

BOTULINUM TOXIN AND COSMETIC FILLERS (CHILDREN) BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Botulinum Toxin and Cosmetic Fillers (Children) Bill as brought from the House of Commons on 12 March (HL Bill 180).

- These Explanatory Notes have been prepared by the Department of Health and Social Care, with the consent of Baroness Laura Wyld, the Peer in charge of the Bill, in order to assist the reader of the Bill and to help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill.

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These Explanatory Notes relate to the Botulinum Toxin and Cosmetic Fillers (Children) Bill as introduced in the House of Lords on 12 March 2021 (HL Bill 180)

Overview of the Bill

- 1 The purpose of the Botulinum Toxin and Cosmetic Fillers (Children) Bill is to prohibit specific cosmetic procedures being performed on young people under the age of 18 years old (U18s) in England, except under the directions of a doctor.
- 2 The policy intends to safeguard children from the potential health risks of botulinum toxins and cosmetic fillers (commonly known as 'dermal fillers'). The procedures will still be available to U18s from a limited range of registered health professionals (doctors, dentists, pharmacists, nurses) where there is an assessed medical need.
- 3 The Bill also imposes a duty on businesses to ensure they do not arrange or perform the procedures on U18s, enforced by a local authority regulatory regime.
- 4 The Bill contains six Clauses covering the following matters:
 - Offence of administering certain substances to a child
 - Offence by persons carrying on a business
 - Offences by bodies corporate
 - Enforcement
 - Consequential amendments
 - Extent, Commencement and Short Title

Policy background

- 5 In January 2012, Sir Bruce Keogh was asked by the then Secretary of State to carry out a review of the regulation of cosmetic interventions following the Poly Implant Prothèse (PIP) breast implants scandal. The review's recommendations were published in April 2013.¹ The Government welcomed the findings of the review and the government response, published in February 2014, accepted the majority of its 40 recommendations. The Department subsequently worked with stakeholders to implement the recommendations.
- 6 In the intervening years there has been a growing prevalence and normalisation of non-surgical cosmetic procedures, arguably associated with the rise in social media and the increasing accessibility and affordability of providers on the high street as technologies and products in this field have advanced.
- 7 The 2017 Conservative manifesto contained a commitment to ensure the effective registration and regulation of those performing cosmetic interventions. The Department has been working with stakeholders to explore the regulation of premises, practitioners, products and consumer safeguards. This includes work to assess whether there are adequate safeguards and regulation of practitioners who perform some of the more invasive cosmetic procedures.
- 8 Currently, children, in the same way as adults, may access botulinum toxin (a Prescription Only Medicine, regulated by the Medicines and Healthcare Regulatory Agency (MHRA)) and cosmetic filler procedures on the commercial market without a medical or psychological assessment. Practitioners do not need to be medically qualified to perform the procedures and there are no mandatory competency or qualification frameworks related to their administration.

¹ Department of Health and Social Care (2013) [Independent report: Review of the Regulation of Cosmetic Interventions](#)

- 9 The potential health risks of the procedures include blindness, tissue necrosis, infection, scarring and psychological impacts.
- 10 Within this context, there are ethical considerations about the extent to which U18s have the emotional and mental maturity to give their informed consent to these invasive procedures, given the health impacts and limited standards framework which apply to their provision.
- 11 A targeted policy restricting access to treatments by U18s as a particularly vulnerable group in society is considered a justifiable and proportionate response to the potential health risks.
- 12 The age restriction has been set at 18 years old. This aligns with age restrictions in England on other comparable body modifications which carry health risks, such as tattooing, sunbed use, teeth whitening, and intimate piercing (in Wales).
- 13 There is provision in the Bill allowing for the continued use of both treatments on U18s under the directions of a doctor. To practise in the UK, doctors must be registered and hold a licence to practise with the General Medical Council, the regulator of doctors. The GMC publishes standards of practice and guidance for doctors, including Good Medical Practice, which covers consent, the treatment of patients under 18 years old and safeguarding vulnerable patients. It also publishes specific ethical guidance for doctors performing cosmetic procedures which requires doctors to only perform cosmetic treatments that are assessed as being in the best interests of their patient. Once a treatment has been approved by a doctor, the Bill then limits the carrying out of these two procedures to dentists, doctors, nurses and pharmacists. As registered health professionals these professions are bound by the standards and guidance of their regulators and must only carry out the procedures when they are within the scope of their professional competence. This model is designed to ensure a high degree of patient safety measures and safeguards are secured in statute for young people undergoing the procedures.
- 14 In line with convention on handout private members' bills there has been no public consultation on the policy. Department officials have consulted with a range of industry stakeholders from both the medical, beauty and pharmaceutical sectors, and there is universal support for the principle of introducing an age restriction on these procedures. There is also support for limiting the range of practitioners that the approved procedure may then be delegated to (doctors, dentists, nurses and pharmacists) and limiting their administration to circumstances where there is an assessed medical need.
- 15 The provisions in this Bill seek to protect children and young people from the potential health risks of the procedures by controlling their access within a restricted framework that safeguards patient safety.

