



Department  
of Health &  
Social Care

# **Health and Care Act 2022**

## **Impact assessments summary document and analysis of additional measures**

Published 4 November 2022

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# 1. Introduction

The Health and Care Act 2022 builds on the proposals brought forward by the NHS following the publication of the Long-Term Plan. These proposals built on extensive engagement by the NHS in 2019 and were further developed in the 2021 White Paper *Integration and Innovation: Working Together to Improve Health and Social Care for All*. The Act advances on the collaborative working seen throughout the pandemic, to shape a system which is best placed to serve the needs of the population.

The core measures in the Act follow three core themes, all of which are integral for helping the system to recover from the pandemic and transform patient care for decades to come.

Firstly, the Act removes barriers which stop the system from being truly integrated, with different parts of the NHS working better together, alongside local government, to tackle the nation's health inequalities.

Secondly, the Act reduces bureaucracy across the system. DHSC wants to remove barriers which make sensible decision-making harder and distracts staff from delivering what matters – the best possible care.

Lastly, DHSC wants to ensure appropriate accountability arrangements are in place so that the health and care system can be more responsive to both staff and the people who use it.

All of these measures are intended to complement, not distract from, the transformation that is already taking place across the system. These policies should be seen in the context of those broader reforms.

Alongside the core measures, there are additional policies to make targeted changes to allow the government to support the social care system, to improve quality and safety in the NHS, to grant the flexibility to take public health measures and to implement worldwide reciprocal healthcare agreements.

These measures will provide a foundation to build upon and our aim is to use legislation to provide a supportive framework for health and care organisations to continue to pursue integrated care for service users and taxpayers in a pragmatic manner.

As the health and care system further emerges from the pandemic, these legislative measures will assist with recovery by bringing organisations together, removing more of the bureaucratic and legislative barriers between them and enabling the changes and innovations they need to make.

## 2. Policies

The Health and Care Act legislates for multiple policy objectives and therefore brings forward a number of different measures. All of the policies where costs and benefits have been identified have an impact assessment (IA) which discusses the options, rationale, costs and benefits in detail.

Several of the policies relate to enabling powers in the Act which do not have quantifiable benefits or costs, as the impact of the policy will ultimately depend upon how the powers are used. Nevertheless, a qualitative assessment of the potential costs, benefits, risks and mitigations have been included as part of this package of IAs.

Furthermore, given that there are multiple policies, several of which do not have quantifiable benefits, it was not deemed appropriate to calculate an overall Net Present Value for the relative costs and benefits across the entirety of the Act. Rather, if costs and benefits have been quantified, then an NPV will be included in that policies respective IA and will be considered in isolation.

Table 1 presents a summary of the IAs published alongside the Act and the individual IA title in which they have been incorporated. Policies on Health Services Safety Investigations Body (HSSIB), and, introducing a 2100-0530 watershed on TV and online ban for paid advertising of food and drink that are High in Fat, Salt and Sugar (HFSS) products, each have their own standalone document dedicated to that respective policy.

**Table 1: Summary of policies and where to find their associated IAs**

<b>Policy</b>	<b>Impact assessment</b>
Commercial dealings in organs for transplantation: extra-territorial offences	Additional measures IA
Eradicating slavery and human trafficking in supply chains	Additional measures IA
Food information for consumers: power to amend retained EU Law	Additional measures IA
Hospital Food Standards	Additional measures IA
Increasing gamete and embryo storage limits to a maximum of 55 years for all	Additional measures IA
Information about payments to persons in the health care sector, enforcement and consent	Additional measures IA
Licensing of cosmetic procedures	Additional measures IA
Medical examiners	Additional measures IA
Medicines information systems	Additional measures IA
Powers allowing further products to be centrally stocked and supplied free of charge to community pharmacies without the need to reimburse them under the standard NHS arrangements	Additional measures IA
Professional regulation	Additional measures IA
Rest of World reciprocal healthcare	Additional measures IA
Water fluoridation	Additional measures IA
Abolishing Local Education Training Boards	Core IA
Accountability and Transparency of Mental Health Spending	Core IA
NHS England mandate: cancer outcome targets	Core IA
Arm's-Length Bodies transfer of functions power	Core IA
Care Quality Commission reviews of Integrated Care Systems	Core IA

Climate change duties	Core IA
Competition	Core IA
Data sharing	Core IA
Designating Integrated Care Boards as Operators of Essential Services under NIS Regulation	Core IA
Duty to cooperate	Core IA
Establishing Integrated Care Boards and Integrated Care Partnerships in law	Core IA
Foundation Trusts capital spend limit	Core IA
Further embedding research in the NHS	Core IA
General power to direct NHS England	Core IA
ICB and NHSE inequalities duty extension	Core IA
Information about inequalities	Core IA
Joint Committees, Collaborative Commissioning and Joint Appointments	Core IA
Merging NHS England and NHS Improvement	Core IA
National Tariff	Core IA
New trusts	Core IA
Provider selection and Choice	Core IA
Public Health power of direction	Core IA
Reconfiguration of services: intervention powers	Core IA
Special Health Authorities Time Limits	Core IA
NHS England Mandate: general (and Better Care Fund)	Core IA
Triple Aim	Core IA
Workforce accountability	Core IA
Adult social care – assurance	Social Care IA
Adult social care – discharge to assess	Social Care IA
Adult social care – provider payments	Social Care IA
<b>Policies with standalone IAs</b>	
Virginity Testing Ban	
Health Services Safety Investigations Body (HSSIB)	
Introducing a 2100-0530 watershed on TV and online ban for paid advertising of food and drink that are High in Fat, Salt and Sugar (HFSS) products	
Hymenoplasty Ban	

There are several policies in the Act which include a requirement to consult, to undertake a review or to produce a report. These policies are: Child safeguarding etc in health and care: policy about information sharing, and; Review into disputes relating to treatment of critically ill children. For these policies an impact assessment has not been included as the impact of the policy will depend upon the outcome of the consultation, its recommendations, and whether or how they are acted upon, or any commitments to action in the report. An impact assessment will be undertaken following consultation/publication as appropriate.

Impact assessments on the policies regarding early medical termination of pregnancy and mandatory training on learning disability and autism are in development and will be published in due course.

### **3. Interactions between policies**

The policies covered in the Act should be seen as mutually reinforcing, rather than policies to be viewed in isolation. Therefore, there are interdependencies between the Act provisions, whereby the success of one policy may depend on the impact of another. This is particularly true of provisions relating to the three principles underlying the Act, which are being put in place to foster collaboration across the health and care system and are covered in the Core IA. Potential interdependencies are outlined below, although this list is not exhaustive and further details can be found in the specific analyses for each policy.

The Triple Aim and Duty to Cooperate provisions make it more likely that other policies covered in the Act will have a system benefit (e.g. appropriate joint working with ICBs and their system partners). The benefits derived from these policies will depend on the success of other measures to deliver beneficial system change. Further detail can be found in the respective sections in the Core IA.

The Professional Regulation provisions have potential interdependencies with the ALB transfer function policy, and, with other existing policies related to health and social care. This is explored in more detail in the Professional Regulation section of the Additional Measures IA.

For the public health measures related to obesity, namely those concerning the advertising of HFSS foods and Food information for consumers: power to amend retained EU Law, the impact of these policies on public health may be difficult to disaggregate as they are part of a wider programme of supporting the public to make better informed choices about their diet.

## 4. Specific Impact Tests

In some cases, the policies included within the Health and Care Act introduce enabling powers, and so the impacts will not materialise until secondary legislation is finalised and implemented. Therefore, at secondary legislation stage, more detailed analysis of the finalised policy will be undertaken, which will also include detailed analysis of specific impacts, such as those on the justice system, trade and the environment where appropriate.

### **Equality**

The policy measures in the accompanying IAs have undergone a equalities assessments as appropriate.

### **Privacy**

The powers that enable data to be required from adult social care providers may have an impact on privacy depending on the form of data required. Any requests that relate to identifiable information will be subject to existing data protection legislation and individual privacy tests will be undertaken as appropriate. Similarly, the power to extend NHS Digital's (NHSD) powers to enable it to require data from private providers may also have an impact on privacy and NHSD will ensure that appropriate safeguards are in place.

### **Justice system**

Justice impacts are anticipated for the HSSIB, Medicines Information Systems, Organ Transplantation, Virginity Testing, Hymenoplasty, Information about payments, Licensing of Cosmetic Procedures Eradicating slavery and human trafficking in supply chains and Commercial dealings in organs for transplantation: extra territorial-offenses.

Restrictions on HFSS advertising may result in some enforcement actions reaching the courts, although this number is expected to be very small.

### **New burdens for local government**

No new burdens on local authorities are anticipated at this stage from the primary legislation. However, this will be under review as the Government continues to implement these policies through guidance and secondary legislation. We expect to produce a new burdens assessment for the Adult Social Care Assurance policies but will continue to keep other areas of the Act under review.

### **Competition and innovation**

The policy in the Core IA relating to competition intends to change the roles in respect of competition of the Competition and Markets Authority (CMA) and NHS Improvement (Monitor functions). The policy aims to create a more nuanced approach to certain NHS transactions that gives greater weight to collaboration. The potential impacts of this on competition are outlined in the Core IA.

The policies relating to provider selection and choice, licensing of cosmetic procedures and eradicating slavery and human trafficking in supply chains may have impacts on competition at secondary legislation stage. This will be explored as part of an impact assessment as appropriate at that point.

Restrictions on HFSS advertising may result in impacts on competition and innovation, which are explored in this policies standalone IA.

### **Small and micro business assessment (SaMBA)**

The policies related to data sharing, provider selection and choice, medicines information systems, Licensing of Cosmetic Procedures, information about payments, hospital food standards, Food information for consumers: power to amend retained EU Law and reciprocal healthcare arrangements for rest of world countries may have impacts on small or micro businesses. It is not possible to provide a robust estimate of these costs, or give details of exemptions, until the relevant powers are used. There is a commitment to examining these impacts if and when secondary legislation is introduced. Further details are given in the respective IA sections.



## 5. Post Implementation Review (PIR)

The PIR of the Health and Care Act 2022 is currently being commissioned through an NIHR Policy Research Programme open-call. DHSC have invited proposals for a single primary research project to provide evidence on the implementation and impact of the Act.

The primary interest of the PIR is to understand the different ways that Integrated Care Boards and Integrated Care Partnerships, and system partners (at system, place, and neighbourhood level) are coming together to design, commission and deliver services, and fulfil their duties, and the potential impacts. The aim is to capture learning to identify how positive changes may have been achieved, the obstacles to this (and how these can be avoided), and to disseminate that learning across the system.

This evaluation will help to spread learning in a timely manner (e.g., learn and disseminate what works in delivering quality integrated care and support). It will also support Ministers and policymakers understand how the system is evolving following the legislative changes, how DHSC can best support ICBs and ICPs in delivering better outcomes and inform future reforms regarding integrated care.

This evaluation will be a mixed methods and multi-phased study, taking around 2-3 years to complete. However, research outputs will be produced and shared before completion to be disseminated with systems, facilitating the sharing of lessons learnt and best practice with systems.

The PIR will be focused on the policies most directly related to the core themes of the Act of *increasing collaboration, reducing unnecessary bureaucracy and accountability*. Policies outside of this core focus will develop their own PIR plans as appropriate. For example, PIR plans would be developed if it were decided to exercise particular powers described in the core IA and additional measures IA. This is because for provisions which include enabling powers, the details of the final policy will not be finalised until the implementation or secondary legislation stage. This means that the specific plans for the PIR cannot be finalised until the final form of the policy, and the specific outcomes it is likely to affect, are known.

Some policies which have standalone IAs, such as the provisions concerning advertising of foods and drinks which are High in Fat, Salt and Sugar (HFSS), have committed to completing a PIR. Details of PIR plans are outlined in these standalone IAs.

## **6. Impact assessments of additional measures**

The proceeding section is the impact assessment for several *additional policies to support public health, and quality and safety*.

<b>Title:</b> Health and Care Act 2022 <b>IA No:</b> 9570 <b>RPC Reference No:</b> RPC-DHSC-5082(1) <b>Lead department or agency:</b> Department of Health and Social Care (DHSC) <b>Other departments or agencies:</b> NHS England and NHS Improvement	<b>Impact Assessment (IA)</b>			
	<b>Date:</b> 27/10/2022			
	<b>Stage:</b> Final			
	<b>Source of intervention:</b> Domestic			
	<b>Type of measure:</b> Primary legislation			
<b>Contact for enquiries:</b> Not applicable				
<b>Summary: Intervention and Options</b>			<b>RPC Opinion:</b> GREEN	

**Cost of Preferred (or more likely) Option (in 2019 prices)**

Total Net Present Social Value	Business Net Present Value	Net cost to business per year	Business Impact Target Status
Unquantified	Unquantified	Unquantified	Non qualifying provision

**What is the problem under consideration? Why is government action or intervention necessary?**

Demographic and social changes have, for a number of years, been changing the shape of the demands on the health and care system. This Act implements the lessons learned from the evolution of the entire Health and Care System, as well as the specific experience of responding to an unprecedented public health emergency during the Covid-19 pandemic. The measures considered in this impact assessment are targeted to address specific problems and remove legislative barriers to allow front line staff and the government to deliver care more efficiently and maximise opportunities for improvement. This is with the ultimate aim of supporting the system in helping people to live healthier, more independent lives for longer.

**What are the policy objectives of the action or intervention and the intended effects?**

Measures considered in this impact assessment relate most directly to the fourth principle of the Health and Care Act, which have the aims of supporting social care, public health, and quality and safety. For example, the policies examined in this impact assessment are targeted changes which will enable government to more effectively support the social care system, and, implement comprehensive reciprocal healthcare arrangements with Rest of World countries (outside the European Economic Area and Switzerland). The impact assessments for seven policies relating to the fourth principle have been collated in this single document as they all entail small or unquantifiable impacts.

**What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)**

This IA covers legislative changes developed by the Department of Health and Social Care, working with a breadth of stakeholders including NHS England & NHS Improvement, and the Department for Levelling Up, Housing and Communities. Given the complexity of the package of measures, this IA is focussed primarily on the leading options for each of the policies and specific legislative changes. Impacts are by default compared against a 'do-nothing' option, although in some cases alternative policy options are outlined.

<b>Will the policy be reviewed?</b> It will be reviewed. <b>If applicable, set review date:</b> Not applicable					
Does implementation go beyond minimum EU requirements?			N/A		
Is this measure likely to impact on international trade and investment?			No		
Are any of these organisations in scope?		<b>Micro</b> Yes	<b>Small</b> Yes	<b>Medium</b> Yes	<b>Large</b> Yes
What is the CO <sub>2</sub> equivalent change in greenhouse gas emissions? (Million tonnes CO <sub>2</sub> equivalent)			<b>Traded:</b> N/A		<b>Non-traded:</b> N/A

*I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.*

Signed by the responsible Minister:  Date: 27/10/2022

**Summary: Analysis & Evidence**

**Policy Option 1**

**Description:**

**FULL ECONOMIC ASSESSMENT**

<b>Price Base</b> Year N/A	<b>PV Base</b> Year N/A	<b>Time Period</b> Years N/A	<b>Net Benefit (Present Value (PV)) (£m)</b>		
			<b>Low:</b> N/A	<b>High:</b> N/A	<b>Best Estimate:</b> N/A

<b>COSTS (£m)</b>	<b>Total Transition</b> (Constant Price)	<b>Years</b>	<b>Average Annual</b> (excl. Transition) (Constant Price)	<b>Total Cost</b> (Present Value)
<b>Low</b>				
<b>High</b>				
<b>Best Estimate</b>	N/A		N/A	N/A

**Description and scale of key monetised costs by ‘main affected groups’**

The policies set out in this IA are complex and to a significant extent consist of creating enabling powers which either lead to practical but limited changes; require secondary legislation or consultation before practical changes can occur; and/or, require system behavioural change before practical changes come into force. It is not possible to robustly estimate an overall cost impact by affected groups, but despite this, costs which may be incurred following secondary legislation have been outlined as best as possible at this stage. The medicines information systems section contains an illustrative example of monetised impacts if those enabling powers were used. An assessment of impacts on businesses, including small or micro businesses, and wider impacts such as those on the environment, trade and competition, will be completed where appropriate alongside secondary legislation.

**Other key non-monetised costs by ‘main affected groups’**

The policies set out in this IA affect NHS providers, commissioners and arms’ length bodies, as well as local authorities, social care providers, and independent organisations providing health and care service. However, as many of these provisions introduce enabling powers, any costs will depend upon how those powers are exercised. If secondary legislation were to be enacted, then an assessment of costs will be completed at that point if appropriate.

<b>BENEFITS (£m)</b>	<b>Total Transition</b> (Constant Price)	<b>Years</b>	<b>Average Annual</b> (excl. Transition) (Constant Price)	<b>Total Benefit</b> (Present Value)
<b>Low</b>				
<b>High</b>				
<b>Best Estimate</b>	N/A		N/A	N/A

**Description and scale of key monetised benefits by ‘main affected groups’**

Benefits relating to these policies have not been monetised in this IA as a robust estimation of likely effects is not possible. This is because the likely effects of, for example, an enabling power will depend upon how those powers are exercised. If secondary legislation were to be enacted, then an assessment of benefits will be completed at that point if appropriate.

**Other key non-monetised benefits by ‘main affected groups’**

It is not possible to monetise the benefits of enabling powers, as the specific circumstances under which those powers may be exercised will influence the potential costs and benefits. If secondary legislation were to be enacted, then an assessment of benefits will be completed at that point if appropriate. However, examples of potential benefits from the policies in this IA include reduced bureaucracy, and therefore, reduced burden on policymakers and providers, improved service provision to patients, and, more informed patients.

<b>Key assumptions/sensitivities/risks</b>	<b>Discount rate (%)</b>	N/A
<p>It is difficult to fully determine the impact of these provisions quantitatively. There is a risk associated with any change programme, even if intended to be limited, that resources are spent on implementing a new system to the detriment of output. A further risk is that some provisions are enabling measures and do not contain substantive provisions. It is therefore difficult to assess with any certainty what the impact of the measures will be, as the detail of those final provisions is not currently available. Any policy that will be implemented using the regulation-making powers provided in these provisions in future will be required to develop an impact assessment as appropriate.</p>		

**BUSINESS ASSESSMENT (Option 1)**

<b>Direct impact on business (Equivalent Annual) £m:</b>	<b>Score for Business Impact Target (qualifying provisions only) £m:</b> Not a qualifying provision
<b>Costs:</b> N/A	<b>Benefits:</b> N/A
<b>Net:</b> N/A	

# Health and Care Act: Evidence base for impact assessment

## Background and overview

The Health and Care Act builds on the experience of previous reforms of the health and care system, as well as the specific experience of responding to an unprecedented public health emergency in the Covid-19 pandemic.

The measures considered in this impact assessment are targeted to address specific problems and remove legislative barriers to allow front line staff and the Government to deliver care more efficiently and maximise opportunities for improvement.

They are not intended to address all the challenges faced by the health and social care system. Instead, these measures are targeted changes to allow the Government to support the social care system, improve quality and safety in the NHS, grant the flexibility to take further public health measures and to implement worldwide comprehensive reciprocal healthcare agreements.

The Government is undertaking broader reforms to social care and public health which will support the system in helping people to live healthier, more independent lives for longer. As with the core provisions impact assessment, many measures covered in this impact assessment will introduce enabling powers and will require further secondary legislation in order to implement the policy.

## Scope of the additional measures impact assessment

There are three guiding themes running through the core policies in the Health and Care Act. These are: *working together and supporting integration; reducing bureaucracy; and ensuring accountability and enhancing public confidence*. Alongside the core measures, there are additional policies to make targeted changes to allow the Government to improve quality and safety in the NHS, to grant the flexibility to take public health measures and to implement worldwide comprehensive reciprocal healthcare agreements.

The 13 policies considered in this impact assessment relate most directly to *additional policies to support public health, and quality and safety*. The analyses have been collated in this single document as they all entail small or unquantifiable impacts. Several other additional policies, such as those relating to social care, have standalone IAs due to the size of the potential impact or because the complexity of the analysis warranted a separate document. Readers should refer to the impact assessments summary document for direction on where to find analysis on the other policies in the Health and Care Act.

## Post Implementation Review (PIR)

The exact details of the PIR for the policies analysed in this IA will be set out once the provisions are used. Please refer to the Impact Assessment Summary Document for further justification.

## Summary of the costs, benefits, risks and mitigations of each policy

This section provides details of each of the proposed changes to support the health and care system.

# 1. Medicine information systems

## Policy summary

Medicines registries provide a valuable resource for assessing and monitoring the safety and effectiveness of medicines. The Independent Medicines and Medical Devices Safety Review<sup>1</sup> (IMMDSR) in 2020 made specific recommendations on the need for a national antiepileptics registry. Following this, the Medicines and Healthcare products Regulatory Agency (MHRA) is seeking regulation making powers to enable NHS Digital to establish and operate UK-wide medicines information systems in order to ensure that comprehensive national registries can be established and built in a sustainable way. This will require powers to be conferred on NHS Digital to enable them to mandate relevant data collection, including from private healthcare providers and devolved administrations, to build one or more comprehensive medicine information system(s). The intention is that the information included in these systems will then be made available to the MHRA to enable it to establish and operate UK-wide registries using existing powers contained in the Human Medicines Regulations 2012.

This policy only creates the power to make regulations to establish medicine information systems. As such while there is no direct cost or impact associated with the clauses in this Act, consideration as to how the regulations are likely to be laid out and their potential impact through an illustrative example is appropriate. A more detailed assessment of costs and impacts can be conducted when the regulations are made and exercised to develop a specific registry.

