

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 introduced in the House of Commons on 5 February 2020 (Bill 13).
- These Explanatory Notes have been prepared by the Department of Health and Social Care, with the consent of Laura Trott MP, the Member 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. So where a provision of the Bill does not seem to require any explanation or comment, the Notes simply say in relation to it that the provision is self-explanatory

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Overview of the Bill

1. The purpose of the Botulinum Toxin and Cosmetic Fillers (Children) Bill is to prohibit specific cosmetic procedures being performed for purely aesthetic purposes on young people under the age of 18 years old in England.
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 2013¹. 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, 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 and cosmetic filler procedures on the commercial market without a medical or psychological assessment.

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

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.

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 has been selected as it 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 where it is for a medical need, rather than a purely elective aesthetic purpose. 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 PMBs 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. Clause 6 sets out the territorial extent of the Bill. Subsection (1) provides for England and Wales extent. However, subsection (2) provides for the amendment of the Consumer Rights Act 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.
17. Any amendments that are subsequently made to subordinate legislation (such as the Human Medicines Regulations) may (depending on the extent of the legislation being amended) also extend to England and Wales, Scotland and Northern Ireland to avoid there being different versions of the same legislation operating in each jurisdiction, although only have practical effect in England.

Commentary on Provisions of the Bill

Clause 1 Offence of administering certain substances to a child

18. 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.
19. Botulinum Toxin is a Prescription Only Medicine, regulated by the Medicines and Healthcare Regulatory Agency (MHRA).
20. 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)).
21. 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.
22. 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.
23. 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.
24. 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.
25. 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.

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26. 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

27. 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 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.
28. Subsection (1) (b) sets out that a person who carries on a business (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.
29. 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.
30. 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

31. Provides that, if an offence under this Act, 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 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

32. Subsection (1) sets out that local authorities (as defined in subsection (1)) can enforce in their area the provisions of clauses 2 and 3.
33. Subsection (2) outlines that the Act 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.
34. Subsection (3) sets out an amendment consequential on subsection (2) to enable local authorities to enforce the provisions set out in the Botulinum Toxin and Cosmetic Fillers (Children) Act 2020 through the powers accorded to them under Schedule 5 of the Consumer Rights Act 2015.

Clause 5 Power to make consequential provision

35. This clause enables amendments to be made to other secondary legislation as a consequence of this Bill.

Clause 6 Extent, commencement and short title

36. Subsection (1) sets out the territorial extent of the Bill.
37. Subsection (2) sets out the territorial extent to which the power to make the consequential provisions set out in Clauses 4(3) and 5.
38. Subsection (3) provides for clauses 1 to 4 to come into force at a time appointed by the Secretary of State
39. Subsection (4) sets out that the power to make consequential amendments and the territorial extent of the legislation come into force on the day the Act is passed in Parliament.
40. Subsection (5) sets out the short title of the legislation as the Botulinum Toxin and Cosmetic Fillers (Children) Act 2020

Parliamentary approval for financial costs or for charges imposed

41. A money resolution is required for the Bill. Such a resolution is required where a Bill authorises new charges on public revenue – broadly speaking new expenditure. In this case there may need to be an increase in revenue support grant 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.

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English Votes for English Laws

42. As the Bill is a Private Member's Bill, the English votes provisions in the Standing Orders of the House of Commons relating to Public Business do not apply to the Bill

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