

TERMINALLY ILL ADULTS (END OF LIFE) BILL

Supplementary Delegated Powers Memorandum

Introduction

1. The Sponsor has tabled amendments to the Terminally Ill Adults (End of Life) Bill for Lords Committee stage, including amendments to delegated powers in relation to clauses 22, 27, 37, 38, 41 and 58. This supplementary memorandum has been prepared for the Delegated Powers and Regulatory Reform Committee, to assist with its scrutiny of the Bill.
2. As the Government is neutral on the Bill, the Government has not provided a justification for why the powers have been taken or for the parliamentary procedure being applied but have instead provided consideration of matters which may affect whether Parliament considers these appropriate.
3. Should the Sponsor table further relevant amendments to the delegated powers in the Bill, the Government will publish further supplementary memoranda on these.

Amendments to Delegated Powers

New clauses replacing clause 22: Independent advocate - regulations making provision about independent advocates.

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Affirmative Procedure

Context and Purpose

4. Clause 22 currently requires the Secretary of State to, by regulations, make provision for independent advocates. The role of the independent advocate, set out in the clause, is to provide representation and support to a qualifying person (as defined in paragraph (4)) 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.
5. In its report, the Delegated Powers and Regulatory Reform Committee noted the inconsistency between clause 22(1) and 54 as to the parliamentary procedure which was to apply to the regulations. The Committee also recommended that, since any legal obligations to ensure the presence of an independent advocate for qualifying persons are a principal aspect of the policy, these obligations should therefore be set out on the face of the Bill.

6. The Sponsor has tabled three amendments to this clause.
7. First, the Sponsor has tabled an amendment that replaces clause 22 with a new clause 22. The amended clause 22 requires certain persons to undertake certain procedural steps to ensure that qualifying persons are informed about and have access to an independent advocate. The clause sets out on the face of the bill the circumstances in which an independent advocate must be available to a qualifying person. An updated definition of qualifying person is provided in paragraph (8), which continues to include (among others) a person who meets the criteria specified in regulations made under the new clause described below.
8. Second, the Sponsor has also tabled an amendment that inserts a new clause (*Independent Advocates: further provision*) after clause 22 and requires the Secretary of State to, by regulations, make provision about independent advocates. These regulations must:
 - a. specify the training, qualifications and experience that a person must have in order to be appointed to a list of persons eligible to act as independent advocates;
 - b. require a specified person to instruct an independent advocate to represent and support a person in certain circumstances; and
 - c. make provision securing that arrangements are made for the provision of independent advocates for persons to whom commissioned VAD services are provided.
9. The regulations may in particular:
 - a. specify the person who is to make appointments to the list of eligible independent advocates;
 - b. provide that a person may be appointed to that list only if the appointment is approved in accordance with the regulations;
 - c. provide that a person may not act as an independent advocate in specified circumstances;
 - d. confer on independent advocates a power to access the medical records of persons they are representing and supporting, or to require information in those medical records to be provided;
 - e. make provision for payments to be made to, or in relation to, persons acting as independent advocates.
10. Third, the Sponsor has tabled an amendment to clause 54(4) to include regulations made under the new clause above as regulations subject to affirmative procedure.

Rationale for taking the power

11. It is understood that these amendments have been tabled to retain a delegated power in relation to independent advocates, however, further detail in relation to independent advocates would be put on the face of the bill if amended and the scope of the delegated power that is retained is now set out in greater detail.
12. Setting out the details of the regime in regulations is consistent with the approach taken in other legislation. The Secretary of State remains subject to 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.

Consideration of the procedure

13. Regulations introduced under the new clause will be subject to the draft affirmative procedure. While the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny may be considered to go beyond usual practice given the operational nature of these regulations. However, the policy on assisted dying is of a novel and controversial nature, and there remains 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 regulations making provision about independent advocates to receive appropriate Parliamentary scrutiny.

