



Department
of Health &
Social Care



Ministry
of Justice

TERMINALLY ILL ADULTS (END OF LIFE) BILL

Memorandum from the Department of Health and Social Care and Ministry of Justice to the Delegated Powers and Regulatory Reform Committee

A. INTRODUCTION

1. This memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee to assist with its scrutiny of the Terminally Ill Adults (End of Life) Bill (“the Bill”). The Bill was introduced in the House of Commons on 16 October 2024 and transferred to the House of Lords on 23 June 2025.
2. This memorandum identifies the provisions of the Bill that confer powers to make delegated legislation. It explains in each case why the power has been taken, as well as the nature, and consideration thus far, of the procedure selected. The Government is neutral on the substantive policy questions relevant to how the law in this area could change and on the principle of assisted dying. As such, the Government has not provided a justification for the powers or parliamentary procedure being applied but has instead provided consideration of matters which may affect whether Parliament considers these are appropriate.

B. PURPOSE AND EFFECT OF THE BILL

3. The Bill makes provision for adults who are terminally ill, subject to safeguards and protections, to request and lawfully be provided with assistance to end their own life. The Bill also makes clear that where a person provides assistance to a person to end their own life in accordance with the Bill; performs any other function under and in accordance with the Bill; or assists a person seeking to end their own life in accordance with the Bill and in connection with the doing of anything under the Bill, they do not commit a criminal offence, including the offence of encouraging or assisting suicide under section 2 of the Suicide Act 1961. The Bill also creates a defence to the offence under section 2 of that Act, where a person performing a function (for example) reasonably believed they were acting in accordance with the Bill and took all reasonable precautions and exercised all due diligence to avoid the commission of the offence. The Bill will come into effect either four years after Royal Assent or at an earlier date appointed by the Secretary of State via regulations in England, with provisions conferring regulation making powers on the Welsh Ministers coming into force at a date appointed by the Welsh Ministers, via regulations. The Bill is in 59 clauses and has 3 schedules.

4. The purpose of the Bill, as described by the Kim Leadbeater MP, as Sponsor of the Bill during its passage through the House of Commons, in their Explanatory Notes and at Second Reading, is:
 - to give those who are already dying a choice over the manner of their death;
 - for the choice of assisted dying to be part of a holistic approach to end-of-life care, rather than a substitute for palliative care;
 - to create a robust legal framework for assisted dying to happen in a manner that is subject to strict eligibility criteria and multiple layers of checks and safeguards;
 - to protect individuals from fear of and actual criminalisation where they assist another person to end their own life, in accordance with the provisions of the Bill.
5. The provisions of the Bill set out:
 - The eligibility criteria that need to be met for a person to be provided with lawful assistance to voluntarily end their own life.
 - The approval process for receiving assistance and various safeguards, including an assessment by a registered medical practitioner, “the coordinating doctor”, a separate assessment by another registered medical practitioner, “the independent doctor”, and an assessment by a multidisciplinary “panel” comprised of a legal member, psychiatrist, and social worker. At each stage, the assessing doctor or panel must confirm that the person satisfies the eligibility criteria, has a clear, settled, and informed wish to end their own life, and has not been coerced or pressured by any other person into doing so.
 - The requirements that the registered medical practitioners acting as the coordinating doctor, independent doctor, or otherwise involved in the process, are required to meet, including specific training, qualifications, and experience that will be set out in regulations.
 - The process to be taken once the person has made the decision to self-administer the approved substance and the final act of doing so.
 - The documentation that will be required at each stage of the process.
 - The Secretary of State’s duty to make provisions securing that arrangements are made for the provision of Voluntary Assisted Dying (VAD) services in England. The Welsh Ministers will have a power to make provisions about VAD services in Wales.
 - The Secretary of State’s power to specify one or more drugs or substances for the purposes of the Bill, and duty to make provision about the supply, administration, transporting, storage, handling or disposal of the drugs or substances.
 - The Secretary of State’s power to issue codes of practice and guidance relating to the operation of the Bill.

- The circumstances in which it is not a criminal offence to assist a person to end their own life, as well as protections for health professionals and others involved in the process.
- Nine new criminal offences to target various behaviours that undermine or abuse the legal assisted dying process, in order to provide safeguards for those seeking an assisted death.
- The scrutiny process to be carried out following an assisted death, and the wording to be used to record the cause of death for the purposes of death certification.

C. **DELEGATED POWERS**

6. The draft Bill contains 42 delegated powers. There are 38 regulation making powers, of which 7 also enable the amendment of primary legislation (sometimes known as Henry VIII powers), in clauses 37, 41, 42 and 43. A list of the delegated powers is set out below.

- i. Clause 8: Initial request for assistance: first declaration – 2 regulation making powers under clause 8(2)(a) and clause 8(7).
- ii. Clause 9: Witnessing first declaration: requirements – regulation making power under clause 9(3).
- iii. Clause 10: First doctor's assessment (coordinating doctor) – 2 regulation making powers under clause 10(3)(b)(iii) and 10(4).
- iv. Clause 11: Second doctor's assessment (independent doctor) – 3 regulation making powers under clause 11(5)(b)(iv), 11(6) and 11(9).
- v. Clause 14: Replacing the coordinating doctor on death etc – regulation making power under clause 14(1).
- vi. Clause 15: Replacing the coordinating or independent doctor where unable or unwilling to continue to act – regulation making power under clause 15(4).
- vii. Clause 17: Determination by panel of eligibility for assistance – regulation making power under clause 17(8)(d).
- viii. Clause 18: Reconsideration of panel decisions refusing certificate of eligibility – regulation making power under clause 18(6)(c).
- ix. Clause 19: Confirmation of request for assistance: second declaration – 2 regulation making powers under clause 19(3)(a) and 19(7)(a).
- x. Clause 21: Signing by proxy – regulation making power under clause 21(5)(b).
- xi. Clause 22: Independent advocate – 2 regulation making powers under clause 22(1) and 22(4)(c).
- xii. Clause 26: Authorising another doctor to provide assistance – regulation making power under clause 26(2)(b).
- xiii. Clause 27: Meaning of "approved substance" – regulation making power under clause 27(1).
- xiv. Clause 28: Final Statement – regulation making power under clause 28(3)(a).

- xv. Clause 29: Report where assistance not provided because coordinating doctor not satisfied of all relevant matters – regulation making power under clause 29(3).
- xvi. Clause 37: Regulation of approved substances and devices for self-administration – 2 Henry VIII regulation making powers under clause 37(1) and 37(5).
- xvii. Clause 38: Investigation of deaths etc – regulation making power to be inserted into the Coroners and Justice Act 2009 under clause 38(2).
- xviii. Clause 39: Codes of practice – 2 powers to issue codes of practice under clause 39(1) and 39(2), and one regulation making power under clause 39(4).
- xix. Clause 40: Guidance about operation of Act – 2 powers to make guidance under clause 40(1) and clause 40(4).
- xx. Clause 41: Voluntary assisted dying services: England - 2 Henry VIII regulation making powers under clause 41(1) and clause 41(3).
- xxi. Clause 42: Voluntary assisted dying services: Wales – 2 Henry VIII regulation making powers under clause 42(1) and clause 42(3).
- xxii. Clause 43: Prohibition on advertising – Henry VIII regulation making power under clause 43(1).
- xxiii. Clause 44: Notifications and provision of information to Commissioner – 2 regulation making powers under clause 44(1) and 44(2).
- xxiv. Clause 45: Information sharing – regulation making power under clause 45(3)(e).
- xxv. Clause 49: Monitoring by Commissioner – regulation making power under clause 49(3)(b).
- xxvi. Clause 53: Power to make consequential and transitional provision etc – regulation making power under clause 53(1).
- xxvii. Clause 58: Commencement – 3 regulation making powers under clause 58(3), 58(5), and 58(6).

Clause 8(2)(a): Initial request for assistance: first declaration – regulations about content and form of first declaration.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and purpose

7. A person who wishes to be provided with assistance to end their own life in accordance with the Bill must make a declaration to this effect, a “first declaration”. This is the first step that a person must take and is a safeguarding procedural step to make sure that the person is fully informed as to their condition, treatment available and any palliative care options. The purpose of the regulation making

power under clause 8(2)(a) is so that the Secretary of State, when making regulations, will set out the form of the first declaration.

8. Clause 8(4) sets out more detail about the content of these regulations. In particular, the regulations must specify that a first declaration contains:
 - (a) the following information:
 - i. the person's full name and address;
 - ii. the person's NHS number;
 - iii. contact details for the person's GP practice;
 - (b) the following further declarations by the person:
 - i. a declaration that they meet the initial conditions for eligibility (see subsection (5));
 - ii. a declaration that they have had a preliminary discussion with a registered medical practitioner, that they were aged 18 or over when they had that discussion, and that they understand the information referred to in clause 5(5)(a) to (c) that was provided during that discussion;
 - iii. a declaration that they are content to be assessed, for the purposes of the Bill, by registered medical practitioners;
 - iv. a declaration that they are making the first declaration voluntarily and have not been coerced or pressured by any other person into making it;
 - v. a declaration that they understand that they may cancel the first declaration at any time.
9. Subsection (5) sets out the definition of "the initial conditions for eligibility" as mentioned in subsection (4)(b)(i).
10. Clause 51(6) in the Bill further sets out that the Secretary of State must consult the Welsh Ministers before making regulations under clause 8(2)(a), and these regulations must make provision for the forms to be in Welsh as well as in English.

Rationale for taking the power

11. It is understood that this power has been taken to enable the Secretary of State to set out what should be included in a first declaration. This is consistent with the use of such powers in other legislation, as the principal and essential components of the first declaration are set out in primary legislation as the mandatory components of regulations. Further details of, and beyond, these principal elements may be set out in regulations. Setting these details out in secondary legislation enables the content to be adjusted based on ongoing review of the process reflects accepted practice. Further, clause 8(4) specifies the key information that a first declaration must include. This would provide a guide as to the types of information that could be set out in regulations made under this power.
12. Changes in NHS structures over time, such as to primary care services or the NHS numbering system, may change the information that persons are expected to

provide in order to be provided with medical assistance or other services. Setting out these details in regulations allows the form to be amended to reflect any changes in a timely manner. Powers setting out administrative details, that may need adjusting in response to changes to the wider organisational structures, have been used in other legislation.

13. Furthermore, setting the details out in regulations allows the Secretary of State to consult the Equality and Human Rights Commission (EHRC), as specified in the Bill, and other persons considered appropriate before specifying these details.

Consideration of the procedure

14. Subsection (4) of clause 54 sets out that regulations made under clause 8(2) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects the technical nature of the matters to be addressed in regulations, and the need to be able to respond to future changes to NHS structures.

Clause 8(7): Initial request for assistance: first declaration – regulations about the training, qualifications, and experience required to act as the coordinating doctor.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

15. In the Bill, a “coordinating doctor” is a registered medical practitioner who meets the requirements set out in clause 8(6), which includes that they must meet the training, qualifications, and experience requirements specified in regulations under subsection (7).
16. The purpose of the regulation making power under clause 8(7) is to confer a duty on the Secretary of State to make regulations about the training, qualifications, and experience required for a registered medical practitioner to act as a coordinating doctor.
17. Clause 8(8) sets out specific training that regulations made under subsection (7) must include, training about: assessing capacity, assessing whether a person has been coerced or pressured by any other person, reasonable adjustments and safeguards for autistic people and people with learning disabilities, and domestic abuse.

