

HTA Board meeting, 5 December 2024

Agenda item	4.1 Code Review
For information or decision?	For information
Decision making to date?	N/A
Recommendation	The Board notes that the Executive is exploring how it may conduct an initial review of the HTA's Codes of Practice in 2025/26 to inform a future framework for maintaining the codes.
Which strategic risks are relevant?	Risk 1: Regulation Risk 2: Sector
Strategic objective	Approach to regulation; Trust & confidence
Core operations / Change activity	Change activity (2025/26)
Business Plan item	Policy and Development – implementing and overseeing changes to regulatory tools to ensure the HTA fulfils its duty to provide practical guidance about licensed activities to licensed establishments.
Committee oversight?	Board only
Finance and resource implications	To be identified in the 2025/26 Business Plan.
Timescales	To be confirmed, potentially starting in 2025/26 business year
Communication(s) (internal/external stakeholders)	The review of any Code of Practice will require significant coordinated internal and external engagement.
Identified legislative implications	The review will be in line with existing legislation.

Code Review

Purpose

1. To inform the Board of the Executive's proposal to undertake an initial review of the Codes of Practice in the 2025-26 business year.

Action

2. The Board is asked to **note** the Executive's proposal to explore how it may develop a process to keep the codes under review, as required by s26(4)(a) of the Human Tissue Act (2004) (the Act).

Overview

3. One of the ways we help licensed establishments comply with the Act is by publishing Codes of Practice.
4. The Authority, under section 26 of the Act has the power to prepare and issue codes of practice for the purpose of:
 - a. giving practical guidance to persons carrying on activities within its remit, and
 - b. laying down the standards expected in relation to the carrying-on of such activities.
5. Section 15 of the Act (General Functions) also gives the Authority the general functions of:
 - (a) maintaining a statement of the general principles which it considers should be followed –
 - (i) in the carrying-on of activities within its remit, and
 - (ii) in the carrying-out of its functions in relation to such activities.
 - (b) providing in relation to activities within its remit such general oversight and guidance as it considers appropriate.
6. The HTA developed guiding principles that are set out in Code of Practice A (Consent and Guiding Principles), namely: consent, dignity, quality, and honesty and openness.
7. Section 26 of the Act ('Preparation of codes') provides that the HTA may prepare and issue codes of practice giving guidance and setting standards in

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relation to activities within its remit, with subsections (2) and (3) listing the matters which must be dealt with in the codes of practice prepared by the HTA.¹

8. Section 29 of the Act ('Approval of codes') provides that draft codes of practice dealing with matters that are subject to a licence requirement must be approved by the Secretary of State and laid before Parliament by him. The code may not be issued by the HTA until it has been before Parliament for 40 days with no resolution not to approve it having been made by either House.²
9. While several of the Codes of Practice have been updated in recent years to reflect legislative changes relating to deemed consent and other minor updates, the Codes of Practice have not been substantially updated since 2017.
10. Some revisions have been made to the guidance to the standards (for example, for certain standards in the Post Mortem and Anatomy sectors).
11. Given the length of time that has passed since the Codes of Practice were last systematically reviewed, the Executive considers it necessary to embark on a programme of work that seeks to review and update as necessary the Codes of Practice and embed into core activity a process for maintaining them.

Process of reviewing and updating the Codes

12. The process for revising the Codes of Practice is a multi-stage process that can be summarised as follows:
 - a. **Identifying potential changes:** This involves bringing together known changes (for example, due to legislative changes, projects or core business) and engaging with internal and external stakeholders to identify other potential changes to the Codes of Practice.
 - b. **Prioritising potential changes:** This involves considering the list of potential changes to determine which should be explored and consulted on for potential inclusion in a revised Code of Practice.
 - c. **Drafting proposed changes:** This involves exploring the proposed changes and developing or amending guidance for those changes.
 - d. **Engaging on proposed changes:** This involves testing the proposed

¹ Section 26, Human Tissue Act (2004); Available at: <https://www.legislation.gov.uk/ukpga/2004/30/section/26> [Link accessed 20 November 2024]

² Section 29, Human Tissue Act (2004); Available at: < <https://www.legislation.gov.uk/ukpga/2004/30/section/29>> [Link accessed 20 November 2024]

changes with relevant stakeholders to ensure they are fit for purpose and practicable. (Note, there is an obligation to consult, including with the relevant Welsh Ministers and Northern Ireland department for codes relating to Wales or Northern Ireland.³)