Amendments to clause 27: Meaning of “approved substance”

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Affirmative Procedure

Context and Purpose

14. The purpose of this power remains to require the Secretary of State to specify one or more drugs or other substances to be approved substances for the purposes of the Act.

15. There have been three amendments tabled by the Sponsor in relation to clause 27, which modify the delegated power of the Secretary of State to make regulations specifying one or more drugs or other substances for the purpose of the Act. Once specified, these substances are defined as 'approved substances'.
16. The first amendment, which amends clause 27 itself, sets out the factors to which the Secretary of State must have regard when specifying substances. These include: its effectiveness, the risk of adverse outcomes, the ease and safety of handling and use, and the way or ways in which the substance may be self-administered.
17. The second amendment, which amends clause 55, makes the exercise of the power to specify approved substances subject to consultation. In the first instance, this will include consultation with the Commission on Human Medicines; but the amendments also allow for a bespoke committee to be established whose remit may include advising the Secretary of State on the specifying of substances and being consulted on the same. Once established, the Secretary of State must consult such committee before making regulations under clause 27.
18. The third amendment, which amends clause 54, makes the exercise of the power to specify approved substances subject to the affirmative procedure.

Rationale for taking the power

19. It is understood that these amendments have been tabled to address the recommendation of the Delegated Powers and Regulatory Reform Committee that, due to the exceptional significance of the matters in clause 27, greater detail in relation to those matters must be provided on the face of the Bill rather than left to regulations. The amendments tabled seek to address the Committee's concern about the lack of detail in the current clause 27 without going as far as specifying substances on the face of the Bill. This would therefore maintain flexibility for Government to address changes to clinical evidence and practice through the use of secondary legislation, which is consistent with the use of delegated powers in other legislation.

Consideration of the procedure

20. Whereas the regulations were previously subject to the negative procedure, regulations made under this clause are now subject to the affirmative procedure. While the Government is neutral on the choice of the regulation making procedure, this level of parliamentary scrutiny reflects the

Committee's concerns about the significance of the matters to be specified by statutory instrument.

Amendments to clause 37: Regulation of approved substances and devices for self-administration

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Affirmative Procedure

Context and Purpose

21. The purpose of this power remains to require the Secretary of State to establish a regulatory framework governing substances and devices used for self-administration under the Bill.
22. There have been five amendments tabled by the Sponsor in relation to clause 37, which modify the delegated power of the Secretary of State to make regulations that make provision about approved substances and devices used for self-administration.
23. The first amendment, which amends clause 37(6), provides greater specificity on enforcement, including about the availability of civil penalties, the potential creation of criminal offences, and maximum penalties.
24. The second amendment, which amends clause 37(7), makes the exercise of the power subject to the limitations in subsection (6)(d) (limitation on provision concerning criminal offences).
25. The third amendment, which amends clause 37, makes the exercise of the power subject to the overarching objective of ensuring the safety of the public and of persons seeking assistance under the Act.
26. The fourth amendment, which amends clause 55, makes the power to make regulations subject to consultation. In the first instance, this will include consultation with the Commission on Human Medicines or the advisory committee for medical devices, as appropriate; but other amendments also allow for a committee to be established whose remit may include advising the Secretary of State on matters relating to approved substances or devices used for self-administration and being consulted under clause 37. Once established, the Secretary of State must consult such committee.

27. The fifth amendment, which introduces a new clause (Pre-laying scrutiny of certain proposed regulations under section 37 and 41) provides that the power to amend primary legislation is subject to a pre-laying scrutiny procedure, followed by the normal affirmative procedure. The overall effect of this is that regulations may not amend the Act itself and additional pre-laying scrutiny applies where regulations amend primary legislation outside of a defined list, which includes the Medicines Act 1968 and Medicines and Medical Devices Act 2021.

Rationale for taking the power

28. It is understood that these amendments have been made because, in its report on the delegated powers in the Bill, the Delegated Powers and Regulatory Reform Committee expressed a number of specific and general concerns, principally that the powers in the Bill were skeletal and should be narrowed.

