Specialised Healthcare Alliance
FOR EVERYONE WITH RARE AND COMPLEX CONDITIONS

Health Bill call for evidence: Submission from the Specialised Healthcare Alliance

1. Executive summary

1.1. The Specialised Healthcare Alliance (SHCA) has significant concerns regarding the implications of the Health Bill for people living with a rare disease:

1.1.1. Theme one: Overall impact of delegation – the bill gives the Government sweeping powers to proceed with the further delegation of specialised services to Integrated Care Board (ICBs). The SHCA is calling for a detailed impact assessment and for changes to specialised commissioning regulations to be subject to public consultation.

1.1.2. Theme two: National standards and accountability – transferring legal accountability for specialised services to ICBs risks weakening oversight and increasing variation, and there is limited clarity on how national standards will be enforced. The SHCA recommends a new clause to strengthen accountability, for example by requiring the Secretary of State to lay an annual report on specialised services performance before Parliament.

1.1.3. Theme three: Clinical leadership – the proposals offer no reassurances that existing clinical expertise and leadership structures will be retained in the new system. The SHCA calls for new clauses legislating for clinical involvement in specialised commissioning and the appointment of a national rare diseases clinical lead.

1.1.4. Theme four: Patient involvement – patient involvement is inconsistent and risks being weakened further by the delegation of specialised services to ICBs. The SHCA recommends extending requirements for meaningful patient involvement and co-production across all specialised commissioning, whether services are commissioned by the Secretary of State or ICBs.

1.1.5. Theme five: Newborn screening – the UK's approach to newborn screening is hindered by delays between UK National Screening Committee (NSC) recommendations and Government implementation. The SHCA proposes a legal duty on the Secretary of State to implement NSC recommendations.

1.1.6. Theme six: Mental health – people with rare diseases face significant unmet mental health needs and poor integration of support within care pathways. The SHCA supports making the Mental Health Investment Standard (MHIS) a statutory requirement on ICBs as a first step towards further improvement.

1.2. Overall, targeted improvements are needed to ensure the reforms deliver timely, high-quality and coordinated care for everyone living with a rare disease in England.

2. Introduction

2.1. The Specialised Healthcare Alliance (SHCA) is a coalition of nearly 140 patient organisations and corporate supporters campaigning on behalf of people with rare and complex conditions.

2.2. There are over 150 specialised services supporting people with a range of rare and complex conditions, covering everything from chemotherapy to hand transplants.[1]

2.3. Specialised services have historically been commissioned at a national level by NHS England (NHSE), but since 2023 NHSE has gradually delegated more responsibility to local Integrated Care Boards (ICBs).[2] ICBs now commission over 70 'delegated' services, while NHSE commissions just over 100 'retained' services.[3]

2.4. In March 2026, NHSE published a letter setting out how specialised commissioning is expected to work after NHSE's functions are merged into the Department of Health and Social Care (DHSC):[4]

2.4.1. The most highly specialised services will be commissioned by DHSC.

2.4.2. DHSC will maintain a framework of standards, service specifications and clinical commissioning policies.

2.4.3. When services are delegated, full accountability – on top of existing responsibility – will transfer from NHSE to ICBs.

2.4.4. Seven Offices for Pan-ICB Commissioning (OPICs) will be established from April 2027 to support ICBs to discharge their commissioning responsibilities, essentially replacing the current role of NHS regions.

2.5. The Health Bill seeks to introduce the legislative provisions needed to enact the changes outlined above.

2.6. The SHCA welcomes the constructive engagement we have had with DHSC and NHSE in recent years. However, we continue to have significant concerns regarding the future of specialised commissioning.

2.7. The remainder of our submission sets out these concerns and our early assessment of the changes we believe are necessary to ensure that everyone living with a rare disease in England has access to timely, high-quality and coordinated care.

