EXPLANATORY STATEMENT

National Health Act 1953

National Health (Botulinum Toxin Program) Amendment Special Arrangement 2022

PB 129 of 2022

Purpose and operation

The *National Health (Botulinum Toxin Program) Special Arrangement 2015* (PB 87 of 2015) (the Botulinum Toxin Special Arrangement) is made under subsection 100(1) of the *National Health Act 1953* (the Act) and sets out legislative provisions regarding the administration and supply of botulinum toxin under the Botulinum Toxin Program. The current Botulinum Toxin Special Arrangement does not permit the supply of botulinum toxin prior to the prescription being provided to the approved hospital authority, conversely to the process that occurs in practice in the vast majority of cases.

The *National Health (Botulinum Toxin Program) Amendment Special Arrangement 2022* (the amending instrument) amends the Botulinum Toxin Special Arrangement to allow an eligible prescriber (who is an eligible medical practitioner) to administer botulinum toxin before a valid Pharmaceutical Benefits Scheme (PBS) prescription has been written and dispensed by an approved hospital authority. The proposed amendment will require eligible prescribers, who have administered botulinum toxin before a prescription is written, to provide a written prescription to an approved hospital authority within seven days of administering botulinum toxin to a patient.

This amendment will ensure that patients can continue to be treated with botulinum toxin before a valid PBS prescription is provided to the hospital pharmacy, in line with current clinical practice.

The amending instrument amends subsection 9(1) of the Botulinum Toxin Special Arrangement to allow eligible prescribers to administer botulinum toxin to eligible patients either prior to or after a valid prescription being written and dispensed by an approved hospital authority.

Background

Generally, under the current practice botulinum toxin is administered as follows:

- The eligible prescriber orders botulinum toxin from an approved hospital authority (via the hospital pharmacy), which is delivered to the prescriber's rooms as imprest supply.
- The patient attends a consultation with the eligible prescriber and after an assessment, botulinum toxin is administered during this appointment from the imprest supply. Depending on the patient's condition and treatment, the prescriber may write a private prescription or a PBS prescription. The prescriber will charge the patient a specialist fee. This differs from the method under the current Botulinum Toxin Special Arrangement, which requires a patient to attend two consultations with the prescriber: one consultation to receive a prescription, and one consultation to receive treatment with botulinum toxin.
- A consent form is completed by the patient and the eligible prescriber at the appointment prior to administration of botulinum toxin. Some of the details included on the consent form include patient details (such as Medicare number) and the date that botulinum toxin was administered. This consent form gives approval for the prescriber to provide this information to the approved hospital authority.
- The consent form is sent directly to the approved hospital authority on the date botulinum toxin was administered, or alternatively is provided to the approved hospital authority at the same time as the PBS prescription is sent. Generally, this is sent to the approved hospital authority within seven days.

- Once the PBS prescription is received, a PBS Claim is submitted by the approved hospital authority which is then repaid for the cost of the botulinum toxin and the PBS co-payment. The patient is then sent an invoice from the approved hospital authority for the PBS co-payment.

The botulinum toxin injection contains a muscle relaxant obtained from the bacterium *Clostridium botulinum*. It works by temporarily relaxing overactive or spastic (contracting) muscles. It can also block signals to the sweat glands, thus reducing excessive sweating (hyperhidrosis), and can also block the release of chemicals in the brain associated with the cause of pain (chronic migraine). When injected into the bladder wall, it works on the bladder muscle to prevent leakage of urine (urinary incontinence). It is used to treat medical conditions associated with overactive muscles and has been shown to reduce the symptoms and improve the quality of life of patients suffering from these conditions.

The size, number and locations of muscles of a patient are some of the factors taken into consideration when prescribing botulinum toxin and determining correct dosage. The Botulinum Toxin Special Arrangement defines these terms for the purposes of patient eligibility based on clinical evidence and the expert opinion of the Pharmaceutical Benefits Advisory Committee (PBAC).

There are checks and balances on the provision of botulinum toxin to prevent harmful effects on patients by restricting who can be an eligible prescriber (prescribers with the appropriate qualifications and experience in the treatment of patients and the use of required equipment). In general, dosing of botulinum toxin is individualised for each patient and always starts with the minimal effective dose. The dosing interval is typically not more frequent than every three months.