18. Clause 8(9) provides that, subject to subsection (8), the regulations made under subsection (7) may allow the required training, qualifications, or experience to be determined by a person specified in the regulations.
19. Clause 8(10) further sets out that regulations made under subsection (7) must specify that training in respect of domestic abuse, including coercive control and financial abuse, is mandatory.

Rationale for taking the power

20. The Bill creates the role of a “coordinating doctor” and sets out that a registered medical practitioner requires particular training, qualifications, and experience to fulfil this role. It is understood that this power has been taken to suitably safeguard any person requesting assistance to end their own life in accordance with the Bill. As a result, it is understood that this power has been taken to ensure that the Secretary of State has a duty to specify the training, qualifications, and experience required for a registered medical practitioner to fulfil the role of the coordinating doctor under the Bill.
21. Deciding on the appropriate training, qualifications, and experience that a registered medical practitioner will need in order to fulfil the role of a coordinating doctor is likely to be complex. The level of detail needed to set this out is more suitably covered in secondary rather than primary legislation.
22. Subsections (8) and (10) specify information that the regulations must include.
23. There are likely to be changes and updates to the training and qualifications required in light of developments in medical practice. Therefore, setting out the details of this in regulations would enable the content to be amended to reflect the most appropriate training available at the time as quickly as practicable.
24. Subsection (9) clarifies that the regulations can provide that the training, qualifications, or experience required of a coordinating doctor can be determined by a specified person. Determining the detailed requirements needed to be a coordinating doctor is likely to require specific medical expertise and, as such, it is appropriate that the Secretary of State is able to delegate the determination of such matters to the relevant specialist body with the relevant expertise.
25. It is noted that, in accordance with clause 55(1), there is a requirement to consult persons the Secretary of State considers appropriate before making regulations under subsection (7). It is likely that bodies such as the General Medical Council (GMC), the Care Quality Commission (CQC), and the Royal Colleges would be considered appropriate to consult before setting out the training requirements.

Consideration of the procedure

26. Regulations made under this power will be subject to the draft affirmative procedure. These regulations will introduce mandatory training, qualifications, and experience requirements for a subset of registered medical practitioners who wish to act as coordinating doctors under the Bill, which therefore has an impact on this subset of registered medical practitioners. These requirements have been introduced to maintain standards of care and safeguard persons who wish to be provided with assistance.
27. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny is more rigorous than usual practice for setting out training requirements. It will enable a debate and vote in both Houses of Parliament, so that the impacts of the regulations can be subject to appropriate parliamentary scrutiny.

Clause 9(3): Witnessing first declaration: requirements - regulations about forms of proof of identity.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

28. The Bill requires that a person who wishes to be provided with assistance to end their own life in accordance with the Bill must, before signing a first declaration, provide two forms of proof of identity to the coordinating doctor and another person, “witness”.
29. The purpose of the regulation making power under clause 9(3) is to provide a power for the Secretary of State to make regulations about the forms of proof of identity that are acceptable for a person to provide when making a first declaration under the Bill, to ensure that the correct person is making the declaration and act as a safeguard.

Rationale for taking the power

30. It is understood that this power has been taken to enable the Secretary of State to set out the acceptable forms of proof of identity for a person to provide when making a first declaration under the Bill. Decisions on proof of identity are administrative in nature. Leaving this level of detail to secondary legislation, rather than setting out an exhaustive list of acceptable forms of proof of identity on the face of the Bill, will allow the Secretary of State to adjust the content based on an ongoing review of the assisted dying process and possible future changes to forms of personal identification as soon as practicable.

Consideration of the procedure

31. Subsection (4) of clause 54 sets out that regulations made under clause 9(3) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation given the technical nature of the matters to be addressed in regulations, and the need to be able to respond to future changes.

Clause 10(3)(b)(iii): First doctor's assessment (coordinating doctor) – regulations specifying other persons who receive a copy of the report.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

32. Clause 10 of the Bill sets out that the coordinating doctor must, as soon as reasonably practicable after a first declaration is made by a person, carry out a first assessment to assess whether a person satisfies conditions set out under subsections (2)(a) to (h). The assessment includes whether the person meets the eligibility criteria under the Bill, has a clear, settled and informed wish to end their own life, and made the first declaration voluntarily and has not been coerced or pressured by any other person into making it. The coordinating doctor must make a report about the first assessment after it has been carried out.
33. Clause 10(3)(b)(i) to (iii) specifies that the report must be provided to the person being assessed and, if the coordinating doctor is not a practitioner with the person's GP practice, to a registered medical practitioner with that practice. The purpose of the regulation making power under clause 10(3)(b)(iii) is to enable the Secretary of State to make regulations which specify who else the coordinating doctor must give a copy of the report to.

Rationale for taking the power

34. It is understood that this power has been taken to enable the Secretary of State to specify any other person who the report of the first assessment must be shared with. This is an operational detail of the assisted dying process which may change over time, due to changes in NHS structures and the procedure of the Commissioner and panels. Setting out these details in secondary legislation allows the regulations to be amended as soon as practicable to specify the most relevant

persons, in accordance with any changes in organisational structures and procedures, and ongoing review of the operation of the Bill.

35. Additionally, clause 55(1) imposes a duty on the Secretary of State to consult such persons the Secretary of State considers appropriate before making regulations under clause 10(4). Setting the details out in regulations allows the Secretary of State to consult the EHRC, as specified in the Bill, and other persons considered appropriate before specifying who else the coordinating doctor must give a copy of the report to.

Consideration of the procedure

36. Subsection (4) of clause 54 sets out that regulations made under clause 10(3)(b)(iii) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation, given the technical nature of the matters to be addressed in regulations and the need to be able to respond to future changes in organisational structures.

Clause 10(4): First doctor's assessment (coordinating doctor) - regulations about content and form of report about first assessment.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

37. Clause 10(4) also relates to the report that must be made by the coordinating doctor about the first assessment after it has been carried out.
38. The purpose of the regulation making power under clause 10(4) is to confer a duty on the Secretary of State to make regulations which specify the content and form of the report made by the coordinating doctor about the first assessment.
39. Clause 10(5) sets out more detail about what must be included in these regulations. In particular, the regulations must provide that the report must:
- (a) contain a statement indicating whether the coordinating doctor is satisfied as to all of the matters set out in subsections (2)(a) to (h);
 - (b) contain an explanation of why the coordinating doctor is, or (as the case may be) is not, so satisfied;
 - (c) contain a statement indicating whether the coordinating doctor is satisfied as to the following:

- i. that a record of the preliminary discussion has been included in the person's medical records;
 - ii. that the making of the first declaration has been recorded in the person's medical records;
 - iii. that the first declaration has not been cancelled;
- (d) be signed and dated by the coordinating doctor.

40. Clause 51(6) in the Bill further sets out that the Secretary of State must consult the Welsh Ministers before making regulations under clause 10(4) and these regulations must make provision for the report to be in Welsh as well as in English.

Rationale for taking the power

41. It is understood that this power has been taken to require the Secretary of State to set out what should be included in a report made by the coordinating doctor about the first assessment. This is consistent with the use of such powers in other legislation, as the content and form of a report about the first assessment is administrative in nature. Setting these details out in secondary legislation enables the content to be adjusted in a timely manner based on ongoing review of the process. Further, clause 10(5) specifies the key information that the report of a first assessment must include. This would provide a guide as to the types of information that could be set out in regulations made under this power.

42. In addition, changes in NHS structures over time, particularly to primary care services or record keeping, may change the information that is expected to be included in reports of assessments. Setting out these details in regulations allows the form and content of the report to be amended, subject to any such changes, and ensure consistency with the requirements of other provisions. Powers setting out administrative details, that may need adjusting in response to changes to the wider organisational structures, have been used in other legislation.

43. Additionally, clause 55(1) imposes a duty on the Secretary of State to consult such persons the Secretary of State considers appropriate before making regulations under clause 10(4). Setting the details out in regulations allows the Secretary of State to consult the EHRC, as specified in the Bill, and other persons considered appropriate before specifying the form and content of the first assessment.

Consideration of the procedure

44. Subsection (4) of clause 54 sets out that regulations made under clause 10(4) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation given the technical nature of the matters to be addressed in regulations, and the need to be able to respond to future changes in NHS structures.

Clause 11(5)(b)(iv): Second doctor's assessment (independent doctor) - regulations specifying other persons to be sent a copy of the report.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

45. Clause 11 of the Bill sets out that where a referral is made under clause 10(3)(c), the independent doctor must carry out the second assessment of the person as soon as reasonably practicable after the first period of reflection has ended. The second assessment is to ascertain whether a person satisfies conditions at subsections (2)(a) to (e). The assessment includes whether, in the opinion of the independent doctor, the person meets the eligibility criteria under the Bill, has a clear, settled and informed wish to end their own life, and made the first declaration voluntarily and has not been coerced or pressured by any other person into making it. The independent doctor must make a report about the second assessment after it has been carried out.
46. The purpose of the regulation making power under clause 11(5)(b)(iv) is to enable the Secretary of State to make regulations which specify who the coordinating doctor must give a copy of the report to.

Rationale for taking the power

47. It is understood that this power has been taken to require the Secretary of State to specify who the report of the second assessment must be shared with. This is an operational detail of the assisted dying process, which therefore may change over time due to changes in NHS structures and procedures, particularly around record keeping, or wider changes to judicial roles. Setting out these details in secondary legislation would allow the regulations to be amended as quickly as practicable to specify the most relevant persons in accordance with changes in structures and procedures, and ongoing review of the operation of the Bill.
48. Additionally, clause 55(1) imposes a duty on the Secretary of State to consult such persons the Secretary of State considers appropriate before making regulations under clause 11(5)(b)(iv). Setting the details out in regulations allows the Secretary of State to consult the EHRC, as specified in the Bill, and other persons considered appropriate before specifying who else the coordinating doctor must give a copy of the report to.

Consideration of the procedure

49. Subsection (4) of clause 54 sets out that regulations made under clause 11(5)(b)(iv) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation, given the technical nature of the matters to be addressed in regulations and to respond to any future changes in organisational structures.

Clause 11(6): Second doctor's assessment (independent doctor) - regulations about content and form of report about second assessment.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

50. Clause 11(6) also relates to the report that must be made by the independent doctor after the second assessment has been carried out.

51. The purpose of the regulation making power in clause 11(6) is to confer a duty on the Secretary of State to make regulations which specify the content and form of the report made by the independent doctor about the second assessment.

52. Clause 11(7) sets out more detail about what must be included in these regulations. In particular, the regulations must provide that the report must:

- (a) contain a statement indicating whether the independent doctor is satisfied as to all of the matters mentioned in subsections (2)(a) to (e);
- (b) contain an explanation of why the independent doctor is, or (as the case may be) is not, so satisfied;
- (c) contain a statement indicating whether the independent doctor is satisfied as to the following:
 - i) that a record of the preliminary discussion has been included in the person's medical records;
 - ii) that the person signed the first declaration;
 - iii) that the making of the first declaration has been recorded in the person's medical records;
 - iv) that the first declaration has not been cancelled;
- (d) be signed and dated by the coordinating doctor.

53. Clause 51(6) in the Bill further sets out that the Secretary of State must consult the Welsh Ministers before making regulations under clause 11(6), and these regulations must make provision for the forms to be in Welsh as well as in English.

