THE WHITEHALL REPORT 2018

MARWOOD GROUP

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INTRODUCTION

The English health and care system is a highly complex structure, subject to direct political intervention and indirectly impacted by wider policy objectives. Providers are subject to national regulatory requirements and can face local oversight and scrutiny arrangements that vary significantly across the country.

Reimbursement responsibilities for health and care services are split between different organisations. Most publicly funded social care is paid for by local authorities, whilst health services can be commissioned either nationally through NHS England or at a local level through Clinical Commissioning Groups.

Public payers have been under pressure to find substantial savings from health and care expenditure. This pressure has acted as both a catalyst for change – encouraging greater innovation and integration – and as a barrier – as budgets are diverted from transformation priorities to plug NHS Trust deficits and relieve short-term social care pressures.

It is vital that investors and corporations understand how these features that influence the functioning of England's health and care systems have evolved over time and are formed through a combination of politics, cultural expectations, and economic conditions. Taking into account these factors is essential for developing market entry strategies and making sound investment decisions. Marwood Group produces its annual *Whitehall Report* as a reference on the current policy environment. In this report we look at the areas of most relevance to investors and corporations operating in the health and care landscape, tailored to the unique regulatory, reimbursement and policy drivers in each area.

We hope you enjoy using our latest *Whitehall Report* as much has happened since our previous publication. Nationally, the NHS received a generous 70th birthday present in the form of a long-term funding settlement, whilst locally, integrated health and care systems are taking shape in the most advanced health economies. It has been another tough year for social care. Local authorities – who have faced severe reductions in central government funding allocations since 2010 – continue to spend cash reserves and cut-back services to avoid following Northamptonshire into bankruptcy, whilst nationally politicians sidestep social care funding reform and rely on short-term cash injections to ensure the sector does not collapse.

The wider political landscape continues to be dominated by Brexit. The impact is being felt across all areas of public policy, and domestic legislation has almost ground to a halt. The Conservative Party, governing on a 'supply and demand' basis with the Democratic Unionist Party, has neither the political will nor the political capital to introduce contentious legislation at this time.

The Labour Party – continuing to face a hostile media and almost as divided as the Conservative Party over Brexit – has been unable to capitalise on the Government's weakness, and remain behind in the opinion polls. Their health and care policy objectives continue to lack clarity over how they will be funded.

Social care has been a casualty of the lack of attention on domestic issues. Already blamed for causing the Conservative Party to lose their parliamentary majority in the 2017 General Election, the need to reform social care financing is recognised across the political spectrum. However, the Social Care Green Paper – originally due in December 2017 – will now not be seen until October 2018, and even then, there is little expectation that it will introduce clear plans for sustainable future funding.

However, some healthcare leaders may be quietly grateful for the political and media focus on Brexit as it has helped to mask the continued decline in NHS performance targets. The NHS has not met the Accident and Emergency 4-hour wait time target since August 2014, and elective care targets have also begun to decline sharply. What is surprising is how little pressure this caused for Jeremy Hunt, as Secretary of State for Health and Social Care, or Simon Stevens, as Chief Executive of the NHS. In previous years, one would have expected very uncomfortable sessions in front of the Health Select Committee and highly critical media attention. However, in the wake of Brexit, this has not materialised.

The announcement of additional NHS funding has provided an opportunity to shake-up the sector. An additional £20.5bn annually for the NHS by 2023/24, agreed outside of the Spending Review, represents a significant coup for the health sector – and meant that Jeremy Hunt left his post not only as the longest serving Health Secretary, but one of the few to leave with their reputation still intact.

Matt Hancock, replacing Jeremy Hunt as Secretary of State, has the enviable position of deciding how the money will be spent. However, he may find himself hemmed in by the politically savvy Simon Stevens on one side, and the Treasury on the other. Significant improvements – and fast – will be the minimum expected by the Treasury in return for their financial commitment. The question remains as to how it will be funded, where it will be spent, and whether any of it will help the crisis in social care.

Early signs indicate that Matt Hancock has carried his love of technology into his new role, and his announcements have suggested a desire to revisit existing strategies, re-allocate previously announced funding, and push for a more joined-up digital system. He has also made an effort to champion the workforce – rebuilding some of the damage caused by Jeremy Hunt's protracted dispute with Junior Doctors. He has been a lot quieter on social care, with his statements primarily sign-posting towards the upcoming Green Paper or talking in terms of the interplay between health and social care.

