RARE CANCERS BILL

EXPLANATORY NOTES

What these notes do

These Explanatory Notes relate to the Rare Cancers Bill as brought from the House of Commons on 14 July 2025 (HL Bill 124).

- These Explanatory Notes have been prepared by the Department of Health and Social Care, with the consent of Baroness Elliott of Whitburn Bay, the Peer in Charge of the Bill in the House of Lords, in order to assist the reader of the Bill and help inform debate on it. They do not form part of the Bill and have not been endorsed by Parliament.
- These Explanatory Notes explain what each part of the Bill will mean in practice; provide background information on the development of policy; and provide additional information on how the Bill will affect existing legislation in this area.
- These Explanatory Notes might best be read alongside the Bill. They are not, and are not intended to be, a comprehensive description of the Bill.

Table of Contents

Overview of the Bill

1 This Bill is intended to support research and investment for rare cancers. The Bill uses the definition of a rare disease consistent with that specified in the UK Rare Diseases Framework: a condition which affects less than 1 in 2,000 people.

2 The Bill specifically achieves this by:

a. Ensuring the Government publishes a review of the law relating to marketing authorisations for orphan medicinal products that are for the diagnosis, treatment or prevention of cancer. The review must consider regulatory approaches in other countries compared to the UK's approach. These relevant regulations are in Part 5 of the Human Medicines Regulations 2012.

b. Placing a duty on the Secretary of State for Health and Social Care in England in order to facilitate or otherwise promote research in relation to rare cancers, to ensure that appropriate arrangements are in place for ensuring patients can be easily contacted about research and that there is adequate oversight of research delivery for rare cancers.

c. Amending the Health and Social Care Act 2012 to ensure that patients with rare cancers can be easily contacted about relevant research and clinical trials, by allowing patient data in NHS England information systems to be disclosed for the purpose of enabling potential participants in those trials to be identified and contacted.

Policy background

3 This Bill was introduced by Dr Scott Arthur MP in the House of Commons and Baroness Elliott of Whitburn Bay is the Peer in charge in the House of Lords.

4 There are different definitions for what is defined as a rare cancer. Some charities define this as, less than 6 in 100,000. However, for the purposes of the Rare Cancers Bill, a rare cancer is defined in line with a rare disease i.e. defined as a condition which affects less than 1 in 2,000 people, as per The UK Rare Diseases Framework[1].

5 Research into treatments for rare cancers can be less appealing for companies than research into common conditions because the smaller patient population can make it more challenging to develop a sufficiently robust evidence base to satisfy regulators, as well as a small market limiting the return on their investments.

6 A disease registry is a collection of data about individuals who have a specific disease or condition. In England, the National Disease Registration Service collects and manages data on individuals diagnosed with cancer which is shared with NHS England through an opt-out process via a Secretary of State Direction[2].

[1] The UK Rare Diseases Framework, Department of Health and Social Care, Published 9 January 2021. Last Accessed 11/02/2025. [https://www.gov.uk/government/publications/uk-rare-diseases-framework/the-uk-rare-diseases-framework]

[2] National Disease Registries Directions 2021, Last Accessed 11/02/2025. [https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/national-disease-register-service-directions]

7 A contact registry is a database that collects and stores information about individuals who are interested in participating in research. Unlike a disease registry, a contact registry helps researchers connect with potential study participants. The Be Part of Research (BPoR) Registry is provided by the National Institute for Health and Care Research (NIHR) in England. It allows individuals across the UK who are interested in taking part in research to find studies – including clinical trials - that are relevant to them and sign up. Research teams are also able to recruit to studies via BPoR who contact those individuals who have signed up.

DHSC/NIHR Research Funding

8 The Department of Health and Social Care invests over £1.6 billion per year in research through the National Institute for Health and Care Research (NIHR) and NIHR research expenditure for all cancers was £133 million in 2023/24.

9 DHSC also funds NIHR infrastructure, which provides world-class research expertise, specialist facilities, a research delivery workforce and support services, which all help to support and deliver research across the NHS and wider health and care system. The NIHR Research Delivery Network (RDN) launched in 2024. Building on the success of the NIHR Clinical Research Network (CRN), its mission is to enable the health and care system to attract, optimise and deliver research across England.