Authority

The PBS is established under the Act and provides Australians with timely, reliable and affordable access to necessary and cost-effective medicines. The Act regulates the listing, pricing, prescribing, supply, and claiming and payment of subsidies for supply of drugs and medicinal preparations as pharmaceutical benefits.

Subsection 100(1) of the Act provides that the Minister may make special arrangements for, or in relation to, providing that an adequate supply of pharmaceutical benefits will be available to certain persons. These are persons who are living in isolated areas; or who are receiving treatment in circumstances in which pharmaceutical benefits are inadequate for that treatment; or if the pharmaceutical benefits covered by the arrangements can be more conveniently or efficiently supplied under the arrangements.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

Subsection 100(3) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII, have effect subject to a special arrangement made under subsection 100(1).

Reliance on subsection 33(3) of the *Acts Interpretation Act 1901*

Under subsection 33(3) of the *Acts Interpretation Act 1901*, where an Act confers a power to make, grant or issue any instrument of a legislative or administrative character (including rules, regulations or by-laws), the power shall be construed as including a power exercisable in the like manner and subject to the like conditions (if any) to repeal, rescind, revoke, amend, or vary any such instrument.

Commencement

This instrument commences on 1 January 2023.

Consultation

The Department of Health and Aged Care (the Department) consulted with Services Australia to ensure administrative systems would continue to support this amendment.

The Department consulted relevant stakeholders (the Chief Executive Officer, Pharmacy Services, Icon Group and EPIC Pharmacy), as well as the manufacturer of botulinum toxin (the Senior Market Access and Pricing Manager at Allergan) who initiated this inquiry in September 2021 around the Department's current requirements and expectations relating to the supply of botulinum toxin.

The Department also consulted with six doctors, nurses and practice managers from across Australia whose practices administer botulinum toxin from imprest supply. All of these practices currently send valid PBS prescriptions to the pharmacy within seven days of administering botulinum toxin.

All stakeholders unanimously considered that amending the Botulinum Toxin Special Arrangement was appropriate and did not identify any issues with the proposed amendments to align current clinical practice with the policy intent of the Botulinum Toxin Program.

General

This instrument is a legislative instrument for the purposes of the *Legislation Act 2003.*

Details of this instrument are set out in the **Attachment A**.

The instrument is compatible with the human rights and freedoms recognised or declared under section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*. A full statement of compatibility is set out in **Attachment B**.

ATTACHMENT A

NATIONAL HEALTH (BOTULINUM TOXIN PROGRAM) AMMENDMENT SPECIAL ARRANGEMENT 2022

Section 1 – Name

This section provides that the name of the instrument is the *National Health (Botulinum Toxin Program) Amendment Special Arrangement 2022* and specifies the PB number as 129 of 2022.

Section 2 – Commencement

This section provides that the instrument commences on 1 January 2023.

Section 3 – Authority

This section provides that the instrument is made under subsection 100(2) of the *National Health Act 1953*.

Section 4 Schedules

This section provides that Schedule 1 sets out the specific terms of amendment and repeal of each instrument, and any other item in the Schedule has effect according to its terms.

Schedule 1 – Amendments

Item 1 – Subsection 9(1)

Item 1 repeals and substitutes subsection 9(1) to allow for botulinum toxin to be supplied in two ways:

- a valid PBS prescription is provided to an approved hospital authority prior to botulinum toxin being supplied/administered to a patient (existing method); or

- botulinum toxin is supplied/administered before the prescription is provided to the approved hospital authority, provided that the eligible prescriber (who is an eligible medical practitioner) gives the prescription to the approved hospital authority within seven days of administering botulinum toxin to the eligible patient (new method).

The amendment to permit the supply of botulinum toxin prior to the prescription being provided to the approved hospital authority has been made to more appropriately reflect current clinical practice.

ATTACHMENT B

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Botulinum Toxin Program) Amendment Special Arrangement 2022

This legislative instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the legislative instrument

The *National Health (Botulinum Toxin Program) Amendment Special Arrangement 2022* (PB 129 of 2022) (the amending instrument) amends the *National Health (Botulinum Toxin Program) Special Arrangement 2015* (PB 87 of 2015) (the Botulinum Toxin Special Arrangement) to allow an eligible prescriber (who is an eligible medical practitioner) to administer botulinum toxin before a valid PBS prescription has been written and dispensed by an approved hospital authority. The proposed amendment will require eligible prescribers, who have administered botulinum toxin before a prescription is written, to provide a written prescription to an approved hospital authority within seven days of administering botulinum toxin to a patient. The amendment will ensure that patients can continue to be treated with botulinum toxin before a valid PBS prescription is provided to the hospital pharmacy, in line with current clinical practice.

