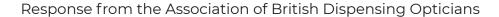
deciding when statutory regulation is appropriate





1. Do you agree or disagree that a qualitative and quantitative analysis of the risk of harm to patients is the most important factor to consider when deciding whether to regulate a health or care profession?

Agree	Disagree	I don't know	
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Please provide reasons for your answer.

The Association of British Dispensing Opticians (ABDO) is the professional body for dispensing opticians in the UK. Dispensing opticians are healthcare professionals registered by the General Optical Council.

Dispensing opticians advise on, fit and supply the spectacle frames and lenses most appropriate for each patient's visual, lifestyle and vocational needs. They also provide clinical advice and guidance on common eyecare conditions, including acute conditions, such as dry eye, and identify and refer those which require emergency care. Dispensing opticians work in community optical practices and other settings, including hospitals, as well as providing domiciliary care.

After gaining a further qualification, dispensing opticians can register as contact lens opticians. This enables them to fit patients with contact lenses and provide follow-up care. Contact lens opticians can also become accredited to provide minor eye conditions services (MECS), which involves dealing with acute issues that might otherwise require patients to visit their GP or accident and emergency department.

ABDO agrees that the purpose of the regulation of health and social care professions is to protect the public from the risk of harm from the provision of health and social care services. We also endorse the Government's view that at the heart of any decision to regulate a profession is ensuring that statutory regulation provides the most effective and proportionate means of delivering this public protection function.

We agree with the broad principle that a qualitative and quantitative analysis of the risk of harm to patients is the most important factor to consider when deciding whether to regulate a health or care profession. However, we encourage the Government to provide further guidance on the range of factors that will be considered as part of this risk analysis.

In our view, the following five factors should be considered in deciding whether to regulate a profession:

- · Risk of harm to patients
- · Risk of harm to the wider public
- · Expected developments in the roles of the relevant health or care professionals
- · Wider regulatory framework in which the relevant professionals work
- · Citizen and wider stakeholder perspective

This list of factors is informed by the National Audit Office (NAO) report Good practice quidance: principles of effective regulation (May 2021).

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Looking at each of our proposed factors in turn:

1. RISK OF HARM TO PATIENTS

We agree that it is necessary to consider the risk of harm to patients and as recommended by the Professional Standards Authority (PSA) in its report Right Touch Regulation, this analysis should involve a qualitative and quantitative element.

We also agree that the assessment of risk should involve both:

- · risk quantification seeks to gauge the likelihood of harm occurring and its severity
- · while risk qualification considers the nature of the harm and understanding how and why it occurs

However, it is important to recognise that there may be limits to this approach.

First, the aforementioned NAO report emphasises the importance of collecting and analysing 'high-quality relevant data' and having a clear and documented data strategy that identifies any gaps and weaknesses in the available data and barriers to addressing them and sets a plan to overcome these issues. In practice, there will often be a dearth of high-quality relevant data. This could make an effective risk analysis difficult to carry out, particularly as an absence of evidence does not equate to an absence of risk.

Secondly, focusing primarily on evidence of the risk of patient harm encourages a backward-looking analysis, whereas it is a feature of health and care professions that roles are evolving to meet patient demand. As well as looking at evidence of the current risk, therefore, it is necessary to take account of expected developments in roles and the likely impact on risk.

Thirdly, risk of harm to the public tends to be equated with risk of harm to patients. For example, the consultation document refers to gauging 'the level of impact the harm would have on an individual'. However, the wider public can also be at risk of harm in relation to the services provided by health and care professionals.

For all these reasons, it is important to also look at the following factors in carrying out the risk analysis.

2. RISK OF HARM TO THE WIDER PUBLIC

It is important to understand and analyse the risk of harm to the wider public, as well as to patients. In the optical sector, for example, a failure to correctly assess and correct the vision of a patient who is a bus driver could create a risk of harm to passengers, pedestrians, motorists and other road users, as well as to the driver.

3. EXPECTED DEVELOPMENTS IN THE ROLES OF THE RELEVANT PROFESSIONALS

It is necessary to carry out a forward-looking analysis of how the roles of health and care professionals will evolve to meet the needs of patients in future and maintain high standards of care. This analysis will need to consider both changes in service design and commissioning and changes in technology.

In the light of the commitment from the government and the devolved administrations to ensuring that the regulation of healthcare professionals continues to be delivered on a UK-wide basis, it will be important to look across the four nations given the differences in service delivery. For example, optometrists in Scotland are already identifying, monitoring and managing more high-risk pathology in the community, NHS England's Eyecare Recovery and Transformation Programme will see dispensing opticians and optometrists taking on further extended clinical roles to relieve the strain on hospitals and reduce avoidable sight loss and planned reforms in Wales will also see optometrists and dispensing opticians providing extended patient care in the community to alleviate pressures in hospitals.