3. Theme one: Overall impact of delegation

3.1. NHSE's March 2026 direct commissioning update indicated that the most highly specialised services would be commissioned by DHSC (the Secretary of State), with all other specialised services commissioned by ICBs.[4]

3.2. However, this is not set in stone. Under the Health Bill, the exact split between which specialised services will be commissioned by the Secretary of State and which will remain the responsibility of ICBs will be set out in regulations.[5]

3.3. The Government's equality impact assessment says *"It is not possible to analyse the impacts for people who will receive specialised services for rare diseases commissioned by ICBs at this stage, because the specific services are not set out in primary legislation, but rather will be set out through regulations, with accompanying equality assessment, as appropriate."*[5]

3.4. A list of specialised services to be commissioned by the Secretary of State is expected to be published during the passage of the bill,[5] but no timeline has been provided. Furthermore, while we know that remaining services will be commissioned by ICBs, exact footprints are unclear – which services will sit with a single ICB versus multiple ICBs? This distinction is important because at ICB level there may not always be the capacity and capabilities needed to effectively support patients with the rarest conditions.

3.5. There is also a lack of information regarding the transfer of NHSE's wider responsibilities for specialised services. For example, arrangements for supporting and monitoring the progress of the 28 Rare Disease Collaborative Networks (RDCNs) across England – groups of providers working together to advance research, increase knowledge and improve patient experience for a particular rare disease – have not yet been confirmed.[6]

3.6. Similarly, it is unclear who will be responsible for specialised commissioning clinical audits, databases and registries. Currently, NHSE can use its powers under directions issued by the Secretary of State to collect, link and analyse data from the registries.[7] NHSE also oversees Specialised Services Quality Dashboards (SSQDs), which are a key tool in monitoring the quality of services, enabling comparison between service providers and supporting continuous improvement.[8]

3.7. This is all preventing a thorough assessment of, and informed debate about, the overall impact of delegation and the broader implications of abolishing NHSE for specialised commissioning. There is evidently confusion at present, with NHSE Chair Dr Penny Dash saying at a recent Health and Social Care Committee oral evidence session that *"Only a couple of days ago it was agreed that quite a lot of highly specialised commissioning is going to ICBs"*.[9] This directly contradicts NHSE's March 2026 direct commissioning update.[4]

3.8. The SHCA asks the Committee to consider:

3.8.1. A new clause requiring the Secretary of State to carry out a detailed impact assessment before any further delegation of specialised services takes effect. This should consider the implications of transferring full accountability from NHSE to ICBs, alongside the future of NHSE's wider responsibilities for specialised services.

3.8.2. An amendment to specify that any changes to specialised commissioning regulations, now and in the future, must be subject to public consultation.

4. Theme two: National standards and accountability

4.1. NHSE is currently responsible for creating national standards that services must meet in the form of service specifications and clinical commissioning policies, which has been an important step towards minimising unwarranted variation. The recent shift in service specifications away from service organisation towards a focus on outcomes is welcome and should continue in the new system.

4.2. Despite the changes to specialised commissioning over recent years, NHSE has also retained ultimate accountability for services. This has been a strength of the system, as it has been clear to the public, politicians, patients and charities where to

engage to highlight problems or challenges. Clear routes of accountability are central to eliminating unwarranted variation, continuous improvement and patient safety.

4.3. The Health Bill changes this: primary legal accountability, as well as responsibility, is being conferred on ICBs. The Government argues that this will provide clarity and allow ICBs to commission services with more autonomy than is the case now. At the same time, the Government notes that realising the benefits of delegating specialised commissioning to ICBs depends on the new system striking the right balance between national consistency and local autonomy.[10]

4.4. We do not believe that the appropriate balance has been struck. Details of how accountability will work in practice are vague:[5]

4.4.1. It is proposed that the Secretary of State's general power of direction over ICBs will be used to set out the national standards (such as service specifications and clinical commissioning policies) applying to delegated specialised services.