10 In England, the NIHR currently has National Specialty Leads for research delivery within the Research Delivery Network (RDN). Their role is primarily to support research delivery in their discipline within health and care settings, with knowledge and experience of the full scope of the NIHR and the wider health and care delivery infrastructure in England. Working with patients, public, health and care professionals (including research and development communities within the NHS and wider care system), academics and life sciences partners, the National Specialty Leads aim to ensure strategic oversight and a focus on continuous improvement of the research delivery portfolio.

11 In September 2024, DHSC, through the NIHR, announced new investment in brain cancer research through a series of targeted calls designed specifically to help stimulate the research community, working with partners such as the Tessa Jowell Brain Cancer Mission to reach the broader community. The most significant element in this approach is the Brain Tumour Research Consortium, a transformative new funding call to bring together the research community to evaluate novel therapies and treatments. Early interest in being part of this new initiative has been extremely strong.

12 DHSC will publish a National Cancer Plan, following the NHS 10 Year Health Plan, which will consider all tumour types, including brain tumours.

Orphan Drugs and Designation

13 An Orphan Drug is a pharmaceutical developed for a rare disease. The MHRA published guidance on orphan medicinal products on 31 December 2020.

14 The MHRA is responsible for reviewing applications from companies for orphan designation at the time of a marketing authorisation application (MAA). There is no orphan designation step prior to application for a marketing authorisation in the UK.

15 To qualify for orphan designation, a medicine must meet the following criteria:

a. it must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronically debilitating.

b. the prevalence of the condition in UK must not be more than 5 in 10,000, or it must be unlikely that marketing of the medicine would generate sufficient returns to justify the investment needed for its development.

c. no satisfactory method of diagnosis, prevention or treatment of the condition concerned exists in UK or, if such a method exists, the medicine must be of significant benefit to those affected by the condition.

16 Satisfactory methods may include authorised medicinal products, medical devices or other methods of diagnosis, prevention or treatment which are used in UK.

Legal background

17 The legal background of the Bill is set out in the *Commentary on Provisions of the Bill* section of this document.

Territorial extent and application

18 Clause 4, subsection (1) and (2) set out the territorial extent of the Bill, which describes the jurisdictions in which the Bill forms part of the law.

19 Clause 1 extends and applies across the UK. Clause 2 and 3 extend to England and Wales and apply in England.

20 See the table in Annex A for a summary of the position regarding territorial extent and application in the United Kingdom.

Commentary on provisions of Bill

Clause 1: Review of law on marketing authorisations

21 Subsection (1) (a) places a duty on the Secretary of State for Health and Social Care, to carry out a review of the law related to marketing authorisations (in Part 5 of the Human Medicines Regulations 2012 (S.I. 2012/1916)) for orphan medicinal products for the diagnosis, prevention or treatment of cancer. These regulations apply UK-wide.

22 Subsection (1) (b) requires that the conclusions of the review must be prepared and published in a report.

23 Subsection (2) provides that the review referenced in subsection (1) must consider regulatory approaches in other countries compared to the UK's approach. This ensures the review must assess international regulatory approaches for orphan medicinal products, with a view to assessing whether the regulations in the UK are considered effective at encouraging research and development for treatments of rare cancers.

24 Subsection (3) requires the report referenced in subsection (1) to be published before the end of the period of three years beginning with the day on which the Act is passed, should the bill become law.

25 Subsection (4) requires that the Secretary of State must lay a copy of the report referenced in subsection (1) before Parliament.

26 Subsection (5) contains a list of relevant definitions of terms which appear in Clause 1 of the Bill.

Clause 2: The Secretary of State's duties as to research

27 Clause 2 amends section 1E of the National Health Service Act 2006, which outlines the Secretary of State for Health and Social Care's duty to facilitate research. The Rare Cancers Bill would amend this section 1E to require that the research the Secretary of State for Health and Social Care is required to facilitate includes research into rare cancers, as below.

28 In discharging that duty, the Secretary of State must ensure appropriate arrangements are in place to facilitate or promote research in relation to rare cancers.