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4. WIDER REGULATORY FRAMEWORK

Registration with a professional regulator gives assurance that an individual is fit to practise and has the necessary knowledge, skills and experience to practise in the relevant profession. This, together with the legal protection of titles, gives the public confidence that they will receive high quality care.

It is also important, however, to examine the wider regulatory framework within which health or care professionals work. This is relevant in the following ways.

First, as the consultation document makes clear, professional regulation is only part of the overall system of regulation which protect the public and it is also necessary to consider the systems within which health and care professionals work and how those systems are regulated. For example, while regulated practices businesses are required to meet the business standards set by the General Optical Council (GOC), they are not inspected by the GOC or the Care Quality Commission, although they are subject to NHS inspections.

Secondly, it is necessary to examine how the functions which health or care professionals carry out are regulated. Some of the functions which are carried out in an optical practice are regulated. For example, only a registered optometrist can carry out an eye examination and only a registered optometrist or dispensing optician can dispense or supervise the dispensing of spectacles to children or visually-impaired adults. However, some functions, such as dispensing spectacles to non-visually impaired adults, are not regulated. This mix of regulated and unregulated functions is workable only if the professionals who carry out the regulated functions are themselves regulated.

5. CITIZEN AND WIDER STAKEHOLDER PERSPECTIVE

Any system of regulation is effective only if it commands the confidence of the public, professionals and wider stakeholders.

This is recognised by the NAO in its aforementioned report: 'We have found from our work that developing a meaningful understanding of citizen perspectives and behaviours is important to ensuring that regulation works in practice.'

The report also emphasises the importance of policy makers considering, 'how to ensure the voice of citizens can be heard and considered fairly alongside other perspectives, including those most affected by the regulated area.'

Therefore, the Government should actively seek, and be informed by, the views of patients, the public and wider stakeholders before deciding whether a profession should be regulated.

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Do you agree or disagree that proportionality, targeted regulation and consistency should also be considered in deciding whether to regulate a health or care profession?

Agree		Disagree		I don't know	
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Please provide reasons for your answer.

ABDO agrees that proportionality, consistency and the need for regulation to be targeted are important principles of effective regulation. We would add that the other principles of effective regulation – accountability and transparency – are equally important.

However, these principles are more useful and relevant when analysing a range of different ways of achieving a regulatory objective. In such a scenario, options can be scored by reference to, for example, how proportionate or targeted they are.

Where the decision in question is whether to regulate a particular health or care profession, it is not clear how helpful these principles will be on their own. We suggest that a more fruitful approach would be to examine the factors we have set out above, namely:

- · Risk of harm to patients
- · Risk of harm to the wider public
- \cdot Expected developments in the roles of the relevant health or care professionals
- · Wider regulatory framework in which the relevant professionals work
- · Citizen and wider stakeholder perspective

Do you agree or disagree that the currently regulated professions continue to satisfy the criteria for regulation and should remain subject to statutory regulation?

Agree	Disagree	I don't know	

Please provide reasons for your answer. If you disagree, please provide any evidence in relation to the criteria outlined above that supports a proposal to remove a currently regulated profession from statutory regulation.

ABDO agrees with the UK Government and devolved administrations that the current make-up of regulated and unregulated professions strikes the right balance in addressing the risks posed by health and care professionals without imposing unwarranted burdens, subject to bringing physicians associates and anaesthesia associates into statutory regulation in line with current plans.

The current regulatory system, including the professions which are regulated, has been decided and tested over the years, including through full debates in Parliament. We welcome the Government's programme of regulatory reform, which will enable to carry out their functions in a more flexible and consistent way. However, in our view, further overhaul of the system is not needed to enhance public protection.

We also agree, therefore, and welcome the clear statement that the four administrations do not, "intend to remove any professions that are currently subject to statutory regulation."

This will help to ensure that health and care professionals can continue to focus on addressing the health and care needs of the UK population, including the backlog of care created by the pandemic.

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Do you agree or disagree that currently unregulated professions should remain unregulated and not subject to statutory regulation?

Agree	Disagree	I don't know	
Agree	Disagree	1 doll t Kilow	

Please provide reasons for your answer. If you disagree, please provide any evidence in relation to the criteria outlined above that supports a proposal to include a currently unregulated profession within statutory regulation.

Our knowledge of health and care professions beyond the optical sector is limited and we can understand that some professions might wish to put forward a case for statutory regulation. We suggest that any such case should be considered with reference to the revised criteria we have set out above, namely:

- · Risk of harm to patients
- \cdot Risk of harm to the wider public
- \cdot Expected developments in the roles of the relevant health or care professionals
- · Wider regulatory framework in which the relevant professionals work
- · Citizen and wider stakeholder perspective