Territorial extent and application

- 16 This Bill relates to public health which is devolved. The Bill applies to procedures carried out or arranged to be carried out in England only.
- 17 Clause 6(1) provides for England and Wales extent. However, subsection (2) provides for the amendment of the Consumer Rights Act 2015 to have wider extent, as the provision being amended extends to England and Wales, Scotland and Northern Ireland. The wider extent does not affect the fact that the offence and duty are only applicable to conduct in England.
- 18 Clause 5 needs to have United Kingdom extent. Consequential amendment is needed to the Human Medicines Regulations 2012 SI 2012 /1916 which extends to Great Britain. Moreover, Westminster makes medicines legislation for Northern Ireland with the permission from Northern Ireland so a legislative consent motion will be sought for the amendment to the Human Medicines Regulations 2012.

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Commentary on Provisions of the Bill

Clause 1: Offence of administering certain substances to a child

- 19 Subsection (1) makes the administration of botulinum toxin and cosmetic fillers by injection on a person under the age of 18 years old an offence.
- 20 Botulinum Toxin is a Prescription Only Medicine, regulated by the Medicines and Healthcare Regulatory Agency (MHRA).
- 21 Subsection (2) provides a definition of the type of substances considered to be a ‘filler’ for the purposes of the legislation. The definition set out in the Bill captures all and any substances that are inserted into the body with the intention of producing a filling effect to change appearance (see subsection (3)).
- 22 Subsection (3) defines when a substance used for dermal or mucous membrane filling would be taken to have been administered for a cosmetic purpose and therefore when its use could result in an offence being committed. Filler products can be used for medical treatment or for aesthetic purposes. The Bill only captures the substances being used or arrangements being made for their use when they are for a cosmetic purpose, enabling the products’ continued use on U18s for medical purposes. The intent and resulting outcome behind the administration or arranging for the administration of the substance inserted is established in this subsection.
- 23 Subsection (4) outlines the statutory defences for a person charged with the offence described in subsection (1) of administering botulinum toxins or a cosmetic filler to a person under 18.
- 24 Subsection (4)(a) sets out that a medical practitioner (doctor) registered with the General Medical Council may administer botulinum toxin or a filler by way of injection to a person under the age of 18 without committing an offence. This enables the procedure to be both approved and delivered by a single practitioner where appropriate. Doctors should, as per their usual practice, follow guidance and standards issued by their regulator, the General Medical Council, when considering the use of either product types. Enforcement officers, as with any agency or member of the public, may escalate concerns about a medical practitioner’s fitness to practise to the regulator, who will conduct an investigation.
- 25 Subsection (4)(b) sets out that a limited number of regulated health professions may administer botulinum toxin or fillers by way of injection on U18s. They must only offer or administer these substances to a patient under the age of 18 years old when they are acting under the directions of a doctor registered with the General Medical Council. The eligible registered health professions who may raise a statutory defence to prosecution on this basis are listed at subsection (7): nurses, dentists or pharmacists. This allows a person to be assessed for one of the named procedures approved by a doctor, then seek a referral either through NHS services (where appropriate and available) or make a private arrangement with a health professional from one of the listed categories, ensuring an appropriately trained and qualified practitioner may conduct the procedure.
- 26 Subsections (4) and (5) sets out an evidentiary burden on the defendant whereby the defence must raise evidence to put the matter in issue and the prosecution must then disprove it beyond all reasonable doubt.
- 27 Subsection (6) sets out that a person who commits an offence is liable on summary conviction to an unlimited fine.