It is anticipated that, when there exists a need justified on public health grounds, the MHRA will assess the option of introducing a particular national medicines registry when alternative approaches to capturing sufficient data are not feasible. The proposal for establishment for a new registry will be presented to the Commission on Human Medicines (CHM) who would need to issue a formal registry-specific recommendation subject to the following criteria:

- i. There are known risks associated with a medicine that can result in serious adverse health outcomes and where adherence to effective risk minimisation measures is critical to ensuring the benefits associated with the medicine outweigh the risks
- ii. There is uncertainty about the safety or effectiveness of a medicine in a population in whom prescribing may occur that means that urgent evidence is required to build the evidence base on the benefit risk balance and inform the need for, and feasibility of, risk minimisation measures

The CHM's final advice on the need for a specific registry will be put to the appropriate authorities to propose issue of a joint direction for NHS Digital to collect the appropriate information required by the registry to be captured within the medicine information system.

A core register of all patients prescribed the specific medicine of interest will form the basis of a bespoke registry. The aim is to use patient-level data already collected within the NHS to form this core register, which should facilitate complete monitoring of patients prescribed specific medicine where necessary. Therefore, powers are also sought to ensure that individual patient-level data can be linked across different national datasets, held by NHS Digital and the devolved administrations, according to the design specification agreed by the Registry Steering Committee for a specific registry. The MHRA will work with the NHS to build and maintain these registries.

## Rationale for intervention

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<sup>1</sup> *First Do No Harm The report of the Independent Medicines and Medical Devices Safety Review*, (2020). [Online]. Available from: [https://www.immidsreview.org.uk/downloads/IMMDSReview\\_Web.pdf](https://www.immidsreview.org.uk/downloads/IMMDSReview_Web.pdf)

At present, there are no government funded UK wide registries for products that pose potential health risks to certain patients. Either when a license is first granted for a medicinal product to be placed on the market, or at a later stage should the need be identified, the MHRA can require a Marketing Authorisation Holder (MAH) to establish a registry for that specific medicine to, for example, identify or monitor adverse effects. This is an existing legal power of the MHRA acting as the UK national competent authority for the regulation of medicine. The requirement for a registry is defined in the terms of the license granted to the MAH. MAH-led medicine registries have had mixed success in generating the strength of evidence required to make fully robust regulatory decisions regarding the safe and effective use of medicine. This is in part because such stand-alone registries are voluntary for clinicians, and full identification of eligible patients is also often challenging due to a hesitance on the behalf of clinicians and their patients to enrol as part of an MAH-sponsored registry due to data confidentiality concerns. Enrolment may also be affected as registries can place additional burden on healthcare providers (HCPs) to supply data.

Academic led initiatives also exist and have demonstrated the value that evidence generated by high quality registries can have in supporting regulatory, HCPs, and patient decision making. The MHRA are increasingly using data from these larger disease registries led by clinical and academic research groups, although these often have issues with sustainability. In addition, voluntary participation means data is not comprehensive or representative, rarely including data from private providers and with regional and clinical speciality variations in terms of coverage. NHS Digital and the devolved administrations already collate extensive data on the use of medicines in the UK but there are gaps in this which need to be addressed.

The key justification for this policy is that it will facilitate a better monitoring system of the use, benefits and risks of medicines, leading to improved evidence bases for regulatory and clinical decision-making and overall patient safety outcomes. The provisions make this possible. A central UK wide medicine information system, or systems, run by the NHS, filling existing data gaps and linking data from different sources will enable the initiation of high-quality inclusive registries operated independently of industry.

## **Other policy options considered**

This IA only presents the option to introduce statutory powers to enable NHS Digital to establish a medicines information system. This system will enable MHRA to set up a comprehensive UK wide registry for a product when CHM considers the criteria for such a registry is met. The baseline status quo option involves the MHRA setting up registries without a medicine information system – either by requiring MAHs to set up voluntary registries or trying to develop UK wide registries without powers to mandate data collection.

### **Option 0 - Business as usual (Do nothing)**

In the counterfactual, the MHRA would continue using existing powers to set up registries but without statutory medicine information systems to support them. This could be through the licensing process where MAHs could be asked to set up and maintain registries for specific products or, for example, as is the case with antiepileptics, a national registry is being set up to address an urgent safety concern as recommended by the IMMDSR, but this is reliant upon existing data feeds and voluntary provision of additional data. Currently, there are gaps in data from prescriptions in private practice and from the devolved administrations as well as a lack of detail on clinical aspects that are vital in order for the registry to meet its objectives. This option was not deemed feasible because the lack of robust, objective and comprehensive evidence poses high risks for patients. Without a robust and complete medicine information system building a comprehensive medicine registry, including all patients prescribed that medicine, independent from industry, which can be necessary if public confidence is to be maintained, gaps in the data would still remain meaning that the registry would not be able to support safe and effective use of medicines in all patients.

## Key impacts

There are no impacts resulting directly from this primary legislation as it only seeks the power to make regulations to establish medicine information systems when the need for a registry is identified.

If this power was exercised and a registry were to be set up utilising the medicine information system, requirements would be placed on NHS Digital and potentially the devolved administrations to capture and process the required data. Where individual health information for a medicine information system is required from healthcare providers within Scotland or Wales it would be collected via an intermediary organisation within those territories, unless an exception applies, rather than, for example, collected directly from healthcare providers. The information would then be shared onwards with NHS Digital. It is not considered that there will be an additional cost to the provider of the data when an intermediary organisation is used as we expect that similar or the same processes for providing the data straight to NHS Digital would be used. There may be small costs for the intermediary organisation, likely to be a public body, in collecting this data, though it is expected that this would be minimal as these bodies would already have infrastructure in place to routinely collect, holds and process data in relation to medicines and health. In establishing each new registry MHRA and NHS digital would work with the intermediary body or colleagues in Wales or Scotland to identify who data is needed from and the best route for collection to minimise burden and cost.

Costs of setting up and running a registry benefiting from a medicines information system are unlikely to be very different from one that does not use a medicines information system. This is because the design of a registry, and hence the requirements in terms of the types and volume of data that would need to be captured, would be determined based on the scientific and regulatory need which would be the same regardless of whether the regulations made based on the powers being sought were in place. The purpose of the medicine information systems provisions is to enable the appropriate authority to make regulations allowing them to direct the Information Centre to collect the required data and to give the Information Centre a power to require provision of that data from the relevant data holders. Regulations will also lay out the legal basis for collating and sharing this data. The technology and supporting governance and documentation required to deliver a medicines registry designed to meet its scientific and regulatory objectives would be the same regardless of if it being underpinned by a medicines information system or not. However, the potential benefits are likely to be greater as the powers provided to require submission of the requested data will increase participation by HCPs and the availability of more comprehensive and timely information. This added information would likely address risks to patient health and the benefits would potentially extend to all patients treated with the medicine.

The provisions will enable NHS Digital to establish and operate UK-wide medicine information system(s), the information from which will then be available to MHRA to establish comprehensive national registries.

A figure for the Equivalent Annual Net Direct Cost to Business (EANDCB) has not been possible to estimate as these provisions are enabling powers. The costs with regards to data provision are largely expected to fall to the NHS and other public organisations. However, dependent on the scope of a specific registry data may be sought from private HCPs for example, the potential impact of data collection on business will depend upon the medicines of interest, remit, scope and duration of the registry and hence the volume and complexity of the data that needs to be made available to the information system. Therefore, at this stage it is not possible to estimate what the potential cost on business may be. Any additional costs to HCPs from contributing to a medicine registry would be examined as part of the business case process.

Furthermore, and for this same reason, a full small and micro businesses assessment (SaMBA) has not been completed as part of the IA for the primary legislation. This can be included in future



assessments when the design of a specific registry, and therefore its impact on SMBs and other potential data holders, is clearer. For context, in 2012 approximately 53% of NHS consultants undertook some private practice, with an estimated 3,000 working entirely in the private sector<sup>2</sup>. There are an estimated 515 private hospitals offering health care services in the UK, which are a mixture of for-profit and non-profit. There are no comprehensive public data on the total number of patients treated in private hospitals, but of the 285 hospitals that submitted data in 2017, 735,522 patients received treatment. By comparison, more than 8.5 million nonurgent patients were treated by the NHS that year<sup>3</sup>. Again in 2012, an estimated 3% of GP consultations were private (~7 million consultations) although this may have increased since. Any impact on SMBs would be around their need to submit data to the information system. This data would only consist of information that they should already be capturing and recording as part of good clinical and healthcare delivery practice to support individual patient management and safety. We believe there may be two key categories of costs: i) familiarisation and training costs and ii) costs associated with the data collection and submission processes. It is plausible that these costs may impact small providers with less IT capacity more disproportionately. However, by working with the NHS to deliver systems that integrate with local systems and capture the data into the information system efficiently we can reduce the burden on businesses. As described earlier, the number and types of HCPs expected to contribute to an information system for a new medicine(s) will be unknown until details of the needs for that medicine are finalised. It is therefore not yet possible to state whether these businesses will be disproportionately affected or whether an exemption would be appropriate. Again, potential costs to small and micro businesses will be considered as part of the individual business case processes. There are no anticipated impacts on competition or international trade.

There are potential impacts on the justice system. In particular, with regards to clauses on new offences related to information disclosure from the medicine information system(s) and potential identification in a specific registry of cases suitable for compensation. A Justice impact test to fully assess the impacts will be completed in conjunction with the Ministry of Justice.

### **Indicative estimates of costs and benefits of a national registry**

This analysis is an illustrative example as the provision relates to delegated powers to make regulations about the establishment and operation of medicine information systems rather than the actual establishment of specific registries. It examines the potential impacts of the use of this power to enable NHS Digital to establish an information system, or systems to support a specific registry. The overall aim would be to provide data from the system to MHRA to set up and maintain such a national registry, using MHRA's existing pharmacovigilance powers. The intention is to provide an initial high-level assessment of the impact that the use of this power could have in the future. This mirrors the approach used to assess the set-up of national registries for medical devices in the MMD Act 2021 Impact Assessment<sup>4</sup>.

Each individual registry is likely to vary in design (size and function) as the specific risks relating to the specific product are likely to be different and as a result so are the potential impacts. To highlight this point, we present cost estimates using data from three existing registries that vary significantly in scope and size (Sodium Valproate<sup>5</sup>, National Joint Registry, Breast and Cosmetic implants).

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<sup>2</sup> The Kings Fund, 'The UK private health market', 2014. [Online]. Available from:

<https://www.kingsfund.org.uk/sites/default/files/media/commission-appendix-uk-private-health-market.pdf>

<sup>3</sup> The private healthcare information network, 'Annual report 2016-17', 2017. [Online]. Available from:

[https://apicms.phin.org.uk/Content/Resource/158-PHIN\\_AR\\_2016-17.pdf](https://apicms.phin.org.uk/Content/Resource/158-PHIN_AR_2016-17.pdf)

<sup>4</sup> Medicines and Medical Devices Bill - IA No: 9556 - 2020

<sup>5</sup> <https://digital.nhs.uk/data-and-information/publications/statistical/mi-medicines-in-pregnancy-registry/valproate-use-in-females-aged-0-to-54-in-england-april-2018-to-september-2020>

Also presented are potential benefits of a national medicines' registry using the England-only Sodium Valproate registry example. Estimates of benefits must be treated with caution as they are based on data available so far from the valproate example which is still being developed. These are for illustrative purposes only. Specific costs and benefits of individual registries must be considered as part of the business case process.

## Costs

### MHRA and NHS Digital – set up and running costs

MHRA would be responsible for establishing and running national registries, bringing in relevant partners as required. This could be through a Registry Steering Committee to provide operational support and clinical guidance, and oversight of the project's set up, running, and translation of its findings. There are likely to be both one off set up and ongoing opportunity costs of MHRA staff time spent on these activities. It is not anticipated that there will be additional costs to Marketing Authorisation Holders.

NHS Digital would collect the data needed for all medicine registries from various sources and hold this in an information system. Data from the information system would be provided to the MHRA to establish and operate/run medicine specific registries.

Table 1 outlines the cost of setting up three different medicines registries. The table demonstrates that depending on specific circumstances such as size and scope, set up and running costs can vary substantially. Similarly, the benefits of the registry may be expected to scale up according to the size and scope of the registry, as for example a greater number of patients or treatments may be covered, thus benefitting a larger patient population.

**Table1: Indicative set up and running costs of national registries per annum**

National registry example	Potential annual costs to MHRA and NHS Digital (Set up / annual running cost)
Sodium Valproate	£1.014m / £183,000 (estimated)
Breast and Cosmetic Implant registry	£83,000 / £183,000
National Joint Registry	£1.8m / £4.1m

### *Sodium Valproate - method to calculate set up and running costs*

Based on the Sodium Valproate example, it is estimated that roughly that about 0.5 FTE hours of a SEO, G6 and SCS costing approximately **£164,000** in MHRA staff resources could be spent on a registry annually<sup>6</sup>. This is an estimated average with likely slightly higher costs in the first 2-3 years, due to the need for more senior staff involvement while the registry is being developed, balanced by slightly lower costs once it is established.

Total NHS Digital potential staff and non-staff costs on Sodium Valproate is estimated at about **£950,000per annum** based upon the costs for the delivery of the second phase of development planned for 2021/22. This amounts to a potential total set up of **£1.014million** annually for the Sodium Valproate registry. However, this estimate must be treated as indicative only as the majority of the cost is to develop the registry and once established running costs will be substantially lower. Beyond the initial set up which is likely to last 2-3 years, maintenance costs could be estimated to be similar to the BCIR as described below given the comparative size. For reference, the first year costs for NHS Digital were substantially lower at approximately £20,000.

<sup>6</sup> Based on average salary data from MHRA Finance

## *National Joint Registry (NJR) and Breast and Cosmetic Implant registry (BCIR) - method to calculate set up and running costs*

The potential costs to NHS Digital below have been taken from the Medicines and Medical Devices Bill IA June 2020<sup>7</sup>. The estimates are based on data from the National Joint Registry (NJR) and Breast and Cosmetic Implant registry (BCIR). The size, scope and amount of activity undertaken i.e. amount of information collected and how it is used would impact costs. The below is therefore an indicative range of costs.

### One off set up costs:

The MMD IA estimates that a large-scale registry such as the NJR (with over 225,000 procedures reported to it in 2018) could require an initial set up cost of **£1.8m**. The BCIR (with just under 15,600 operations reported over a year July 2018-June 2019) could involve set up costs of about **£83,000**. The costs are likely to cover any IT systems set up, and staff resources to design the registry and publish guidance for participating providers.

### Ongoing costs:

The MMD IA reports ongoing costs of **£4.1m** per annum for the NJR and **£183,000** per annum for BCIR. Ongoing costs are likely to cover – auditing data collected, analysing and reporting on safety alerts, communicating with HCPs, researchers, government and the public, IT systems development as registry evolves.

## **Administrative costs to NHS and private healthcare providers**

It will be mandatory for all HCPs to contribute to an information system. This could involve clinical staff time spent on undergoing training on the new registry and on an ongoing basis, recording the data. Some providers may already be providing this data voluntarily to existing MAH registries and for them the additional costs are unlikely to be significant. The number of HCPs this will impact is unknown as it will depend on each specific registry and the prescribing trends of each medicine. In general, HCPs can refer to GPs, private and state hospitals but could also include nurses, midwives, pharmacists for some registries. However, it is unlikely that the overall costs to HCPs will be high, as most of the data required are likely to already be collected by HCPs as part of clinical management.

In the case of Sodium Valproate, women should have annual appointments with a neurologist who should review their treatment and ensure patients complete a signed annual risk acknowledgement form (ARAF), which is part of the Pregnancy Prevention Plan. There are currently estimated to be 625 consultant neurologists<sup>8</sup> in England who might review a woman's valproate treatment. Given that they already have to undertake regular reviews with patients on their Sodium Valproate use, the inclusion of an ARAF on the registry is unlikely to increase administrative burdens.

## **Benefits**

### **More informed patients and greater public confidence in the health system:**

Patients can directly report on safety issues and may be more informed on the risks and benefits of their medicines. This is likely to enable patients to take more informed decisions about their health.

### **Improved regulatory system:**

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<sup>7</sup> Medicines and Medical Devices Bill - IA No: 9556 - 2020

<sup>8</sup> Association of British Neurologists, Neurology Workforce Survey, 2020. [Online]. Available from: [https://cdn.ymaws.com/www.theabn.org/resource/collection/219B4A48-4D25-4726-97AA-0EB6090769BE/2020\\_ABN\\_Neurology\\_Workforce\\_Survey\\_2018-19\\_28\\_Jan\\_2020.pdf](https://cdn.ymaws.com/www.theabn.org/resource/collection/219B4A48-4D25-4726-97AA-0EB6090769BE/2020_ABN_Neurology_Workforce_Survey_2018-19_28_Jan_2020.pdf)

Information from medicine information systems will support the establishment of national registries. This would allow the MHRA to use registries to more widely support safe use of a medicine through inclusion of it in regulatory information and prescribing guidelines, and to take swift informed regulatory action, as it is likely to receive timely and more complete data on risks associated with the specific medicines.

**Improved service provision to patients:**

Information from a medicine information system and the resulting medicines registry should allow HCPs to analyse reports on data to evaluate outcomes. HCPs could recall/amend patient treatment if necessary and offer more efficient and effective services.

**Avoided patient harm:**

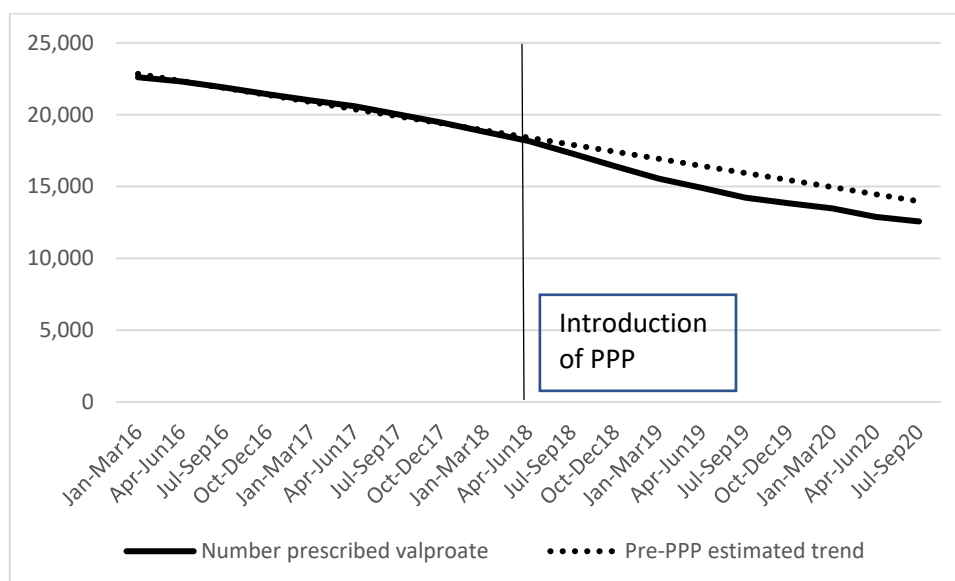
Most importantly, information from medicine information systems and the resulting medicines registry is likely to give healthcare professionals timely access to more complete information – including at the individual patient level. This would enable them to take rapid action and avert potential risks to patient health from adverse effects.

***Illustrative example – avoided patient harm from Sodium Valproate registry:***

Currently the Sodium Valproate registry, which is the basis of the planned antiepileptics registry is not mandatory and coverage may not be comprehensive, particularly for women treated in the private sector. One of the aims of introducing a comprehensive mandatory Sodium Valproate registry is to increase coverage which should in turn further accelerate the decline in prescribing and reduce the number of exposed pregnancies. Reducing the number of exposed pregnancies was a key aim of the 2018 Pregnancy Prevention Plan (2018). The proposed power would enable NHS Digital to collect data, subject to a Direction, from private prescribers and from devolved administrations, which would then be provided to MHRA to establish a comprehensive valproate/anti-epileptic drugs registry. Therefore, the data illustrated below is a useful example of the possible impact of enactment of the proposed enabling power.

Figure 1 presents data published by the NHS Business Services Authority on the number of women aged 14-45 in England prescribed Sodium Valproate over time. Figure 1 shows that in the two years prior to the introduction of the PPP prescribing in women aged 14-45 was falling by approximately 15%. Following the PPP, prescribing fell approximately by an additional 10%.

**Figure 1: The number of female patients aged 14-45 prescribed valproate over time before and after introduction of the Pregnancy Prevention Plan**



The first retrospective data from the non-mandatory Sodium Valproate registry suggest that between April 2018 and Sept 2020, 181 pregnancies have been exposed to Sodium Valproate (or approximately 70 per year). One hypothesis is that if a mandatory comprehensive drug registry were in place, some of these exposures may have been avoided as there would be more complete data on adherence by prescribers to best prescribing practices and implementation of the Pregnancy Prevention Programme. Using an arbitrary assumption of a further 20% reduction in the exposure to Sodium Valproate following the introduction of a mandatory registry, it is estimated that this would reduce the number of pregnancies exposed by a further 11 in the year September 2020-21.

#### *Net benefits of the Sodium Valproate registry*

This simple analysis examines what Quality Adjusted Life Year (QALY) gains are required to compensate for the cost of setting up and running the Sodium Valproate registry. The estimated cost for setting up and running the registry in the second year is £1.014million. The best estimate for the value society places on a QALY is £60,000<sup>9</sup>. Therefore, it is estimated that approximately 16.9 QALYs would have to be generated per annum through development to account for the initial annual cost of the registry. If a 20% reduction in exposure is achieved this would equate to 1.5 QALY per exposed pregnancy avoided. However, in future years this would be lower at approximately 3 QALYS generated per annum and a 0.3 QALY per exposed pregnancy avoided. Given valproate exposure during pregnancy is associated with an approximately 50% risk of severe and lifelong physical and neurological disorders this threshold would be reached. This demonstrates that with a very modest reduction in exposure, only limited QALY gains are required for the net benefits of the registry to break-even once the initial set up is complete.

<sup>9</sup> HM Treasury: The Green Book: appraisal and evaluation in central government, (2020). [Online]. Available from: <https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-government>

### **Avoided costs to NHS from compensation / litigation and additional treatment:**

Through early identification of risks and reducing scope for error (outlined above), harm to patients could be prevented. This might in turn avoid potential claims and litigation costs against the NHS. Costs to NHS of providing additional treatment to affected patients could also be avoided<sup>10</sup>.