- e. **Refining proposed changes:** This involves amending the proposed changes as necessary based on the feedback received.
- f. **Preparing the draft codes:** This involves preparing new documents, including formatting the draft revised Codes of Practice and completing accessibility checks.
- g. **Seeking Board approval:** This involves seeking Board approval on the proposed changes. (Note: this is likely to happen at stages throughout the process but final approval is required from the Board as it is the Authority that has the power to produce Codes of Practice.) The Authority may not issue a Code of Practice unless a draft of it has been sent and approved by the Secretary of State as outlined in *sub paragraph h*.
- h. **Approval of the Codes:** For Codes of Practice relating to matters mentioned under section 26 (a to c and e to j of subsection 2) the process for approval requires the Secretary of State for Health & Social Care to have been sent and approved a draft and then to have laid the draft before both Houses of Parliament, and a 40-day period must have elapsed without either House resolving not to approve the draft. There are similar (although not identical) provisions concerning Codes relating to Wales and Northern Ireland (s29(2) - (5)). The approval process involves extensive engagement with DHSC and the Devolved Administrations in Wales and Northern Ireland.⁴
- i. **Publishing the updated Codes of Practice:** The Authority has the power to publish a code of practice 'in such a way as, in its opinion, is likely to bring it to the attention of those interested' (s26(6) the Act.⁵ The HTA has previously published a draft (watermarked) version of the revised code several months before the date the revised Code comes into force, to allow those affected sufficient time to prepare for any new requirements. Thereafter it involves publishing a clean version of the Codes of Practice.
- j. **Coming into force:** Section 26(7) provides that 'A code of practice issued under this section shall come into effect on such day as may be appointed by directions.'⁶ Therefore, a final but significant piece of work that is required is the development and publication of directions.

³ Section 26(5) Human Tissue Act (2004); Available at: <<https://www.legislation.gov.uk/ukpga/2004/30/section/26>> [Link accessed 20 November 2024.]

⁴ Section 29 Human Tissue Act (2004); Available at: <<https://www.legislation.gov.uk/ukpga/2004/30/section/29>> [Link accessed 20 November 2024.]

⁵ Section 26(6) Human Tissue Act (2004); Available at: <<https://www.legislation.gov.uk/ukpga/2004/30/section/26>> [Link accessed 20 November 2024.]

⁶ Section 26(7) Human Tissue Act (2004); Available at: <<https://www.legislation.gov.uk/ukpga/2004/30/section/26>> [Link accessed 20 November 2024.]

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13. Legal review and advice will be required throughout the revision process by the HTA, DHSC and potentially the Devolved Administrations to support the development of a draft code.
14. Given the number of steps, stakeholders, sectors and Codes of Practice involved, undertaking a fundamental review and update of all the Codes of Practice is expected to span a number of years.
15. It is envisaged that work to review or programme updates could commence in the 2025/26 business year, subject to the business planning and prioritisation process.

Current status

16. Through the business planning process, the Executive will consider the scale and scope of any future revisions to the Codes of Practice.
17. There are a number of different options and approaches that may inform how the work to review and update the Codes of Practice is taken forward over future years:
 - a. a **fundamental review** that could consider revisions to all the Codes of Practice, as well as their format, useability, and essential ancillary material, such as, the guidance to the Codes of Practice;
 - b. a **large-scale review** that could consider revisions to specific Codes of Practice or specific thematic elements that cut across more than one Code;
 - c. a **mid-scale review** that could consider revisions to just one or two closely related Codes of Practice or just one narrow theme present in one or two Codes of Practice; or
 - d. a **prioritised review** against specific standards in one or two closely related and mirrored Codes of Practice, such as Code B Post Mortem and Code C Anatomy, given our ongoing work to enhance the dignity of the deceased.
18. Much of the activity in 2025/26 would involve identifying (step a) and prioritising (step b) potential changes. This may take place, for example, through a desk-based review of the existing Codes of Practice, workshops with internal stakeholders, and engagement with external stakeholders (through a professional and / or public consultation). A confirmed list of proposed changes would need to be agreed before the actual process of revision can commence.

Recommendation

19. The Board is asked to **note** the paper and the Executive's intention to commence activity to develop a process for identifying and prioritising reviews of the Codes of Practice over the next business year and beyond.

Next steps

20. Over the remainder of this business year and into 2025/26, the Executive will explore the scale of changes that might be made to the Codes of Practice and agree a prioritised approach to managing those having regard to the 2025-26 and subsequent business plans.