Clause 2: Offence by persons carrying on a business

- 28 Subsection (1) sets out that a person who carries on a business (a “business owner”) commits an offence if a person, other than a doctor, or a regulated health professional acting in

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accordance with the directions of a doctor, administers botulinum toxin or a filler by way of injection for a cosmetic purpose to a person under the age of 18 years old, in England.

- 29 Subsection (1)(b) sets out that a business owner commits an offence if they, or someone acting on their behalf (which may include a business owner's employees, a self-employed person contracted to work for the business owner, a member of staff from an agency or a person gaining unpaid work experience with the business), makes arrangements for botulinum toxin or a filler to be administered by injection for a cosmetic purpose to a person under the age of 18 years old, in England. This would cover, for example making an appointment, or agreeing via digital or social media to undertake the procedure. This would not apply where the arranged procedure will be administered by a doctor, or a regulated health professional acting in accordance with the directions of a doctor.
- 30 By making it an offence for arrangements to be made to administer one of the products covered by the legislation to a person aged under 18, prosecutions are able to be brought even where the person aged under 18 did not go on to have the procedure administered because, for example, the person changed their mind or an enforcement agency intervened.
- 31 Subsection (2) defines when a substance used for dermal or mucous membrane filling would be taken to have been administered for a cosmetic purpose and therefore when its use could result in an offence being committed. Filler products can be used for medical treatment or for aesthetic purposes. The Bill only captures the substances being used or arrangements being made for their use when they are for a cosmetic purpose, enabling the products' continued use on U18s for medical purposes. The intent and resulting outcome behind the administration or arranging for the administration of the substance inserted is established in this subsection.
- 32 If a person carrying on a business fails to comply with the requirements in subsection (1), that person commits a criminal offence punishable on summary conviction by an unlimited fine (subsection (3)). The offence is a strict liability offence, which means that the business owner commits the offence if a person aged under 18 is administered, or arrangements are made for the administration of one of the substances covered by the Bill for a cosmetic purpose. However, the strictness of this approach is tempered by the availability of a 'reasonable precautions and due diligence defence' (subsection (4)). If a business owner can demonstrate that they took all reasonable precautions and exercised all due diligence, then the business owner has a defence to the offence. So, for example, the business owner may show that the business has a strict policy requiring proof of a person's age before allowing any appointments to be booked for the injection of one of the substances covered in the legislation, and that the policy was properly implemented but was circumvented by a high quality fake 'proof of age' document which would fool a reasonable person.

Clause 3: Offences by bodies corporate

- 33 This Clause provides that, if an offence under this Bill, which is committed by a body corporate is committed with the consent or connivance of, or is attributable to the neglect of, an officer of a body corporate, then that officer as well as the body corporate is guilty of the offence. These actions may have been undertaken, or neglected by, any person from the executive or management team members of the body corporate, or a person who proclaimed or implied they were acting in such a role. For example, this could apply if a national aesthetic clinic chain neglected to implement training programmes for staff alerting them to the offence and the actions that could be taken to prevent the offence occurring, or if a hotel allows the hire of a function room or suite to a business without undertaking checks to establish the nature of the business activities that will be taking place.

Clause 4: Enforcement

- 34 Subsection (1) sets out that local authorities (as defined in subsection (1)) can enforce in their area the provisions of Clauses 2 and 3.
- 35 Subsection (2) outlines that the Bill does not create any new enforcement or investigatory powers, and local authorities are to use the powers already accorded to them under Schedule 5 of the Consumer Rights Act 2015.
- 36 Subsection (3) sets out an amendment consequential on subsection (2) to enable local authorities to enforce the provisions set out in this Bill through the powers accorded to them under Schedule 5 of the Consumer Rights Act 2015.