## **Risks and Mitigations**

The purpose of a medicine registry is to generate evidence. This evidence will be used by MHRA and other organisations to inform regulations and guidance and to drive changes in clinical practice. However, the economic benefits will only be fully realised if those changes actually happen, and patient safety is improved. MHRA have an established role in leading within this area. This is highlighted in the MHRA 2018-2023 Corporate plan<sup>11</sup> and the 2020/21 Business plan<sup>12</sup>, which lay out the strategy to reshape post-market vigilance to run proactive life-cycle monitoring, of which this policy is a component, and to increase MHRA influence on clinical practice through further engagement with patients and key strategic healthcare partners.

## **2. Professional regulation**

### **Policy summary**

The powers in this Act form part of a wider programme to create a more flexible and proportionate professional regulatory framework that is better able to protect patients and the public. These powers will make it easier to ensure that professions protected in law are the right ones and that the level of regulatory oversight is proportionate to the risks to the public.

Section 60 of the Health Act 1999 already provides powers to make changes to the professional regulatory landscape through secondary legislation. The Act widens the scope of section 60 and will enable us, where necessary, to make further changes in secondary legislation to ensure the professional regulation system delivers public protection in a modern and effective way, and, ensure professions are regulated in the most appropriate manner.

The new powers enable:

- i. the abolition of an individual health and care professional regulatory body where the professions concerned have been deregulated or are being regulated by another body;
- ii. the removal of health care professions from regulation where regulation is no longer required for the protection of the public;
- iii. the delegation of certain functions to other regulatory bodies through legislation (which was previously prohibited); and
- iv. the regulation of groups of workers concerned with physical or mental health of individuals, whether or not they are generally regarded as a profession i.e. senior managers and leaders.

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<sup>10</sup> The literature review carried out by NICE estimates the percentage of hospital admissions due to ADRs in the UK to be 6-7%. Of these ADRs, it is estimated that 1.6-3.7% were to be preventable. One review estimated that the overall impact of ADRs in England was 4 out of 100 hospital bed stays with an equivalent cost of about £380 million a year to the NHS in England. <https://cks.nice.org.uk/topics/adverse-drug-reactions/background-information/health-financial-implications-of-adrs/>

<sup>11</sup> Medicines and Healthcare products Regulatory Agency (MHRA), 'Corporate plan 2018-23', 2018. [Online]. Available from:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/702075/Corporate\\_Plan.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/702075/Corporate_Plan.pdf)

<sup>12</sup> Medicines and Healthcare products Regulatory Agency (MHRA), 'Business plan 2021-21', 2020. [Online]. Available from:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/889864/MHRA\\_Business\\_Plan\\_2020\\_to\\_2021.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/889864/MHRA_Business_Plan_2020_to_2021.pdf)

The use of these additional powers will be subject to public consultation and the resulting secondary legislation would be subject to the affirmative Parliamentary process. DHSC will work with the regulatory bodies, the Professional Standards Authority and devolved administrations on provisions to make further improvements to professional regulation through secondary legislation in line with the other uses of the delegated powers in Section 60, Government will undertake wider stakeholder engagement including with patient safety groups and the public prior to bringing forward any legislation using the new powers.

The measures form part of a broader programme to modernise the regulatory system for health and care professional in the UK. The programme is commencing with legislation that will reform the legal framework for the General Medical Council and introduce two new professions, anaesthesia associates and physician associates, into regulation by means of an Order in Council using powers in the Health Act 1999. This will be followed by further legislation to extend these changes to all regulated professions. The powers in the Act complement this transition to a modern and effective professional regulatory system, by making it easier to deliver a reduction in the number of healthcare professional regulators and make other changes which are being considered as part of this work.

## **Rationale for intervention**

The UK model of professional regulation for healthcare professionals has become increasingly rigid and complex and needs to change to better protect patients, support the provision of health services, and help the workforce better meet current and future challenges.

In 2017, the four UK governments consulted on high-level principles for reform of professional regulation and set out their five objectives, to:

- improve the protection of the public from the risk of harm from poor professional practice;
- support the development of a flexible workforce that is better able to meet the challenges of delivering healthcare in the future;
- deal with concerns about the performance of professionals in a more proportionate and responsive fashion;
- provide greater support to regulated professionals in delivering high quality care; and
- increase the efficiency of the system.

The consultation *Promoting professionalism, reforming regulation* included questions relating to the provisions in the Act. The link to the consultation can be found [here](#). The consultation set out the proposals that were welcomed by key stakeholders, including professional organisations, regulators and employers. The link to the consultation response can be found [here](#).

The consultation response also highlighted the case for broader changes to the regulatory landscape including reducing the number of regulators. The Secretary of State for Health and Social Care further committed to reviewing the number of health and care professional regulators in the November 2020 *Busting Bureaucracy* policy paper and DHSC has commissioned an independent review, led by KPMG, who submitted their report at the end of last year and which we are now considering.

A further consultation *Regulating healthcare professionals, protecting the public* was published in May 2021 which sets out reform proposals for all of the regulators. The implementation process will start with changes to the General Medical Council's legislation and the other regulators will follow. A response to the consultation will be published in the next few months.

The Government has also consulted on the criteria for determining when statutory regulation of a healthcare profession is appropriate. The consultation, Healthcare regulation: deciding when statutory regulation is appropriate, ran from January to March 2022. While the Government believes that there is no immediate case to change the groups that are regulated, the consultation sought views on the proposed criteria to make decisions on which professions should be regulated; whether there are regulated professions that no longer require statutory regulation; and whether there are unregulated professions that should be brought into statutory regulation. The consultation responses are currently being considered and a response will be published in due course.

Additional wider reforms have also been considered such as the government response to the Law Commission's review of UK law relating to the regulation of healthcare professionals, and, the recent review of the fit and proper persons test (further details are included in the fourth power below).

The powers in the Act are:

- i) the abolition of an individual health and care professional regulatory body where the professions concerned have been deregulated or are being regulated by another body

There is the inevitable duplication in having nine regulatory bodies (10 including Social Work England) that perform similar functions in relation to different professions. A reduction in the number of regulators would deliver public protection in a more consistent way, while also delivering financial and efficiency savings. Powers under section 60 already allow for the creation of new regulators through secondary legislation. However, similar powers are not currently available to close a regulator, and this can only be done via primary legislation.

This change would enable Parliament to use secondary legislation to abolish a regulator where its regulatory functions have been merged or subsumed into another body or bodies, or where the professions that it regulates have been removed from regulation.

The July 2019 Government response to the *Promoting professionalism, reforming regulation* consultation set out the Government's intention to consider reducing the number of regulators. The Secretary of State for Health and Social Care further committed to reviewing the number of health and care professional regulators in the November 2020 *Busting Bureaucracy* policy paper and DHSC has commissioned an independent review, led by KPMG, who submitted their report at the end of last year and which we are now considering. Use of these powers would be subject to consultation and the affirmative parliamentary procedure.

- ii) the removal of health care professions from regulation where regulation is no longer required for the protection of the public

Statutory regulation should only be used where it is necessary for public protection. The level of regulatory oversight for each profession should be proportionate to the activity carried out and the risks to patients, service users and the public.

The landscape of the health and social care workforce is not static, meaning that the risks to the public will change over time as practices, technology and roles develop. While statutory regulation may be necessary now for a certain profession, over time the risk profile may change, such that statutory regulation is no longer necessary. Clearly, in order to protect the public, professionals such as doctors, nurses, dentists and paramedics will always be subject to statutory regulation.

The Government has recently consulted on the criteria for determining when statutory regulation of a healthcare profession is appropriate. While the Government believes that there is no immediate case to change the groups that are regulated, the consultation sought views on the proposed



criteria to make decisions on which professions should be regulated; whether there are regulated professions that no longer require statutory regulation; and whether there are unregulated professions that should be brought into statutory regulation. The consultation responses are currently being considered and a response will be published in due course.

A provision to enable the removal of a profession from statutory regulation through secondary legislation will make it easier to ensure that the protections and regulatory barriers that are in place remain proportionate for all health and care professions. Any use of these powers would be subject to consultation and parliamentary approval using the affirmative procedure.

iii) the delegation of certain functions to other regulatory bodies through legislation (which was previously prohibited)

Currently, there are legal restrictions in place which limit the functions that professional regulators can delegate to another body. This prohibits regulators from delegating the functions of the keeping of a register of persons permitted to practise; determining standards of education and training for admission to practice; giving advice about standards of conduct and performance; and administering procedures relating to misconduct and unfitness to practise.

The removal of these restrictions would enable further collaboration in how regulation is delivered, which could drive up quality, reduce costs and provide greater consistency. This would enable a single regulator to take on the role of providing a regulatory function, such as the holding of a register, the assessment of international applicants or the adjudication process for fitness to practice, across some or all regulators. This will help to deliver public protection in a more consistent fashion and may also increase efficiency. Where a function is delegated, a regulator would retain responsibility for that function.

iv) the regulation of groups of workers concerned with physical or mental health of individuals, whether or not they are generally regarded as a profession i.e. senior managers and leaders

While the definition of those groups which can be included in regulation using the powers in Section 60 of the Health Act 1999 is broad in relation to healthcare professionals, the proposed changes allows for the regulation of groups of workers concerned with physical or mental health of individuals, whether or not they are generally regarded as a profession, to be regulated. For example, those in senior management and leadership roles and other groups of workers are within the scope of future regulation.

The 2019 Kark review of the fit and proper persons test recommended putting in place stronger measures to ensure that NHS senior managers and leaders have the right skills, behaviours and competencies. While it stopped short of recommending full statutory regulation, NHS England/Improvement is currently considering how best to take forward the recommendations.

Extending the scope of professions who can be regulated using the powers in Section 60 of the Health Act 1999 would provide additional flexibility to extend statutory regulation to, for example NHS managers and leaders in the future, if further measures are needed.

## **Other policy options considered**

### **Option 0 - Business as usual (Do nothing)**

Not being able to expand the scope of Section 60 of the Health Act 1999 will restrict the extent of reform can be made. Proposals are currently being developed using the powers available to reform professional regulation in the areas of fitness to practise, governance and operating

framework, and the registration and education and training functions. However, the aim is to go further to modernise professional regulation and the new powers will support this.

#### **Option 1 - Seek fewer powers**

If fewer powers were established through the Act, then it would be expected that primary legislation would be pursued for the remaining powers in the near future. This is because all of the powers proposed are expected to be required as part of our reform programme. This will delay completion of our reform programme.

#### **Costs**

These provisions seek new powers to be taken forward through secondary legislation. There are therefore no costs associated with these powers coming into force. An impact assessment which calculates associated costs will be completed if the powers are put into effect.

#### **Benefits**

As mentioned above, these provisions seek new powers to be taken forward through secondary legislation. Therefore, the benefits from all provisions are indirect and depend on the actions of the Secretary of State. The potential benefits of these enabling powers, if put into effect through secondary legislation, are outlined in the Rationale for Intervention section. An impact assessment which calculates associated benefits will be completed if the powers are put into effect.

#### **Important note**

We are currently engaging with the devolved administrations, Treasury, Cabinet Office, Department for Education and the Department for Business, Energy and Industrial Strategy regarding the reform proposals.

## **3. Medical examiners**

### **Policy summary**

This policy allows NHS bodies in England and Welsh NHS bodies in Wales to appoint medical examiners instead of local authorities and local health board respectively. This is so that medical examiners employed in the NHS system will have access to information in the sensitive and urgent timescales required to register a death. The following paragraphs of the policy summary section set out the steps taken in the development of this policy.

The Department of Health and Social Care (DHSC) has developed policy over the past several years which aims to provide a reformed system for certifying non-coronial deaths which improves the quality and accuracy of Medical Certificate of Cause of Deaths (MCCDs) and provides adequate scrutiny to identify and deter criminal activity or poor practice. The legal framework of this system is set out in Part 1 of the Coroners and Justice Act 2009, but remains uncommenced at this time, save for sections 18 and 21 as set out below.

As part of this work, DHSC ran a consultation from March to June 2016 seeking views on the detail of the operation of the proposed reforms to the death certification process and draft regulations setting out the system within which the services would operate. The consultation document proposed the introduction of a unified system of scrutiny by independent medical examiners, hosted by local authorities, of all deaths in England and Wales that are not investigated by a coroner as set out in the Coroners and Justice Act 2009 and described how the Government saw the new system working in practice.

The Department's [consultation response](#) was published in June 2018 and set out an approach to introduce a non-statutory medical examiner system by April 2019, where medical examiners were to be appointed within the NHS without the introduction of a new fee at that time. An [Impact Assessment](#) was published alongside the June 2018 consultation response, outlining three policy options and associated costings for England. Option 3 outlined the impact of introducing a Medical Examiners system hosted within the NHS. Since the publication of the 2018 consultation response and impact assessment, a non-statutory medical examiner system has been set up within the NHS in England. To date, all NHS Trusts which require a medical examiner office (based on number of deaths) under a statutory system have done so on a non-statutory basis. In terms of the impacts of the amendment on Wales, an Impact Assessment has been published and can be found here: [Introduction of the medical examiner role and reforms to death certification | GOV.WALES](#)

The consultation response also outlined the Government's intention to commence sections 18 and 21 of the Coroners and Justice Act 2009. Section 18 was commenced in 2019 and section 21 in 2018. They make provisions for regulations to require medical practitioners to report deaths to the coroner which the coroner has a duty to investigate, and, for the appointment of a National Medical Examiner respectively.

The Health and Care Act includes provisions to amend the Coroners and Justice Act 2009 to allow NHS bodies to appoint medical examiners instead of local authorities in England, and for Welsh NHS bodies rather than only local health boards in Wales. The Secretary of State and Welsh Ministers will have a duty to ensure that there are sufficient medical examiners and that they are adequately funded, as well as a power to issue directions to ensure that the duty is met.

At the appropriate time the statutory provisions underpinning the medical examiner system set out in the Coroners and Justice Act 2009 together with the amendments will be commenced. Regulations will then also be laid for the Medical Certificate of Cause of Death ('MCCD') (under s.20 of the Coroners and Justice Act 2009), Medical Examiners (under s.19) and the National Medical Examiner (under s.21).

We had planned to provide an updated IA when laying regulations for the fee mechanism. However, the medical examiner system will now be centrally funded, and a fee regulation is no longer required. We are satisfied that the 2018 IA contains all relevant analysis for the three regulations to be laid which put in place the centrally funded system.

## **Rationale for intervention**

While the arrangements for scrutinising the cause of death have remained largely unchanged for over 50 years, there are concerns about their efficacy and efficiency, particularly for those cases which are not referred to a coroner. The statutory system was outlined in the Coroners and Justice Act 2009 after the Shipman Inquiry concluded that it was no longer suitable to have different certification processes for cremations and burials, and that all MCCDs should be subject to independent medical scrutiny. As set out above, most of the provisions in the Coroners and Justice Act have not yet been commenced. The rationale behind the provisions in the Health and Care Act allowing NHS bodies in England and Welsh NHS bodies in Wales to appoint medical examiners instead of local authorities and local health board respectively, is that medical examiners employed in the NHS system will have access to information in the sensitive and urgent timescales required to register a death.

## **Other policy options considered**

An [Impact Assessment](#) was published on the gov.uk website alongside the June 2018 consultation response, outlining three policy options and associated costings for England. This IA was cleared across all departments (including HM Treasury) via write-round. The IA outlined in this paragraph is England specific.

The preferred option (and that consistent with the consultation response) was option 3:

*“Reform the current system for cremations and burials by introducing a new universal check by a Medical Examiner (ME) applicable to all non-coronial deaths. The system will initially be funded through cremation form fee revenues sourced from efficiencies in the system and DHSC. Following the interim period, the ME system would be primarily funded through a fee for cremations and burials.”*

## **Costs and benefits**

The impacts of the full statutory system for England are set out in the June 2018 impact assessment, and for Wales in a separate [impact assessment](#) which uses the same methodology, where policy Option 3 set out the estimated costs and benefits of introducing a national statutory system of medical examiners based in the NHS. The national statutory medical examiners system set out at Option 3 in these IAs is an accurate representation of the system (apart from funding solution) which we intend to be in place following the coming into force of the Coroners and Justice Act 2009, the Health and Care Act and of the underlying regulations which set out operational details.

The key policy change since 2018 is on funding. During the pandemic, cremation form 5 (the cremation form completed by the second doctor) was suspended, and funding for the non-statutory ME system was provided by central government. In March 2022, the suspension of cremation form 5 was made permanent through legislation, and from that point forward funding for the ME system in England and Wales will be provided centrally, rather than from a public fee.

### Costs to Business

As the June 2018 (England) IA sets out in para 77-79, it is anticipated that any new net cost to business from implementing the statutory system would be minimal or zero. These included potential familiarisation costs for doctors employed in both the NHS and private sector to understand new procedures and establish contacts with new medical examiners, although those costs ought to be mitigated to a large extent as DHSC is not proposing significant changes to the MCCD itself.

In this previous version of this impact assessment and the 2018 impact assessment, we also outlined that there may have been the potential for increased costs to funeral directors who must collect cremation fees from the bereaved on the behalf of doctors. However, central funding for the ME system removes this risk entirely. Minimal or zero costs to businesses are also expected in Wales from policy option 3.

DHSC have further confidence that there will be no additional costs to businesses stemming from this policy, as a non-statutory national system of medical examiner offices has been established from 2019 within the NHS in England. This means that the ME system has moved away from the ‘Do Nothing’ option which was the baseline for the 2018 IA. Importantly, to date, all NHS Trusts which require a medical examiner office under a statutory system have done so on a non-statutory basis. Hence moving from the non-statutory system to the statutory system is unlikely to result in further ME offices being established, thus resulting in minimal set up costs.

### Updated Costs

The June 2018 IA for England outlines that the set up and running costs of the statutory system will not fall on private businesses. The non-statutory arrangements currently in place in trusts reflect the arrangements that would be in place in the statutory scheme.

For clarity, the June 2018 IA gave an estimated running cost (to DHSC and the public) of approx. £34-£41 million per annum<sup>14</sup> in England (using 2018 prices). Based on more representative and

recent cost data, NHSE estimate that the cost of the medical examiner system will be £54m for 2022/23 (in 2022 prices), which is a public sector cost. The benefits of the scheme are not monetised and remain the same as outlined in the 2018 IA (for England). These costs and benefits are for the statutory system as a whole and relate to the set of primary and secondary legislation which underpins it. Economic costs for Wales are outlined in the Welsh IA and have recently been revised with more up-to-date data with a best estimate of £3.1 million per annum.

In summary, DHSC considers that our previous assessment of the costs and benefits of the medical examiner system published in the 2018 English impact assessment, and Welsh impact assessment, remain sufficiently accurate for the purposes of estimating the costs and benefits of establishing a statutory scheme. As such, readers are referred to the previous impact assessments for the purpose of understanding the impact of the statutory scheme once it is commenced.

## 4. Hospital food standards

### Policy summary

The provision in the Act introduces a regulation making power afforded to the Secretary of State for Health and Social Care to adopt secondary legislation mandating and enforcing NHS Hospital Food Standards across the NHS in England. If introduced, these would be enforced by the Care Quality Commission.

The Independent Review of NHS Hospital Food<sup>13</sup> made eight recommendations to improve the standard of food across the NHS estate. NHSEI are leading on implementing recommendations from the Food Review and are establishing an expert group to facilitate this. The new power in the Act will allow the Secretary of State to make Food Standards mandatory. Granting this power will allow the Government to deliver swiftly on its ambition to improve hospital food by putting it on a statutory footing and ensuring its delivery via enforcement by the CQC and will send a clear message that improving hospital food is a priority for the Government.

### Rationale for intervention

The Food Review published on the 26th of October 2020 highlights that there is clear scope for improvement in the provision of food in the NHS estate. Overall, patients in NHS hospitals are satisfied with the quality of hospital food, with a 2019 survey<sup>14</sup> finding that 22% of NHS hospital patients rated the food they received as very good, whilst 36% rated it as good. However, the report also states that the public perception of hospital food is poor, and that 39% of NHS staff felt that food and catering facilities offered in their workplaces were poor. The Food Review also outlines detailed justification for the improvement of hospital foods. These include the role of food and nutrition in the treatment of patients (“food as medicine”), the importance of food safety, and the role of the food supply chain with respect to sustainability.

The Food Review recommended for improved NHS food and drink standards for patients, staff, and visitors to be put on a statutory footing. Granting the Secretary of State for Health and Social Care powers to adopt secondary legislation and provide for a mechanism to enforce failure to meet

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<sup>13</sup> Department of Health and Social Care, “Report of the Independent Review of NHS Hospital Food.”, October 2020. [Online] Available: [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/929234/independent-review-of-nhs-hospital-food-report.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/929234/independent-review-of-nhs-hospital-food-report.pdf)

<sup>14</sup>

Care Quality Commission, “Adult inpatient survey 2019,” July 2020. [Online]. Available: <https://www.cqc.org.uk/publications/surveys/adult-inpatient-survey-2019>

these required standards will allow Ministers to deliver swiftly on the Government's ambitions to improve hospital food standards via secondary legislation.

## **Other policy options considered**

### **Option 0 - Business as usual (Do nothing)**

Under the business as usual (do nothing) option, this statutory instrument would not be introduced. At present, without the proposed reform, changes to food standards would be challenging to implement and measure. Monitoring methods for food targets are already in place but do not go far enough to ensure the highest quality of food standards are carried out and prioritised by all organisations. Given the recommendations from the Food Review, this was not deemed a viable option as it would restrict the extent of reform that can be made.

## **Costs**

The provision brings forward a statutory instrument which in itself has no direct impact, An Equivalent Annual Net Direct Cost to Business (EANDCB) has not been estimated, as any costs would not be incurred until these powers are exercised. However, it is acknowledged that this primary legislation does grant powers, if exercised, which could entail costs to businesses who provide catering services in hospitals. This may result in increased costs to adhere to higher food standards, through for example, requirements to serve more fresh produce in hospital meals. The true extent of these costs or savings cannot be estimated until the use of the power is finalised. In particular, there are additional steps to be completed, such as Public Consultation, which will inform the food standards which may be put in place. A full examination of costs to businesses will be completed at that stage.