29 Such arrangements are to:

a. enable potential participants in clinical trials to be identified and contacted. This is intended to ensure patients with rare cancers can be easily contacted about relevant research, including clinical trials, by creating a bespoke contact registry service for patients with rare cancers. For example, DHSC funds a contact registry service called Be Part of Research which could undergo further development to deliver a bespoke offering for rare cancer patients.

b. ensure that a person (known as "the National Specialty Lead for rare cancers") is appointed, with a job description including promoting and facilitating research into rare cancers by providing advice in relation to the design and planning of research and facilitating collaboration between interested persons. This is intended to ensure there is adequate oversight of research delivery for rare cancers by providing leadership and

advice with a view to improve rare cancer research. There are already National Specialty leads in the NIHR Research Delivery Network (RDN) that serve this purpose for specific disease areas. It is envisaged this legislation would mandate a specialty lead for rare cancers, through an extension to existing cancer specialty lead roles in the NIHR RDN.

30 Subsection (4) provides a definition of the term "rare cancer". This has been defined as a cancer that affects not more than 1 in 2000 persons in the UK which is consistent with the UK Rare Diseases Framework. The wording allows for either 'incidence' or 'prevalence' approaches to be used to define a rare cancer.

Clause 3: Disclosure of information for research purposes

31 Clause 3 amends Section 261 of the Health and Social Care Act 2012 ('the 2012 Act') which confers on NHS England a power to disclose information obtained in connection with information systems. The amendments ensure that NHS England has a power to disclose such information for the purpose of facilitating clinical trials in relation to rare cancers. The intention is that the Secretary of State for Health and Social Care would direct NHS England to exercise this power in order to share information from the National Disease Registration Service with the NIHR 'Be Part of Research' Registry, so that patients may be identified and contacted.

32 Subsection (2) inserts new paragraph (da) into section 261(5) of the 2012 Act. The amendment ensures that NHS England may disclose information which it obtains by complying with a direction under section 254 or a request under section 255 of the 2012 Act for the purpose of facilitating the carrying out of relevant clinical trials by enabling potential participants to be identified and contacted.

33 Subsection (3) inserts into section 261 new subsection (5A) which defines "relevant clinical trials" (and terms used within that definition) for the purpose of new section 261(5) (da).

34 Subsection (4) inserts new subsections (6A) and (6B) into section 261 of the 2012 Act. These provide that where section 261 confers a power to disclose information, that power does not override the data protection legislation. This ensures compatibility of the processing of data under section 261 with the data protection legislation.

35 Insofar as subsection (4) is not limited to rare cancers (i.e. new subsections (6A) and (6B) are not limited to new subsection (5)(da) inserted into section 261 but instead apply to section 261 in its entirety), the provision made by subsection (4) is consequential in nature i.e. its purpose is to avoid doubt as to whether the rest of section 261 otherwise allows for the processing of information in contravention of the data protection legislation. Since section 261 is already considered to be subject to the data protection legislation, new subsections (6A) and (6B) do no more than restate that position. The amendment made by subsection (4) thus spells out the position rather than amends the current position under section 261 and, accordingly, subsection (4) does not change the law other than for rare cancers.

Clause 4: Extent

36 Subsection (1) indicates that the territorial extent of Clauses 2 and 3 in the Bill is England and Wales. The relevant legislation applies in England only.

37 Subsection (2) provides that the territorial extent of Clause 1 in the Bill is England and Wales, Scotland and Northern Ireland. The aim of Clause 1 is to mandate a review of the Human Medicines Regulations 2012, which are UK wide in extent and application, and the review required under this clause will look at the operation of those Regulations. Medicines are reserved in respect of Scotland and Wales, but fully transferred in respect of Northern Ireland.

Clause 5: Commencement

38 Clause 5 make provision for the commencement of the Bill.

Clause 6: Short title

39 Clause 6 sets out the short title.

Commencement

40 Clause 5 provides for all sections to come into force at the end of the period of two months beginning with the day on which this Act is passed.

Financial implications of the Bill

41 The Bill is expected to have some financial implications for central Government, but these are not expected to be significant.

42 The financial implications will include

a. the requirement for the Government to publish a review of Orphan Drug Regulations after three years (Clause 1).

b. the financial implications of ensuring there is adequate oversight of research delivery for rare cancers (Clause 2 Subsection (2)(a)).

c. the duty to ensure that potential clinical trials participants may be identified and contacted (Clause 2 Subsection (2)(b)).

d. financial implications of further data sharing by NHS England, to be met by DHSC (Clause 3).