4.4.2. It is stated that the collaborative working driven by OPICs is intended to ensure that ICBs have access to the right expertise to commission specialised services and *"act as a safeguard for service provision."*

4.4.3. The Government states that *"DHSC has oversight of ICB services and there will be enhanced oversight of ICB specialised commissioning to monitor compliance with national standards and service specifications. Monitoring how ICBs carry out their commissioning functions will be a part of the annual ICB performance assessment process."*

4.5. This leaves far too many unanswered questions. For example:

4.5.1. Will national standards, such as service specifications and clinical commissioning policies, be given statutory status?

4.5.2. What will *"enhanced oversight of ICB specialised commissioning"* involve in practice?

4.5.3. What actions will be taken if individual ICBs or OPICs fail to meet national standards?

4.5.4. How will the Secretary of State be held accountable for commissioning the most highly specialised services?

4.5.5. Who will be responsible for supporting and monitoring the progress of RDCNs, a role currently performed by NHSE?

4.5.6. Who will be responsible for specialised commissioning data (clinical audits, databases, registries and SSQDs), another role currently held by NHSE?

4.5.7. How will transparency be improved, given the current lack of publicly available data on whether national standards are being met (for example, SSQD data is not published)?

4.6. The SHCA asks the Committee to consider:

4.6.1. A new clause requiring the Secretary of State to produce and lay before Parliament an annual report on the performance of specialised services, including compliance with national standards.

4.6.2. A new clause requiring the Secretary of State to ensure the regular publication of data on specialised services, such as the information on quality and outcomes currently captured within SSQDs.

5. Theme three: Clinical leadership

5.1. The current system has a range of mechanisms to provide clinical input and advice to ensure that services are designed to deliver high-quality care, from the leadership provided by National Clinical Directors (NCDs) and National Specialty Advisers (NSAs) to the role and structure of Clinical Reference Groups (CRGs).

5.2. It is vital that this clinical expertise is retained and strengthened as NHSE's functions are merged into DHSC, yet the bill – and broader communications from DHSC and NHSE – have not provided any reassurances on this matter. It is notable that there are a number of clauses on patient and public involvement (for example, clause 5 and clause 15), but none on clinical involvement.

5.3. In addition, rare diseases leadership should be established at a senior level. The introduction of a national lead for rare cancers via the Rare Cancers Act 2026 provides a model for broader adoption.[11] This particular lead will have a mandate to speak up for rare cancers, and to provide clinical advice and support for the delivery of relevant actions in the National Cancer Plan. They will sit on the National Cancer Board and advise ministers directly and independently on what actions should be taken to improve outcomes.[12]

5.4. More broadly, the changes to specialised commissioning have raised questions regarding the future of national workforce planning and specialist training. This is not a general workforce issue, rather it is about safeguarding the expertise that is integral to the delivery of specialised services. It is an issue that has received little attention to date and must not be overlooked.

5.5. The SHCA asks the Committee to consider:

5.5.1. A new clause to legislate for clinical involvement in the commissioning of specialised services (whether commissioned by the Secretary of State or ICBs).

5.5.2. A new clause to legislate for the appointment of a national rare diseases clinical lead to oversee specialised services and act as a champion for people affected by rare diseases.

6. Theme four: Patient involvement

6.1. While there are some mechanisms that are intended to support patient input into specialised services, such as Patient and Public Voice (PPV) members of CRGs,

the voice of patients and patient organisations is not consistently heard at the national level, while the delegation of services to ICBs has also created challenges in engagement at the local level.

6.2. It is important that new mechanisms are put in place that provide consistency across local areas in strengthening patient involvement, building on the existing infrastructure for PPV involvement in CRGs, to give patients confidence that the system is listening and responding to input and feedback.

6.3. It is also important that data reporting on patient outcomes is strengthened as part of quality assurance, including through patient reported outcome measures.

6.4. The bill introduces a duty on the Secretary of State to make arrangements for the continued involvement of individuals, their carers and representatives in (1) the planning of commissioning arrangements, (2) in the development and consideration of proposals for changes in those arrangements where the changes would have an impact on the delivery or range of services, and (3) decisions affecting the operation of those arrangements. However, we believe this duty can go further.