All eyes will be on the Autumn announcements, which will detail future funding for the NHS, spending priorities contained with a wider 10-year NHS plan, a joint health and care workforce strategy, and the Social Care Green Paper. Taken together, these hugely significant publications will act as a credibility test for the Government's commitment to health and social care. We will be following them all closely.

Our annual *Whitehall Repor*t acts as an important reference document to decode the complexity of health and care in England. We hope our insights into the key developments affecting the regulatory, reimbursement, and policy levers impacting on the health, social care and pharmaceutical markets in England help support you to make the right decisions for your business.

We hope you enjoy our *Whitehall Report*, and would be more than happy to discuss further any topics that we have covered.

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A SHIFT TOWARDS INTEGRATED CARE SYSTEM AND LOCAL HEALTH ECONOMIES

Tackling funding and quality challenges in the NHS is a highly politicised issue, and health policy is often a reflection of a government's ideology. As a result, the health system in England is never static. It will always be subject to political intervention, whether it is local Members of Parliament trying to stop hospital closures, or a health minister announcing plans for system-wide reform.

However, the last four years have seen a broad consensus develop among politicians, policy makers, and medical professionals about the core objectives for the health service, and how it needs to evolve. These objectives are set out in the Five Year Forward View, and are leading to major changes in the way care is delivered across England.

This consensus emerged during Jeremy Hunt's six-year stint as Secretary of State for Health and Social Care. It is unlikely that his replacement, Matt Hancock, will seek to radically shift current policy as the wider political environment is focussed on Brexit, and the Conservative Party is unwilling to engage in contentious health reform during this period.

The additional funding for the NHS announced in July 2018, alongside the creation of a 10-year plan to give the NHS long-term strategic objectives, will signpost the Government's continuing commitment towards system transformation. There will be pressure to deliver clear improvements in specific clinical areas, such as cancer and elective care, and there is a risk that there will be little actual money remaining to fund necessary transformation.

The Five Year Forward View: Making the case for change

The Five Year Forward View (FYFV) was published in October 2014. Its vision was agreed by those bodies responsible for setting the national direction of the health system; NHS England, Care Quality Commission, Health Education England, Public Health England, and Monitor and the NHS TDA (who would merge to form NHS Improvement).

It framed the importance of providing a sustainable solution to health funding by talking in terms of three widening gaps that threatened to undermine the ability to deliver a fully tax-funded, free at the point of use NHS.

1. The Health and Wellbeing Gap
2. The Care and Quality Gap
3. The Funding and Efficiency Gap

The FYFV identified a £30bn funding gap for NHS services by 2020/21 if there was no change. The result was that the Treasury allocated an additional £8bn in real term funding over five years as part of the Spending Review settlement in 2015. Alongside this, the health system was to meet the remaining £22bn through (1) doing the same things better or more efficiently, and (2) delivering services through new models of care.

Progress towards meeting this target has not been effectively measured but increased demand in acute hospitals, and the reallocation of funding to support hospital deficits, has led to a general consensus that the overall health system is not on track to find £22bn to meet the funding gap.

New models of care

In developing new service models, NHS England focussed on developing 50 'vanguard' sites to test ideas. Their experience would act as a benchmark for other areas, spread good practice, and shape the wider healthcare landscape in the medium and long terms. Five distinct models were tested across the 50 vanguard sites.

VANGUARD TYPE	HOW IT WILL IMPROVE CARE
Integrated Primary and Acute Care System (PACS)	Urgent care is integrated with primary, community, mental health and social care. More services are delivered outside of hospital in home or community settings, through multi-agency teams reducing total emergency/unplanned admissions. They would cover a patient population of around 250,000 people.
Multispecialty community providers (MCP)	Based around primary care, it combines delivery of primary care and community-based health and care service. Unlike a PACS, it is unlikely to contain hospital services. They were assumed to cover a patient population of around 100,000, but early models are looking at coverage of 30,000-50,000 patient populations.
Acute care collaboration	NHS Trusts are encouraged to join in formal or informal arrangements through the use of networks, group models or integrated clinical pathways. This may involve sharing back-office support across Trusts, or innovative shared service clinical models in areas like diagnostics.
Enhanced health in care homes	Developing joined-up care between health and social care providers. Solutions have often focused on small-scale interventions rather than larger system change.
Urgent and emergency care	New approaches to improve the coordination of services and reduce pressure on Accident & Emergency (A&E) departments. This vanguard stream has now been mainstreamed into wider NHS activities.