Clause 5: Power to make consequential provision

- 37 This Clause enables regulations which may be consequential on this Bill to be made by statutory instrument.

Clause 6: Extent, commencement and short title

- 38 Subsection (1) sets out the territorial extent of the Bill. Sections 4(3) and 5, which contain the power to make consequential provisions, extend to England and Wales, Scotland and Northern Ireland. The other provisions in the Bill extend to England and Wales only.
- 39 Subsection (3) provides for Clauses 1 to 4 to come into force at a time appointed by the Secretary of State by statutory instrument.
- 40 Subsection (4) sets out that the power to make consequential amendments and the territorial extent of the Bill come into force on the day the Act is passed in Parliament.
- 41 Subsection (5) sets out the short title of the Bill as the Botulinum Toxin and Cosmetic Fillers (Children) Act 2020.

European Convention on Human Rights

- 42 This is a Private Member's Bill and the Department of Health and Social Care is not required to give a statement of compatibility with the Human Rights Act 1998, in accordance with section 19(1)(a) of that Act. The Department of Health and Social Care has, nevertheless, considered the question of compatibility and has concluded that the provisions of the Bill are compatible with the Convention Rights.
- 43 The Bill restricts the choice of U18s in their personal choices as to an individual's desired appearance, whether in public or in private life. This could constitute an interference with their rights under Article 8 of the European Convention on Human Rights ("ECHR"). The rights in Article 8 are qualified in particular so as to permit necessary measures for the protection of health. It is considered necessary and proportionate to protect the health of persons under the age of 18 such that the administration of botulinum toxin and cosmetic fillers is only carried out by doctors or a regulated health practitioner acting in accordance with directions of a doctor registered with the General Medical Council ("GMC").
- 44 The GMC has issued guidance to doctors about the cosmetic treatment of persons under 18. It is considered that the restriction in the Bill as to administration of the products in question to persons under 18 is a necessary and proportionate response, having regard in particular to the potential harm and the GMC guidance, to the need to protect their health. It is further considered that the measures introduced by this Bill will demonstrate compliance with the positive obligation under Article 8, to have in place appropriate measures for the protection of public health.

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- 45 The Bill restricts the administration of those products to U18s so that they can be administered only by a doctor; or by a nurse, dentist, pharmacist (or Northern Ireland equivalent) in accordance with the directions of a doctor. This affects existing business practices and gives rise to a question under Article 1 of Protocol 1 ECHR. An interference with property can be justified under that Article if it is in the public or general interest.
- 46 The justification for the restriction in the Bill is to increase protection for children and young people by ensuring that any procedures authorised on the basis of a medical need by an appropriately qualified, insured and regulated practitioner. The restrictions apply only in respect of minors, who are at a vulnerable stage of their physical and emotional development (and in respect of whom the potential risks to both physical and emotional health can result from these procedures), it is considered that any interference could be justified on the basis that it serves a legitimate interest (the protection of public health).

Financial Implications of the Bill

- 47 The provisions in this Bill may result in an increase in revenue support paid under the Local Government Finance Act 1988 to enable local authorities in England to carry out the new functions conferred on them by Clause 4 of the Bill.

Parliamentary Approval for Financial Costs

- 48 A money resolution is required for the Bill. On 17 November 2020 Parliament gave approval to pass the money resolution and associated costs for the Bill.

Related Documents

- ‘Review of the Regulation of Cosmetic Interventions’ Sir Bruce Keogh’s Independent report 2013: <https://www.gov.uk/government/publications/review-of-the-regulation-of-cosmetic-interventions>
- ‘Government Response to the Review of the Regulation of Cosmetic Interventions’ – UK Government 2014: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/279431/Government_response_to_the_review_of_the_regulation_of_cosmetic_interventions.pdf
- ‘Good Medical Practice’ – General Medical Council guidance for doctors: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/good-medical-practice>
- ‘Guidance for doctors who offer cosmetic interventions’ - General Medical Council guidance for doctors: <https://www.gmc-uk.org/ethical-guidance/ethical-guidance-for-doctors/cosmetic-interventions>

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