43 Quantified costs (below) all fall within Department of Health and Social Care budgets. The requirements are not expected to come into force until the next Spending Review period (post March 2025). The below reflect the best estimates for costs currently and may be subject to change.

a. It is difficult to estimate the resourcing costs required for the Orphan Drug review, since the exact scope remains to be agreed. However, the estimated cost to the Department of Health and Social Care to produce and publish a report on Orphan Drug Regulations is approximately £0.14m in relation to staff resource. This reflects the cost of 0.3 x SCS staff, 1 x FTE Grade 6 or Grade 7 staff, 0.3 x Grade 7 staff and 0.5 x SEO staff for one year.

b. This Bill is expected to have an annual cost of approximately £16,000 per year for a National Specialty Lead role for rare cancers in England, to be funded through the National Institute for Health and Care Research.

c. The Bill is expected to have a one-off cost of £0.25m for development to ensure that that potential clinical trials participants may be identified and contacted, by developing a tailored registry support service via 'Be Part of Research'.

d. The financial implications of further data sharing by NHS England, per Clause 3, are dependent on a Secretary of State direction being produced to provide the specifics of how the data should be shared, so the financial costs are variable. To achieve the specific policy aims of the Bill, it is estimated this would cost approximately £175,000 every three years. This is the cost of Data Access Request Service (DARS) charges and will be met by the Department of Health and Social Care.

44 These figures may rise with inflation over time and are therefore subject to change. The Bill is not specific on how Clause 2 Subsections (2)(a) and (b) should be implemented to allow for a degree of flexibility and the above figures reflect the Governments current position at the time of writing.

45 The Government has produced an Impact Assessment in line with Better Regulation guidance. The Bill is not considered a regulatory provision.

Parliamentary approval for financial costs or for charges imposed

46 The Bill will require a money resolution to authorise new charges on the public revenue (broadly speaking, new public expenditure). The resolution is required to cover additional expenditure incurred by the Secretary of State in discharging the duty to take certain steps to facilitate or otherwise promote research into rare cancers (clause 2) and additional expenditure incurred by NHS England in sharing information for the purpose of facilitating the carrying out of clinical trials by enabling potential participants in those trials to be identified and contacted (clause 3).

47 The Bill will not require a ways and means resolution (which, broadly speaking, is required in relation to a charge on the people or for other payments into the Consolidated Fund).

Compatibility with the European Convention on Human Rights

48 It is not necessary for Ministers to sign a statement under section 19(1)(a) of the Human Rights Act 1998 in respect of compatibility with the European Convention on Human Rights if the Bill is a Private Member's Bill.

49 Despite this, the Government's view is that the Rare Cancers Bill is compatible with the European Convention on Human Rights.

Related documents

50 The following documents are relevant to the Rare Cancers Bill and can be read at the stated locations:

- **The UK Rare Diseases Framework**, Published 9 January 2021 [https://www.gov.uk/government/publications/uk-rare-diseases-framework/the-uk-rare-diseases-framework]

- **National Disease Registries Directions 2021**, Published 30/09/2021 [https://digital.nhs.uk/about-nhs-digital/corporate-information-and-documents/directions-and-data-provision-notices/secretary-of-state-directions/national-disease-register-service-directions]

Annex A – Territorial extent and application in the United Kingdom

Provision	England	Wales		Scotland		Northern Ireland	
	Extends to E & W and applies to England?	Extends to E & W and applies to Wales?	Legislative Consent Motion process engaged?	Extends and applies to Scotland?	Legislative Consent Motion process engaged?	Extends and applies to Northern Ireland?	Legislative Consent Motion process engaged?
Clause 1	Yes	Yes	No	Yes	No	Yes	Yes
Clause 2	Yes	No	No	No	No	No	No
Clause 3	Yes	No	No	No	No	No	No

Subject matter and legislative competence of devolved legislatures

51 Clause 1 extends and applies to England, Wales, Scotland and Northern Ireland, and a legislative consent motion is required for Northern Ireland. Clauses 2 and 3 of the Bill extend to England and Wales but apply in England only.

RARE CANCERS BILL

EXPLANATORY NOTES

These Explanatory Notes relate to the Rare Cancers Bill as brought from the House of Commons on 14 July 2025 (HL Bill 124).

Ordered by The House of Lords to be printed, 16 July 2025

PUBLISHED BY AUTHORITY OF THE HOUSE OF LORDS