The PACS and MCP models have the greatest implications for the wider healthcare system. These could potentially reshape the healthcare landscape by creating care models similar in structure to the American model of an 'Accountable Care Organisation'.

These two models are concerned with how to deliver 'population health' rather than just being reactive to individual care needs. It goes further than designing single-service integrated clinical pathways, and in its most advanced conception it encompasses budget- and risk-sharing across multiple separate legal entities (care providers), the commissioning of services against capitated, population-based budgets, and integrated system planning across a local area.

These increasingly integrated models will look to move care out of acute hospital settings. They will make more use of care based in the community and look at widening the scope of traditional primary care centres, such as by potentially moving diagnostic and rehabilitative services into new settings. Traditional NHS hospitals will be used to treat those with the highest level of need, and primary care, joined-up with public, private and voluntary providers, will be at the centre of future care models.

Development has been slower than planned. This is due to the difficulty in creating a model that meets the legal requirements of the Health and Social Care Act 2012, and overcoming structural barriers, such as the

Treasury refusing to grant VAT-exemption to new legal entities, which create disincentives to change. There has also been public pressure, with two judicial reviews seeking to block proposed changes. However, in Summer 2018, NHS England published a consultation on the Integrated Care Provider contracts, which is likely to provide the basis for local areas to move further in this direction.

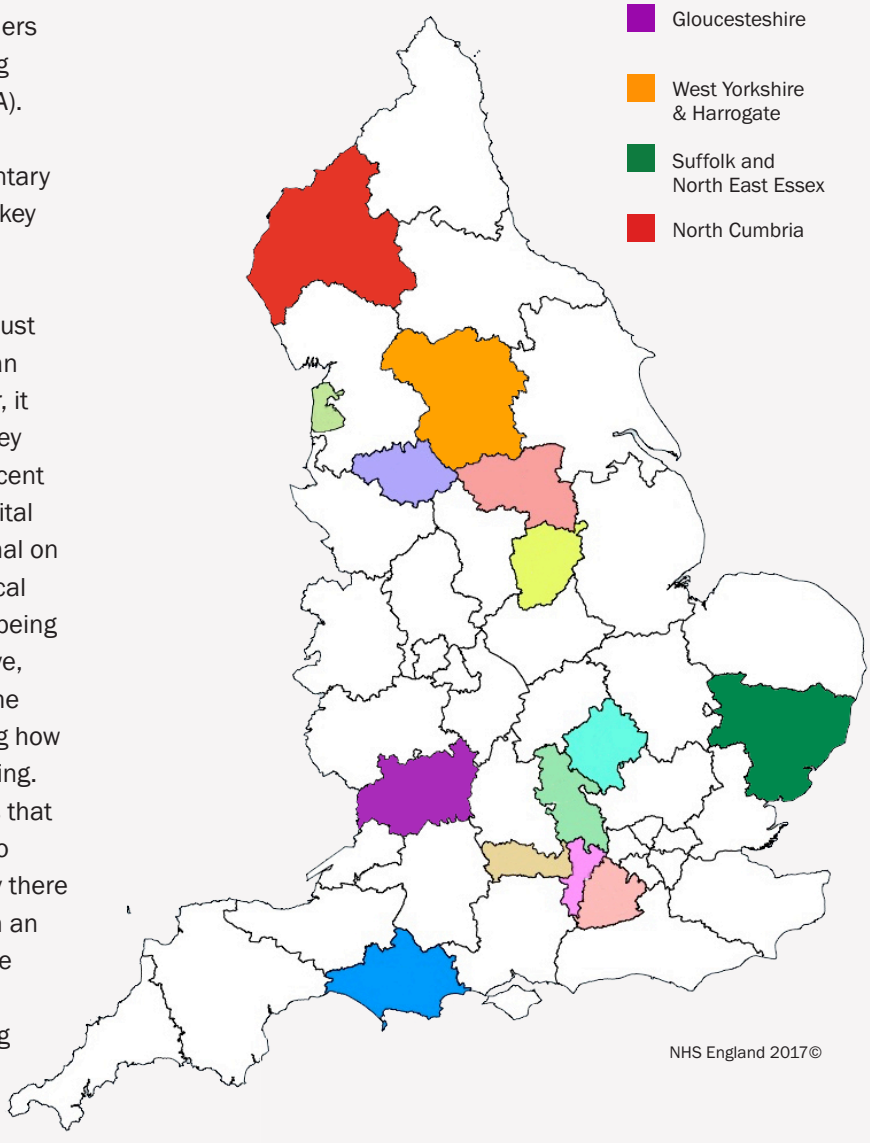
From Sustainability Transformation Partnerships to Integrated Care Systems

Sustainability Transformation Partnerships (STPs) were created in 2016, and cover all of England. There are 44 in total, and their purpose is to drive forward integrated working at a local level. Their membership, purpose and core priorities vary from area to area. However, they will contain key stakeholders from NHS Trusts, Clinical Commissioning Groups (CCGs), and Local Authorities (LA). They should have representatives from Healthwatch, local community and voluntary organisations, and representation from key private sector providers.