29. The amendments tabled seek to address these concerns while maintaining flexibility for the Government to set out operational and technical matters in regulations. Such matters are suited to being set out in secondary legislation given continuing developments in relation to approved substances and devices used in connection with such substances.

Consideration of the procedure

30. Regulations made under this clause remain subject to the affirmative procedure. Additional pre-laying scrutiny applies where regulations amend primary legislation outside of a defined list, which includes the Medicines Act 1968 and Medicines and Medical Devices Act 2021.

Amendments to clause 38: Investigation of deaths etc

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Draft Affirmative Procedure

Context and Purpose

31. Clause 38 currently contains two delegated powers, both of which were subject to recommendations by the Delegated Powers and Regulatory Reform

Committee. There have been 3 amendments tabled by the Sponsor in relation to clause 38 in relation to delegated powers, as set out below, in response to those recommendations.

32. The first amendment amends the new subsection (4A)(b) of the Coroners and Justice Act 2009 (CJA) inserted by clause 38(2) of the Bill. This amendment changes the power for the Secretary of State to make regulations under section 20(1) of the CJA to include such further provision as the Secretary of State considers appropriate. The amendment clarifies that provisions under this power are limited to the processes and procedures for establishing and certifying the deceased's cause of death.
33. The purpose of this power remains to amend existing regulation making provisions contained in section 20 of the CJA to enable any necessary changes to secondary legislation in relation to the certification of Assisted Deaths. It clarifies that any changes would be limited to provisions relating to the processes and procedures for establishing and certifying the cause of death (for assisted deaths).
34. The second amendment relates to the new subsection 4A of the CJA inserted by clause 38(2) which provides that regulations made under section 20(1) CJA 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" and record the terminal illness which allowed the individual to receive assistance under the Bill. The purpose of this clause remains the same but the amendment results in the requirements being set out on the face of the CJA rather than contained within regulations and therefore no longer requiring a delegated power.
35. The third amendment amends the CJA so that the regulation making powers under clause 38(2)(4A) would be subject to the affirmative procedure.

Rationale for taking the power

36. It is understood that these amendments have been made to meet the recommendations of the Delegated Powers and Regulatory Reform Committee. The Committee observed that the power in new (4A)(b) of the CJA is exceptionally broad and the first tabled amendment ensures that it is explicit that this power would be limited to provisions relating to the processes and procedures for establishing and certifying the cause of death (for assisted deaths). A delegated power, however, remains necessary to ensure

consistency in death certification procedures and requirements. 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. 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.

37. In relation to the second amendment, the Committee observed that it was unclear why the objective of the provision (new section 20(4B) of the CJA inserted by clause 38(2) of the Bill) is achieved by including it in a delegated power when the same objective could be achieved by making provision on the face of the Bill. The second amendment removes the delegated power and makes the provision on the face of the Bill as an amendment to the CJA.

Consideration of the procedure

38. Due to the third amendment which amends section 176 of the CJA, the regulation-making power in the new section 20(4A) of the CJA (as inserted by clause 38(2) of the Bill) would be subject to the affirmative procedure.

Amendments to clause 41: Voluntary assisted dying services: England

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: Affirmative procedure or pre-scrutiny period and affirmative procedure

Context and Purpose

39. At the time of receiving the Delegated Powers and Regulatory Reform Committee report, clause 41 contained two delegated powers (41(1) and 41(3)). The purpose of clause 41(1) remains to impose a duty on the Secretary of State to make regulations securing that arrangements are made for the provision of voluntary assisted dying (VAD) services in England.