Rationale for taking the power

54. It is understood that this power has been taken to ensure that the Secretary of State has the power to set out what should be included in a report made by the independent doctor about the second assessment. This is consistent with the use of such powers in other legislation, as the content and form of a report about the first assessment is administrative in nature. Setting these details out in secondary legislation enables the content to be adjusted based on ongoing review of the process. Further, clause 11(7) specifies the key information that the report of a second assessment must include. This would provide a guide as to the types of information that could be set out in regulations made under this power.
55. In addition, changes in NHS record keeping over time may change the information that is expected to be included in reports of assessments, or other services. Setting out these details in regulations allows the form and content of the report to be amended in a timely manner, in response to such changes and to ensure consistency with the requirements of other provisions. Powers setting out administrative details, that may need adjusting in response to changes to wider organisational structures and procedures, have been used in other legislation.
56. Additionally, clause 55(1) imposes a duty on the Secretary of State to consult such persons the Secretary of State considers appropriate before making regulations under clause 11(6). Setting the details out in regulations allows the Secretary of State to consult the EHRC, as specified in the Bill, and other persons considered appropriate persons before specifying details of the form and content of the second assessment.

Consideration of the procedure

57. Subsection (4) of clause 54 sets out that regulations made under clause 11(6) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation, given the technical nature of the matters to be addressed in regulations and the need to be able to respond to future changes in NHS structures and procedures.

Clause 11(9): Second doctor's assessment (independent doctor) - regulations about training, qualifications, and experience required to act as independent doctor.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

58. In the Bill, an “independent doctor” is a registered medical practitioner who meets the requirements set out in clause 11(8)), which includes that they must meet the requirements specified in regulations under subsection (9).
59. The purpose of the regulation making power under clause 11(9) is to confer a duty on the Secretary of State to make regulations about the training, qualifications, and experience that a registered medical practitioner must have in order to carry out the functions of the independent doctor.
60. Clause 11(10) sets out that regulations made under subsection (9) must include training about: assessing capacity, assessing whether a person has been coerced or pressured by any other person, and domestic abuse.
61. Clause 11(13) further sets out that regulations made under subsection (9) must specify that training in respect of domestic abuse, including coercive control and financial abuse, is mandatory.
62. Clause 11(11) provides that, subject to subsection (10), the regulations made under subsection (9) may allow the required training, qualifications, or experience to be determined by a person specified in the regulations.

Rationale for taking the power

63. The Bill creates the role of an “independent doctor” and sets out that a registered medical practitioner requires particular training, qualifications, and experience to fulfil this role. It is understood that the purpose of setting standards for training, qualifications, and experience required of independent doctors is to suitably safeguard any person requesting assistance to end their own life in accordance with the Bill. As a result, it is understood that this power has been taken to ensure that the Secretary of State has a duty to specify the training, qualifications, and experience required for a registered medical practitioner to fulfil the role of the independent doctor under the Bill.
64. Deciding on the appropriate training, qualifications, and experience that a registered medical practitioner will need in order to fulfil the role of an independent doctor is likely to be complex. The level of detail needed to set this out is therefore suitably covered in secondary rather than primary legislation.
65. Subsections (10) and (13) specify information that the regulations must include. This level of specificity is greater than might be usual in other primary legislation.
66. In addition, there are likely to be changes and updates to the training and qualifications required as a result of developments in medical practice. Therefore, setting out the details of this in regulations would enable the content to be amended

as quickly as practicable to reflect the most appropriate training that is available at the time.

67. Subsection (11) clarifies that the regulations can provide that the training, qualifications, or experience required of an independent doctor can be determined by a specific person. Determining the detailed requirements needed to be an independent doctor is likely to require specific medical expertise, and as such, it is appropriate that the Secretary of State is able to delegate the determination of such matters to the relevant specialist body with the relevant expertise.

68. It is noted that, in accordance with clause 55(1), there is a requirement to consult persons the Secretary of State considers appropriate before making regulations under subsection (9). It is likely that bodies such as the GMC, CQC, and the Royal Colleges would be considered appropriate to consult before setting out the training requirements.

Consideration of the procedure

69. Regulations made under this power will be subject to the draft affirmative procedure. These regulations will introduce mandatory training, qualifications, and experience requirements for a subset of registered medical practitioners, who wish to act as independent doctors under the Bill, which therefore has an impact on this subset of registered medical practitioners. These requirements have been introduced to maintain standards of care and safeguard persons who wish to be provided with assistance.

70. Whilst the Government is neutral on the choice of parliamentary procedure, this level of parliamentary scrutiny is more rigorous than usual practice for setting out training requirements, which will enable a debate and vote in both Houses of Parliament.

Clause 14(1): Replacing the coordinating doctor on death etc - regulations about the replacement of a coordinating doctor.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

71. Clause 14(1) in the Bill provides a power for the Secretary of State to make regulations where a coordinating doctor has died or, through illness or otherwise, is unable or unwilling to carry out the functions of the coordinating doctor, after a first declaration has been witnessed by them.

72. The purpose of clause 14(2) is to set out that the Secretary of State may, under the regulation making power at subsection (1), make provision:
- (a) relating to the appointment, with the agreement of the person who made the first declaration, of a replacement coordinating doctor who meets the requirements of clause 8(6) and is able and willing to carry out the functions of the coordinating doctor;
 - (b) to ensure continuity of care for that person despite the change in coordinating doctor.

Rationale for taking the power

73. It is understood that this power has been taken to enable the Secretary of State to provide for cases where the original coordinating doctor becomes unable or unwilling to continue to carry out these functions part-way through the process.
74. This is an operational detail of the assisted dying process which may change over time, for example, due to changes in medical procedure, or changes to NHS guidance on continuity of care. Setting out such details in secondary legislation allows the procedure of replacing a coordinating doctor to be amended as quickly as practicable in the case of organisational and procedural changes. Furthermore, there is a varied range of circumstances under which a coordinating doctor may be unable or unwilling to continue to carry out their functions in the assisted dying process, and it would not be practical to set these out on the face of the Bill.

Consideration of the procedure

75. Subsection (4) of clause 54 sets out that regulations made under clause 14 are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation given the technical nature of the matters to be addressed in regulations, and the need to respond to any future changes to NHS structures and procedures.

Clause 15(4): Replacing the coordinating or independent doctor where unable or unwilling to continue to act – regulations making provision for the replacement of coordinating doctor

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

76. Clause 15(4) in the Bill provides a power for the Secretary of State to make regulations relating to the appointment of a replacement coordinating doctor, where the coordinating doctor is unable or unwilling to continue to carry out their functions

under the Bill after they have witnessed the first declaration. The replacement coordinating doctor must meet the requirements of clause 8(6) and be able and willing to carry out the functions of the coordinating doctor.

77. Clause 15(5) sets out that the regulations under subsection (4) may also make provision to ensure continuity of care for the person seeking assistance, despite the change in coordinating doctor.

Rationale for taking the power

78. It is understood that this power has been taken to enable the Secretary of State to provide for cases where the original coordinating doctor becomes unable or unwilling to continue to carry out their functions part-way through the process.

79. This is an operational detail of the assisted dying process which may change over time, for example, due to changes in medical procedure, or changes to NHS guidance on continuity of care. Setting out such details in secondary legislation allows the procedure of replacing a coordinating doctor to be amended as quickly as practicable in the case of organisational and procedural changes. Furthermore, there is a varied range of circumstances under which a coordinating doctor may be unable or unwilling to continue to carry out their functions in the assisted dying process, and it would not be practical to set these out on the face of the Bill.

Consideration of the procedure

80. Subsection (4) of clause 54 sets out that regulations made under clause 15 are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation given the technical nature of the matters to be addressed in regulations, and the need to respond to any future changes to NHS structures and procedures.

Clause 17(8)(d): Determination by panel of eligibility for assistance – regulations specifying persons the panel must notify.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

81. Clause 17(8) provides a list of individuals to whom the assisted dying review panel must notify of its decision to grant or refuse a certificate of eligibility under clause 17(7). Clause 17(8)(d) provides the Secretary of State the power to add, by regulations, to the list of individuals who must receive the panel's decisions, including a copy of the certificate of eligibility.

Rationale for taking the power

82. Taking this power to add to the list of specified persons in clause 17(8) ensures that if other categories of individuals require notification of the panel's decision and a copy of the certificate of eligibility, there is a power to allow them to access both.
83. It is consistent with powers in other legislation that the Bill contains a power to add to the list of specified persons in secondary legislation, as this is an administrative detail of the process.

Consideration of the procedure

84. Whilst the Government is neutral on the choice of parliamentary procedure, these regulations complement the existing list of specified persons in clause 17(8), and this level of parliamentary scrutiny reflects accepted practice in other legislation given the administrative nature of the matters to be addressed in regulations.

Clause 18(6)(c): Reconsideration of panel decisions refusing certificate of eligibility – regulations specifying persons to receive Commissioner's reconsideration decision.

Power conferred on: Secretary of State

Power exercised by: Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

85. A person may apply to the Commissioner for a reconsideration of the first panel's decision to refuse to grant a certificate of eligibility on the grounds that the first panel's decision contained an error of law, is irrational, or was procedurally unfair. If the Commissioner is satisfied that any of the grounds in subsection (2) apply, they must as soon as reasonably practicable refer the person's case to a different Assisted Dying Review Panel for a fresh determination under clause 17.
86. The purpose of this clause is to confer on the Secretary of State a power to make regulations to add to the list of individuals who will receive the Commissioner's reconsideration decision under clause 18(4) (whether the Commissioner has decided to grant or refuse a reconsideration application). The persons specified in clause 18(6), including those to be specified by regulations by the Secretary of State, must be notified of the Commissioner's decision and receive a document containing reasons for the decision.

Rationale for taking the power

87. With this power to add to the list of specified persons in clause 18(6), it is understood that the rationale is to ensure that if other categories of individuals require notification of the Commissioner's reconsideration decision and reasons, there is a power to allow them to access both. It is consistent with powers in other legislation that the Bill contains a power to add to the list of specified persons in secondary legislation, as this is an administrative detail of the process.

Consideration of the procedure

88. Whilst the Government is neutral on the choice of parliamentary procedure, these regulations complement the existing list of specified persons in clause 18(6), and this level of parliamentary scrutiny reflects accepted practice in other legislation due to the secondary nature of the matters to be addressed in regulations.

Clause 19(3)(a): Confirmation of request for assistance: second declaration - regulations about content and form of second declaration.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

89. Clause 19 in the Bill sets out that where a certificate of eligibility has been granted by the panel in respect of a person, and the second period of reflection has come to an end, if the person wishes to be provided with assistance to end their own life in accordance with this Bill, the person must make a further declaration to this effect, a "second declaration". The purpose of clause 19(3)(a) is so that the Secretary of State, when making regulations, sets out the form of the second declaration.

90. Clause 19(4) sets out more detail about the content of these regulations. In particular, the regulations must specify that a second declaration contains:

(a) the following information:

- i. the person's full name and address;
- ii. the person's NHS number;
- iii. contact details for the person's GP practice;
- iv. specified information about the certificate of eligibility;

(b) the following further declarations by the person:

- i. a declaration that they have made a first declaration and have not cancelled it;
- ii. a declaration that they understand that they must make a second declaration in order for assistance to be provided under the Bill;
- iii. a declaration that they are making the second declaration voluntarily and have not been coerced or pressured by any other person into making it;

- iv. a declaration that they understand that they can cancel the second declaration at any time.