Similarly, a Small and Micro Business Assessment (SaMBA) which quantifies the costs to SMBs is not possible at this stage. Current high-operable data suggests that 659 contracts across 48 companies associated with the 216 NHS Trusts would be impacted by legislation; however, at this point that impact cannot be clearly defined. An impact assessment would be produced before the regulation making power is exercised. Any secondary legislation would take into account views and needs of small and micro businesses, and potentially nutritional standards would not impact any organisation, small, medium, or large. Any exemption for small or micro businesses from the regulations would be investigated at the time of secondary legislation being developed, and at that point a SaMBA will be produced.

If the Secretary of State uses the powers granted to him as part of the statutory instrument, then there may be costs for trusts to train staff or to buy equipment to meet the food standards. These costs will be considered as part of an impact assessment if these enabling powers are exercised and secondary legislation is enacted.

## **Benefits**

The benefits of this policy are indirect and will depend upon how the enabling powers are exercised. Granting the Secretary of State for Health and Social Care powers to adopt secondary legislation that will implement the national standards for food across the NHS will enable the government to move more swiftly in acting and ensuring delivery of the recommendations outlined in the Food Review.

## **Risks**

It should be noted that this provision introduces enabling powers with a duty to consult stakeholders prior to introducing legislation and does not in itself contain substantive provisions as the standards will be detailed in secondary legislation made under the power. It is therefore difficult to assess with any certainty what the impact of the measures will be. Any policy that will be implemented using the regulation-making powers provided in future will be required to develop an

impact assessment for the settled policy at the point at which the government is ready to legislate.

### **Important note**

Any future regulatory policies that intend to introduce secondary legislation via the enabling provision in the Act will need to be consulted upon and will need to be accompanied by an impact assessment.

## **5. Water fluoridation**

### **Policy Summary**

The provisions in the Act, once commenced, will transfer the current powers and duties of local authorities (LAs) in respect of water fluoridation to the Secretary of State, including the power to propose new, variations or terminations to fluoridation schemes, the responsibility for ensuring that schemes are operable and efficient and the duty to consult.

The Secretary of State was already legally responsible for capital and revenue funding for water fluoridation schemes, and exercised the statutory power to require LAs to meet (i.e. reimburse) the revenue costs. Following the commencement of the clauses in the Act, revenue costs will be met by central Government. The Act introduces future flexibility to seek contributions in respect of all water fluoridation costs, though it is not currently intended to exercise this power. Arrangements will continue to be held and managed by central Government. Water companies are funded under these arrangements to install and maintain fluoridation schemes and their role is unchanged. They are refunded for the revenue and capital costs they incur. Any proposed changes to the funding arrangements will be subject to regulations, consultation, engagement, and assessment of impacts.

There will be a requirement for the Secretary of State to consult on water fluoridation schemes, except in certain circumstances, and the Secretary of State will continue to be responsible, as now, for directly entering into arrangements with water undertakers. Central Government will also continue to be responsible for managing contracts with water undertakers and for monitoring the effects of water fluoridation schemes on the health of people living in the areas covered by these arrangements, and to produce reports at no greater than four-yearly intervals will remain. This will include the monitoring of health outcomes. There will be no significant operational changes to existing schemes.

### **Rationale for intervention**

Fluoride is widely agreed to be a clinically effective intervention for oral health<sup>15</sup>. Around 70% of five-year-old children live in areas with naturally low levels of fluoride. If they were to drink fluoridated water, then there would be between 17-28% fewer children with tooth decay. Research has shown that drinking fluoridated water benefits children and adults so there could be a significant public health benefit.

Fluoride mitigates the impact of poor diet and/or poor oral hygiene. It can be applied directly to teeth via toothpaste (most toothpastes now contain fluoride) and mouthwash, or professionally applied through varnishes and gels or added to the water supply (water fluoridation). All methods of delivery are effective, but water fluoridation has the strong advantage that no action or change in

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<sup>15</sup> Public Health England, "Water Fluoridation: Health Monitoring Report for England 2018", 2018. [Online]. Available:

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/692754/Water\\_Fluoridation\\_Health\\_monitoring\\_report\\_for\\_England\\_2018\\_final.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/692754/Water_Fluoridation_Health_monitoring_report_for_England_2018_final.pdf)



behaviour is required by the individual or dentist and it has a greater impact on reducing oral health inequalities.

Fluoride is naturally present in drinking water, but apart from a few areas in England, is at too low a level to be effective against tooth decay. A community water fluoridation scheme involves raising the level of fluoride in water to 1mg of fluoride per litre of water (mg/L), the level accepted in the UK to be most effective in reducing tooth decay whilst minimising unwanted effects.

Current community water fluoridation schemes in England serve around 6 million people, resident in 28 upper tier and unitary local authorities, including large areas of the North East and the Midlands. This means about 10% of the population in England currently receive fluoridated water. Whilst fluoride is naturally present in most water supplies, it is only present at an optimum level for dental health in a small number of areas such as Hartlepool and Braintree.

From 2013 LAs were responsible for proposing new fluoridation schemes, and for variations and terminations to existing schemes. However, the Secretary of State had a significant role in the process, in confirming that the proposals were operable and efficient and responsibility for entering into any resulting arrangements with the water companies. LAs also had responsibility for carrying out and funding the actions needed to take forward a proposal. This included feasibility studies and public consultations. However, in the last 7 years no new schemes were successfully implemented.

The transfer of responsibility for proposing schemes to the Secretary of State recognised that LAs faced a number of specific barriers to proposing and leading discussion on new schemes:

- Water flows usually cross LA boundaries and all LAs affected must be invited to take part in the decision-making process. Everyone who is affected by the proposal must be consulted- even if their LA chooses not to take part in the decision-making process. Where multiple LAs are involved in the process this adds procedural complexity and the challenge of establishing consensus across multiple organisations.
- The structure of LAs can add further time and complexity. LAs coordinating the process across more than one decision-making body face multiple committee stages which creates problems of coordination, particularly if the LAs have different election cycles.
- Cost is another barrier. For an individual LA the cost of feasibility studies and public consultations may be a significant deterrent particularly as LAs have no guarantees that the proposal will be agreed and result in an operational scheme.
- Overall, the existing framework had multiple complex processes built in which, taken together, presented a significant barrier for LAs.

## **Other policy options considered**

The prevention green paper *Advancing our Health: Prevention in the 2020s*, published in July 2019, set out the Government's initial intention to explore the funding barriers to water fluoridation expansion. Transferring LAs' existing responsibilities to the centre was decided following consideration by Ministers as the only way to effectively remove the entirety of barriers facing LAs. The responsibilities of all current parties with a role in water fluoridation are set out in the WIA 1991 and these powers and duties can only be altered by primary legislation. The existing legislation required amendment to allow:

- The Secretary of State to directly initiate, vary or terminate water fluoridation schemes.
- LAs' powers to be removed.
- A duty for the Secretary of State to consult.
- Transitional arrangements to require water undertakers currently providing existing fluoridation schemes to transition onto new contracts to enable them to comply with the new legislative regime.
- To enable possible future cost sharing between the Secretary of State and other entities.



## Costs

The costs of existing schemes will not be affected by the provisions. As part of the reforms, responsibility for revenue costs (estimated to be £3.7m for 2021/22) will pass from LAs to DHSC. This means a transfer of costs for existing schemes but no overall increase in costs. Capital costs are already borne by central government (DHSC). The changes include flexibility to allow for future cost sharing with water companies and/or public sector bodies, however, any firm proposals will be subject to regulations, engagement, consultation, and assessment of impacts.

The Water Industry Act 1991 places a duty on the Secretary of State for Health to reimburse water companies any costs incurred that are associated with water fluoridation. Therefore, the transfer of responsibilities for existing water fluoridation schemes to the Secretary of State has no direct costs for water companies, and so the Equivalent Annual Net Direct Cost to Business (EANDCB) is zero for this particular aspect of the policy. However, the provisions allow for possible future cost sharing with water companies which if exercised, may introduce costs on water companies to fluoridate water. It is not possible to estimate what this cost would be until details of how the power will be exercised are known. Any proposal will be subject to an impact assessment and an EANDCB will be calculated at that stage.

There are 16 statutory water undertakers (i.e. regional monopolies) in England that provide either water services, or both water and sewerage services<sup>16</sup>. There are a number of other regulated companies, including: local companies providing either water or sewerage services or both; water supply and sewerage licensees that offer water and sewerage retail services to business customers; and infrastructure providers delivering large infrastructure projects. However, there are currently no small or micro businesses which would be responsible now or in the future for fluoridating water supplies. There is no current intention to exempt any small or micro businesses who may provide water fluoridation from possible future cost sharing. However, were the enabling powers to be exercised, any secondary legislation would take into account views and needs of small and micro businesses, and any exemption for small or micro businesses from the regulations would be investigated at the time of secondary legislation being developed. At that stage a SaMBA would be produced, and as mentioned at the end of this section, DHSC will continue to engage, as appropriate, with DEFRA and water companies as any proposals develop.

The transfer of responsibilities is intended to streamline and make the process of proposing and consulting on new schemes less burdensome. Decisions on any future schemes will be taken in the context of wider financial decisions on health and care, including through Spending Reviews.

## Benefits

The Act, when commenced, will transfer the power to propose new schemes, variations or terminations to central government and as part of this LAs will no longer be required to undertake consultations or feasibility studies which may generate some savings in terms of reduced resourcing costs. This is in order to reduce the burdens on local authorities and allow for the process to be streamlined. The legislation has preserved the duty to consult on any proposed new schemes or changes to schemes, except in certain circumstances.

## Risks and mitigations

There is a potential risk that, in transferring these powers to the centre, the benefits of greater autonomy are forgone. However, the barriers LAs face in effectively proposing new fluoridation schemes, or in varying or terminating existing ones mean that no new schemes have been established in the past seven years. Transferring these powers to the centre aims to break down these barriers to implementing fluoridation schemes which will have positive public health benefits.

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<sup>16</sup> Drinking water 2020, The Chief Inspector's report for drinking water in England, 2020, p13. [Online]. Available from: [Drinking water 2020 - The Chief Inspector's report for drinking water in England \(dwi.gov.uk\)](https://www.dwi.gov.uk/publications/drinking-water-2020) and confirmed by internal analysis from PHE.

## **Important note**

The changes remove responsibilities and costs from LAs and are subject to DLUHCs reverse burdens process.

DEFRA is the other government department with a direct interest (through the role of water companies). The department has engaged the water companies and DEFRA on the provisions and they were content that the provisions do not substantively affect the current relationship with the water companies and the Secretary of State for Health and Social Care. However, any decisions to alter the duty to reimburse water companies will alter the relationship between water companies and the Secretary of State and will be subject to regulations, engagement, consultation and assessment of impacts.

## **6. Food information for consumers: power to amend retained EU Law**

### **Policy summary**

The retained Regulation (EU) No. 1169/2011 of the European Parliament and of the Council on the provision of food information to consumers ('Regulation (EU) No. 1169/2011') was incorporated into domestic law, carried forward and modified according to the EU (Withdrawal) Act 2018. It sets out requirements on the provision of food information to consumers which includes the labelling of prepacked food and drink in the UK. Due to its status as retained direct principal EU legislation, primary legislation is often required to amend or otherwise, modify the provisions contained within Regulation (EU) No. 1169/2011.

The Act confers a power on the Secretary of State and Ministers of Scotland and Wales to amend and modify by regulations parts of the retained direct principal EU legislation, set out in Regulation (EU) No. 1169/2011. The intention of the power is to broaden the reach for any modifications to Regulation (EU) No. 1169/2011 to those matters that fall within the scope of section 16 (1) (e) of the Food Safety Act 1990. Regulations made under the new power are subject to the affirmative process.

The new power to amend retained direct principal EU legislation, Regulation (EU) No. 1169/2011 will enable the Secretary of State and Ministers in Scotland and Wales to implement new policies for food information by amending food labelling requirements so they meet the needs of their respective nations and territories. For example, the Government's obesity strategy: 'Tackling obesity: empowering adults and children to live healthier lives'<sup>17</sup> included a commitment to consult on front of pack nutrition labelling and whether to mandate alcohol calorie labelling to help support consumers make healthier choices. If consultations indicate that changes to food and drink labelling and/or presentation is required, this provision will enable Ministers to introduce key policies, whilst retaining a level of scrutiny on any proposed changes. It will also support the alignment of labelling policies across the three nations, by allowing each nation to make changes applicable to their relevant territories.

### **Other policy options considered**

**Option 0** - Business as usual (Do nothing)

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<sup>17</sup> DHSC, 'Tackling obesity government strategy', 2020. [Online]. Available from: <https://www.gov.uk/government/publications/tackling-obesity-government-strategy/tackling-obesity-empowering-adults-and-children-to-live-healthier-lives>

Not taking forward these powers would restrict the extent that reform can be made to labelling and food information if consultations indicate that changes to food and drink labelling and/or presentation is required.

## **Costs**

This Act provides enabling powers; no immediate impacts are expected as the exercise of powers in the provisions are subject to any secondary legislation which may or may not be implemented in future. An impact assessment would be undertaken prior to any regulations under the new power being made.

Costs of any future secondary legislation using this power will likely be the costs associated with businesses having to implement changes to labelling requirements, as well as burden placed on local authorities and the justice system for enforcing it. DHSC will look to align its work on labelling with other government departments, namely DEFRA, where possible.

An EANDCB figure has not been provided as the impact of the power will depend upon whether and how the powers are exercised. Any exercising of this power is likely to affect a large number of manufacturers and / or retailers. Depending on how the power is used, there may be familiarisation costs to manufacturers who need to put the new labelling practices into place, as well as greater administrative costs as companies are required to provide more information on their products. This may disproportionately affect smaller businesses where administration costs may account for a larger proportion of their overheads.

DEFRA report that “There were approximately 7,130 micro, small and medium sized enterprises (SMEs) in the food and drink sector with turnover of around £21 billion and 135,000 employees in 2019. In the food sector (excluding beverages) SMEs accounted for 79% of businesses, 27% of employment and 17% of turnover.”<sup>18</sup> This suggests that small and micro businesses, along with medium sized enterprises, account for a significant proportion of food and drink market share. At this stage it is not possible to state whether and the extent to which small and micro businesses will be impacted by any secondary legislation introduced using these powers, as these proposals have not yet been brought forward or finalised. Any secondary legislation would take into account views and needs of small and micro businesses, and by extension any exemption for small or micro businesses from the regulations would be investigated at the time of secondary legislation being developed. At the secondary legislation stage an EANDCB will be calculated as part of an impact assessment, and, a SaMBA will be produced.

Costs may be further influenced by factors such as the extent of the labelling change (major or minor) and length of implementation period. These costs are illustrative and would depend upon if and how the enabling power is used. Any potential wider costs and benefits (such as those on the environment) of future secondary legislation would be covered in an impact assessment.

## **Benefits**

The Health and Care Act grants the flexibility to act on the evidence, once final policy proposals have been fully consulted on. Scientific evidence and consumer needs continue to evolve, and due to the limitations and restrictions set out in Regulation (EU) No. 1169/2011 DHSC did not have the legislative ability to respond to those changes as and when they occur. Having left the European Union, this provision in the Health and Care Act will allow us to continue to meet consumers’ needs in the future.

When secondary legislation is enacted using the enabling powers in this Act then this will be done in circumstances where the government considers that there is sufficient evidence to support such measures as necessary to improve food information for consumers, potentially resulting in

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<sup>18</sup> DEFRA, Foot statistics in your pocket: Food chain, 2020. [Food Statistics in your pocket: Food Chain - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

consumers making better informed dietary choices. This may have the spill-over effect of preventing ill health, such as illnesses linked to poor diet such as diabetes or coronary heart failure<sup>19</sup>, and by extension reduce cost to the NHS and public services further down the line<sup>20</sup>. This may not be applicable for all possible regulations introduced using the power, and because the details of possible secondary legislation have not yet been finalised, it is not possible to give greater detail on the possible benefits of the regulations which may be enacted using this enabling power.

## **Risks**

It should be noted that this Act contains enabling powers and does not contain substantive provisions as the specific details of any legislative requirements will be set out in any secondary legislation made under these powers. At this stage, it is therefore difficult to assess with any certainty what the impact of the measures will be. For example, the government has gathered views and evidence on its current multiple traffic light label, new international examples and whether FOPNL should reflect updated dietary advice for free sugar and fibre, and is considering the results. The government also intends to publish a consultation on whether to introduce calorie labelling requirements on alcoholic drinks. Since these policies are at consultation stage it is not possible to assess the potential impacts until the evidence has been considered and any policy options deemed necessary are finalised. At the point the government is ready to legislate using the regulation-making powers provided in this provision, industry will be consulted, and a detailed impact assessment will be produced for the settled proposals.

## **Important note**

Any future regulatory policies that intend to introduce secondary legislation via the enabling provision in the Act, will need to be consulted upon and will need to be accompanied by an impact assessment. Since changes to Regulation (EU) No. 1169/2011 will require an affirmative process, any policies using this power will be scrutinised and approved by both Houses of Parliament.

# 7. Reciprocal healthcare arrangements with Rest of World countries

## **Policy summary**

The Act will provide the Secretary of State with powers to make secondary legislation to fund and implement reciprocal healthcare arrangements with countries around the world. Until these provisions come into force the UK is limited to implementing comprehensive reciprocal healthcare arrangements with the EEA and Switzerland.

The UK has multiple reciprocal healthcare agreements outside of the EEA with countries such as Australia and New Zealand. However, without financial reimbursement or data sharing mechanisms, these agreements are limited in scope and reach and take the form of simple equal treatment or waiver agreements. The new powers will enable the government to strengthen existing agreements and to implement new comprehensive reciprocal healthcare agreements with Rest of World countries.

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<sup>19</sup> NHS, Obesity (web page). Available from: <https://www.nhs.uk/conditions/obesity/>

<sup>20</sup> DHSC, *Advancing our health: prevention in the 2020s – consultation document*, (2019). [Online]. Available from: <https://www.gov.uk/government/consultations/advancing-our-health-prevention-in-the-2020s/advancing-our-health-prevention-in-the-2020s-consultation-document>

These provisions in the Act have no immediate impacts as the exercise of powers are subject to the negotiation of future reciprocal healthcare arrangements with Rest of World countries.

## **Rationale for intervention**

Establishing reciprocal healthcare agreements with Rest of World countries is in line with the government's Global Britain strategy, looking to invest and strengthen the UK's relationships with countries across the globe and strengthen international healthcare cooperation.

Comprehensive reciprocal healthcare agreements with Rest of World countries could offer benefits for UK residents when they travel abroad for tourism or short-term business purposes. Such agreements make healthcare in other countries more accessible and can support individuals with long-term conditions who usually pay higher travel insurance premia or face difficulties in getting comprehensive insurance cover. They can also foster closer collaboration on healthcare with our international partners, supporting improved health outcomes for all.

## **Other policy options considered**

### **Option 0 - Business as usual (Do nothing)**

If the Secretary of State does not use the regulation making powers the UK will only be able to implement comprehensive reciprocal healthcare arrangements with the EEA and Switzerland. This would restrict the government's ability to strengthen existing agreements and to implement new comprehensive reciprocal healthcare agreements with Rest of World countries. Agreements with other countries would be limited to either: i) waiver agreements, where any fees associated with accessing the healthcare system are waived at the point of access and there is no provision made for the costs incurred to be reimbursed or ii) an agreement for equal treatment, whereby visitors to a country have the same access to healthcare as the residents of that country, facing the same fees and/or exemptions as regular users of the system.

## **Costs**

As this provision introduces enabling powers, there are no costs associated with its introduction. Any policy using the regulation-making powers provided as well as future agreements which will be implemented under the proposed powers will be subject to a new impact assessment as appropriate.

While the expected costs of implementing new Rest of World reciprocal healthcare agreements are currently unknown, the following types of costs could occur depending on the content of future agreements:

- Costs to the UK government to reimburse other countries' governments for healthcare provided to UK residents while travelling abroad and to administer the system.
- Costs to the NHS in terms of forgone income where the agreements result in lower tariff charges in England for Rest of World residents receiving NHS treatment than currently. There may also be increased demand for NHS services if visitors are entitled to treatment when visiting the UK. This is because the likelihood may increase of visitors using the NHS for needs-arising treatment during their visit compared to if they were directly charged for treatment, although the impact is expected to be minimal.
- Until the details of the reciprocal healthcare agreements are finalised, it is not possible to produce an Equivalent Annual Net Direct Cost to Business figure, nor is it possible to identify whether small or micro businesses would be disproportionately affected. An EANDCB and SaMBA will be completed when reciprocal healthcare arrangements are implemented via secondary legislation.
- Were a reciprocal healthcare arrangement to be introduced, the types of businesses impacted may be travel insurance companies as lower premiums and reduced income from excess payments may result in forgone profit for insurance companies. Furthermore, businesses who have staff that travel abroad may be affected, although the impact on these firms is expected to be small as savings stem from cheaper travel insurance premia.

- There is the potential for reciprocal healthcare agreements to affect trade in goods and services. The nature of these impacts will not be fully understood until details of the reciprocal healthcare agreements are finalised. DHSC will engage with the Department for International Trade when reciprocal healthcare arrangements are being agreed with rest of world countries to fully examine these impacts in line with Better Regulation guidance.

