule and s100 HSD Program and means that consistent legislative requirements apply to medical practitioners and authorised NPs prescribing these medicines under s100 HSD Program arrangements.

The removal of prescriber accreditation requirements previously applying to hepatitis B and hepatitis C medicines under the s100 HSD Program is consistent with the approach taken to implementing recent recommendations of the Pharmaceutical Benefits Advisory Committee for expanded NP prescribing of s100 HSD medicines (i.e. without imposing legislated requirements for bespoke accreditation/approval processes applying to prospective NP prescribers of the medicines concerned).

The removal of prescriber accreditation requirements previously applying to hepatitis B and hepatitis C medicines under the s100 HSD Program does not preclude the delivery of relevant prescriber education and training programs where suitable and clinically appropriate, however these no longer form part of the mandated conditions of PBS subsidy.

What do these changes mean for PBS prescribers of hepatitis B and/or hepatitis C medicines?

From 1 September 2026:

- any medical practitioner or authorised NP can prescribe PBS-subsidised hepatitis B medicines (for both initiation and maintenance treatment) for eligible patients under s100 HSD Community Access arrangements; and
- any authorised NP (in addition to any medical practitioner) can prescribe PBS-subsidised hepatitis C medicines (for both initiation and maintenance treatment) for eligible patients receiving treatment in a hospital setting under s100 HSD Public/Private Hospital arrangements.

In each of these scenarios, a legislated requirement for individual practitioners to obtain prior accreditation as an s100 hepatitis B or hepatitis C prescriber no longer applies. Prescribers must continue to ensure that they are operating within the remit of state and territory-based prescribing regulations and their individual scope of practice.

In prescribing PBS-subsidised hepatitis B and/or hepatitis C medicines under the s100 HSD Program from 1 September 2026, prescribers must still ensure that the relevant patient and prescriber eligibility criteria (as applicable) are met.

For hepatitis B medicines, the applicable criteria are set out in the PBS restrictions for the relevant medicine/s available on [PBS Online](#).

For hepatitis C medicines, the applicable criteria are contained in the [General Statement](#), which applies across the s85 General Schedule and s100 HSD Program listings of these medicines. They include treatment criteria specifying that patients must be treated by a medical practitioner or an authorised NP experienced in the treatment of chronic hepatitis C infection; or in consultation with a relevant experienced specialist (gastroenterologist, hepatologist or infectious diseases physician).

Patient eligibility criteria for PBS-subsidised access to these medicines and other listing details (such as listed maximum quantities and repeats) remain unchanged.

What do these changes mean for patients receiving PBS-subsidised treatment with these medicines?

From 1 September 2026, eligible patients can obtain PBS prescriptions for hepatitis B medicines listed on the s100 HSD Program from any medical practitioner or authorised NP. It is no longer the case that the treating medical practitioner or authorised NP must be an accredited s100 hepatitis B prescriber.

From 1 September 2026, eligible patients can obtain PBS prescriptions for dual-listed hepatitis C medicines from any medical practitioner or authorised NP who is eligible to prescribe these medicines under the [General Statement](#). It is no longer the case that an authorised NP prescribing a hepatitis C medicine for subsidised supply under s100 HSD Program arrangements must be an accredited s100 hepatitis C prescriber.

There are no changes to patient eligibility criteria for PBS-subsidised access to hepatitis B or hepatitis C medicines from 1 September 2026, nor any change to how often patients will need to see their treating practitioner/s to renew their PBS prescription for a hepatitis B or hepatitis C medicine. PBS prescriptions provided by accredited s100 hepatitis B or hepatitis C prescribers prior to 1 September 2026 remain valid.

Dispensing arrangements for PBS-subsidised hepatitis B and hepatitis C medicines supplied under the s100 HSD Program remain unchanged from 1 September 2026, including in terms of the cost to patients for these medicines. Patient contributions for PBS prescriptions for hepatitis B and hepatitis C medicines supplied under the s100 HSD Program continue to count towards the patient's PBS Safety Net threshold.

Where do I go for further information on the changes?

If further information or clarification is required in relation to the 1 September 2026 changes to prescribing requirements for hepatitis B and/or hepatitis C medicines under the PBS s100 HSD Program, please contact s100programs@health.gov.au.