The current Botulinum Toxin Special Arrangement does not permit the supply of botulinum toxin prior to the prescription being provided to the approved hospital authority, conversely to the process that occurs in practice. Amending the Botulinum Toxin Special Arrangement to allow eligible prescribers to supply/administer botulinum toxin to eligible patients either prior to or after a valid prescription being written and dispensed by an approved hospital authority will ensure consistency between the policy intent of the Botulinum Toxin Program and current clinical practice.

The amendment will ensure that the appropriate pharmaceutical benefits listed in Schedule 1 to the Botulinum Toxin Special Arrangement are available for eligible patients who require treatment in line with their diagnosis and clinical circumstances.

Human Rights Implications

The Instrument engages the following rights:

- The right to social security in Article 9 of the International Covenant on Economic, Social and Cultural Rights (ICESCR);
- The right to health in Article 12(1) of ICESCR and Article 24(1) of the Covenant on the Rights of the Child (CRC); and
- The right to equality and non-discrimination in Articles 2 and 26 in the International Covenant on Civil and Political Rights (ICCPR).

This Legislative Instrument assists with the advancement of these rights by ensuring access to PBS subsidised botulinum toxin treatment for patients in line with their diagnosis and appropriate dosing. Further, it positively impacts people living in remote areas by enabling them to require only one visit to their eligible medical practitioner - to be both assessed and administered with botulinum toxin.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

This Legislative Instrument engages Article 9 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which provides for the progressive realisation by all appropriate means of the right of everyone to social security. The instrument engages these rights by allowing prescribers to administer botulinum toxin before a valid PBS prescription has been written and dispensed by an approved hospital authority, noting botulinum toxin is used to treat medical conditions associated with overactive muscles and has been shown to reduce the symptoms and improve the quality of life of patients suffering from these conditions.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

This Legislative Instrument engages Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) which provides for the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. The instrument engages these rights by allowing prescribers to administer botulinum toxin before a valid PBS prescription has been written and dispensed by an approved hospital authority, noting botulinum toxin is used to treat medical conditions associated with overactive muscles and has been shown to reduce the symptoms and improve the quality of life of patients suffering from these conditions.

The Legislative Instrument also engages Article 24 of the Convention on the Rights of the Child. Article 24(1) relevantly provides for the right of the child to the highest attainable standard of health and ensuring no child is deprived of his or her right to access to such health care services. Article 24(2) goes on to provide that States Parties to the Convention shall take appropriate measures to (b) ensure the provision of necessary medical assistance and health care to all children.

The Right to Equality and Non-discrimination

Articles 2 and 26 includes that each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognised in the present Covenant, without distinction of any kind, such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status; that everyone shall have the right to recognition everywhere as a person before the law; and all persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

This instrument engages the right to equality and non-discrimination, on the grounds of place of residence within a country, in Articles 2 and 26 of the International Covenant on Civil and Political Rights (ICCPR) as it makes special arrangements for certain persons living in isolated areas by enabling them to require only one visit to their eligible medical practitioner - to be both assessed and administered with botulinum toxin.

Analysis

The PBS is a benefit scheme which assists with advancement of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health by providing for subsidised access for people to medicines. The PBS provides timely, reliable and affordable access to necessary medicines for Australians.

The botulinum toxin injection contains a muscle relaxant obtained from the bacterium Clostridium botulinum. It works by temporarily relaxing overactive or spastic (contracting) muscles. It can also block signals to the sweat glands, thus reducing excessive sweating (hyperhidrosis), and can also block the release of chemicals in the brain associated with the cause of pain (chronic migraine). When injected into the bladder wall, it works on the bladder muscle to prevent leakage of urine (urinary incontinence). It is used to treat medical conditions associated with overactive muscles and has been shown to reduce the symptoms and improve the quality of life of patients suffering from these conditions.

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There are checks and balances on the provision of botulinum toxin to prevent harmful effects on patients by restricting who can be an eligible prescriber (prescribers with the appropriate qualifications and experience in the treatment of patients and the use of required equipment). In general, dosing of botulinum toxin is individualised for each patient and always starts with the minimal effective dose. The dosing interval is typically not more frequent than every three months.

Conclusion

This legislative instrument is compatible with human rights because it promotes the protection of human rights.

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