## **Benefits**

As noted above, as an enabling measure, there are no direct benefits arising from the power coming into force. Any benefits associated with the power being used will be subject to future analysis. As an indication, the types of benefits that could arise from reciprocal healthcare agreements are:

- Cost recovery rates for the NHS may be improved due to the introduction of a reimbursement mechanism which means that healthcare costs could be covered by governments instead of direct charging. The UK government will therefore receive income for the treatment of residents from other countries (though this may be offset against the NHS costs of providing the treatment depending on the agreements).
- Incorporating reimbursement/data exchange mechanisms to facilitate reimbursement into new or updated existing agreements will allow for improved monitoring and evaluation of the cost-effectiveness of these agreements over time. Existing waiver agreements do not routinely include accurate data exchange, limiting our ability to evaluate the effectiveness of these arrangements.
- There may also be operational savings to the NHS from reduced administration costs required to administer the current system of directly charging patients.
- Savings to individuals, including avoided costs of paying directly for healthcare treatment abroad, lower travel insurance premiums and increased ease and convenience of travel.
- If agreements cover treatment for certain long-term conditions, it will be easier for these groups of people to travel, improving equality of opportunity. Treatments such as kidney dialysis, oxygen and antenatal care have been covered by the UK's reciprocal agreement with the EU.
- UK businesses, charities and the UK government may benefit from reduced costs when providing travel insurance for business trips due to the likelihood that insurance premiums might be reduced.
- Revisiting existing agreements would also support broader healthcare cooperation and diplomacy, especially with our closest allies (e.g. British Overseas Territories, Crown Dependencies, Commonwealth countries).
- Widening the scope of agreements could encompass other areas of strategic interest, including on wider healthcare cooperation. This could build on existing relationships and dialogues, including on COVID-19.

## **Risks**

The relevant provisions in the Act are an enabling measure. They do not contain substantive provisions in relation to the content of future reciprocal healthcare agreements with Rest of World countries which will be subject to negotiations. It is therefore currently difficult to assess with any certainty what the impact of the measures will be.

## **Important note**

An impact assessment will be conducted for any new reciprocal healthcare agreement with Rest of World countries.

Ahead of future agreements there would also be extensive engagement with stakeholders as appropriate on the feasibility and impact of any proposed arrangements.

## 8. Powers allowing further products to be centrally stocked and supplied free of charge to community pharmacies without the need to reimburse them under the standard NHS arrangements

### Policy summary

This amendment adds to Section 164 of the NHS Act 2006 and Section 88 of the NHS (Wales) Act 2006 enabling regulations to be made that would allow no reimbursement under the standard NHS arrangements for certain products centrally stocked and supplied free of charge to community pharmacies. This adds to the pre-existing exemption introduced in 2017 for unlicensed medicines, more commonly known as ‘specials’.

### Rationale for Intervention

Without this provision, the only practical way to achieve this on a secure legal footing would be to for the NHS to sell stock to wholesalers. These wholesalers would in turn sell to community pharmacies who are reimbursed by the NHS. Such an approach would be inefficient compared to supplying the products directly, as there is an additional step in the supply chain which may entail costs (such as resource costs to community pharmacies purchasing products from wholesalers). Therefore, where it is deemed appropriate this amendment proposes to allow further exemptions from the obligation to reimburse pharmacies for products to centrally stocked and supplied free of charge to community pharmacies. This provision is enabling, and the exact circumstances of when the powers may be used (if any) have not been finalised.

### Other policy options considered

#### Option 0 - Business as usual (Do nothing)

Not taking forward these powers would restrict the extent that reform can be made if it is identified that changes to the provision of certain medical products is required.

### Costs

This provision provides enabling powers; no immediate impacts are expected as the exercise of powers are subject to any secondary legislation which may or may not be implemented in future. Were the powers to be exercised, we anticipate that the main costs would fall on actors within the medicines supply chain, for example, if the role of wholesalers in the supply chain changed from the role of a purchaser to a purely logistical role. Due to the limited cases where these powers are likely to be exercised, any potential costs are also likely to be limited.

To provide some additional context with a simplified model of the medicines supply chain, medicines flow from manufacturers to pharmaceutical wholesalers to end points, such as hospitals and pharmacies, who in turn supply to patients. There are approximately 1,500 registered pharmaceutical wholesalers, but only a very small number are considered a ‘full line wholesaler’ (i.e. they sell nearly all medicines). There are also specialist wholesalers, for example those who deal with hospital only medicines, unlicensed medicines, generics or appliances. Additionally, some have a wholesaler dealer’s license because they are, for example, a pharmacy or a hospital but do a small amount of wholesaling as part of their business. To give an idea of the size of the market, in primary care alone, one of the main ‘full-line’ wholesalers will normally make two deliveries a day to each of the 11,200 community pharmacies, and the total spend in primary care is approximately £5.2 billion of branded medicines, £3.2 billion of generic medicines and £1.2 billion of appliances annually. When the wholesalers sell to pharmacies, they sell at more than the price they purchased them at to pay for the distribution and a profit margin. However, there are some medicines (mainly brands) where the manufacturer sells directly to the pharmacy/hospital and procure a logistic service from the pharmaceutical wholesalers.



This amendment is an addition to a pre-existing exemption with a legal precedent. The changes are restricted to vaccinations and immunisations, medicinal products used for the prevention or treatment of disease in a pandemic, and associated products such as diluents and syringes. Although it is not possible to predict the future scenarios where we may consider this option, we do not anticipate that this will be a significant number of products when compared to the total number of products delivered by wholesalers (there are over 10,000 products listed in the NHS Business Service Authority's Dictionary of Medicines and Devices). The aim of the provision is not to radically change NHS pharmaceutical service provision or payment mechanisms to community pharmacies or the pharmaceutical supply chain that they use. The aim is to strengthen the legal basis for scenarios when the usual supply routes are bypassed. As a result, the specific products for which this power may be used have not been decided, meaning estimating a quantified impact of the provision is not possible. For example, without knowing the particular medicine (or the level of margin associated with it), it is not possible to state how many units of the product may be provided centrally, and hence the scale of impacts on the wholesaler sector.

The impact on pharmaceutical wholesalers would vary according to the proposed scenario, in the case of a new vaccine or treatment such as COVID vaccinations the stock, supply and associated business is entirely new and therefore does not deprive or interfere with pre-existing market conditions in the sector. In the case of an existing vaccine or treatment, depending on the exact nature of the alternative arrangements, distributors will still be needed to deliver the product to pharmacies. Pharmaceutical wholesalers may undertake this function although this will be under the terms of contracts performing the role of logistics suppliers rather than purchasers. While pharmaceutical wholesalers in general might not lose out, particular pharmaceutical wholesalers may potentially lose out while others may benefit, dependant on which pharmaceutical wholesalers might have bought the stock under the traditional model and which pharmaceutical wholesalers perform the role of logistic suppliers for centrally secured stock.

To take a counterfactual example, one such approach could see DHSC putting out to tender to a number of vaccine suppliers as a direct contract to supply seasonal influenza vaccines. The vaccine would be paid for centrally by the government as a split agreement award with either a small number of manufacturers or all manufacturers, according to the tendering process. The annual NIC for flu vaccinations is valued at £27.9 million (2020/2021 flu season) wholesalers would currently earn a margin out of this when they sell it to pharmacies. As outlined above, rather than denying wholesalers the business this would probably be recalibrated as per the contracts agreed with the government with the additional benefit to wholesalers of reduced risk due to wastage of expired stock, particularly applicable to this example due to the seasonal nature of flu vaccinations.

Although it is not possible to determine at this stage the specific circumstances and therefore number of products when this exemption may be used, it is anticipated that this would be small, and a full impact assessment, including an assessment of costs to businesses (EANDCB) and small and micro businesses (SaMBA), would be conducted to accompany each regulatory change as they are required.

## **Benefits**

Overall, it is anticipated that the proposed amendment would result in benefits to the NHS, as an efficient alternative option to distribute vaccinations or treatments connected to a pandemic when the usual supply routes need to be bypassed.

## **Risks**

This amendment is enabling only and as such would require regulations to be made to allow any of the proposed products to be supplied in this way. Therefore, aside from counterfactual examples it is not possible to accurately predict what the impacts will be.



## 9. Increasing gamete and embryo storage limits to a maximum of 55 years for all

### Policy summary

In the UK, laws and regulations of assisted reproduction, including fertility preservation, are governed by the Human Fertilisation and Embryology Act 1990 (the 'HFE Act'). The HFE Act was introduced in 1990 and was amended by the Human Fertilisation and Embryology Act 2008. Today, family units and family formation are vastly different than they were in 2008. Many more people are benefitting from assisted conception and fertility preservation; for example, same-sex couples, individuals who are choosing to start their families later in life, those who become prematurely infertile due to medical conditions, or less commonly, those who undergo gender re-assignment.

Fertility preservation is achieved through the freezing and storage of gametes (eggs and sperm) or embryos. The current maximum storage limit for frozen gametes and embryos is set out in the HFE Act at 10 years. However, the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) Regulations 2009 (the '2009 Regulations') permit an extension of the baseline storage limit for 10-year periods up to a maximum of 55 years for those who can demonstrate a medical need.

Since the last [review](#) of the legislation on statutory storage limits in 2008, when limitations to the technology meant that egg freezing in particular was poor, cryopreservation techniques have improved significantly. Today there are no scientific or technical barriers in place for the use of frozen gametes and embryos. Frozen gametes and embryos lead to comparable IVF success rates as using fresh gametes or embryos.

To seek views from the public about whether the current gamete and embryo storage limits are appropriate, the Government launched a public [consultation](#) on 11 February 2020. The consultation ran for 12 weeks and closed on 5 May 2020.

The consultation explored whether the storage limit should be changed and if so to what, whether there should be restrictions or additional conditions applied to gametes or embryos being stored and if so, what these conditions should be, and whether gametes and embryos should have a different limit placed on them.

The [responses to the consultation](#) were overwhelmingly in favour of increasing the storage limits for everyone, although there was not an obvious consensus on what the new limit should be. Following careful consideration of the views expressed in the consultation, the Government decided to offer 10-year renewable storage periods to everyone, regardless of medical need, up to a maximum of 55 years. As part of this new settlement, there will be a statutory requirement for 10-year review periods. Explicit written consent from the patient will be required to continue storage.

Introduction of the new maximum storage limit via the Health and Care Act 2022 will amend the HFE Act to bring the legislation in line with both societal and technological advances.

### Rationale for Intervention

Individuals across the UK are increasingly choosing to freeze and store their gametes (eggs and sperm) and embryos. The HFE Act limits the storage of gametes and embryos to a maximum of 10 years.

The government has received representations from Parliamentarians and other interested parties about the current provisions of the HFE Act concerning the storage of gametes and embryos and whether they remain fit for purpose. The government recognises that current storage limits

people's reproductive choices, and therefore launched a public consultation to seek views about changing the statutory storage limits for gametes and embryos in 2020.

The results of the public consultation strongly supported increasing the limit from the current 10-years, with 74% respondents agreeing that the limit should be increased. Many respondents expressed a view that the current distinction between those who wish to freeze their gametes or embryos for social vs medical purposes was unfair and should be ended.

In response to the COVID pandemic, the Department of Health and Social Care introduced the Human Fertilisation and Embryology (Statutory Storage Period for Embryos and Gametes) (Coronavirus) Regulations 2020 to allow individuals storing gametes or embryos an additional 2-year extension so that they are not penalized, if their 10-year storage limit ran out during a time when clinics could not treat patients. The effect of these regulations will end on the 30 June 2022. Patients who are nearing the end of their storage limits would lose out on the offer of the new scheme, if this legislative change is not introduced via the Health and Care Act.

Overall, without this intervention, the current unfair distinction would remain in place between individuals who wish to freeze their gametes or embryos for social vs medical reasons.

### **Other policy options considered**

Following response to the public consultation, the Government considered four options. These were:

- Business as usual (do nothing)
- Increase the storage limit to 20 years
- Increase the storage limit to 55 years (with 10-year consent renewal periods)
- Increase the storage limit to the donor's lifetime

#### Option 1: Business as usual (do nothing)

There was overwhelming support for an increase in the statutory limits of some kind. Leaving the baseline at 10 years would perpetuate the unfairness, especially for women, for whom 10 years no longer offers reasonable reproductive choice. It would also leave in place the current unfair differentiation between individuals who wish to freeze their gametes or embryos for social vs medical reasons. Finally, it would also be in direct opposition to the results of the public consultation, where 74% of respondents expressed the view that the maximum storage limit should be increased from the current 10 years.

#### Option 2: Increase the storage limit to 20 years

There was some support in the consultation for a new limit of 20 years, mostly from those with ethical reservations. Such a limit would facilitate more reproductive choice for men and women with non-medical needs but would still be a relatively short storage period in an individual's fertility lifetime and is less likely to be 'futureproof', as societal attitudes continue to move towards accepting older parenthood. For those freezing their gametes at a very young age in order to preserve fertility (e.g. children undergoing cancer treatment) and others with a medical need, a flat rate of 20 years would not be sufficient and an extended offer to cover their medical needs, similar to the existing 2009 Regulations of up to 55 years, would be required. The system would therefore remain as complex to administer as now, and the current unfair differentiation between individuals who wish to freeze their gametes or embryos for social vs medical reasons would remain in place.

#### Option 3: Increase the storage limit to 55 years (with 10-year consent renewal periods)

This option reflects the current maximum limit for prematurely infertile patients, which could then apply the same limit to everyone, irrespective of medical need. This option would facilitate reproductive choice for all patients equally and simplify administration. For extremely young

children storing their gametes (e.g. children undergoing cancer treatment), this limit would continue to enable patients to use their gametes up to their 60s.

#### Option 4: Increase the storage limit to the donor's lifetime

Some individuals and organisations supported a maximum storage limit of the donor's lifetime. This option could cause some disquiet for those with ethical issues around embryo freezing and disposal. Without a maximum year limit, there may be an increased storage burden on clinics as patients may defer indefinitely decisions to use or dispose of material.

## **Costs and Benefits**

The [2021 Regulatory Triage Assessment](#) provides rationale and analysis for the estimated impacts of the increase in statutory storage limits for gametes and embryos from the current 10 years to 10-year renewable periods up to a maximum of 55 years. **Readers should refer to the 2021 RTA for the full assessment of costs and benefits.**

#### Direct and indirect impacts on business

Two main costs were identified to have a direct impact on businesses:

1. Familiarisation costs with the measure (which is estimated on a per-business basis)
2. Additional communication costs (the cost of contacting all patients, estimated on a per-patient basis).

The breakdown of the calculation of familiarisation and additional communication costs are given in the 2021 RTA, including a full list of indirect, negligible, or net zero costs (which include current and additional storage costs which are passed on in full to patients).

As in the 2021 RTA under the costs to business paragraph, we anticipate that in the first-year total direct costs to private business will be between £0.82 million and £1.64 million. This comprises of £28,000 to £56,000 of one-off familiarisation costs, and £790,000 to £1.58 million in communication and implementation costs per year. Familiarisation costs are estimated on a per business basis. There are 113 licensed storage facilities in the UK, 44 of which are owned by 10 private clinic groups, leaving 69 as standalone. This means total familiarisation costs are calculated on the basis on 79 businesses. Communication and implementation costs are calculated on a per patient basis, at a cost of between £158 to £316 per patient based on medical professionals' time and administration costs.

#### Other direct and indirect costs and benefits

If current patients choose to continue to store their gametes or embryos beyond the initial ten-year period, then the patient will be liable for the cost of storage (and not the business). The option of destroying patient's gametes or embryos still applies after the introduction of this policy. This allows the estimated 11,000 to 20,000<sup>21</sup> patients who currently have gametes or embryos in storage, and any future patients, the option to extend the storage period while retaining the option to end the storage period at that point. Therefore, this does not constitute an additional cost to patients unless they choose to opt-in and continue to store their gametes or embryos beyond the ten-year period. This has the benefit of providing patients with a choice that was previously only available to patients who could demonstrate a medical need. It is uncertain how many additional samples the policy will lead to being stored, although these costs will be passed onto patients only if they choose to opt-in.

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<sup>21</sup> [Regulatory triage assessment: for increasing gamete and embryo storage limits to a maximum of 55 years for all - GOV.UK \(www.gov.uk\)](#)

## **Risks and Mitigations**

There is a small risk that initial implementation of the new policy will be difficult for fertility clinics and storage facilities, with the potential for mistakes. This is because patients will have to be migrated from multiple old schemes to the new one, as their consents expire. To mitigate this, there will be a two-year implementation period, from the 1 July 2022 until 30 June 2024, during which time fertility clinics and storage facilities will be able to migrate patients storing gametes or embryos onto the new scheme. The regulator, the Human Fertilisation and Embryology Authority, will be supported by the DHSC during this period to ensure that the legislation is rapidly and appropriately translated into guidance.

## **10. Commercial dealings in organs for transplantation: extra-territorial offences**

### **Policy summary**

The UK has long been opposed to the commercialisation of organ transplantation and is a signatory of the Council of Europe Convention Against Trafficking in Human Organs and supports the Declaration of Istanbul on Organ Trafficking and Transplant Tourism.

The Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006 already prevent commercial dealings in human material for transplantation in the UK, and overseas when a substantial part of the offence takes place in the UK. The Modern Slavery Act 2015, the Human Trafficking and Exploitation (Scotland) Act 2015, and the Human Trafficking and Exploitation (Criminal Justice and Support for Victims) (Northern Ireland) Act 2015, also cover cases where a UK national arranges or facilitates the travel of an organ donor who is exploited in any part of the world.

There have been concerns that the existing legislation will not cover all scenarios in which a person from this country might engage in the purchase and sale of organs, as it is possible that there are commercial dealings in organs which involve UK nationals or residents but where no part of that dealing takes place here and where the UK national is not involved in the travel of the donor.

Left unchanged, there is a risk that people with a close connection to this country may be seen to be complicit in perpetuating human rights abuses by purchasing organs overseas, and that the UK may be seen to tolerate such abuses. Though no evidence that UK nationals seek to purchase organs overseas at any scale is available, DHSC recognises the value of addressing the gap in the existing legislation so as to deter any patients who might be considering purchasing an organ abroad and to signal this country's opposition to organ commercialisation. This provision should lead to minimal adverse consequences to legitimate donors or recipients while also minimising additional resource burdens.

This clause inserts new section 32A into the Human Tissue Act 2004 and new section 20A into the Human Tissue (Scotland) Act 2006, to extend the prohibition of commercial dealings in human material for transplantation to acts done outside of the UK when the material concerned is a human organ and when the act is committed by a person who is habitually resident in England, Wales or Scotland or is a UK national who is not habitually resident in Northern Ireland. It would make it an offence, anywhere in the world, to pay for the supply of an organ, pay for an offer to supply an organ, or seek somebody willing to supply an organ for payment. It would also make it an offence to supply, or offer to supply, an organ for payment. This includes initiating or negotiating any arrangement involving the giving of a reward for the supply of, or for an offer to supply, an organ, and taking part in the management of a body that does so.

The Department is working with NHS Blood and Transplant to provide guidance to organ donation and transplantation professionals on the change in the law and how to communicate it to their patients.

### **Rationale for intervention**

The new provisions should help to deter those who may be considering purchasing an organ overseas. Once in place, transplant professionals will be able to inform patients most likely to consider purchasing that transplant tourism is against the law in all circumstances.

We believe that transplant tourism among UK residents and nationals who need an organ donation is likely to be rare. NHS Blood and Transplant collect data on patients who receive an organ transplant overseas and return to the UK for follow up treatment. This data suggests there has been a consistent downwards trend in the number of those who receive transplants abroad since 2006, where 72 patients received follow up treatment for organs received overseas, to seven patients in 2019. This reduction is likely to reflect a better supply of organs for donation, through improvements to technology, donor matching, and donation rates. During this period, the total number of transplants in the UK rose from 3,087 in the 2006-07<sup>22</sup> reporting year to 4,761 in 2019-20<sup>23</sup>. This indicates that not only has the absolute number of overseas donations to UK residents decreased greatly, but the relative significance of the remaining overseas donations has diminished.

This data may represent mostly legitimate donations, particularly given that a significant proportion of UK residents have family overseas, though it is possible that some of the transplants recorded in this data have been paid for. Additionally, there are no data recorded for patients going overseas for a transplant and not subsequently returning.

Despite indications that the scale of transplant tourism is small, the new provisions represent progress to the extent that, beyond the deterrence effect they create, they provide assurance to those who are concerned about gaps in the existing legislation and signal to other countries that people in this country cannot legally be complicit in the abuses associated with organ commercialisation.

### **Other policy options considered**

#### Option 0: Business as usual (do nothing)

Not taking forward this amendment would mean the existing legislative gaps would remain and potential benefits of deterrent would not be realised.

#### Option 1: Ban the receipt of an organ overseas without consent or for payment

This option would have criminalised the receipt of an organ abroad without proof of consent or for financial or comparable gains.

Though this option would have been effective in prohibiting transplant tourism, targeting the recipient of an organ, rather than the trafficker or their customers, could have negative impacts on vulnerable people. This proposal would have also captured patients taken overseas for a transplant who are not made aware of how their organ was sourced – if it were sourced illicitly they would have been targeted for prosecution when they return to the UK, despite having no involvement in arranging the purchase or sale of the organs.

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<sup>22</sup> NHS, Blood and transplant activity in the UK, 2006-7. [https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1290/transplant\\_activity\\_uk\\_2006-2007.pdf](https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/1290/transplant_activity_uk_2006-2007.pdf)

<sup>23</sup> NHS, Organ donation and transplantation, Activity Report 2019/20:

<https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19481/activity-report-2019-2020.pdf>

This option may have had a disproportionate impact on those who legitimately receive organs overseas, who are more likely to be from minority ethnic backgrounds, as it would have been likely to prevent some from seeking follow up treatment for fear of being treated like a criminal suspect. Though this remains a concern for the preferred option, it mitigates this by not specifically targeting recipients and not setting consent requirements.

Option 1 would have required officials to report on the state of every deemed consent system in the world and on the public understanding of each system, every year. Though this would have given the Department a nuanced picture of where donations made under deemed consent are likely to be legitimate or illegitimate, this seems a disproportionate use of resources given the comparatively small number of reported cases.

Finally, this option would have required specified persons to keep patient identifiable records for all instances of UK citizens who have received transplant procedures performed outside the United Kingdom and report these instances to NHS Blood and Transplant. This measure would have improved record keeping. However, in doing so, it could have also place NHS staff, who are likely to have been the specified persons obliged to keep patient-identifiable records, in an inappropriate position. Their questioning of transplant patients could have led to a criminal prosecution, which we did not want to burden professionals with as their primary focus should be on patient wellbeing.