Rationale for taking the power

- 91. It is understood that this power has been taken to enable the Secretary of State to set out what should be included in a second declaration. The principal and essential components of the second declaration are set out in primary legislation as the mandatory components of regulations. Further details of and beyond these principal elements may be set out in regulations. Setting these details out in secondary legislation enables the content to be adjusted based on ongoing review of the process. Further, clause 19(4) specifies the key information that the form of a second declaration must include. This would provide a guide as to the types of information that could be set out in regulations made under this power.
- 92. In addition, changes to NHS operational practice over time may change the information that persons are expected to provide in order to be provided with medical assistance or other services. Setting out these details in regulations allows the form to be amended as quickly as practicable, subject to these changes, and for consistency with the requirements of other provisions. Powers of this kind have been used in other legislation for setting out administrative details that may need adjusting in response to changes to the wider organisational structures and procedures.
- 93. Clause 51(6) in the Bill further sets out that the Secretary of State must consult the Welsh Ministers before making regulations under clause 19(3)(a), and these regulations must make provision for the form of the second declaration to be in Welsh as well as in English.
- 94. Additionally, clause 55(1) imposes a duty on the Secretary of State to consult such persons the Secretary of State considers appropriate before making regulations under clause 19(3)(a). Setting the details out in regulations allows the Secretary of State to consult the EHRC, as specified in the Bill, and other appropriate persons before specifying these details.

Consideration of the procedure

- 95. Subsection (4) of clause 54 sets out that regulations made under clause 19(3)(a) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation given the technical nature of the matters to be addressed in regulations, and the need to respond to any future changes to NHS structures and procedures.

Clause 19(7)(a): Confirmation of request for assistance: second declaration - regulations about content and form of statement regarding the second declaration.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

96. Clause 19(5) outlines that the coordinating doctor may witness a second declaration only if the coordinating doctor is satisfied (immediately before witnessing it) that the person requesting to end their own life in accordance with the Bill meets the criteria set out in subsections (5)(a) to (d). Namely, that the person making the declaration is terminally ill, has the capacity to make the decision to end their own life, has a clear, settled and informed wish to end their own life, and is making the declaration voluntarily and has not been coerced or pressured by any other person into making it. Clause 19(6) provides that if the coordinating doctor is satisfied as to the criteria in subsections (5)(a) to (d), they must make a statement to this effect.

97. The purpose of clause 19(7)(a) is so that the Secretary State, when making regulations, specifies the form of the statement under subsection (6). Clause 19(8) sets out more detail about what must be included in these regulations. In particular, the regulations must provide that the statement contains:

(a) the following information:

- i. the person's full name and address;
- ii. the person's NHS number;
- iii. the coordinating doctor's full name and work address;
- iv. specified information about the certificate of eligibility;

(b) the following declarations by the coordinating doctor (in addition to a declaration that they are satisfied of all of the matters mentioned in subsection (5)(a) to (d)):

- i. a declaration that they are satisfied that a certificate of eligibility has been granted in respect of the person;
- ii. a declaration that the second declaration was made after the end of the second period for reflection;
- iii. if the second declaration was made before the end of the period mentioned in subsection (2)(a), a declaration that they have the belief mentioned in subsection (2)(b);
- iv. a declaration that they are satisfied that neither the first declaration nor the second declaration has been cancelled.

Rationale for taking the power

98. It is understood that this power has been taken to require that the Secretary of State sets out what should be included in a statement made by the coordinating doctor about the second declaration. This is consistent with the use of such powers in other legislation, as the content and form of a statement about the second declaration is administrative in nature. Setting such details out in secondary legislation enables the content to be adjusted based on ongoing review of the process. Further, clause 19(8) specifies the key information that the report of a statement must include. This would provide a guide as to the types of information that could be set out in regulations made under this power.
99. In addition, changes to NHS operational practice over time may change the information that is expected to be included in statements before the provision of medical assistance or other services. Setting out these details in regulations allows the form and content of the second statement by the coordinating doctor to be amended as quickly as practicable subject to these changes. Powers of this kind have been used in other legislation for setting out administrative details that may need adjusting in response to changes to the wider organisational structures and procedures.
100. Additionally, clause 55(1) imposes a duty on the Secretary of State to consult such persons the Secretary of State considers appropriate before making regulations under clause 19(7)(a). Setting the details out in regulations allows the Secretary of State to consult the EHRC, as specified in the Bill, and other appropriate persons before specifying the content of the second statement.

Consideration of the procedure

101. Subsection (4) of clause 54 sets out that regulations made under clause 19(7)(a) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation given the technical nature of the matters to be addressed in regulations, and the need to respond to any future developments.

Clause 21(5)(b): Signing by proxy – regulations on meaning of a proxy.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

102. Clause 21 in the Bill makes provision for cases where the person intending to make a first declaration or second declaration is unable to sign their own name.

They can authorise another person to sign the declaration on their behalf. The other person, a “proxy”, is someone who has known the person making the declaration personally for at least 2 years, or a person of a description specified in regulations by the Secretary of State.

103. The purpose of clause 21(5)(b) is to enable the Secretary of State to make regulations specifying the description of a proxy.

Rationale for taking the power

104. It is understood that this power has been taken to enable the Secretary of State to set out the meaning of “proxy” under the Bill. The meaning of proxy is unlikely to be contentious, in particular given the mandatory requirement for the person making the declaration to have known the proxy personally for two years, or to be a person of a description specific in regulations made by the Secretary of State. Including this power in secondary legislation provides the necessary flexibility to amend the persons in scope of the meaning of proxy to respond to any future changes in its meaning in comparable situations, whether medical or otherwise.

105. Furthermore, setting the details out in regulations allows the Secretary of State to consult persons considered appropriate before specifying the definition of a proxy under the Bill, if the Secretary of State chooses to do so.

Consideration of the procedure

106. Subsection (4) of clause 54 sets out that regulations made under clause 21(5)(b) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation, given the technical nature of the matters to be addressed in regulations and the need to respond to any future changes to NHS structures or procedures.

Clause 22(1): Provision for independent advocates in end-of-life decision making - regulations making provision as to the appointment of persons as independent advocates.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

107. Clause 22(1) would require the Secretary of State to, by regulations, make provision for independent advocates to provide assistance to qualifying persons. The role of the independent advocate, set out in the clause, is to provide support

and advocacy to a qualifying person seeking to understand options around end-of-life care, including the possibility of requesting access to assisted dying to enable them to understand and engage with the provisions of the Bill.

108. A qualifying person is defined in subsection (4), which is set out in relation to the separate power under clause 22(4)(c).

109. The clause sets out that the regulations may provide the following:

- (a) that a person may act as an independent advocate only in such circumstances, or only subject to such condition, as may be specified in the regulations;
- (b) for the appointment of a person as an independent advocate to be subject to approval in accordance with the regulations;
- (c) persons that may appoint independent advocates;
- (d) provision for payments to be made to, or in relation to, persons carrying out the function of an independent advocate under this clause;
- (e) training that such advocates must undertake before being appointable; and
- (f) obligations on persons performing functions under this Bill to ensure the presence of an independent advocate for qualifying persons.

Rationale for taking the power

110. It is understood that this power has been taken to require the Secretary of State to establish and make provision for an independent advocacy role under the Bill. Setting out the details of any arrangements via regulations is consistent with the approach taken in other legislation. Further, Clause 22(2)(a) to (f) provides a guide as to what these regulations may include.

111. The Secretary of State has various duties to consult persons considered appropriate before making regulations under the Bill, and the outcomes of these consultations, particularly those with disability rights organisations, are likely to have an impact on what would be considered necessary to include in regulations providing for independent advocates. This power would allow the Secretary of State to take into account this consultation before making the regulations.

112. Furthermore, setting the details out in regulations allows the Secretary of State to consult persons considered appropriate before specifying the details in relation to independent advocates, if the Secretary of State chooses to do so. This could include, for example, the EHRC.

Consideration of the procedure

113. Regulations introduced under Clause 22 will be subject to the draft affirmative procedure. Whilst the Government is neutral on the choice of regulation making procedure, given the operational nature of these regulations, in that they are distinct from the contentious and most sensitive elements of the Bill, this level of parliamentary scrutiny may be considered to go beyond usual practice. However,

the policy on assisted dying is of a novel and controversial nature, and there has been a high level of parliamentary interest relating to safeguarding requirements, particularly in relation to disabled people. Therefore, enabling a debate and vote in both Houses of Parliament will allow for the provision of independent advocates to receive appropriate Parliamentary scrutiny.

Clause 22(4)(c): Provision for independent advocates in end-of-life decision making – regulations setting out criteria to be defined as a qualifying person.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

114. Paragraphs 22(4)(a) and (b) set out criteria that would determine whether a person is a “qualifying person”. Clause 22(4)(c) provides a power for the Secretary of State to make regulations specifying criteria as to who is a “qualifying person”. The qualifying person would access support and advocacy from an “independent advocate” to enable them to effectively understand and engage with all the provisions of this Bill.

115. A qualifying person is defined in the clause as someone who (i) has a learning disability, a mental disorder (as defined by the Mental Health Act 1983), or autism or (ii) may experience substantial difficulty in understanding the processes or information relevant to those processes or communicating their views, wishes, or feelings or (iii) meets criteria as may be specified by the Secretary of State in regulations.

Rationale for taking the power

116. It is understood that this power has been taken to enable the Secretary of State to further define a “qualifying person” who can receive the support of an independent advocate under the Bill. This power is consistent with the approach taken in other legislation as defining a “qualifying person” is a specific operational detail. In addition, subsections (4)(a)(i) to (iii) and (4)(b) of the clause provide a guide as to the relevant criteria that the Secretary of State may specify in regulations.

117. The Secretary of State has various duties to consult persons considered appropriate before making regulations under the Bill, and the outcomes of these consultations, particularly those with disability rights organisations, are likely to have an impact on what is considered necessary to include in regulations providing

eligibility criteria to qualify for support from an independent advocate. This power would allow the Secretary of State to take into account this consultation before making the regulations.

118. Furthermore, setting the details out in regulations allows the Secretary of State to consult persons considered appropriate before specifying details on eligibility, if the Secretary of State chooses to do so. This could include, for example, the EHRC.

Consideration of the procedure

119. Regulations introduced under clause 22(4)(c) will be subject to the draft affirmative procedure. Given the operational nature of these regulations, this level of parliamentary scrutiny may be considered to go beyond usual practice. However, the policy on assisted dying is of a novel and controversial nature, and there has been a high level of parliamentary interest relating to safeguarding requirements, particularly in relation to persons with disabilities. Therefore, enabling a debate and vote in both Houses of Parliament will allow for the impacts of the regulations relating to the provision of independent advocacy to receive adequate parliamentary scrutiny.

Clause 26(2)(b): Authorising another doctor to provide assistance – regulations about assigning another registered medical practitioner to provide assistance.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

120. Clause 26(1) sets out that the coordinating doctor may authorise another named registered medical practitioner to exercise the coordinating doctor's functions under clause 25 in connection with the provision of assistance to a person to end their own life. The purpose of clause 26(2)(b) is to provide a power for the Secretary of State to specify the required training, qualifications, or experience that a registered medical practitioner must have before a coordinating doctor can authorise that registered medical practitioner to carry out their functions under clause 25. In addition, clause 26(3) provides that the regulations made under subsection 2(b) may allow the required training, qualifications, or experience to be determined by a person specified in the regulations.