40. The purpose of clause 41(3) remains to enable the Secretary of State to make other provision about VAD services in England, whether or not the services are commissioned VAD services.
41. There have been six amendments tabled by the Sponsor in relation to clause 41 in order to add more detail to the face of the Bill in response to the recommendations by the Committee. This includes one further delegated power in clause 41(2A), bringing the tally to three delegated powers within clause 41.
42. Clause 41 as drafted does not name a commissioner of commissioned VAD services. The first amendment specifies that under clause 41(1), the Secretary of State must by regulation require one of the following bodies to commission a VAD service: NHS England, the Secretary of State, or each Integrated Care Board. The purpose of this amendment is to provide more detail as to who may be required to commission VAD services which also constrains the broader Henry VIII power.
43. Currently clause 41(3) empowers the Secretary of State to make provision for VAD services to be regulated but does not expressly state that VAD services (commissioned and private) must be regulated or by whom. The second amendment inserts 41(2A) which requires the Secretary of State by regulations to make provision securing that all VAD services (commissioned VAD services and those provided privately) will be regulated by the Care Quality Commission (CQC) or NHSE, or both. This added detail narrows the Henry VIII power on this point.
44. The third and fourth amendments insert clause 41(5)(b) and a new definition under clause 41(7). These amendments would enable the Secretary of State to confer some of the existing duties of NHS commissioners (as specified on the face of the Bill) onto commissioners of commissioned VAD services. It indicates that the commissioners of commissioned VAD services will be subject to the same or similar duties as NHS commissioners are currently subject to.
45. The Henry VIII power in clause 41(6) is maintained and the fifth amendment inserts a new clause which specifies a list of existing legislation that are anticipated to be amended under the powers in clause 41 and will be subject to the affirmative procedure (for example the NHS Act 2006). Any amendments to Acts not cited on the list would be subject to the pre-laying scrutiny procedure, followed by the normal affirmative procedure. The purpose of this amendment is to provide more transparency as to the Acts

which will likely be amended by regulations under clause 41 (and clause 37) and to add additional scrutiny to any Acts not cited.

46. The sixth amendment places a duty on the Secretary of State when exercising his regulation making powers under clause 41 to have regard to the principles of (a) the safety of the public and of persons seeking assistance under this Act, and (b) ensuring the availability and quality of voluntary assisted dying services in England, in exercising his regulation making power. The purpose of this amendment is to narrow the Henry VIII power by imposing a duty on the Secretary of State to have regard to key principles in exercising his powers.

Rationale for taking the power

47. It is understood that these amendments have been made because, in its report on the delegated powers in the Bill, the Committee expressed a number of specific and general concerns, principally that the powers in the Bill were skeletal and should be narrowed. The amendments tabled seek to address these concerns.

48. The delegated powers allow for the securing of arrangements for the provision of VAD services in England. The details of any Assisted Dying process would be developed by the Government after Royal Assent, and this may include amendments and modifications to primary legislation. These arrangements are also 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.

Consideration of the procedure

49. Regulations made under this clause remain subject to the affirmative procedure. Regulations which amend Acts not cited on the face of the Bill (under the new clause following clause 55), will additionally be subject to a pre-laying scrutiny procedure.

Amendments to clause 58: Commencement – regulations on commencement

Power conferred on: Secretary of State

Power exercised by: Regulations made by Statutory Instrument

Parliamentary Procedure: None

Context and Purpose

50. Clause 58 contains powers for the Secretary of State and the Welsh Ministers to make regulations that commence certain provisions in the Bill. Currently, clause 58(8) states that these regulations are to be made by statutory instrument. The Sponsor has tabled an amendment such that the regulations are now to be made by 'Welsh Statutory Instrument' in the case of Welsh Ministers.

Rationale for taking the power

51. This amendment is a technical amendment to the delegated power to reflect the introduction of the Legislation (Procedure, Publication and Repeals) (Wales) Act 2025, which provides for a new regime for subordinate legislation made by Welsh Ministers.

Consideration of the procedure

52. Regulations made under clause 58 remain not subject to any parliamentary procedure, as standard with commencement powers.

Department of Health and Social Care

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