## **Costs**

We believe very few cases will be brought to trial, and therefore the costs of enforcement are likely to be very low. The number of prosecutions under existing provisions supports this view. The Crown Prosecution Service has confirmed that, from their records dating back to 2007, they have made no prosecutions under the existing Section 32(1) of the Human Tissue Act, which covers the most serious organ commercialisation offences and is being extended to actions made overseas by this amendment. They made one prosecution under Section 32(2) of the Act which covers publishing or distributing an advertisement related to the purchase or supply of an organ for reward.

DHSC and NHS Blood and Transplant would need to invest resources into producing and disseminating guidance for transplantation professionals. There are likely to be some familiarisation costs for professionals who themselves may spend time understanding and communicating the new legal implications of transplant tourism to their patients. Given the relatively small number of people estimated to be receiving organs abroad and needing follow up treatment in the NHS, we expect the cost of communication to be relatively low.

It is possible that in deterring patients from purchasing an organ for transplantation overseas we would be incurring a health loss to those patients as they are likely to have to wait longer for a legitimate organ transplant, which would also maintain a longer waiting time for others. However, this potential cost is offset by the increased likelihood that an organ purchased overseas will not be appropriate for the recipient, leading to worse health outcomes for the patient (including, possibly, the need for another organ transplant) and associated costs for the health service on the patient's return to the UK. Again, these effects are likely to be extremely small or negligible, particularly as only seven patients received follow up treatment for organs received overseas in 2019.

## **Benefits**

It is difficult to assess the scale of the benefits, though it may deter some patients from seeking to pay for an organ overseas and will signal the UK government's opposition to human rights abuses.

If the legislation acts as a deterrent to illicit organ transplants abroad, there may also be benefits in that the NHS may treat fewer individuals who receive inappropriate organs overseas. As with the costs above, this benefit is likely to be extremely small or negligible, particularly as only seven patients received follow up treatment for organs received overseas in 2019.

## **Risks and mitigations**

There is a risk that efforts to communicate the change in legislation will inadvertently draw attention to transplant tourism as an option for desperate patients who previously had not considered it. We plan to mitigate this by directing information to transplant professionals, rather than patients themselves, about the change in the law and guide them towards communicating this change with those they deem already most at risk of seeking a transplant overseas.

This measure may cause concern among people who legitimately receive organs overseas, who are also more likely to be from ethnic minority backgrounds, that they will be treated as a criminal suspect. However, we believe our provision is the option which minimises these risks while achieving the policy objectives.

There is a small risk that the exemption for UK nationals who are habitual residents of Northern Ireland is exploited by patients from the rest of the UK who are considering purchasing an organ abroad, as they may attempt to evade the law by moving to Northern Ireland before travelling overseas to purchase their organ. Our assessment is that this is unlikely, especially as many activities associated with transplant tourism are covered by existing legislation which does apply in Northern Ireland.

## **11. Information about payments to persons in the healthcare sector, enforcement and consent**

### **Policy summary**

Through the Health and Care Act of 2022, the Government has introduced enabling powers which will allow the Secretary of State to make regulations requiring manufacturers and commercial suppliers of healthcare products to make details of the payments or other benefits they provide to healthcare providers public. Regulations will define the detailed operation and scope of this new duty, ensuring that it is proportionate and effective in reaching the main policy goals: to improve patient and public confidence in the healthcare system and to strengthen patient safety by helping to ensure clinical decisions are made independently of any conflicts of interest.

### **Rationale for intervention**

There are professional, academic, and commercial links between healthcare providers and manufacturers and commercial suppliers of healthcare products. However, it is not mandatory for details of these to be made publicly available.

The Independent Medicines and Medical Devices Safety (IMMDS) Review<sup>24</sup> of July 2020 considered where improvements related to safety needed to be made by hearing experiences of patients treated by three medical interventions (the hormone pregnancy test Primodos, the anti-epileptic drug sodium valproate and pelvic mesh surgical implants). The review made recommendations to improve the healthcare system and raised concerns about perceived and real conflicts of interest in the provision of healthcare where financial links and personal and/or professional interests are involved.

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<sup>24</sup> <https://immndsreview.org.uk/index.html>

For medicines manufacturers, a voluntary disclosure scheme already exists under the Association of the British Pharmaceutical Industry's (ABPI) Disclosure UK programme<sup>25</sup>, where, in 2020, 126 ABPI members and non-members disclosed payments or transfers of value made to healthcare professionals and organisations. Disclosure UK is seen as a leading disclosure platform in Europe. However, there is currently no similar disclosure scheme, voluntary or otherwise, for manufacturers of medical devices.

Even though ABPI's voluntary scheme exists, only around 18%<sup>26</sup> of medicines manufacturers disclose their payments via Disclosure UK. A further challenge has been that clinicians' consent to being named in relation to payments declared is sought<sup>27</sup>. To incentivise reporting, the ABPI have been supporting their members to move towards a 'legitimate interest' model for the reporting year 2021.

The IMMDS Review found that several professional bodies and patient groups recognised that "patients and the public were not satisfied with the lack of detail in voluntary declarations", arguing that "without legislative power, clarity about where responsibility lies, and support of the profession" no major changes could occur. The Review therefore suggested that the UK should enact an equivalent to the US Physician Payments Sunshine Act, where manufacturers have a responsibility to disclose any payments or transfers of value to physicians or teaching hospitals. In the US, this information is then centrally published for the public to access.

The IMMDS review recommended "there should be mandatory reporting for pharmaceutical and medical device industries of payments made to teaching hospitals, research institutions and individual clinicians." In its response to the Review, the Government accepted this recommendation in principle and committed itself to exploring options of making reporting mandatory through legislation.

The costs and benefits mentioned below are expected to arise as a result of the legislation for mandatory reporting of industry payments. As the Health and Care Act of 2022 only contains enabling powers, these will not arise until regulations are laid pursuant to the powers in the Act.

## **Costs**

The provision will generate direct ongoing administrative costs to in-scope businesses in the form of the resource required to complete and publish payment declarations. In addition, businesses and/or trade associations, depending on who sets up a payment scheme or portal, will incur direct monitoring costs and initial set-up costs, including but not limited to: web-page and/or web-portal set-up, software download, familiarisation, training, and, potentially, recruitment and legal costs.

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<sup>25</sup> <https://www.abpi.org.uk/reputation/disclosure-uk/>

<sup>26</sup> This is based on the 126 medicines manufacturers that disclosed payments as part of the Disclosure UK scheme in 2020 out of the 695 manufacturers of basic pharmaceutical products and pharmaceutical preparations as stated by the Office of National Statistics in 2021; <https://www.ons.gov.uk/businessindustryandtrade/business/activitysizeandlocation/datasets/ukbusinessactivitysizeandlocation>

<sup>27</sup> <https://www.abpi.org.uk/media/news/2021/december/abpi-champions-use-of-legitimate-interests-to-boost-transparency/>



Where administrative costs of completing and publishing payment declarations will fall completely on in-scope businesses, monitoring and initial set-up costs will fall more significantly on the party setting up a scheme, whether that be in-scope businesses, trade associations, or the government. Although, monitoring and initial set-up costs will be significantly higher if multiple schemes are set-up under multiple in-scope businesses and/or trade associations. Furthermore, costs to patients in accessing this information would be significantly higher where information on payments is spread across multiple locations through multiple schemes.

Furthermore, there may be indirect unquantified costs to manufacturers and healthcare providers if the need to declare payments leads to a change in relationships. There may be potential financial costs to healthcare providers currently receiving payments if the number of payments being made by businesses and/or accepted by healthcare providers falls. There may also be costs to businesses of reduced usage of their products and costs to healthcare providers of fewer provisions for training, education and research. Although, if these relationships inappropriately influence clinical decision-making, we anticipate that there will be a net benefit to society. Furthermore, a change or reduction in these relationships from less payments may discourage recruitment and retention in the healthcare sector.

There may also be costs in the form of reduced foreign and domestic investment in the UK Life Sciences Sector if regulations are too burdensome. This could have indirect costs to in-scope businesses through less investment in production and expansion activities and therefore further indirect costs to the healthcare sector receiving payments through less provisions from in-scope businesses overall.

## **Benefits**

The legislation to make reporting of industry payments mandatory will address the conflicts of interest concerns mentioned in the IMMDS Review. The disclosure will increase the transparency of the relationship between manufactures and suppliers of healthcare products and a person or organisation who provides healthcare (e.g. a doctor or hospital) and a person or organisation who carries out activities connected with health (i.e. one degree away from that direct patient interface, e.g. charity arms of hospitals) .

With this will come increased accountability for healthcare professionals and organisations, who are therefore likely to become more hesitant about accepting payments that would have to be declared under the duty<sup>28</sup>. In turn, this could lead to a reduction in any relationships that inappropriately influence clinical decision-making<sup>29</sup> or which could

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<sup>28</sup> Three experiments found that disclosures of conflicts of interest can deter acceptance of conflicts of interest so there is nothing to disclose except for the absence of conflicts. Sah, S. and Loewenstein, G. (2014). "Nothing to Declare: Mandatory and Voluntary Disclosure Leads Advisors to Avoid Conflicts of Interest", *Psychological Science*, 25(2), 575-84

<sup>29</sup> Centers for Medicare & Medicaid Services, Department of Health and Human Services (2013). "Medicare, Medicaid, Children's Health Insurance Programs; transparency reports and reporting of physician ownership or investment interests. Final rule", *Federal Register*, 78(27): 9457-528

undermine public trust. This will positively impact patient safety by reducing the risk of prescribing behaviour influenced by payments<sup>30,31</sup>.

Another benefit could be increased patient confidence and trust in the healthcare sector and the treatment they receive as a result of the increased transparency of industry-doctor relations. With increased confidence and knowledge<sup>32</sup> of these relations, patients will feel more confident to make informed decisions on healthcare professionals, choice, and treatment. Together, clinicians and patients may choose more cost-effective treatment choices (see footnote 30), improving value for money for the NHS.

Increased transparency can also benefit industry as more information and a reduction of use of payments may help drive competition or reduce the barriers to market entry, increasing efficiency within the market. Increasing competition may also improve value for money for the NHS as price competition leads to lower prices of healthcare products. Although, we recognise that competition will have distributional impacts on industry.

The powers also allow companies to be exempt if they participate in an equivalent scheme. There is currently insufficient data to say whether participation in these schemes would result in a net cost or benefit compared to companies reporting separately. Furthermore, this duty would support professional regulation bodies uphold their own conflict of interest policies, providing a check and balance with declarations made by professionals and NHS Trusts.

## **Risks and mitigations**

There are risks to consider with the mandatory reporting of industry payments. There could be a risk that in the change of some industry-doctor relationships, appropriate relationships may change too due to fear of being wrongly perceived. This will result in a net loss to society. Beyond that, this could have impacts on costs for the NHS if manufacturers for generic medicines and medical devices increase product prices on the basis of a change in relationships.

Furthermore, increasing competition could lead to an inflation of the value and number of payments being made to healthcare providers.

Another risk is that some manufacturers may adapt how they deliver payments or change their operating procedures to keep out of scope of the regulations, and so full disclosure may not be achieved.

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<sup>30</sup> A study by ProPublica in 2016 concluded that doctors who received payments were two times as likely to be high brand-name prescribers and two to three times as likely to have very high brand-name prescribing rates than doctors who did not receive payments. Jones, R. G. and Ornstein, C. (2016). "Matching Industry Payments to Medicare Prescribing Patterns: An Analysis", *ProPublica*

<sup>31</sup> A study on payments received by orthopaedic and non-orthopaedic surgeons found that mandatory reporting in the US may be successfully mitigating some of the potential for undue influence in the healthcare sector. The findings show that there has been an increase in the number of general payments received, but a decrease in their median value, but there has been no change in research payments between 2014 and 2017. Rhee, T. G.; Stanic, T. and Ross, J. S. (2020). "Impact of US industry payment disclosure laws on payments to surgeons: a natural experiment", *Research Integrity and Peer Review*, 5(1)

<sup>32</sup> A study found that there was a significant increase, of almost 10% points, in awareness that payments information was publicly available in the US since the launch of the Open Payments programme as part of the US Physician Sunshine Payments Act. Kanter, G. P.; Carpenter, D.; Lehmann, L. and Mello, M. M. (2019). "Effect of the public disclosure of industry payments information on patients: results from a population-based natural experiment". *BMJ Open*, 9(2)

As this information on payments is published and the conflicts of interest awareness increases, there is a political risk that public distrust could in fact increase<sup>33,34</sup> for the healthcare sector. We will mitigate this by reinforcing existing norms set by professional regulators that encourage discussions on conflicts of interest between the practitioner and their patient. By normalising discussions about conflicts of interest, this will ensure that doctor-patient relationships are strengthened and public trust in professionals is maintained and improved.

There is a further cost risk that the government may need to spend additional money to solve any limits to delivering the patient transparency objective if self-publication is the preferred option over reporting into a central database. There may be practical problems with disclosing payments where this information is not accessed or used by the public as they may remain unaware of it<sup>35</sup> or it may be too complicated to access, in which case patients may not be able to make well-informed choices.

Employing the same mitigation of encouraging disclosures of conflicts of interest in the consultation room would help ensure that patients would have the option whilst not being expected to access this information themselves. This would reduce overall reliance on publication systems and instead embed disclosures in patient-practitioner conversations.

Finally, there are data limitations due to the lack of available data on the payments that are currently made. We have considered data and studies from systems in the US and some European countries.

## 12. Eradicating slavery and human trafficking in supply chains

### **Proposal summary**

Modern slavery encompasses the offences of slavery, servitude, forced and compulsory labour and human trafficking. The NHS has a significant role to play in combatting it, including through taking steps to ensure that NHS supply chains and business activities are free from ethical and labour standards abuses. Government relies on its suppliers for the delivery of many important public services, and we expect the highest standards of business ethics from our suppliers and their agents.

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<sup>33</sup> A US study found that patients' trust in their own physicians and medical profession decreased after the release of the Open Payments programme. Kanter, G. P., Carpenter, D., Lehmann, L. S. and Mello, M. M. (2019). "US Nationwide Disclosure of Industry Payments and Public Trust in Physicians", *JAMA Network Open*, 2(4)

<sup>34</sup> A US study found that physicians receiving high payments were perceived to be less honest and less committed to patients' best interests than physicians who received no payments. However, there was no effect on trust in the medical profession or pharmaceutical and medical device industry. Hwong, A. R., Sah, S. and Lehmann, L. S. (2017). "The Effects of Public Disclosure of Industry Payments to Physicians on Patient Trust: A Randomized Experiment", *Journal of General Internal Medicine*, 32(11): 1186-92

<sup>35</sup> A US study which used a survey found that since the launch of the Open Payments programme, only 13% of respondents knew that information on payments was available and only 3% of respondents knew whether their doctor had received payments. Reference the same as footnote 32.

The Health and Care Act 2022 (The Act) requires the Secretary of State to take two actions towards the risk of Modern Slavery in NHS supply chains:

1. **Review:** Under Section 47, the Secretary of State must carry out a review into the risk of slavery and human trafficking taking place in relation to people involved in NHS supply chains.
2. **Regulations:** Under Section 81 of the Act (which inserts a new section 12ZC into the National Health Service Act 2006), the Secretary of State must by regulations make such provision as the Secretary of State thinks appropriate with a view to eradicating the use in the health service in England of goods or services that are tainted by slavery and human trafficking.

### **Review**

The Secretary of State may determine which NHS supply chains to consider as part of the review into the risk of slavery and human trafficking, or otherwise limit its scope – it does not necessarily need to include all of the supply chains in the NHS.

The review must at least consider a significant proportion of NHS supply chains for cotton-based products in relation to which companies formed under section 223 of the National Health Service Act 2006 (taken as a whole) exercise functions. This is intended to ensure that the review includes the supply chains of a significant proportion of cotton products procured by the organisation NHS Supply Chain, which manages the sourcing, delivery and supply of healthcare products, services and food for NHS trusts and healthcare organisations across England and Wales.

The Secretary of State must publish and lay before Parliament a report on the outcome of the review before the end of the period of 18 months beginning with the day on which this section comes into force, which was 1st July 2022. This report must include the scope of the review, and the methodology used in carrying it out. It must also include any views of the Secretary of State as to steps that should be taken to mitigate the risk of slavery and human trafficking taking place in relation to people involved in NHS supply chains.

### **Regulations**

The regulations that must be made by the Secretary of State can, in particular, include steps that the NHS should be taking to assess the level of risk associated with their supply chains; provisions in relation to procurement processes, including the basis on which the NHS should exclude suppliers from a tendering process; and measures that must be included in contracts.

The regulations can apply to public bodies procuring goods or services for the health service and will be in line with DHSC's existing procurement approach as set out in the UK Government Modern Slavery Statement, which includes a zero-tolerance approach to modern slavery and a commitment to ensure that respect for human rights is built into all contracts, self-assessments, audits, training and capacity-building opportunities. This approach – and measures taken through regulations – will apply to public bodies undertaking procurements of goods or services for use in the health service in England.

### **Existing modern slavery measures**

NHSE also have a number of complementary internal policies that support the commitment to eradicating Modern Slavery, such as:

- Freedom to Speak up Whistleblowing Policy
- Managing Safeguarding Allegations Policy
- Safeguarding Policy
- Procurement Policy

NHSE supports NHS organisations to use the UK Government’s Supplier Registration Service to undertake both Modern Slavery and Labour Standard Assessments where thorough risk assessments indicate if a category or country is high risk.

NHSE agreed their latest modern slavery and human trafficking statement in March 2022, in which they committed to a number of policies to strengthen their approach, including in onboarding suppliers and supply chain management: [NHS England » NHS England modern slavery and human trafficking statement](#)

The costs and benefits below are provided for illustrative purposes.

### **Rationale for intervention**

The UK is committed to taking steps to prevent and address human trafficking in government procurement practices, recognising that the Government has significant financial leverage and policy options at our disposal that can help to prevent human trafficking in global supply chains.

As well as supporting the NHS to identify and mitigate risk with a view to resolving issues, the intention is to send a signal to suppliers that the NHS will not tolerate human rights abuses in its supply chains and to create a significant incentive for suppliers to review and improve their practices, both through the review and the regulations.

### **Other policy options considered**

**Option 0: Business as usual (do nothing).** Not taking forward this review and making the regulations would restrict the extent to which reform can be made if goods or services used within the NHS are tainted by slavery and human trafficking.

### **Costs**

Procurement across the NHS takes place through a variety of routes with circa 80,000 suppliers. To illustrate the likely impact of this review and these regulations, see below a few examples of routes through which procurement occurs.

- i. NHS trusts, foundation trusts, and Clinical Commissioning Groups (CCGs) procurement via compliant routes, including full procurements initiated by the trusts, via frameworks established by NHSE, Crown Commercial Services (CCS), Shared Business Services (SBS) and others. Integrated Care Boards will (from July 2022) replace CCGs and be able to enter into legal contracts for the provision of goods and services.
- ii. NHS England (including Commissioning Support Units (CSUs), and Commercial Medicines Unit (CMU))

iii. NHS Supply Chain, or Supply Chain Coordinated Limited (SCCL)

For the purposes of this impact assessment, below is a summary of a proposed approach to supply chain analysis in these example procurement routes that make up a large majority of the total spend on goods and services by the NHS, to illustrate the impact of the Act and the potential regulations made under it.

This impact assessment addresses NHSE and NHS Supply Chain spend. If further investigation determines that changes are needed, further analysis and planning to include all NHS spend, including trusts, will be completed at a later stage where appropriate, to illustrate the impact on all areas of the system.

Overall, the total cost of these clauses is not yet known but has the potential to be substantial.

### **Costs associated with the review clauses**

#### **NHS England**

In response to the review requirement in the Health and Social Care Act 2022, NHS England will nominate a National Director-Level sponsor to oversee the approach to the mitigation of slavery and human trafficking in the supply chain. This work will require staff time, some of which will be met within existing resources by re-allocating staff time (or re-prioritisation) and, some additional resource which may require further spend, although that is currently unknown.

NHSE will also lead the coordination of a focused and proportionate supply chain mapping exercise (cost/resource associated with this exercise outlined below). This exercise will include the supply chain mapping outlined below undertaken by NHS Supply Chain. Additional resources will be required by NHS England and indicative costs are outlined below:

- A team within responsible for programme management and assurance.
- Digital system to provide visibility of supply chain mapping, the cost of which will be verified through procurement of services and dependent on the viability of the Supplier Registration Service supply chain mapping tool. This is expected to be a substantial investment which, in the first instance, will require a focused group of suppliers to submit information (costs outlined below).
- Third-party auditing and auditing software in addition to existing processes to assure compliance - costs to be verified through procurement of services. On-site auditing typically costs £20k per audit. Without knowing the exact number of suppliers identified for auditing as part of the analysis it is a challenge to calculate a total cost for this activity.
- Legal and assurance (internal and external which will therefore incur additional cost) support will be required.

- NHS wide procurement processes will need to build in the requirement for full supply chain visibility and audit access to the NHS.

Existing staff time to update and assure Modern Slavery processes in the governance and commercial process – costs and impact assessment to existing teams and processes will need to be calculated in scoping phase of analysis.

Increased engagement from NHS England will be required to support NHS procurement teams with guidance, training and support. This resource will require additional FTEs although the exact number is currently unknown.

### **NHS Supply Chain**

The scope of the review will be agreed with the Secretary of State, who will request NHSE to assist in the carrying out of the review.

At a minimum, NHS Supply Chain, who are a company wholly owned by NHSE, will complete an assessment of products identified as high risk by geography and / or material assessment as part of the review, including cotton products. This will cover:

- country of origin information to understand the overarching risks
- establish the overall risk of labour standards abuse
- put in place a proportionate response to assess and establish the “on the ground” reality

Any further scope is to be agreed with the Secretary of State.