121. Clause 26(7) further sets out that regulations made under subsection (2)(b) must specify that training in respect of domestic abuse, including coercive control and financial abuse, are mandatory.

Rationale for taking the power

122. It is understood that this power has been taken to enable the Secretary of State to specify the required training, qualifications, or experience that a registered medical practitioner must have before they can be authorised by a coordinating doctor to provide a person with assistance to end their own life in accordance with clause 25. This provides that a registered medical practitioner requires particular training, qualifications, and experience in order to be authorised by a coordinating doctor to provide assistance to a person under clause 25. This is to maintain standards of care and suitably safeguard any person requesting assistance to end their own life in accordance with the Bill.
123. Consistently with the power in Clause 8(7), the appropriate training, qualifications, and experience that a registered medical practitioner will need in order to be authorised to provide assistance under clause 25 is likely to be complex. The level of detail needed to set this out is more suitably covered in secondary rather than primary legislation. Subsection (7) specifies information that the regulations must include.
124. In addition, there are likely to be changes and updates to the training and qualifications required as a result of developments in medical practice. Therefore, it would be appropriate for the details for this provision to be set out in regulations, which can be amended as quickly as practicable to reflect the most appropriate training that is available at the time.
125. Subsection (3) clarifies that the regulations may provide that the training, qualifications, or experience required of a coordinating doctor can be delegated to a specified person. Determining the detailed requirements needed to carry out the coordinating doctor's functions is likely to require specific medical expertise, and as such, it is appropriate that the Secretary of State is able to delegate the determination of such matters to the relevant specialist body with the relevant expertise.
126. In accordance with clause 55(1)(b), there is a requirement to consult persons the Secretary of State considers appropriate before making regulations under subsection (2)(b). It is likely that bodies such as the GMC, CQC, and the Royal Colleges would be considered appropriate to consult before setting out the training requirements.

Consideration of the procedure

127. Regulations made under clause 26 will be subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, the Government notes that these regulations will introduce mandatory training, qualifications, and experience requirements for registered medical practitioners before they can be authorised by a coordinating doctor to provide assistance under

clause 25. It is expected that the regulations made under clause 26(2)(b) will mirror those made under clause 8(7) and clause 11(9), which are both subject to the draft affirmative procedure.

Clause 27(1): Meaning of “approved substance”- regulations specifying drugs or substances.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

128. The purpose of clause 27(1) is to confer a duty on the Secretary of State to make regulations specifying one or more drugs, or other substances, that could be used by a person for the purposes of this Bill.

Rationale for taking the power

129. It is understood that this power has been taken in order to require the Secretary of State to specify one or more drugs or other substances that could be used by a person to end their own life. This anticipates that the list of approved substances will need to be amended as the evidence base, through clinical use, continues to develop. Specifying these substances in secondary legislation retains the necessary flexibility to respond to technical advancements and developments in drugs and other substances, which is consistent with the use of such powers in other legislation.

130. In addition, the specification of approved substances is technical and, as a result, more suited to secondary legislation.

Consideration of the procedure

131. Subsection (4) of clause 54 sets out that regulations made under clause 27(1) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects the technical nature of specifying approved substances, and the need to be able to respond in a timely way to technical advancements and developments in drugs and other substances.

Clause 28(3)(a): Final Statement – regulations about form and content of final statement.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

132. Clause 28 sets out that where a person has been provided with assistance to end their own life in accordance with the Bill, and has died as a result, the coordinating doctor must complete a statement, “a final statement”, to this effect. The purpose of clause 28(3)(a) is to require the Secretary of State, when making regulations, to set out the form of the final statement in those regulations.

133. Clause 28(5) sets out further detail that the regulations must specify. A final statement must contain the following information:

- (a) the person’s full name, date of birth, sex, ethnicity, and last permanent address;
- (b) whether, immediately before death, the person had a disability within the meaning of section 6 of the Equality Act 2010 (other than a disability consisting of the illness or disease which caused the person to be terminally ill within the meaning of this Bill);
- (c) the person’s NHS number;
- (d) the name and address of the person’s GP practice (at the time of death);
- (e) the coordinating doctor’s full name and work address;
- (f) the date of each of the following:
 - (g) the first declaration;
 - (h) the report about the first assessment of the person;
 - (i) the report about the second assessment of the person;
 - (j) the certificate of eligibility;
 - (k) the second declaration;
 - (l) the statement under clause 19(6);
- (m) details of the illness or disease which causes the person to be terminally ill (within the meaning of the Bill);
- (n) the approved substance provided;
- (o) the date and time of death;
- (p) the time between use of the approved substance and death.

Rationale for taking the power

134. It is understood that this power has been taken to require the Secretary of State to set out what should be included in a final statement. The content of a final statement is administrative in nature, and setting these details out in secondary legislation would enable the content to be adjusted based on ongoing review of the process. Further, clause 28(5) specifies the key information that the form of a final statement must include. This would provide a guide as to the types of information that could be set out in regulations made under this power.

135. In addition, wider changes to reporting practices may change the information that is expected to be recorded after a person has died or received other medical

interventions. Setting out these details in regulations allows the content and form to be amended as quickly as practicable in response to such changes, and for consistency with the requirements of other provisions.

136. Clause 51(6) in the Bill further sets out that the Secretary of State must consult the Welsh Ministers before making regulations under clause 28(3)(a), and these regulations must make provision for the final statement to be in Welsh as well as in English.

137. Additionally, clause 55(1) imposes a duty on the Secretary of State to consult such persons the Secretary of State considers appropriate before making regulations under clause 28(3)(a). Setting the details out in regulations allows the Secretary of State to consult the EHRC, as specified in the Bill, and other appropriate persons before specifying the form and content of the final statement.

Consideration of the procedure

138. Subsection (4) of clause 54 sets out that regulations made under clause 28(3)(a) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation given the technical nature of the matters to be addressed in regulations, and the need for flexibility to respond to any future changes to NHS structures and procedures.

Clause 29(3): Report where assistance not provided because coordinating doctor not satisfied of all relevant matters – regulations on the content and form of report

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

139. Clause 29 applies where a person is not provided with assistance under clause 25 of the Bill, because the coordinating doctor is not satisfied as to all of the matters mentioned in clause 25(5).

140. Clause 29(3) in the Bill provides the Secretary of State a power to make provision about the content or form of the report that the coordinating doctor must make, pursuant to clause 29(2), where a person is not provided with assistance because the coordinating doctor is not satisfied of all relevant matters. This report must set out the matters as to which the coordinating doctor is not satisfied and contain an explanation of why they are not satisfied of those matters.

Rationale for taking the power

141. It is understood that this power has been taken to ensure that the Secretary of State has the power to set out what should be included in a report made by the coordinating doctor where they are not satisfied of all relevant matters. This is consistent with the use of such powers in other legislation, as the content or form of this report is administrative in nature. Setting these details out in secondary legislation enables the content to be adjusted based on ongoing review of the process. Further, clause 29(2) provides an outline of what the report must contain, which would provide a guide as to the types of information that could be set out in regulations made under this power.

142. In addition, changes in NHS record keeping practices over time may change the information that is expected to be included in reports of assessments, or other services. Setting out these details in regulations allows the form and content of the report to be amended in a timely manner in response to such change and ensures consistency with the requirements of other provisions. Powers setting out administrative details that may need adjusting in response to changes to wider organisational structures and procedures have been used in other legislation.

Consideration of the procedure

143. Subsection (4) of clause 54 sets out that regulations made under clause 29(3) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation, given the technical nature of the matters to be addressed in regulations and the need to be able to respond to future changes in NHS structures and procedures.

Clause 37(1): Regulation of approved substances and devices for self-administration – regulations making provision about approved substances

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

144. Clause 37(1) imposes a duty on the Secretary of State to make regulations containing provision about approved substances. Subsections (2), (3), and (4) set out further details to be included in these regulations. Clause 37(2) sets out that these regulations must make provision about:

- a. the supply or offer for supply, or administration, of approved substances;
- b. the transportation, storage, handling and disposal of approved substances;

- c. the keeping of records of matters relating to approved substances.
145. Subsection (3) of clause 37 provides that the regulations may make provision:
- a. about the manufacture, importation, preparation or assembly of approved substances;
 - b. for or in connection with the monitoring of matters relating to approved substances;
 - c. requiring persons specified in the regulations, in specified cases, to give information to the Secretary of State.
146. Subsection (4) sets out that the regulations may:
- a. make provision relating to approved substances that is similar to, or that corresponds to, any provision of the Human Medicines Regulations 2012;
 - b. make provision applying any provision of those Regulations, with or without modifications, in relation to approved substances.
147. Subsection (6) also provides that regulations made under this clause must make provision about enforcement, which must include, but need not be limited to, provision imposing civil penalties.
148. Subsection (7) specifies that regulations under this clause may make any provision that could be made by an act of Parliament, but they may not amend the Act arising from this Bill. This means that the regulation making power under this Bill is a Henry VIII power. The broad power in subsection (7) is needed to allow the regime to adapt in an agile way to currently unknown issues or products, or to respond to regulatory or safety concerns. This may require the creation of new offences or bodies, or amendment to be made to aspects of the Human Medicines Regulations 2012 or Medical Devices Regulations 2001, and consequential changes to be made thereupon to the Medicines Act 1968.

Rationale for taking the power

149. It is understood that this power has been taken to require the Secretary of State to make regulations about the supply, administration, transportation, storage, handling and disposal of approved substances, and related record keeping, as well as making provision about monitoring and enforcement.
150. The information that would go into these regulations is largely operational and is likely to require a high level of detail, which would be suited to being set out in secondary legislation.
151. In addition, setting out this duty in secondary legislation provides flexibility to maintain a safe and robust system, by enabling regulations to be amended in response to continuing developments in the prescribing, dispensing, transportation,

storage, handling and disposal of approved substances, and related record keeping.

152. A duty to make provision about enforcement in these regulations is also considered necessary to ensure that relevant enforcement authorities have the powers needed to enforce the regulations made under the Bill.

Consideration of the procedure

153. Subsection (3) of clause 54 sets out that regulations made under clause 37 are subject to the draft affirmative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects the ‘Henry VIII’ nature of the power, as it provides the Secretary of State the power to amend the Human Medicines Regulations.

154. The draft affirmative procedure will ensure that both Houses have the opportunity to consider and debate these regulations.

Clause 37(5): Regulation of approved substances and devices for self-administration – regulations making provision about devices in connection with the self-administration of approved substances

Power conferred on: Secretary of State

Power exercised by: Regulations by Statutory Instrument

Parliamentary Procedure: Draft Affirmative

Context and Purpose

155. Clause 37(5) provides a power for the Secretary of State to make regulations making provision about devices made for use or used for, or in connection with, the self-administration of approved substances. In this clause, “device” includes information in electronic form for use in connection with a device.

156. Subsection (6) of clause 37 sets out that these regulations must make provision about enforcement, which must include, but need not be limited to, provision imposing civil penalties.

157. Subsection (7) specifies that regulations under this clause may make any provision that could be made by an act of Parliament, but they may not amend this Bill. This means that the regulation making power under this Bill is a Henry VIII power. The broad power in subsection (7) is needed to allow the regime to adapt in an agile way to currently unknown issues or products, or to respond to regulatory

or safety concerns. This may require the creation of new offences or bodies, or amendment to be made to primary legislation, such as the Medicines Act 1968.