STPs have faced criticism that they are just an additional bureaucratic layer within an already highly complex system. However, it is increasingly the case that public money is linked to STP activity. For instance, recent announcements concerning funding digital technology in NHS Trusts were conditional on the Trust bids being signed-off by the local STP. Workforce planning is increasingly being considered from an STP-wide perspective, with workforce strategies considering the staffing need across a region – including how social care can be integrated into planning. The next phase of this system change is that the most advanced STPs are turning into Integrated Care Systems (ICS). Currently there are 14 ICS spread across the country. In an ICS, local system partners take collective responsibility for managing resources, delivering NHS standards, and improving the health of the population they serve. *See diagram right.*

The Labour Party has said that they would look to halt STP development and review their plans, However, it is only focussed on those closing services, and the reality is that it is most likely to slow reform rather than reverse it.

System change has developed in different ways, and at different speeds, across England – with some far more advanced than others. This has meant that it has become increasingly important to understand the political and policy dynamics of local areas when considering how system changes may impact on existing care provision or shape the future service structure.



A NEW LONG-TERM FUNDING SETTLEMENT FOR THE NHS

The NHS turned 70 this year and, after years of below-inflation funding uplifts, was beginning to creak under the strain of rising patient demand. Despite it not being a manifesto commitment, a concerted lobbying campaign by Jeremy Hunt – possibly emboldened by surviving a political reshuffle in early 2018 – and Simon Stevens, the powerful and politically savvy Chief Executive of the NHS, convinced Theresa May and Phillip Hammond, Chancellor of the Exchequer, to risk the wrath of Conservative backbenchers and open up the purse-strings. Cleverly positioned as a 'Brexit dividend', it meant that pro-Leave MPs had little ground to complain against this raid on the public finances.

The NHS in England will be receiving an additional £20.5bn funding annually by 2023/24. This equates to an average real-term increase of 3.4% per year from 2019/20; a substantial improvement on average annual increases of less than 2% since 2010/11. Yet, it falls short of the 4% that many identified as the minimum required for the NHS to both meet existing commitments and invest in the transformation necessary to keep up with future demand.

The headline announcement masks a critical point that the funding uplift is only applied to the NHS England ringfenced budget. If the uplift was seen in context of the wider Department of Health and Social Care budget, the increase would be close to 3% per annum. Sitting outside of the ringfence are critical areas such as public health, regulation, and capital funding.

Final details on how the increase will be funded, and where the money will be spent, will not be formally announced until the Autumn Budget. There have been a number of hints as to the priority areas that will benefit from targeted funding.

- **Elective care** – The recent deterioration in NHS performance targets may see elective care as one of the biggest beneficiaries. Elective care performance can be significantly improved using cash incentives to encourage doctors to take on more shifts, or to outsource more capacity to the private sector.

- **Cancer services** – Simon Stevens has specifically spoken of prostate, lung cancer, and colorectal as areas open to pathway redesign.

- **Young people's mental health services** – The Government's recent Green Paper would suggest it continues to be a priority area and will require a significant cash injection to fund new Mental Health Support Teams.

- **Primary care real estate** – Whilst the Royal College of General Practitioners (GPs) have asked for a direct injection into GP spending, Simon Stevens may target capital funding. He has stated many GP practice premises are not fit for purpose and investing here may be seen as a mechanism for driving ahead with wider system transformation ambitions.

- **Services that tackle health inequalities** – Smoking cessation services have been cut back heavily as local authority budgets come under pressure, and there has been acknowledgement that the burden for these services cannot fall on local authorities alone.

As the Budget looms closer, it is likely that more clarity will emerge around funding plans. We also know that the Government intends to publish the Social Care Green Paper, and the Joint Health and Care Workforce Strategy, during the same period. This suggests an intention to align policy and funding objectives, and it is likely that a focus on reducing delayed transfers of care and improved medical services to older people in order to keep them out of hospital may form part of the plans.