### **NHS – trusts, foundation trusts, ICBs (from July 2022)**

The outputs from the analysis outlined above will inform regulations, and guidance and advice to the 219 trusts across England and the Integrated Care Boards (ICBs) established by the Health and Care Act 2022.

### **Suppliers**

Suppliers of goods and services to the NHS will incur costs from partaking in the review, by submitting information to the digital system. The suppliers are typically private businesses. The total additional cost of the review on suppliers will depend on the complexity of supplier supply chains, and the level of maturity the suppliers are already operating to uphold high ethical standards. The additional cost per supplier of taking part in the review may also be influenced by the size of the supplier. There is an absence of data and therefore a robust [EANDCB](#) figure cannot be provided. However, below sets out the best possible evidence and illustrative costs on potential costs of the review clauses.

### **Number of suppliers affected**

The number of suppliers affected is not currently known. The scope of the review will be agreed in due course with the Secretary of State and included in the published report on the outcome of the review. NHS England could take a risk-based approach to supply chain mapping, focusing on detailed review of potential high-risk products. Were a risk-based

approach to be taken, the number of suppliers in scope will depend upon the supply chain mapping and the number of suppliers judged as high risk, meaning it is currently uncertain how many suppliers will be asked to partake.

There are circa. 80,000 suppliers to the NHS. A risk-based approach would reduce the number of suppliers in scope because not all of these suppliers will be operating in high-risk regions or providing products or services susceptible to slavery and human trafficking. If all NHS suppliers were included within the scope of the review, for an illustrative scenario, it may be determined that 10-15% of NHS suppliers would need to be mapped, leading to 8,000-12,000 suppliers impacted.

The review will include the supply chains of a significant proportion of cotton products procured by NHS Supply Chain. NHS Supply Chain is a wholly owned company of NHS England, through which c.60% of NHS spend on products is procured via pre-agreed frameworks.

### Unit costs to suppliers

There may be costs to suppliers to submit information for the supply chain mapping digital system being coordinated by NHSE. Although it is the intention to minimise the resource burden, the information return is likely to require suppliers to undertake a supply chain mapping, which mainly entails costs in terms of supplier staff time. Estimating a cost per business is not possible owing to the absence of data and the lack of similar analyses. We have however attempted to provide an illustrative example below.

Undertaking a supply chain mapping is a complex task with a range of potential costs. The task for suppliers would be to trace their goods or services upstream through the production steps in the supply chain. Taking the example of a cotton product, such as face masks, the supply chain may have several tiers. An ultra-simplified supply chain is outlined below:

**Figure 1:** Simplified cotton facemask supply chain

This is included to demonstrate potential complexity and length of supply chains, with the reality that for each stage each supplier is likely to have multiple suppliers

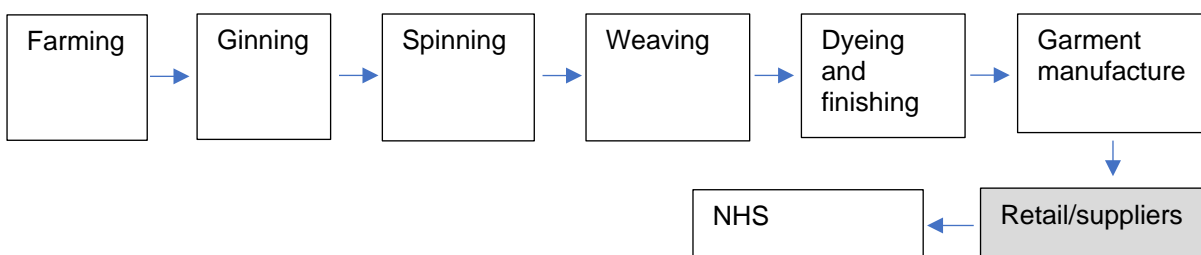




Figure 1 demonstrates that there may be several tiers in the production of cotton goods before they arrive with suppliers (with one box representing one tier). These tiers may be undertaken by different companies or subsidiaries and in different locations. The length of the supply chain will also differ based on the nature and complexity of the goods produced, which is particularly relevant as the NHS procures many hundreds of different goods and services from private suppliers. There is no available data on the complexity and length of supply chains for suppliers to the NHS, and much of this information will become apparent once the review begins.

It is expected that the cost of the review for a particular supplier to be positively related to the number of tiers being reviewed. The more tiers being reviewed (for example two tiers below the supplier, as opposed to one), would increase the resource demands on the supplier. Compared to a relatively 'simple' supply chain with very few manufacturing steps and few input materials, a long, highly complex supply chain will take more resource to fully understand. For example, a 'complex' supply chain may involve multiple input materials and sources of labour, over a long time period and in multiple locations, making the mapping more difficult. The depth of the supply chain mapping required (i.e. the number of tiers being reviewed) is not currently known. Therefore, it is not possible to give an indication of the potential complexity of the mapping task being set on suppliers.

Potential steps of a supply chain mapping for a supplier would be:

- Establish a documentation structure, and identify which products and materials are in scope.
- Gather information and data on the 1<sup>st</sup> tier suppliers (e.g. manufacturers).
- Repeat the above step for all relevant tiers.
- For each relevant tier, gather information on material and labour inputs. This involves tracing products back to their raw materials.
- Document all materials and transport routes for each tier.

The resource required for each of these steps will vary depending on the product. To achieve a detailed mapping, engagement with upstream suppliers will be important, and this collaboration may be ongoing to ensure the supplier provides the required information. This engagement will entail a resource cost on the supplier to the NHS. Further costs may be project management time and resources to track overall process of the mapping, along with supplier staff time to check and verify the information provided by upstream suppliers.

We envisage the return to ask suppliers to set out the provenance of raw materials and key manufacturing locations. The availability of this information, and the subsequent reporting resource required from suppliers, will depend on the suppliers' knowledge of its supply chain and inherent complexity. It is also likely there will be indirect costs to upstream suppliers for providing information. These costs will mainly entail time and resource costs for completing information returns to their downstream supplier. There are a wide range of scenarios for potential resource burdens on suppliers of sourcing this

information. We cannot accurately state the costs of this until the exercise itself takes place, and therefore an EANDCB has not been provided.

The cost of the review may disproportionately affect smaller businesses, although the extent to which this is the case is not known owing to the lack of data on the resource burden of mapping supply chains. The [Modern Slavery Act 2015 impact assessment](#) sets out that “*There is not a strong rationale for requiring small businesses to disclose information about supply chains over which they have little control.*”<sup>36</sup> Therefore consideration for the involvement of small businesses will be made when the review commences. Without the visibility provided by the initial stages of the review, the information required to expand on what businesses will be in scope is not available.

Illustrative examples are provided below to demonstrate how the size of the business affect potential impacts. Assume that the three suppliers below all provide the NHS with the same good (e.g. cotton masks), which have a relatively complex supply chain. The burden on the smaller businesses may be disproportionately larger, although it is unclear what proportion of total NHS suppliers each of these theoretical scenarios may apply to:

- Scenario 1: Large supplier (>250 employees) with large procurement team and an existing deep knowledge of their supply chains. This supplier has a high level of existing resource that can be shifted to work, for a short period, on the information return or an audit. Large companies with a turnover of >£36m are also required to produce a modern slavery transparency statement, as set out in the [Modern Slavery Act 2015](#). The [impact assessment](#) sets out a rationale that increased transparency (of these large companies) may lead to them taking further action on modern slavery in their supply chains, and therefore it may be the case that they already have an in-depth understanding of their supply chain so can easily source the information required for the information return, and experience in completing such requests, resulting a low level of additional burden on the organisation.
- Scenario 2: Medium sized supplier (50-250 employees) but a lower level of existing understanding. Resourcing the information return takes a small % of overall staff time and no additional FTEs are recruited to complete the exercise, but it there is an opportunity cost for the organisation to complete the return (i.e. staff are displaced from other activities within the organisation).
- Scenario 3: A small supplier with <50 employees. The supply chain mapping requires skills that the company do not possess, accessing information that is not regularly collected and that the company has little leverage over their supply chain to request. Collating this information would be notably more burdensome for smaller companies and it would be more difficult for them to find and release useful information about global supply chains<sup>37</sup>. There is also a risk they do not complete the information return to the required level of detail.

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<sup>36</sup> [https://www.legislation.gov.uk/ukia/2015/293/pdfs/ukia\\_20150293\\_en.pdf](https://www.legislation.gov.uk/ukia/2015/293/pdfs/ukia_20150293_en.pdf) , p6

<sup>37</sup> [https://www.legislation.gov.uk/ukia/2015/293/pdfs/ukia\\_20150293\\_en.pdf](https://www.legislation.gov.uk/ukia/2015/293/pdfs/ukia_20150293_en.pdf), p6

As part of the analysis, some high-risk suppliers to the NHS will need to be audited and undertake other transparency measures. This will increase workload for NHS procurement teams and contract managers to ensure requirements are delivered effectively. There may be costs to high-risk suppliers partaking in the audits, although we anticipate this being a small number of all suppliers. These costs may involve staff time cooperating with auditors and providing relevant information on supply chains. If there are costs to suppliers from taking part in the audits or reviews, it is a risk that some of these may be passed onto prices resulting in indirect impacts on the costs of goods and services.

Depending on the findings and recommendations of the supply chain risk analysis, alternative routes of supply may be needed for certain products. The scale and impact of this is not known until the analysis is conducted. See below for the potential risks of this recommendation.

### **Existing requirements for suppliers**

Suppliers of goods and services to the NHS are already expected to uphold high ethical standards, reflected in the requirements of the NHS Standard Terms and Conditions. Therefore, particularly owing to the requirements, it is plausible that the information required for the review is already held by suppliers to the NHS, but there is no information or data to verify whether this is the case. It should be noted that these terms are not exclusively used within the NHS, and other terms and conditions are used, therefore this may not apply to all contracts. The relevant clauses within the NHS Terms and Conditions are included below:

- it shall: (i) comply with all relevant Law and Guidance and shall use Good Industry Practice to ensure that there is no slavery or human trafficking in its supply chains; and (ii) notify the Authority immediately if it becomes aware of any actual or suspected incidents of slavery or human trafficking in its supply chains;
- it shall at all times conduct its business in a manner that is consistent with any anti-slavery Policy of the Authority and shall provide to the Authority any reports or other information that the Authority may request as evidence of the Supplier's compliance with this Clause 10.1.29 and/or as may be requested or otherwise required by the Authority in accordance with its anti-slavery Policy;
- it will fully and promptly respond to all requests for information and/or requests for answers to questions regarding this Contract, the Goods, the provision of the Services, any complaints and any Disputes at the frequency, in the timeframes and in the format as requested by the Authority from time to time (acting reasonably).

### **Potential costs of regulations**

Regulations created under this power will comprise of provisions with the overarching aim to eradicate the use in the health service in England of goods or services that are tainted by slavery and human trafficking. These will include:

- provisions in relation to processes for the procurement of goods and services for the health service by public bodies, with a focus on the circumstances in which a supplier is excluded for consideration for the award of a contract;
- steps that must be taken by public bodies for assessing and addressing the risk of modern slavery in supply chains, ensuring that the risk is minimised with a view to eradicating the use in the NHS of goods created with forced labour;
- matters for which provision must be made in contracts for goods or services entered into by public bodies for the purposes of the health service.

The development of these regulations will include an evaluation of existing processes, requirements under existing government policy, and NHSE policy, with a focus on areas of risk of use of goods and services with an aim to eliminate all use over time.

The provisions to be created under the regulation-making power have not yet been agreed, and therefore a detailed assessment of costs cannot be made at this stage. It is plausible that if the review suggests, and results in, changes to procurement processes to mitigate the risk of procuring goods tainted by slavery and human trafficking, then this will result in time and resource costs for the NHS in complying with new rules. For example, if additional assurance steps are included in the procurement process, this will increase the amount of NHS staff time required to procure goods and services. There may be subsequent indirect costs on suppliers (who may be private businesses) if their goods are tainted by slavery and human trafficking, in that they may have to address issues in their supply chain to comply with NHS procurement rules (although this ultimately will be beneficial for the NHS and its commitment to eradicating modern slavery in supply chains). These are illustrative costs and cannot be quantified at this stage.

A full impact assessment, including an assessment of costs to businesses (EANDCB) and small and micro businesses (SaMBA), would be conducted to accompany any regulatory change if appropriate.

### **Benefits**

The NHS has a vast and complex supply chain, which through an appropriate, proportionate, and targeted analysis of the supply chain, can have a beneficial impact, although these benefits are not monetisable.

The supply chain review analysis will increase supply chain transparency, support wider NHS supply chain resilience and may reduce risk of future modern slavery and labour standard violations. This may ultimately benefit lower tier supply chain workers. Review analysis may also support other NHS objectives, such as improved Social Value creation (Modern Slavery is an NHS priority area under the [Social Value Model](#) theme of 'Equal Opportunity').

Regulations will aim to eradicate the use of goods and services in the NHS tainted by modern slavery, which will aim to ensure that government maintains the highest standards of business ethics from our suppliers and their agents. Taxpayers expect that government's suppliers will behave in an ethical manner and this will further provide assurance of the highest standards of business ethics from suppliers and their agents in the supply of goods and services funded by the public purse.

The Modern Slavery Act 2015 [impact assessment \(p. 16\) also outlines a more general account of benefits to businesses. For example,](#) business transparency on modern slavery in supply chains could also reduce businesses' exposure to risk and unforeseen costs, retention and recruitment of employees, and improving brand image. See this impact assessment for further detail.

### **Risks and mitigations**

Modern Slavery and Human Rights issues often occur in the lowest levels of the supply base, beyond the organisation that may be in contract with the NHS. This is also true in the manufacturing of products where there are a number of entities between the NHS and the manufacturing facilities or materials extraction points where the Modern Slavery and Human Rights issues will most likely occur. Therefore, the resource required to complete the analysis to this depth is not yet fully understood. Given the complexities and costs involved, it is proportionate to take a risk-based approach to any supply chain analysis and mapping exercise.

It is important to note that there are likely to be products under consideration (i.e. being reviewed) that are essential goods and services required by the front line of the NHS and this needs to be considered as part of the assessment. Should an alternative supply of a product be recommended following the analysis, it should be determined that there is a sustainable, alternative supply available, should improvement measures not be agreed with existing suppliers.

The approach taken to modern slavery risk in supply chains, and to regulations made under section 81 of the Act, needs to be consistent with continuing to ensure that the burdens in public procurement remain as low as possible both for contracting bodies and for suppliers, especially small businesses and VCSE organisations, to mitigate the risk of barriers for small business to supplying public bodies.

## **13. Licensing of cosmetic procedures: Section 180 and Schedule 19 of the Health and Care Act**

### **Policy summary**

This section makes provision for a licensing scheme to ensure that those who offer non-surgical cosmetic procedures to the public are suitably trained and qualified, hold appropriate indemnity cover and operate from premises which meet the necessary

standards of hygiene and cleanliness. The legislation permits the Secretary of State to make regulations providing for a licensing scheme consisting of two interlinked components: a practitioner licence and a premises licence:

- Regulations made under the provisions will ensure in respect of a practitioner license that those who offer certain non-surgical cosmetic procedures to the public are suitably trained and qualified, hold appropriate indemnity cover, and operate from premises which meet the necessary standards of hygiene and cleanliness.
- Regulations made under the provisions will ensure that a premises licence will be dependent on the premises being deemed a suitable environment for the procedures being performed, through demonstrating compliance with hygiene standards and infection control measures. Under the scheme, licensed practitioners must operate only from premises which are themselves licenced.

The licensing scheme includes provision for regulations to be made that impose penalties on those who fail to meet these standards and prevent them from operating. The licensing scheme will be administered and enforced by Local Authorities.

This is a fast-changing industry, and the provisions in the Act mean that the licensing scheme can be adapted as new treatments come to the market. This flexibility is essential to ensure that the licensing scheme can continue to apply to the highest risk procedures.

This legislation provides powers to make regulations to establish a licensing scheme for non-surgical cosmetic procedures. As such there is no direct cost or impact associated with the clauses in this Act. Consideration as to how the regulations are likely to be laid out and their potential impact through illustrative examples (see Annex A) is appropriate.

Another impact assessment, with a detailed assessment of costs, benefits and impacts including costs to businesses and small and micro business impacts will be conducted when the subsequent regulations are made, and stakeholders and the public have been consulted. We will also conduct an equalities impact assessment.

#### *How will the proposed licensing scheme operate?*

If this power is exercised and a licensing scheme set up, the licensing scheme will consist of two interlinked components: a practitioner licence and a premises licence. The subsequent regulations will set out the detail of the licensing scheme, as well as the standards that practitioners and premises will have to meet to be granted a license.

In addition, the powers provide for an offence to be created prohibiting an individual from carrying out non-surgical cosmetic treatments without a license. Any regulations made using the powers will be subject to public consultation (Section 180(4)) and to legislative scrutiny through the affirmative parliamentary procedure (Section 183(4)).

The definitions in section 180 cover those procedures considered to have the highest potential to cause harm, while also allowing flexibility for new procedures to be added in the future. This future proofing is essential for ensuring that the licensing scheme can continue to apply to the highest risk procedures. The definition of licensed procedures can be further narrowed through the regulations. However, our initial intention is that the following procedures will be licensed: Botulinum toxins, Dermal fillers, Laser, Intense

Pulsed Light (IPL) and Light Emitting Diode (LED), Chemical peels, PDO cog threads, and cryolipolysis.

We will finalise the list of procedures in the regulations after stakeholders and the public have been consulted. Once we have finalised the list of procedures in scope, we will also be able to carry out a more detailed impact assessment and provide a comprehensive assessment of costs and benefits. We will also conduct an equalities impact assessment.

### **Rationale for intervention**

All cosmetic procedures have some risks and can lead to serious injury or harm if not performed correctly. The provisions will provide regulations intended to replace the pre-existing regulatory framework around non-surgical cosmetic interventions which is a patchwork of different standards relating to either products, premises or practitioners, overseen by a range of regulatory agencies. The pre-existing regulatory framework places few restrictions on who may perform non-surgical cosmetic interventions. The provisions also provide powers to legislate for nationally recognised requirements or standards covering the education, training and qualifications required for the administration of these treatments. Prior to these provisions, we did not have the ability to legislate to provide assurance that the premises in which non-surgical cosmetic interventions are carried out meet hygiene standards, or that individuals carrying out procedures have appropriate indemnity and insurance arrangements in place.

There is growing evidence of the risk that non-surgical cosmetic procedures present to members of the public. There is, however, no central collection of data on complications following cosmetic interventions and hence no consistent or robust information on the type or frequency of complications. This presents a partial barrier to making informed policy decisions regarding the industry.

Recent reports and reviews on the cosmetic sector highlight how much there is for the Government to do to ensure that non-surgical cosmetic procedures do not present a public safety risk. These reports and reviews include:

- The Review of the Regulation of Cosmetic Interventions by Sir Bruce Keogh: [Review of the Regulation of Cosmetic Interventions - GOV.UK \(www.gov.uk\)](http://www.gov.uk) 2013.
  - The Keogh review covered both surgical and non-surgical cosmetic procedures. The review highlighted that non-surgical interventions are almost entirely unregulated.
  - The report found that cosmetic surgery providers rely, in part, on the NHS to treat clinical complications. There is limited data on the costs incurred by the NHS in dealing with the clinical problems caused by cosmetic procedures. However, data submitted to the Keogh Review by surgeons indicate that the costs of dealing with adverse reactions to dermal fillers for one individual resulted in costs of over £4,028 to the NHS.
  - The report found that complications following botulinum toxin injections, laser/IPL treatment, and dermal fillers were the most common issues upon which patients consulted their GP.
  - 57 plastic surgeons reported seeing 380 patients with complications of non-surgical treatments. Nearly two-thirds of the complications reported were irreversible.



- The review subsequently provided 40 recommendations to strengthen the regulatory framework around cosmetic procedures.
- The Chartered Institute of Environmental Health (CIEH) reports on regulating cosmetic treatments: [A Fragmented Picture](#) and [The Ugly Side of Beauty](#), 2020.
  - The CIEH reports highlight that whilst cosmetic treatments are rapidly growing in popularity, the existing regulatory regime is poorly equipped to keep the public safe.
  - The data used in these reports show that out of 934 reports in 2018, common complaints related to dermal fillers (66%) followed by 'Botox' or Botulinum Toxins (24%). Of these complaints, 41% resulted in corrective procedures and 4% in visits to GPs and A&E.
  - The reports also found the largest proportion of treatments that go wrong, are carried out in domestic settings.
  - The reports show significant support for legislative change among environmental health and licensing practitioners, with 90% (out of 258 professionals surveyed) agreeing that an England-wide licensing scheme could improve the regulatory system.
- The Beauty, Aesthetics and Wellbeing (BAW) All-Party Parliamentary Group (APPG) report: [APPG-BAW-Report-on-aesthetic-non-surgical-cosmetic-treatments-21.07.21-3.pdf \(baw-appg.com\)](#). 2021
  - In 2021 the Beauty, Aesthetics and Wellbeing (BAW) All-Party Parliamentary Group (APPG) completed its inquiry into advanced aesthetic non-surgical cosmetic treatments.
  - The report found that practitioners (both medics and non-medics) can perform treatments which they do not have enough training, knowledge or experience of, thus putting the public at risk.
  - The report provides illustrative examples from members of the public who have suffered complications from non-surgical cosmetic procedures, including; vascular occlusion (blockage of a blood vessel), and necrosis (death of tissue).
  - The subsequent APPG report set out 17 recommendations, including three relating to the introduction of a national licensing scheme for some non-surgical cosmetic procedures.

In response to patient safety concerns and the expansion of the cosmetic interventions market, there is increasing Parliamentary and stakeholder pressure to strengthen the regulatory framework

In light of the above, in 2021, Parliament passed [The Botulinum Toxin and Cosmetic Fillers \(Children\) Act](#) to prohibit the availability of 'Botox' and cosmetic fillers (commonly known as 'dermal fillers') to under 18s for cosmetic purposes.