Rationale for taking the power

158. It is understood that this power has been taken to allow the Secretary of State to make regulations about devices made for use or used for, or in connection with, the self-administration of approved substances, for the purpose of ending one's life.

159. The information that would go into these regulations is largely operational and technical, which would be suited to being set out in secondary legislation.

160. In addition, setting this power out in secondary legislation provides flexibility to maintain a safe and robust system by enabling regulations to be amended in response to continuing developments in devices that may be used in connection with approved substances.

161. A duty to make provision about enforcement in these regulations is also considered necessary to ensure that relevant enforcement authorities have the powers needed to enforce the regulations made under the Bill.

Consideration of the procedure

162. Subsection (3) of clause 54 sets out that regulations made under clause 37 are subject to the draft affirmative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects the 'Henry VIII' nature of the power, as it provides the Secretary of State the power to amend for example, the Medicines Act 1968.

163. The draft affirmative procedure will ensure that both Houses have the opportunity to consider and debate these regulations.

Clause 38(2): Investigation of deaths etc – regulation making power to be inserted into the Coroners and Justice Act 2009

Power Conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative

Context and Purpose

164. Clause 38(2) adds in a new sub-section to section 20 of The Coroners and Justice Act 2009 (CJA 2009) and provides a power for any regulations made by the Secretary of State under powers in s.20(1) CJA 2009 (in relation to the medical certificate of cause of death) to include similar, corresponding or additional provisions (as considered appropriate by the Secretary of State) in respect of assisted deaths where assistance was provided in line with the Bill.

165. The new provision inserted by clause 38(2) also provides that regulations made under s.20(1) CJA 2009 must provide that where the person issuing the medical certificate of cause of death (MCCD) believes to the best of their knowledge and belief that the cause of death is the self-administration of an approved substance in accordance with the Bill, the MCCD must state the cause of death to be “assisted death”. Further, that the terminal illness which allowed the individual to receive assistance under the Bill must be recorded on the MCCD.

Rationale for taking the power

166. The clause amends existing regulation-making provisions, ensuring consistency in deaths certification procedures and requirements by conferring a power enabling any necessary changes to secondary deaths certification legislation in relation to the certification of assisted deaths.

167. The detail in relation to procedural requirements for completing the MCCD, including the forms to be completed, is predominantly governed by secondary legislation (the Medical Certificate of Cause of Death Regulations 2024). The level of detail required to give effect to the detailed operational framework is not suitable for primary legislation.

168. The delegated power also enables flexibility in adjusting the detailed framework, for instance to accommodate future changes to the detailed operational framework for MCCD completion or changes that may be needed for the current framework to operate effectively in respect of assisted deaths.

169. The power is restricted to the death certification procedure for the specific purpose of completing the MCCD; specifically in relation to assisted deaths.

170. Taking into account the restricted nature of the power, it is considered that this regulation making power is appropriate for the purpose of accommodating a new cohort of deaths (assisted deaths under the Bill’s provisions) to the existing deaths certification legislative framework.

Consideration of the procedure

171. By virtue of s.176 CJA 2009, the regulation making power in clause 38(2) is subject to the negative procedure. This is considered appropriate given the limitations on the power and the fact that the existing secondary legislation-making power it amends does not confer powers to amend primary legislation. Further, the current regulation making powers within s.20(1) CJA 2009 are subject to the negative procedure, and this would ensure consistency in procedure.

Clause 39(1): Codes of practice – codes of practice relating to the operation of the Bill.

Power conferred on: Secretary of State

Power exercised by: Codes of Practice

Parliamentary Procedure: None directly, although regulations giving effect to Codes of Practice are subject to the draft affirmative procedure

Context and Purpose

172. Clause 39(1) imposes a duty on the Secretary of State to issue one or more codes of practice in connection with the operation of the Bill.

173. The Secretary of State must issue codes of practice relating to:

- (a) the assessment of whether a person has a clear and settled intention to end their own life, including:
 - i. assessing whether the person has capacity to make such a decision;
 - ii. recognising and taking account of the effects of depression or other mental disorders (within the meaning of the Mental Health Act 1983) that may impair a person's decision-making;
- (b) the information which is made available, as mentioned in clauses 5 and 12, on treatment or palliative, hospice, or other care available to the person and, under clause 12, on the consequences of deciding to end their own life;
- (c) the provision of information and support to persons with learning disabilities who are eligible to request assistance to end their own life under this Bill, including the role of advocates for such persons;
- (d) ensuring effective communication in connection with persons seeking assistance under this Bill to end their own lives, including the use of interpreters;
- (e) the arrangements for providing approved substances to the person for whom they have been prescribed, and the assistance which such a person may be given to ingest or self-administer them;
- (f) the arrangements for a qualifying person requesting assistance to end their own life to receive the support of an independent advocate under clause 22;
- (g) responding to unexpected complications that arise in relation to the administration of the approved substance under clause 25, including when the procedure fails;
- (h) the forms of proof of identity that are acceptable for the purposes of clause 9.

Rationale for taking the power

174. Codes of practice primarily relate to operational matters under the Bill. Setting such details out in codes of practice would be consistent with the use of such powers in other legislation and enable the content to be adjusted based on ongoing review of the process. In addition, the operational guidance is likely to be highly detailed and technical in nature, which is more suitably covered in codes of practice

rather than in legislation. These codes are matters to which persons exercising functions must have regard to (see clause 39(6)) but are not directive in nature. Accordingly, they may contain general and advisory statements.

175. The contents of the codes will be the subject of consultation with relevant organisations, such as the GMC and CQC, in accordance with the duty to consult under clause 39(3). They will also be laid before Parliament along with the regulations that bring them into force in accordance with subsections (4) and (5). Further, the codes of practice may be revised following review under clauses 49 and 50 of the Bill.

176. For these reasons, and in line with the framework established by other provisions in this Bill, it is appropriate that operational details be contained in codes of practice, brought into force by secondary legislation, rather than on the face of the Bill.

Consideration of the procedure

177. Codes of practice issued under this power are not themselves subject to a prescribed parliamentary procedure. The role of codes of practice issued under clause 39 is to provide guidance on the operation of the Bill, which those persons who carry out functions under the Bill must have regard to (subsection (6)). However, clause 39(4) also provides that codes of practice issued under subsection (1) only come into force by regulations made by the Secretary of State, which are subject to the draft affirmative procedure. This would enable both Houses of Parliament to consider and debate the codes of practice.

Clause 39(2): Codes of practice – codes of practice relating to the operation of the Bill not covered under subsection (1)

Power conferred on: Secretary of State

Power exercised by: Codes of Practice

Parliamentary Procedure: None

Context and Purpose

178. Clause 39(2) provides that the Secretary of State may issue codes of practice in connection with any matter relating to the operation of the Bill, not already required under clause 39(1), as the Secretary of State considers appropriate.

Rationale for taking the power

179. As stated in relation to the power under clause 39(1), codes of practice primarily relate to operational matters under the Bill. Setting these details out in codes of practice would be consistent with the use of such powers in other legislation and would enable the content to be adjusted based on ongoing review of the process. In addition, the operational guidance is likely to be highly detailed and technical in

nature, and so is more suitably covered through codes of practice rather than primary legislation.

180. The content of those codes will be the subject of consultation with relevant organisations, such as the GMC and CQC, in line with the duty to consult under clause 39(3). Further, they may be revised following review under clauses 49 and 50 of the Bill.

181. For these reasons, and in line with the framework established by other provisions in this Bill, it is appropriate that these details be contained in codes of practice, rather than via new provisions on the face of the Bill.

Consideration of the procedure

182. Codes of practice issued under this power are not subject to a prescribed parliamentary procedure. The role of codes of practice issued under clause 39 is to provide advice on the operation of the Bill, which those persons who carry out functions under the Bill must have regard to (subsection (6)). Codes of practice under clause 39(1) are associated with regulations which will be subject to the draft affirmative procedure, because of their centrality to contentious issues in the Bill. Codes of practice under clause 39(2) will act as guidance in relation to ancillary matters.

Clause 39(4): Codes of practice – regulations on codes of practice relating to the operation of the Bill

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

183. Clause 39(4) specifies that a code issued under clause 39(1) does not come into force until the Secretary of State brings them into force by regulations. Clause 39(5) provides that the codes of practice set out in clause 39(1) must be laid before Parliament at the same time as the draft regulations relating to that code are laid. A person performing any function under the Bill must have regard to any relevant provision of these codes and a failure to do so may be taken into account in any criminal or civil proceedings.

Rationale for taking the power

184. It is understood that this power has been taken to enable the Secretary of State to bring codes of practice in relation to the operation of the Bill into force. Codes of

practice can be considered necessary to provide detailed guidance, to ensure that a person performing any function under the Bill suitably fulfils their role.

Consideration of the procedure

185. Subsection (3) of clause 54 sets out that regulations made under this power will be subject to the draft affirmative procedure. These regulations will bring into force codes of practice which persons involved in the assisted dying process will need to have regard to. This will therefore have an impact on persons with functions under the Bill, notably registered medical practitioners.

186. In addition, there is a wide scope of matters under the Bill that may be covered within these codes of practice, and failure to do so may be taken into account in criminal or civil proceedings. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects this wide scope by enabling a debate and vote in both Houses of Parliament.

Clause 40(1): Guidance about operation of Act

Power conferred on: Secretary of State

Power exercised by: Statutory Guidance

Parliamentary Procedure: None

Context and Purpose

187. Clause 40(1) confers a duty on the Secretary of State to prepare and publish guidance relating to the operation of the Bill. This guidance need not relate to matters that the Welsh Ministers may issue guidance about under subsection (4) of clause 40, but may do so.

188. Subsection (3) of clause 40 sets out that the Secretary of State must consult:

- a. the Chief Medical Officer for England,
- b. the Chief Medical Officer for Wales,
- c. such persons with learning disabilities and other persons who have protected characteristics as the Secretary of State considers appropriate,
- d. such persons appearing to represent providers of health or care services, including providers of palliative or end of life care, as the Secretary of State considers appropriate,
- e. if any part of the guidance relates to Welsh devolved matters, the Welsh ministers, and
- f. such other persons as the Secretary of State considers appropriate.

189. Subsection (7) of clause 40 sets out that the Secretary of State must have regard to the need to provide practical and accessible information, advice and guidance to persons requesting or considering requesting assistance to end their own lives

(including persons with learning disabilities), the next of kin and families of such persons, and the general public.

190. Subsection (4) provides a separate power to the Welsh Ministers to issue guidance about matters within devolved competence, relating to the operation of the Bill in Wales. This is considered further below.

Rationale for taking the power

191. It is understood that this power has been taken to ensure that the Secretary of State provides guidance, so that there is practical and accessible information about the operation of the Bill, and advice and guidance for persons considering requesting assistance under the Bill (including persons with learning disabilities), their families, and the public.

192. The content of the guidance will be distinct from the codes of practice which will be issued in accordance with clause 39(1) and which will contain material on the most contentious issues. Any statutory guidance issued under clause 40 would be capable of being adjusted as appropriate, for example, to reflect adjustments identified in the course of a review of the Bill's operation (as provided for elsewhere in the Bill), or to reflect changes to NHS structures or ways of working over time.