6.5. The SHCA supports the Health and Social Care Committee's proposed amendment requiring the Secretary of State to make arrangements for the co-production of any health service commissioned by the Secretary of State.[13] However, we would like to see further amendments made to explicitly require patient involvement in all specialised commissioning, regardless of whether the commissioner is the Secretary of State or ICBs.

7. Theme five: Newborn screening

7.1. The UK has fallen behind comparable countries in its approach to newborn screening over the past few decades.[14] There is an urgent need for a change in approach to address the diagnostic odyssey for rare diseases, reduce health inequalities, and improve the lives of people with rare diseases and their families.

7.2. One issue is the gap between recommendations made by the UK National Screening Committee (NSC) and implementation. Currently, it is not a legal requirement for the Government to accept a recommendation and there is no timeframe within which a recommendation must be responded to or implemented.

7.3. For example, there was a gap of over three years between the most recent recommendation made by the NSC for a national newborn screening programme, for tyrosinaemia in 2022, with implementation only beginning in late 2025.

7.4. The NSC is proposing to move from its current data-based approach to reviewing prospective screening programmes to one that is based on real-world testing. This will hopefully result in the expansion of screening and reduce the gap between the UK and other countries. However, this new approach will only succeed if decision-taking and implementation take place at pace.

7.5. The SHCA asks the Committee to consider a new clause placing a legal duty on the Secretary of State to implement recommendations made by the NSC (similar to the legal duty that already exists for recommendations on vaccination programmes and medicines).

8. Theme six: Mental health

8.1. The SHCA has published numerous reports on the unmet mental health needs of people living with a rare disease.[15, 16] For example, when we surveyed our members in 2024:[15]

8.1.1. 76% said that the average wait to access mental health support is six months or longer.

8.1.2. Only 12% described current mental health provision for the rare disease community as 'good', with 62% describing it as 'poor'.

8.1.3. 72% said mental health support is poorly integrated into the wider care pathway.

8.2. It is worth remembering that 1 in 17 people in the UK are affected by a rare disease at some point in their lives.[17] This means that the mental health needs of people living with a rare disease are relevant to – and require action from – every ICB.

8.3. The SHCA supports the Health and Social Care Committee's proposed amendment that the Mental Health Investment Standard (MHIS) should be a statutory requirement on ICBs.[13] This alone will not resolve all the challenges experienced by people living with a rare disease, but we see it as a vital foundation for further improvements.

9. Next steps

9.1. The SHCA welcomes the opportunity to make this submission to the Committee at an early stage in the passage of the Health Bill. We will now be undertaking further consultation with our members to discuss potential amendments in more detail. We look forward to keeping the Committee updated on the progress of this work. If you would like to get in touch, please contact us on shca@incisivehealth.com.

June 2026

Appendix 1 | Draft amendments

The draft amendments below are intended as a starting point for further debate. We would welcome the opportunity to discuss these with the Committee in more detail.

Theme one: Overall impact of delegation

To move the following Clause—

"Specialised services impact assessment

(1) Before proceeding with the further delegation of specialised services, the Secretary of State must conduct and publish a detailed impact assessment considering—

(a) the consequences of delegating full accountability;
(b) the availability of commissioning expertise at Integrated Care Board level;
(c) the suitability of existing national standards and arrangements for monitoring compliance with those standards;
(d) the implications for patient experience and outcomes, including the potential for unwarranted variation between different populations and geographies;
(e) the transfer of NHS England's wider responsibilities for specialised services, beyond the commissioning of individual services."

Explanatory statement: This new clause requires the Secretary of State to carry out a detailed impact assessment before any further delegation of specialised services takes effect. This should consider the implications of transferring full accountability from NHS England to Integrated Care Boards, alongside the future of NHS England's wider responsibilities for specialised services.

Clause 11, page 7, line 33, at end insert—

"(5) A direction under 14Z61 may not be given in relation to the delegation of any specialised service unless the Secretary of State has—

(a) undertaken a public consultation on the proposed direction;
(b) had regard to the responses of that consultation."