	TOTAL NHS BUDGET (£ BN)	REAL-TERM GROWTH
2018/19	114.60	
2019/20	120.55	3.6%
2020/21	126.91	3.6%
2021/22	133.15	3.1%
2022/23	139.83	3.1%
2023/24	147.76	3.4%

BRITAIN LEAVING THE EU AND THE IMPACT ON HEALTH AND SOCIAL CARE

The ongoing negotiations concerning Britain leaving the EU have had major impacts on the health and social care landscape, even before the terms of any deals are agreed. Large declines in the number of non-UK EU nurses registering with the Nursing and Midwifery Council have been blamed on the uncertainty of future workers' rights, whilst pharmaceutical companies have been asked about drug stockpiling to ensure a readily available supply in case of no withdrawal agreement with the EU. Brexit has also had indirect impacts on health and social care. Most notably, politically contentious legislation has been shelved, with a major casualty likely to be social care. Given a sustainable solution is almost to require unpopular funding reform, it is unlikely the Conservative Party will seek to introduce legislation until more certainty around Brexit is known, and reform may potentially be delayed until after the next general election.

The July 2018 White Paper on Britain's future relationship with the EU provided the first clear views of the Government's negotiating position. Despite securing Cabinet agreement for the proposals, within 48 hours it prompted the resignation of leading Brexiteers, David Davies and Boris Johnson. The resultant cabinet reshuffle placed pro-EU MPs in some key positions, including Jeremy Hunt leaving the Department for Health and Social Care to become Foreign Secretary. The shake-up has also allowed the Prime Minister to take a much more active role over future negotiations.

These changes may make agreeing a deal with the EU more likely and will make it easier for Theresa May to personally negotiate with EU member state leaders, effectively bypassing Michel Barnier and the EU negotiating team. However, it has also angered pro-Leave MPs who view it as

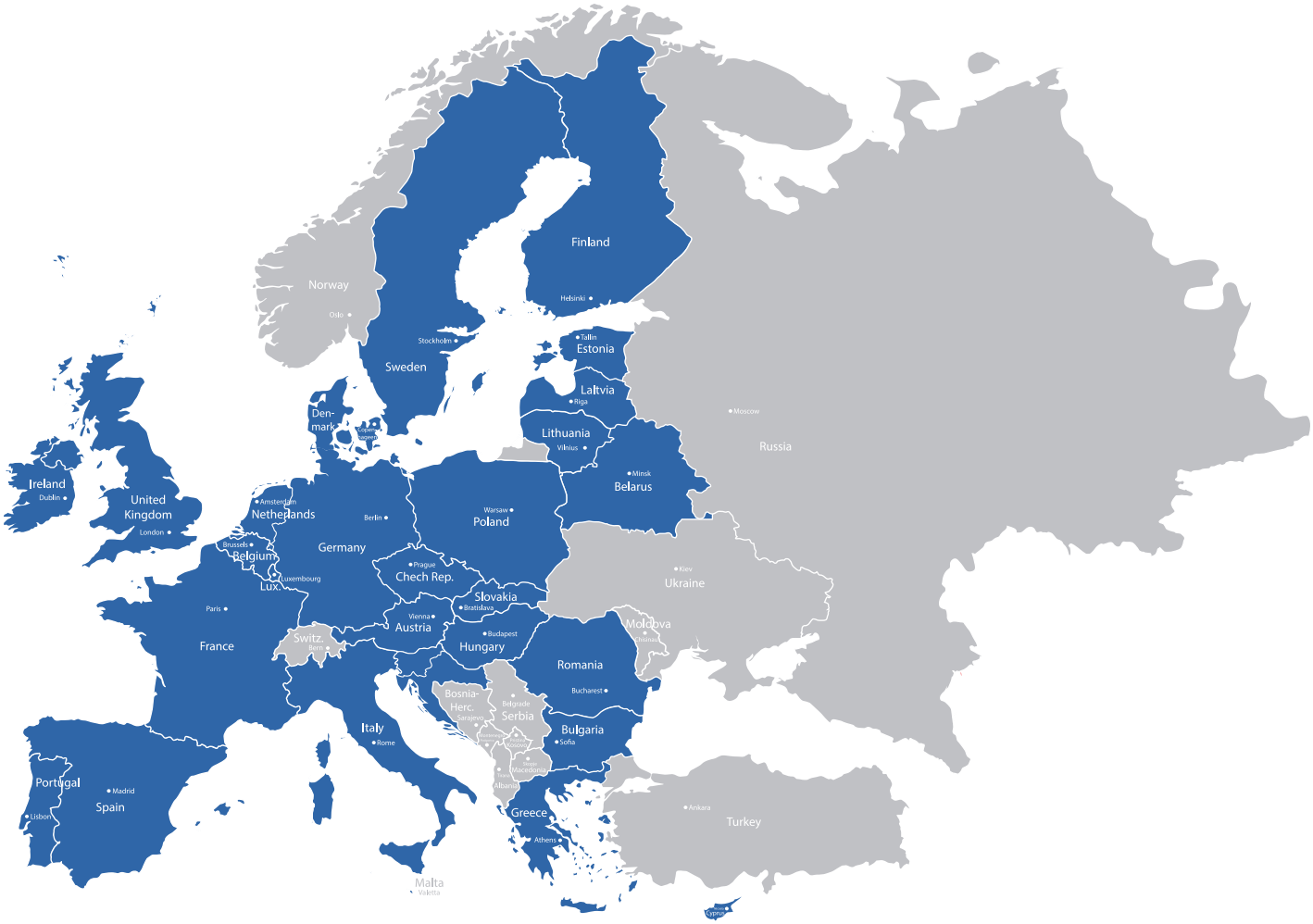
a betrayal of the core principles of Brexit, and who may agitate for a more hardline proposal or even a no-deal exit.