193. Finally, setting these details out in guidance allows the Secretary of State to meet various duties to consult a range of persons considered appropriate before making guidance on the operation of the Bill, namely, the relevant Chief Medical Officers, persons with learning disabilities, persons with protected characteristics, persons appearing to represent providers of health or care services, where relevant, the Welsh Ministers, and such other persons the Secretary of State considers appropriate.

Consideration of the procedure

194. Guidance made under this power is not subject to a prescribed procedure, which reflects usual practice for statutory guidance.

Clause 40(4): Guidance about operation of Act – guidance about the operation of the Act in Wales (on matters within devolved competence)

Power conferred on: Welsh Ministers

Power exercised by: Statutory Guidance

Parliamentary Procedure: None

Context and Purpose

195. Clause 40(4) provides a power for Welsh Ministers to issue guidance relating to the operation of the Bill in Wales.
196. The guidance must only be about matters within devolved competence, which for this purpose means that provision would be within the legislative competence of Senedd Cymru if it were contained in an Act of the Senedd.
197. Subsection (6) of clause 40 sets out that before issuing guidance under subsection (4), the Welsh Ministers must consult:
- a. the Chief Medical Officer for Wales
 - b. the Secretary of State
 - c. such persons with learning disabilities and other persons who have protected characteristics as the Welsh Ministers consider appropriate
 - d. such persons appearing to represent providers of health or care services, including providers of palliative or end of life care, as the Welsh Ministers consider appropriate, and
 - e. such other persons as the Welsh Ministers consider appropriate.
198. Subsection (7) of clause 40 sets out that, when preparing guidance under this clause, the Welsh Ministers must have regard to the need to provide practical and accessible information, advice and guidance to persons requesting or considering requesting assistance to end their own lives (including persons with learning disabilities), the next of kin and families of such persons, and the general public.

Rationale for taking the power

199. It is understood that this power has been taken to allow the Welsh Ministers to provide guidance about matters relating to the operation of the Bill in Wales, where these matters are within devolved competence.
200. The content of the guidance is operational in nature, therefore, setting this out in guidance would enable the content to be adjusted as appropriate. This may be, for example, to reflect adjustments identified following a review of the Bill's operation (as provided for elsewhere in the Bill), or to reflect changes to NHS structures or ways of working over time.
201. It is therefore appropriate that the guidance can be amended as quickly as is practical in order to reflect such changes.
202. Finally, setting these details out in guidance allows Welsh Ministers to meet their various duties to consult a range of persons considered appropriate before making guidance on the operation of the Bill, such as the Welsh Chief Medical Officer, the Secretary of State, persons with learning disabilities and protected characteristics, persons appearing to represent providers of health or care services and such other persons as the Welsh Ministers consider appropriate.

Consideration of the procedure

203. Guidance made under this power is not subject to a prescribed parliamentary procedure, which reflects usual practice for statutory guidance.

Clause 41(1): Voluntary assisted dying services: England – regulations securing arrangements for the provisions of voluntary assisted dying services in England

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

204. It is proposed that VAD services will be provided through the National Health Service in England.

205. The purpose of clause 41(1) is to impose a duty on the Secretary of State to make regulations securing that arrangements are made for the provision of VAD services in England.

206. Subsection (4) of this clause sets out that these regulations may, for example, provide that specified references in the National Health Service Act 2006 to the health service continued under section 1(1) of that Act include references to commissioned VAD services. Further, subsection (5) sets out that regulations must provide that section 1(4) of the National Health Services Act 2006, “services to be provided free of charge except where expressly provided for”, applies in relation to commissioned VAD services.

207. Attention is drawn to clause 41(6) which sets out that regulations under this clause may make any provision that could be made by an Act of Parliament, but they may not amend this Bill. The regulation making power is therefore a Henry VIII power

Rationale for taking the power

208. It is understood that this power has been taken to require the Secretary of State to secure that arrangements are made for the provision of VAD services in England. If the Bill passes in accordance with Parliament’s will, this power will be required to fulfil the policy intent of the Bill, as there is no current provision for a VAD service in England.

209. Securing arrangements for the provision of VAD services in England will be a complex and technical process, the details of which will likely require significant

time and input of the Department of Health and Social Care, and other key stakeholders, and which are therefore suited to secondary legislation rather than primary legislation. Complex legislation will be required to ensure commissioned VAD services can be delivered, including amendments and modifications to primary legislation. This would include, for example, putting a service model in place, and conferring or modifying functions on commissioners to enable commissioning of VAD services. These arrangements are also highly dependent on NHS structures and commissioning practices, so setting out such details in regulations allows the provision to be amended as quickly as practicable subject to future changes and developments.

210. In addition, the Secretary of State has various duties to consult persons considered appropriate before making regulations under the Bill, and the outcomes of these consultations are likely to have an impact on what is considered necessary to include in the arrangements for the provision of VAD services in England.

Consideration of the procedure

211. Regulations made under this power will be subject to the draft affirmative procedure. These regulations may amend the National Health Service Act 2006 and or other relevant healthcare legislation in order to introduce a novel service in England, hence why this is a Henry VIII power.

212. As such, the draft affirmative procedure is appropriate as it will enable a debate and vote in both Houses of Parliament, so that the impacts of the regulations can be subject to appropriate parliamentary scrutiny.

213. The provision of VAD services in England is expected to be complex and generate interest in the implementation.

Clause 41(3): Voluntary assisted dying services: England – regulations making consequential provision for the provisions of voluntary assisted dying services in England

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary procedure: Draft Affirmative Procedure

Context and Purpose

214. Clause 41(3) confers a power on the Secretary of State to make other provision about VAD services in England via regulations.

Rationale for taking the power

215. It is understood that this power has been taken to enable the Secretary of State to make other provision about VAD services in England, whether or not the services are commissioned VAD services, in addition to the regulations set out in subsection (1) of clause 41. This power therefore extends beyond the power set out in clause 41(1).

216. Complex arrangements will be required to ensure structures are in place to ensure VAD services can be delivered, including amendments and modifications to primary legislation. This will include ensuring the appropriate provisions are in place for a service model, for example, ensuring that VAD services are regulated. Further, depending on the service model adopted, uses of the power are likely to include ensuring that various existing NHS schemes, relating to licencing, the amount payable for NHS-funded secondary healthcare, and provider selection, apply to commissioned VAD services.

217. The power also allows scope for it to be utilised to ensure the Secretary of State can issue directions to bodies exercising functions in relation to VAD services. As set out in the previous power, there are various duties to consult before making regulations pertaining to the Bill, and the outcomes of these may identify further provision that is needed to secure arrangements for the provision of the service. The level of detail needed to set this out is therefore more suitably covered in secondary rather than primary legislation, in line with the use of such powers in other legislation.

218. Attention is drawn to clause 41(6) which sets out that regulations under this clause may make any provision that could be made by an Act of Parliament, but they may not amend this Bill. This confirms that the regulation making power under this subsection (3) is a Henry VIII power.

Consideration of the procedure

219. Regulations made under this power will be subject to the draft affirmative procedure. The provision of VAD services in England is likely to be complex and generate interest in the implementation.

220. The draft affirmative procedure would enable a debate and vote in both Houses of Parliament, so that the impacts of the regulations can be subject to appropriate parliamentary scrutiny.

Clause 42(1): Voluntary assisted dying services: Wales – regulations securing arrangements for the provisions of voluntary assisted dying services in Wales

Power conferred on: Welsh Ministers

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

221. The purpose of clause 42(1) is to provide a power for the Welsh ministers to make provision through regulations about VAD services in Wales. Clause 42(6)(b) specifies that references to “provision about VAD services” includes in particular provision securing that arrangements are made for the provision of such services.

222. Attention is drawn to clause 42(2) and 42(5). Subsection (2) sets out that regulations under this clause may make any provision that could be made by an Act of Senedd Cymru, and would be within the legislative competence of the Senedd if it were contained in such an Act. Subsection (5) sets out that regulations under this clause may not amend this Bill. This confirms that the regulation making power under this clause is a Henry VIII power.

223. Clause 51 further sets out that regulations made under clause 42 must make such provision as the Welsh Ministers consider appropriate for the purpose of ensuring that, where a relevant person (being a person in Wales who wishes to be provided with assistance to end their own life in accordance with this Bill) indicates that they wish to communicate in Welsh, all reasonable steps are taken to secure that:

- (a) communications made by a person providing a voluntary assisted dying service to the relevant person are in Welsh, and
- (b) any report about the first or second assessment of the relevant person is in Welsh.

Rationale for taking the power

224. It is understood that this power has been taken to enable the Welsh Ministers to make provision about VAD services in Wales. If the Bill passes in accordance with Parliament’s will, this power will be required to fulfil the policy intent of the Bill, as there is no current provision for a VAD service in Wales.

225. It is understood that the rationale for taking this power is to ensure that Welsh Ministers have sufficient powers to enable them to provide for an effective service in Wales. Making provision for VAD services in Wales will likely be a very complex and technical process. Complex legislation will be required, which is likely to include amendments or modifications to primary legislation. The legislation will need to set out who will commission, provide, and regulate the VAD service and ensure the necessary structures are in place for this to take place. Therefore, these arrangements would be more suitably set out in secondary legislation, rather than on the face of the Bill.

226. There are also various duties on the Secretary of State to consult before making regulations under the Bill, and this power would allow the Welsh Ministers to take the outcome of these consultations into account before making regulations about VAD services in Wales.

Consideration of the procedure

227. Regulations made under this power will be subject to the draft affirmative procedure. These regulations can make any provision that can be made by an Act of Senedd Cymru and would be within the legislative competence of the Senedd, if it were contained in such an Act, making this a Henry VIII power.

228. Additionally, the provision of VAD services in Wales is likely to be complex and generate interest in the implementation.

229. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny would enable a debate and vote in the Senedd, so that the impacts of the regulations can be subject to appropriate parliamentary scrutiny.

Clause 42(3): Voluntary assisted dying services: Wales – regulations making consequential provision for the provisions of voluntary assisted dying services in Wales

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

230. Clause 42(3) confers a power on the Secretary of State to make provision about VAD services in Wales via regulations. Clause 42(6)(b) specifies that regulations made under this clause may include provision securing that arrangements are made for the commissioning of VAD services. Subsection (4) provides that regulations under subsection (3) may make any provision that (a) could be made by an Act of Parliament and (b) would not be within the legislative competence of the Senedd, if it were contained in an Act of the Senedd. This confirms that the regulation making power under subsection (3) is a Henry VIII power.

Rationale for taking the power

231. It is understood that this power has been taken to allow the Secretary of State to make provision about VAD services in Wales, where the ability to do so is not within the legislative competence of the Senedd. This power allows flexibility of regulations to ensure that the provision for services in Wales is comprehensive and

is not limited to that set out in 42(1).

232. It is considered appropriate for these devolution powers to be set out in secondary rather than primary legislation, as the details of these regulations are likely to be complex and technical.

233. As set out in the previous power, there are various duties to consult before making regulations pertaining to the Bill, and the outcomes of these may identify further provision that is needed to secure arrangements for the provision of the service. Setting this power out in secondary legislation would therefore enable further provision to be made, if needed.

234. While the Bill sets out that it is for Welsh Ministers to make arrangements for the provision of VAD services in Wales, the duties to consult, and other regulation making powers under the Bill, are on the Secretary of State. Therefore, the Secretary of State is likely to be appropriately placed to identify additional provision to be set out in regulations.