Explanatory statement: This amendment specifies that any changes to specialised commissioning regulations, now and in the future, must be subject to public consultation.

Theme two: National standards and accountability

To move the following Clause—

"Specialised services accountability

(1) Six months after the passage of this Act, and every 12 months thereafter, the Secretary of State must produce and lay before Parliament a report on the performance of specialised services.

(2) A report under subsection (1) must contain a detailed assessment of—

(a) compliance with national standards both nationally and at Integrated Care Board level, including service specifications and clinical commissioning policies;
(b) expenditure on specialised services both nationally and at Integrated Care Board level;
(c) patient experience and outcomes, including any unwarranted variation between different populations and geographies;
(d) the extent and effectiveness of mechanisms for patient and clinical involvement.

(3) A report under subsection (1) must, where relevant—

(a) identify any specific areas of concern or underperformance;
(b) set out the steps that the Secretary of State or other relevant bodies propose to take in response."

Explanatory statement: This new clause would require the Secretary of State to produce and lay before Parliament an annual report on the performance of specialised services, including compliance with national standards.

To move the following Clause—

"Specialised services data transparency

(1) The Secretary of State must ensure that data relating to the performance of specialised services in England is published at intervals of not more than three months.

(2) Data published under subsection (1) must include—

(a) data on service provision and waiting times;
(b) information captured within Specialised Services Quality Dashboards or any equivalent successor.

(3) Data published under subsection (1) must be published in a form that is accessible and suitable for analysis."

Explanatory statement: This new clause would require the Secretary of State to ensure the regular publication of data on specialised services, such as the information on quality and outcomes currently captured within Specialised Services Quality Dashboards.

Theme three: Clinical leadership

To move the following Clause—

"Clinical involvement in specialised commissioning

(1) The Secretary of State must make arrangements to ensure that all specialised commissioning, including specialised commissioning at Integrated Care Board level, is informed by clinical involvement in the—

(a) planning of the commissioning arrangements;
(b) design of services and arrangements for service delivery;
(c) monitoring of the performance of specialised services."

Explanatory statement: This new clause requires clinical involvement in the commissioning of specialised services, whether commissioned by the Secretary of State or Integrated Care Boards. This could include, but is not limited to, maintaining NHS England's existing infrastructure of Clinical Reference Groups, National Clinical Directors and National Specialty Advisers.

To move the following Clause—

"National rare diseases clinical lead

(1) The Secretary of State must, within six months of the passing of this Act, appoint a national rare diseases clinical lead, situated within the Department of Health and Social Care.

(2) The functions of the national rare diseases clinical lead are to—

(a) act as an independent voice for people with rare and complex conditions;
(b) advise the Secretary of State on the actions that should be taken to continuously improve patient experience and outcomes;
(c) promote coordination across the Department of Health and Social Care, Integrated Care Boards and other relevant bodies;
(d) take proactive steps to identify and reduce health inequalities in rare disease care."

Explanatory statement: This new clause requires the appointment of a national rare diseases clinical lead to oversee specialised services and act as a champion for people affected by rare diseases.

<u>Theme four: Patient involvement</u>

Clause 16, page 13, line 27, at end insert—

"14Z45E Patient involvement in specialised commissioning

(1) Regulations must make provision as to the arrangements that Integrated Care Boards must make, in the exercise of their specialised commissioning functions, for enabling patient involvement in the—

(a) planning of the commissioning arrangements;
(b) design of services and arrangements for service delivery (co-production)."

Explanatory statement: The SHCA supports the Health and Social Care Committee's proposed amendment requiring the Secretary of State to make arrangements for the co-production of any health service commissioned by the Secretary of State.[13] However, we would like to see further amendments made to explicitly require patient involvement in all specialised commissioning, regardless of whether the commissioner is the Secretary of State or Integrated Care Boards.

Theme five: Newborn screening

To move the following Clause—

"Newborn screening

(1) The Secretary of State must ensure that recommendations made by the UK National Screening Committee in relation to newborn screening are implemented in England.