The Health and Care Act 2022 provisions will further increase public safety and confidence by introducing regulations around who can carry out non-surgical cosmetic procedures, as well as where such procedures can be carried out. This will reduce the risk of harm to members of the public who choose to have a non-surgical cosmetic procedure.



## **Other policy options considered**

The Department has assessed a range of options at a high level. This is set out below and supports the amendment. This IA recommends the expansion of local authority oversight of non-surgical cosmetic procedures as the recommended response to the issues raised.

### **Option 1: Business as usual (do nothing)**

Non-surgical cosmetic procedures are not currently regulated. In recent years there has been increasing parliamentary and stakeholder pressure to strengthen the regulatory framework, citing poor practice in this area.

The risk to the public and to the NHS has been highlighted in the reviews and reports listed above.

The 'Do Nothing' option will mean the public remains at risk from serious complications if they choose to undergo a non-surgical procedure. This is a significant risk to public safety.

This option could also burden the NHS who in some cases have to treat complications from non-surgical cosmetic procedures if they arise.

### **Option 2: Voluntary register**

There are currently two Professional Standards Authority accredited registers in operation:

- [Save Face](#): operates a voluntary register for doctors, nurses and dentists who provide non-surgical cosmetic treatments. This register only covers regulated healthcare professionals.
- [Joint Council for Cosmetic Practitioners](#): operates a voluntary register open to all practitioners working in the fields of cosmetic treatments. Practitioners must demonstrate evidence of competence and proficiency to join the JCCP register.

Voluntary registers would not prevent risks to public safety. They are already in operation and the vast majority of practitioners continue to operate outside of them.

The Save Face accredited register is only open to practitioners who are also registered with a healthcare professional regulator. Pursuing this option would have significant implications for many current practitioners/businesses, as it would prevent anyone who was not a healthcare professional from registering.

A number of different voluntary registers, which have different requirements to join, is also inconsistent and difficult for the public to navigate.

### **Option 3: Registration scheme**

In England, under the Local Government Miscellaneous Provisions) Act 1982, local authorities already have powers to register providers of acupuncture, tattooing, ear and cosmetic piercing, electrolysis, skin colouring and sunbeds. These powers could be expanded to cover other cosmetic procedures or services. This would require providers to meet basic hygiene standards. Some local authorities have made byelaws to vary their local requirements but the content of these is restricted to securing the cleanliness of premises, fittings, persons, instruments, materials and equipment.

A registration scheme builds on a pre-existing regulatory framework and therefore could support the development of an evidence base to determine whether more robust regulation of cosmetic interventions is justifiable and proportionate.

A registration scheme does not allow Local Authorities to carry out robust checks on practitioners or on premises. Local authorities also have few powers to refuse registration or to place conditions on practitioners' competence and qualifications.

Stakeholders have also raised that it is difficult for Local Authorities to remove practitioners from the register once included, and that this presents a significant public safety risk.

#### **Option 4: Regulation of activity – make cosmetic procedures CQC regulated activities**

This would extend the CQC's remit to regulating providers of non-surgical cosmetic interventions, in addition to its existing responsibilities for surgery.

There is currently no option to register with the CQC to provide non-surgical cosmetic procedures, as they are not a CQC regulated activity. The CQC would, therefore, have to expand its remit to include non-surgical cosmetic procedures.

An estimated 15,200 businesses provide injectable cosmetic treatments in England alone. CQC enforcement would involve significant additional resources and increased costs to Government

It would also be logistically difficult and financially burdensome for mobile and small/self-employed businesses to register with the CQC. The fees for CQC registration are significantly higher than the current licensing fees (as modelled on the Nottingham and Croydon examples above).

The 2019/2020 annual fee for a health care single speciality services (i.e., a diagnostic imaging centre) to register with the CQC ranged from £1,743 for 1 location, through to £55,662 for more than 15 premises.

#### **Option 5: Statutory Professional Regulation**

Statutory regulation of practitioners carrying out cosmetic interventions would bring them in line with regulated health and care professionals, such as doctors, nurses, pharmacists and dentists.

This option would require Government funding to set up a new regulatory body. This would be a significant financial investment. It is currently difficult to gather a strong evidence base to indicate that this level of regulation is proportionate.

There is no pre-existing profession to regulate due to the diversity of practitioners who currently perform cosmetic procedures in England.

#### **Option 6: Licensing scheme**

The proposed licensing scheme will consist of two interlinked components: a practitioner licence and a premises licence.

Licences for both practitioners and for premises will be issued by Local Authorities who will work with a range of partners to operate and enforce the scheme. The enforcement of regulation will be at the discretion of each Local Authority. A licensing scheme builds on existing models for 'special treatments' as evidenced through the illustrative examples.

We will finalise the list of non-surgical cosmetic procedures in the regulations after stakeholders and the public have been consulted. However, as set out in the introduction, it is essential that the licensing scheme applies to the highest risk procedures and at present our intention is that the following procedures will be licensed: Botulinum toxins, Dermal fillers, Laser, Intense Pulsed Light (IPL) and Light Emitting Diode (LED), Chemical peels, PDO cog threads, and cryolipolysis

The introduction of a licensing scheme is supported by many key stakeholders. It has also been recommended in a number of recent reports and inquiries on the cosmetic sector. In 2020, a report published by the Chartered Institute of Environmental Health found 90% of the 258 professionals (Environmental Health Practitioners (EHPs) and Licensing Practitioners (LPs)) surveyed agreed that an England-wide licensing scheme could improve the regulatory system. The introduction of a licensing scheme was also a key recommendation of the 2021, Beauty, Aesthetics and Wellbeing (BAW) All-Party Parliamentary Group (APPG) report.

We would have to ensure the licensing scheme does not place unnecessary burden to business, particularly those who are currently self-employed or who run or who are employed by Small and Micro Enterprises (SME).

### **The Government's preferred option is to take forward a licensing scheme**

We will finalise the scope of the licensing regime following consultation with both stakeholders and the public. We will then carry out a more detailed impact assessment and provide a comprehensive assessment of costs and benefits.

### **Costs**

There are no impacts resulting directly from this primary legislation as it only seeks the power to make regulations to establish a licensing scheme.

If this power was exercised and a licensing scheme established, then we anticipate the following costs to be incurred:

- **Costs to practitioners/business (familiarisation costs, and ongoing costs of licenses, costs of training/qualifications)**
- **Costs to Local Authorities (on going costs of licensing, enforcement, and familiarisation)**
- **Cost to education and training bodies (familiarisation costs, on-going)**
- **Cost to criminal justice system (familiarisation, and ongoing costs)**
- **Costs to manufacturers/suppliers of cosmetic products (loss of profit)**

A detailed overview of potential impact and costs can be found at **Annex B**.

### **Benefits**

This legislation will support public safety by limiting the risk of injuries and complications from non-surgical cosmetic procedures. It will do this by introducing regulations around

who can carry out non-surgical cosmetic procedures, as well as regulating where such procedures can be carried out. This will reduce the risk of harm to members of the public who choose to undergo a non-surgical cosmetic procedure.

The reviews and reports listed above, along with substantial anecdotal evidence, suggests that the current model relies on the NHS being there to act as a safety net to treat clinical complications. In some cases, it may be that the private provider does not have the competence or equipment required to treat a specific condition. By making sure that practitioners carrying out non-surgical procedures are properly trained and qualified and have insurance if things do go wrong, the burden on the NHS will be reduced.

### **Risks and mitigations**

We need to ensure that regulation of non-surgical cosmetic procedures is consistent across England and that it is a mandatory requirement for all practitioners offering non-surgical cosmetic procedures.

The purpose of this legislation is to provide the power to create regulations. We will now work across government and with external stakeholders to develop the regulations and guidance.

This means the economic impact can only be comprehensively assessed once we are clear of the specific non-surgical procedures in scope, the costs to qualification bodies training business around setting up and implementing a national curriculum and have worked with local authorities to quantify the anticipated resources for licensing/enforcement.

We are aware there may be a risk of businesses closing, particularly SMEs as a result of the licensing scheme. This could also have an impact of the profit of cosmetic manufacturers/suppliers of cosmetic products. However, the purpose of this amendment is not to ban procedures, stifle innovation or close businesses down, but rather to ensure that consumers who choose to undergo a cosmetic procedure can be confident that the treatment they receive is safe and of a high standard.

To mitigate the risk to business, we will ensure that the regulations are proportionate to the risk that the procedures present to the public. We will work with local authorities and training bodies to ensure that the cost of qualifications and the cost of licensing fees are not prohibitively expensive for sole practitioners and/or SMEs.

There is a risk that practitioners may continue to operate outside of the licensing scheme. This presents a continued risk to patient safety. However, if practitioners operate outside of the licensing scheme, they will be committing an offence. The licensing scheme will provide members of the public with assurances, as they will be able to check if a practitioner is licensed before choosing to undergo a procedure. We are, therefore, of the view that the benefits of the licensing scheme outweigh the risks of the practitioners who may choose to operate outside of it.

## 7. Annex A: Licensing of non-surgical cosmetic procedures: Illustrative examples

### Existing licensing scheme for cosmetic treatments

A small number of Local Authorities in England have opted to introduce local licensing schemes for certain procedures. This includes:

- **Nottingham:** introduced separate practitioner and premises licence for the following procedures: cosmetic piercing; hair electrolysis; lasers; massage; saunas; steam rooms; tanning; sunbeds; semi-permanent make-up; tattooing.
- The fees and requirements vary for each procedure. However, as an example, the fees for cosmetic piercing are:
  - Practitioner: £67.00
  - Premises: £129.00
- Once the application form and fee are received, Nottingham Local Authority send an Environmental Health Officer to inspect the premises for suitability. More information can be found on the website: [Health and Beauty Licences - Nottingham City Council](#)
- **Croydon:** introduced a 'special treatments licence' for a number of treatments. This includes: Massage; acupuncture; manicure; piercing and tattooing; sauna and light; electric or vapour treatments.
- All premises offering special treatments must comply with the special treatments licence conditions. Practitioners also need to send a copy of relevant qualifications.
- The total cost for a new licence is £439, annual renewal cost is £383, transfer cost is £254, and variation cost is £260.
- The licence is valid for one calendar year.
- Members of some professional associations and organisations are exempt from special treatment licensing.
- More information can be found on the website: [Special treatments licence | Croydon Council](#)

### The Animal Welfare (Licensing of Activities Involving Animals) (England) Regulations

We anticipate the licensing scheme for nonsurgical cosmetic procedures will also be comparable to the Animal Welfare (Licensing of Activities Involving Animals) (England) Regulations 2018.

The Animal Welfare Regulations provide for the licensing of persons involved in England in selling animals as pets, providing or arranging for the provision of boarding for cats or dogs, hiring out horses, breeding dogs and keeping or training animals for exhibition.

The regulations provide for local authorities to be the licensing authorities; sets out how a person may apply to the local authority for a licence; and sets out the conditions an

individual must meet to be granted a licence or have their licence renewed. It provides for a local authority to charge fees to cover costs related to compliance with the regulations, enforcement, and administration.

A person who undertakes licensed activities involving animals in England without a licence commits an offence.

## 8. Annex B: Initial assessment of impact and costs for a cosmetic licensing scheme

### Key impacts

There are no impacts resulting directly from this primary legislation as it only seeks the power to make regulations to establish a licensing scheme.

If this power was exercised and a licensing scheme established requirements would be placed on Local Authorities to ensure that businesses and practitioners met the required standards.

### Costs

The costs of licensing will fall on individual practitioners; public sector (e.g. local authorities, courts); and private businesses who provide or supply non cosmetics services.

This next section provides a narrative of the types of cost that the regulations will incur, this includes transitional, set up, familiarisation and ongoing costs and how they impact upon practitioners/business; Local Authorities; education and training bodies; and the Criminal Justice System.

### ***Costs to practitioners/business (familiarisation costs, and on going costs of licenses, one off costs training/qualifications)***

There would be a national agreed fee set out in regulations for both practitioner and premises licenses, and licenses would be renewed on a yearly basis. Practitioners would also be required to have indemnity insurance in place, which would be an additional annual cost

The cost of the license may have a financial impact on small and micro business owners, that represent around 97% of all businesses in the market in scope.<sup>36</sup>

At present, there are also no regulations around mobile practitioners and the proposed licensing scheme will also prevent mobile practitioners from operating. This impact is justified for public safety reasons.

### Impacts of policy on businesses

Reliable information about the number of businesses and/or practitioners who offer non-surgical cosmetic procedures in England is difficult to determine. This is because the industry operates through a complex variety of businesses involving manufacturers of products, private hospitals and clinics, hotels and spas, beauty salons and self-employed practitioners. Practitioners range from regulated healthcare professionals such as doctors, dentists and nurses through to individuals who have no medical qualifications.

The Nuffield Council of Bioethics report “Cosmetic procedures: ethical issues” concluded that most cosmetic procedures are provided within the private health sector and that business models through which procedures are offered vary<sup>37</sup>. These include:

- **self-employed health professionals** who provide cosmetic procedures to private patients on an individual basis, often as a complement to their work in the NHS
- **private hospitals and clinics** that offer cosmetic procedures alongside a range of other procedures.
- **large commercial ‘group’ providers** who specialise in cosmetic procedures rather than offering these alongside medical services
- **beauty salons, spas, gyms and other parts of the beauty and ‘wellness’ sector** – providers in this sector are thought to be a significant supplier of non-surgical cosmetic interventions, and they vary from single practitioners in stand-alone beauty parlours to chains of salons; practitioners may be self-employed or employed and may come from a variety of professional backgrounds.

Discussions with stakeholders, including the Joint Council for Cosmetic Practitioners (JCCP), emphasised that this is a challenging industry to capture and describe. Additionally, it was noted that many practitioners are mobile rather than being based in one salon or clinic, and that self-employed practitioners typically provide services to multiple businesses where they are not directly employed. Nevertheless, we have estimated the number of businesses and practitioners we expect to be in scope of this policy using a similar methodology to the modelling used for the Botox and Fillers Act.

We estimate that around **16,100** businesses will be in scope of the policy (as they are involved in non-surgical cosmetic procedures), which consists of **11,500 unregistered** sole traders, 1,300 registered sole traders and **3,300** employers. This corresponds to around **25,300** practitioners in total. “Registered” in this case refers to businesses that are registered for VAT or PAYE.

These figures were estimated using the latest BPE and BRES data as follows. The number of businesses was determined by the latest BIS Business Population Estimates (BPE) publication.<sup>38</sup> In particular, the industries with the following SIC codes were analysed:

- **86** Human health activities
- **96** Other personal service activities

LaingBuisson data (2018) suggests that the non-surgical cosmetic market is worth £2.75bn in the UK. The total turnover of these industries (i.e., industries with SIC codes 86 and 96) amounts to £66.5bn, which was also provided in the BPE publication. When adjusting both these figures to England only (using the proportion of the population of England relative to the UK as a proxy), these figures are around £2.3bn and £56.1bn respectively. This suggests that **4.1%** of the wider turnover in these industries can be attributed to the non-surgical cosmetic market. This was used as a proxy to determine the number of businesses (including sole traders and employers) in the non-surgical cosmetic market in England as all these figures are provided in the wider industries in the BPE publication.

The number of practitioners was determined using the Business Register and Employment Survey (BRES) data.<sup>39</sup> Reviewing the report on UK Standard Industrial Classification of



Economic Activities<sup>40</sup> and conducting a search on Companies House identified that known providers of cosmetic procedures were recorded under the following Standard Industrial Classification (SIC) codes:

- **8622** Specialist medical practice activities
- **8690** Other human health activities
- **9602** Hairdressing and other beauty treatment
- **9609** Other personal service activities N.E.C.

The total number of those employed under these SIC codes can be determined using the BRES data. The 4.1% (i.e., estimated proportion of non-surgical cosmetic market relative to wider industries) was again used as a proxy to determine the number of practitioners expected to be in scope of the policy.

### Impact on small and micro businesses

The preferred option is likely to impact businesses providing non-surgical cosmetic procedures and practitioners who carry out non-surgical cosmetic interventions. The majority of these are likely to be small and micro businesses.

The BIS Business Population Estimates (BPE) publication provides the most comprehensive source on the number of businesses in the UK since it combines information on registered businesses (i.e., those registered for VAT and/or PAYE) with an estimate of the number of unregistered businesses in the UK<sup>41</sup>. It also breaks down the number of businesses by employment size.

Similar to the process of estimating the total number of businesses in scope, the industries with SIC codes **86** (human health activities) and **96** (other personal service activities) were analysed.

	Businesses by Employment Size Band – England			
	Micro (0 to 9)	Small (10 to 49)	Medium-sized (50 to 249)	Large (250+)
<b>86 Human health activities</b>	94.9%	4.6%	0.5%	0.1%
<b>96 Other personal service activities</b>	98.1%	1.8%	0.1%	0.0%
<b>Average</b>	<b>96.7%</b>	<b>3.0%</b>	<b>0.3%</b>	<b>0.0%</b>

Using the estimated number of businesses calculated earlier (16,100) and applying the average proportion of micro and small businesses calculated above, the estimated number of businesses in these categories can be estimated. This results in approximately 15,600 micro and 490 small businesses

Given almost 100% of businesses are small and micro it is therefore unlikely that the policy objectives will be met if they are exempt. However transitional arrangements will be considered as part of the policy development and consultation which may help mitigate the disproportionate impacts of this policy on small and micro businesses.

### ***Costs to Local Authorities (on going costs of licensing, enforcement, and familiarisation)***

Licences for practitioners and for premises will be issued by local authorities who will work with a range of partners to operate and enforce the scheme. These will include enforcement partners including Environmental Health Officers, Trading Standards Officers and the Health and Safety Executive.

The enforcement of regulation will be at the discretion of each Local Authority. In England, the structure of local authorities varies between:

- ***Two-tier authorities:*** where the responsibility for services is split between county and district councils; and,
- ***Unitary authorities:*** where the responsibility for all services in the area fall to one council body.

In two-tier councils, Environmental Health operate in this space at district council level whilst Trading Standards operate at county council level; some two-tier councils may decide it is most appropriate to enforce through Trading Standards, others may feel it is the responsibility of Environmental Health. Unitary authorities will likely operate through Trading Standards.

We do not know which enforcement route will be preferred by local area. Costs estimated may differ depending on how local authorities decide to license and enforce the scheme.

All local authorities will, however, need to appoint appropriate authorised officers to carry out duties to secure compliance. Existing officers who are experienced in carrying out enforcement duties in relation to businesses, such as environmental health officers and Trading Standards Officers, could potentially carry out this work and could incorporate this work into their other inspection activities. However, some local authorities will most likely need to recruit additional officers.

We anticipate that the scheme will, therefore, require funding and resources for Local Authorities. Our assumption is that the licensing regime will eventually be self-funded but there will be initial start-up costs to support training and familiarisation.

### ***Cost to education and training bodies (familiarisation costs, on-going)***

We will need to work with stakeholders to develop a clear framework and standard curriculum to cover the material that professionals providing non-surgical cosmetic procedures must know.

The Joint Council of Cosmetic Practitioners (JCCP) has already developed a competency framework covering high risk non-surgical cosmetic procedures. The JCCP has advised that all treatments at level 6 and 7 in the JCCP/CPSA Competency Framework should be subject to a system of licensing.

The power conferred through the amendment provides flexibility when developing the regulations and the training and education required. This means that new procedures can be added to the regulations, as and when they are developed. This flexibility does, however, have an impact as education bodies will have to develop new education and training courses to cover new procedures.

Stakeholder engagement suggests that the following training bodies are currently operating:

- Four universities: UCL; Queen Mary University of London; Manchester; and University of South Wales USW– (USW university provides a UK distance learning programme which has been approved by JCCP) The University of Salford are also in the process of developing a programme.
- FE Colleges: There are approximately 60 colleges providing programmes in England. Most of these programmes focus on procedures out of scope of the proposed licensing scheme. However, certain colleges, such as Birmingham University College, is developing a programme that would link to further education and provide training for procedures covered by the licensing scheme.
- Private training companies: There are over 1000 companies operating on the High Street for lower-level beauty treatments. Of these approximately 250 provide training for procedures that would be in scope of the licensing scheme.
- Ofqual approved qualifications: There are a range of Ofqual approved qualifications that are delivered by recognised Ofqual awarding Bodies, such as VTCT, OTHM, Qualifi, CIBTAC. The awarding bodies then approve private training companies to deliver the approved qualifications. These include organisations such as Cosmetic Courses and the Harley Academy.

Education and training costs will therefore impact on:

- Organisations developing the curriculum
- Businesses providing the training
- Practitioners who will have to pay for the training courses/qualification.

***Cost to criminal justice system (familiarisation, and on going costs)***

The regulations may create offences related to: (i) a breach of the prohibition in the clause (ii) a breach of conditions related to the personal licence or the premises licence, and (iii) the provision of false or misleading information to a local authority in connection with these licences. Such an offence would be punishable on summary conviction with a fine.

***Costs to manufacturers/suppliers of cosmetic products (loss of profit)***

The licensing scheme may prevent businesses (particularly SMEs) from operating. This may have a marginal impact on the volume of product sales by cosmetic manufacturers/suppliers in the UK and therefore on their profit levels. As the licensing scheme would cover a variety of non-surgical cosmetic procedures, the impact would be spread across multiple manufacturers. Profit margins in the pharmaceutical industry are commercially sensitive and it is a highly competitive market. As we will not know which non-surgical cosmetic procedures will be licensed until after consultation with stakeholders and the public, it is challenging to estimate the potential monetised losses that manufacturers and suppliers will face as a result of the policy.

However, given the growth of the non-surgical cosmetic sector, any reduction in sales due to the licensing scheme is likely to be overridden if the industry continues to grow at the projected rate.

## 9. Glossary

CHM	Commission on Human Medicines
EANDCB	Equivalent Annual Net Direct Cost to Business
IMMDSR	Independent Medicines and Medical Devices Safety Review
LA	Local Authority
MAH	Marketing Authorisation Holders
MHRA	Medicines and Healthcare products Regulatory Agency
NHSEI	NHS England and NHS Improvement
SaMBA	Small and Micro Business Assessment

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