Consideration of the procedure

235. Regulations made under this power will be subject to the draft affirmative procedure. The provision of VAD services in Wales is likely to be complex and generate interest in the implementation.

236. This level of parliamentary scrutiny will enable a debate and vote in both Houses of Parliament, so that the impacts of the regulations can be subject to appropriate parliamentary scrutiny.

Clause 43(1): Prohibition on advertising – regulations to prohibit advertisements promoting a voluntary assisted dying service

Power conferred on: Secretary of State

Power exercised by: Regulations by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

237. Clause 43(1) imposes a duty on the Secretary of State to make regulations prohibiting advertisements to promote services relating to voluntary assisted dying under the Bill.

238. Specifically, the regulations must prohibit:

- a. the publication, printing, distribution or designing (anywhere) of advertisements whose purpose or effect is to promote a voluntary assisted dying service;

- b. causing the publication, printing, distribution or designing of such advertisements.

239. Subsection (2) of clause 42 sets out that the regulations may contain certain exceptions (for example, for the provision of certain information to users or providers of services).

240. Subsection (3) sets out that regulations under this clause may make any provision that may be made by an Act of Parliament. This confirms that the regulation making power under this clause is a Henry VIII power. Subsection (3) is limited by subsection (4) which states that such regulations may not amend this Bill and must provide that any offence created by the regulations is punishable with a fine.

Rationale for taking the power

241. It is understood that this power has been taken to require that the Secretary of State makes provision to prohibit advertisements promoting services relating to voluntary assisted dying. This power provides for a type of detailed regulation that would conventionally be set out in secondary legislation, because it is to give effect to the principal policy as set out in legislation. It is therefore likely to be detailed and technical, and may need ongoing refinement or updating.

242. A regulation making power enables a degree of flexibility to determine the details of and exceptions to the prohibition of advertising once the service has been operationalised, and to future proof against any changes in advertising techniques that regulations may not cover in the first instance.

Consideration of the procedure

243. Subsection (3) of clause 54 sets out that regulations made under clause 43 are subject to the draft affirmative procedure. These regulations may amend any relevant legislation to prohibit the advertising of a VAD service, which could impact business.

244. Whilst the Government is neutral on the choice of the regulation making procedure, the draft affirmative procedure is appropriate as it will enable a debate and vote in both Houses of Parliament, so that the impacts of the regulations can be subject to appropriate parliamentary scrutiny. The policy on assisted dying is of a novel and controversial nature, and there has been a high level of parliamentary interest relating to this issue.

Clause 44(1): Notifications and provision of information to Commissioner – regulations requiring practitioners to notify the Commissioner

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

245. The purpose of clause 44 is to provide the Secretary of State with powers to require practitioners to notify the Commissioner of any event specified in the regulations, and to enable the Commissioner to require persons or groups of persons to give the Commissioner information.

246. Clause 44(1) provides the Secretary of State with the power to make regulations requiring practitioners to notify the Commissioner of the occurrence of any event specified in the regulations.

247. Subsection (3) of the clause sets out more detail about what may be included in these regulations. In particular, they may:

- (a) specify the information which must be contained in a notification under subsection (1);
- (b) specify the manner in which such a notification must be given;
- (c) make provision about enforcement of the regulations.

Rationale for taking the power

248. It is understood that this power has been taken to enable the Secretary of State to require practitioners to notify the Commissioner of specified events. The information to be shared with the Commissioner would be an operational element of the process. Setting out the details of this in secondary legislation will enable the content to be adjusted based on ongoing review of the process. Furthermore, clause 44(3) provides a guide as to the details that may be specified in regulations made under this power.

Consideration of the procedure

249. Subsection (4) of clause 54 sets out that regulations made under clause 44(1) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects accepted practice in other legislation, given the technical nature of the matters to be addressed in regulations and the need to be able to make changes in response to ongoing review of the process.

Clause 44(2): Notifications and provision of information to Commissioner – regulations specifying persons to give the Commissioner information

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary procedure: Negative Procedure

Context and Purpose

250. Clause 44(2) provides the Secretary of State with the power to enable the Commissioner to, by notice, require persons (or a specified description of persons) to give the Commissioner information (or a specified description of information).

Rationale for taking the power

251. It is understood that this power has been taken to enable the Secretary of State to require persons, or a specified description of persons, to give the Commissioner information, or a specified description of information. The persons and kinds of information to be specified in these regulations would be an operational element of the assisted dying process, and as such are suited to secondary legislation rather than the face of the Bill. In addition, the Commissioner has monitoring and reporting duties under clause 49 of the Bill, and the introduction of this power allows the Secretary of State to enable the Commissioner to obtain the appropriate information from specified persons, in order for the Commissioner to prepare a report of the provisions of the Bill.

Consideration of the procedure

252. Subsection (4) of clause 54 sets out that regulations made under clause 44(2) are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making power, this level of parliamentary scrutiny reflects the technical nature of the matters to be addressed in regulations and the need to be able to make changes in response to ongoing reviews of the process.

Clause 45(3)(e): Information sharing – regulations specifying persons who may disclose information to the Commissioner

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

253. Clause 45 enables the sharing of information between the Commissioner and certain persons. The purpose of clause 45(3)(e) is to enable the Secretary of State to make regulations specifying persons that may disclose information to the Commissioner for the purposes of any function of either the Commissioner or those persons.

Rationale for taking the power

254. It is understood that this power has been taken to allow the Secretary of State to specify persons who may disclose information to the Commissioner for the purposes of either their or the Commissioner's functions.

255. Identifying persons that can share information with the Commissioner is an operational part of the process. Certain persons have been set out in subsection (3)(a) to (d), which provides a guide as to the kinds of additional organisations that may be identified in regulations. Including this power in secondary legislation provides flexibility to amend the regulations in response to future changes or additions to persons who have relevant information to share, subject to any changes to the NHS organisational structure or other ways of working.

Consideration of the procedure

256. Subsection (4) of clause 54 sets out that regulations made under clause 45 are subject to the negative procedure. Whilst the Government is neutral on the choice of the regulation making power, this power is considered to afford an appropriate level of parliamentary scrutiny given the technical nature of the matters to be addressed in regulations, and the need to be able to make changes in response to ongoing reviews of the process and changes in organisational structures.

Clause 49(3)(b): Monitoring by Commissioner – regulations specifying descriptions of persons the annual report must include information about

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

257. Clause 49 confers monitoring, investigation, and reporting functions on the Commissioner. Clause 49(3)(b) provides that the annual report to be submitted by the Commissioner must include information about the application of the Bill to persons who have protected characteristics.

258. Clause 49(3)(b) provides the Secretary of State the power to add, by regulations, any other descriptions of persons with regard to whom the annual report must include such information.

Rationale for taking the power

259. It is understood that implementing this power seeks to ensure that if relevant information needs to be included in the annual report regarding the application of

the Bill to a specific description of persons, in addition to those with protected characteristics, then there is a power to specify such persons by way of regulations. This could include, for instance, those belonging to different socio-economic backgrounds, geographical locations etc.

260. Given these regulations complement the existing list of specified persons, i.e., those with protected characteristics, in respect of whom information regarding the application of the Bill must be provided in the annual report, it would be prudent for the Bill to contain a power to specify such other descriptions of persons in secondary legislation.

Consideration of the procedure

261. Whilst the Government is neutral on the choice of regulation making procedure, any regulations made under this power are subject to the negative procedure since the power is limited and relates to specific reporting details of the Bill.

Clause 53(1): Power to make consequential and transitional provision etc – regulations making consequential and transitional provision

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Negative Procedure

Context and Purpose

262. Clause 53(1) confers a power on the Secretary of State to make provision that is consequential on this Bill or transitional in nature. This power may be needed to make amendments to legislation, if required, in consequence of this Bill to give it effect.

Rationale for taking the power

263. This power may only be exercised to make provision that is consequential in this Bill. The power is required to enable consequential amendments to secondary legislation, of which the Government is aware, and it is standard practice to make such amendments through secondary legislation. Therefore, there is a possibility that further consequential amendments may be required to give effect to the Bill and that the commencement of the replacement provisions in the Bill will potentially be made at different stages. It would, therefore, align with accepted practice for the Bill to contain a power to deal with these in secondary legislation.

Consideration of the procedure

264. Any regulations made under this power are subject to the negative procedure, since changes are unlikely to be substantive and will only be ensuring the effectiveness of the provisions.

Clause 58(3): Commencement – regulations on commencement

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: None

Context and Purpose

Clause 58(3) contains a power for the Secretary of State to commence provisions, other than those in clauses 47, 53 to 59 and clause 4, except subsection 4(4), and Schedule 1, of the Bill in England, on a date they have determined until the end of the period of 4 years beginning with the day on which the Bill is passed. Clause 58(4) sets out that if any provision of the Bill has not been fully brought into force before the end of this 4-year period, the provision will come into force at the end of that period in England. Regulations made under this clause can be used to make different provisions for different purposes.

Rationale for taking the power

265. It is understood that this power has been taken to allow the provisions of the Bill, other than the clauses set out in clauses 58(1) and 58(2), to be brought into force via regulations. If the Bill is passed, there will likely be significant work to undertake on implementation of the provisions of the Bill, as well as to develop, and if applicable, publish, regulations, guidance, and codes of practice.

Consideration of the procedure

266. Regulations providing for the coming into force of these provisions of the Bill are not subject to any parliamentary procedure. This is standard with commencement powers, as Parliament will have approved the principle of the provisions to be commenced by enacting them. Commencement by regulations enables the provisions to be brought into force at an appropriate time.

Clause 58(5): Commencement: Regulation making power for Welsh Ministers to commence provisions in the Bill in Wales

Power conferred on: Welsh Ministers

Power exercised by: Regulations made by Statutory Instrument

Parliamentary procedure: None

Context and Purpose

267. Clause 58(5) contains a power for the Welsh Ministers to commence the provisions of this Bill under clauses 42(1) and (2) and 51(2) and (3) on such day appointed by the Welsh Ministers in regulations. There is no date by which the Welsh Ministers must have brought the regulations into force.

Rationale for taking the power

268. It is understood that this power has been taken to allow the provisions of the Bill within devolved competence to be brought into force in Wales via regulations made by the Welsh Ministers.

269. A power to bring the provisions of the Bill into force via regulations is consistent with the use of such powers in other legislation, given the significant work that will need to be undertaken on implementation if the Bill passes, including on the development of regulations, guidance, and codes of practice.

Consideration of the procedure

270. Regulations providing for the coming into force of these provisions of the Bill are not subject to any parliamentary procedure. This is standard with commencement powers, as Parliament will have approved the principle of the provisions to be commenced by enacting them. Commencement by regulations enables the provisions to be brought into force at an appropriate time.

Clause 58(6): Commencement: Transitional or saving provision

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: None

Context and Purpose

271. Clause 58(6) provides the Secretary of State may make transitional or saving provision in connection with the coming into force of any provision of this Bill.

Rationale for taking the power

272. It is understood that this power has been taken to allow the Secretary of State to make transitional or saving provision in connection with the coming into force of any provision of this Bill. This would enable any necessary transitional or saving provision, in connection with the commencement of the Bill, to be made in order to ensure the effective implementation of the operative provisions.

Consideration of the procedure

273. As is usual with a power to make transitional or saving provision in connection with the coming into force of the provisions of a Bill, regulations made under this clause are not subject to any parliamentary procedure.

Department of Health and Social Care

Ministry of Justice

26 June 2025