(2) The Secretary of State must ensure that any such recommendation is implemented within 90 days of its publication, unless a longer period is specified by the UK National Screening Committee."

Explanatory statement: This new clause requires the Secretary of State to implement recommendations made by the UK National Screening Committee.

Theme six: Mental health

The SHCA supports the Health and Social Care Committee's proposed amendment that the Mental Health Investment Standard should be a statutory requirement on ICBs.[13]

---

[1] NHS England. *Specialised services*. No date. Available at: https://www.england.nhs.uk/commissioning/spec-services/
[2] NHS England. *Roadmap for integrating specialised services within Integrated Care Systems*. 2022. Available at: https://www.england.nhs.uk/wp-content/uploads/2022/05/PAR1440-specialised-commissioning-roadmap-addendum-may-2022.pdf
[3] NHS England. *Commissioning integration: delegation of specialised services to integrated care boards 2025/26*. 2024. Available at: https://www.england.nhs.uk/long-read/commissioning-integration-delegation-of-specialised-services-to-integrated-care-boards-2025-26/
[4] NHS England. *Direct commissioning update*. 2026. Available at: https://www.england.nhs.uk/long-read/direct-commissioning-update/
[5] Department of Health and Social Care. *Health Bill: ICBs as strategic commissioners – equality impact assessment*. 2026. Available at: https://www.gov.uk/government/publications/health-bill-icbs-as-strategic-commissioners-equality-impact-assessment/health-bill-icbs-as-strategic-commissioners-equality-impact-assessment
[6] NHS England. *Rare disease collaborative networks*. No date. Available at: https://www.england.nhs.uk/commissioning/spec-services/highly-spec-services/rare-disease-collaborative-networks/#how-often-does-the-rdcn-have-to-update-nhs-england-on-their-progress
[7] NHS England. *Clinical audits and registries: A best practice guide*. 2026. Available at: https://www.england.nhs.uk/long-read/clinical-audits-registries-best-practice-guide/
[8] NHS England. *Specialised services quality dashboards*. No date. Available at: https://www.england.nhs.uk/commissioning/spec-services/npc-crg/spec-dashboards/
[9] Health and Social Care Committee. *Oral evidence: The work of NHS England, HC 583*. 2026. Available at: https://committees.parliament.uk/oralevidence/17625/pdf/
[10] Department of Health and Social Care. *Final stage impact assessment (Health Bill: abolishing NHS England)*. 2026. Available at: https://publications.parliament.uk/pa/bills/cbill/59-02/0009/ia_Abolishing_NHS_England.pdf
[11] UK Government. *Rare Cancers Act 2026*. 2026. Available at: https://www.legislation.gov.uk/ukpga/2026/8
[12] Department of Health and Social Care. *The National Cancer Plan for England: delivering world class cancer care*. 2026. Available at: https://assets.publishing.service.gov.uk/media/69dce11fd3e08b8871b6662c/national-cancer-plan-for-england-delivering-world-class-cancer-care.pdf
[13] Health and Social Care Committee. *Health Bill 2026-27*. 2026. Available at: https://committees.parliament.uk/publications/53577/documents/299136/default/
[14] Genetic Alliance UK. *Time to Decide: Learning from international approaches to newborn screening decision-making*. 2025. Available at: https://geneticalliance.org.uk/news/time-to-decide-learning-from-international-approaches-to-newborn-screening-decision/
[15] SHCA. *SHCA survey: unmet mental health needs of people living with a rare or complex condition*. 2024. Available at: https://shca.info/wp-content/uploads/2024/04/SHCA-survey-%E2%80%93-unmet-mental-health-needs-.pdf
[16] SHCA. *Are you okay? Rare diseases and mental health – A case study report*. 2025. Available at: https://shca.info/wp-content/uploads/2025/07/%E2%80%98Are-you-okay-Rare-diseases-and-mental-health-%E2%80%93-A-case-study-report.pdf
[17] Genetic Alliance UK. *Facts and figures*. No date. Available at: https://geneticalliance.org.uk/campaigns-and-research/facts-and-figures/