The Government's Brexit White Paper and the implications for health, social care, and pharmaceuticals

The Government published its formal position on the UK's future relationship with the EU in July 2018. The White Paper offers the first clear insights into how the Government would like to position Britain following its exit from the EU. This is not the final agreed position, and it is also not a guarantee that Britain will reach agreement with the EU – in which event Britain may exit the EU without any deal in place.

Taken on its merits, the White Paper offers a view of a softer Brexit than many Leave supporters would have wished. It has faced criticisms that it amounts to little more than a wish list and lacks any technical detail on implementation or how existing legal hurdles may be cleared.

Healthcare is mentioned at several points, but there is little detail on what the proposals would mean for specific sectors, apart from noting the importance of securing recognition of professional qualifications for the healthcare sector. The following table looks at the wider principles announced by the Government to provide an overview of what they may mean for health, social care, and pharmaceuticals.



Above: EU Members as of 2018

GOVERNMENT PROPOSAL	IMPLICATIONS FOR HEALTH, SOCIAL CARE AND PHARMACEUTICALS
Establish a 'common rulebook' for all goods, with Britain committing to harmonisation with EU rules	The 'common rulebook' is the Government's proposal for position that allows Britain to stay in the Single Market without staying in the EU. It would harmonise some EU rules to enable 'frictionless trade' and would commit to regulatory harmonisation on issues that have a cross-border impact. It would mean Britain accepting the rules of the European Medicines Agency, no tariffs on goods to/from the EU, and the common rulebook on manufactured goods. Although the proposal may work in theory, pro-Leave supporters have suggested it will make the UK beholden to the EU without being able to influence it, whilst EU negotiators have suggested that it is impossible to sub-divide Single Market access in this way.
Establish cooperative arrangements between regulators	This will increase the chances of a smooth transition on regulatory alignment issues, easing potential pressure on Britain's highly valued pharmaceutical and life sciences industry. It should also mean that future drug and medical technology access from EU member states will not be compromised as part of Britain leaving the EU.
Non-regression of labour standards	Workers' rights will be retained at their existing levels of protection. Businesses may not get increased flexibilities around workforce management. This may disappoint social care providers, where operators are under significant pressure, and who are already concerned about the impact of potential limits on lower skilled workers from EU countries.
End 'freedom of movement' but include a framework that allows EU citizens visa-free travel to UK for work as part of their existing job, study and for tourism	The current position avoids discussing future migration for permanent hires. This is a critical factor for health and social care organisations, who are reliant on EU member states for both skilled and unskilled workers. This may be a major negotiating stumbling block, as the EU appears unwilling to discuss Single Market access without Britain's concessions on freedom of movement. However, controlling migration is one of the touchstone issues for Leave voters, and Theresa May will be under considerable internal pressure not to cede ground in this area.
Seek a system for 'mutual recognition' of qualifications	It is not clear how this would work in practice, but a system similar to the existing mutual recognition process would be advantageous for health and social care employers. This is not felt to be a difficult issue to agree as part of negotiations.
Cooperative accords in key areas, including science and innovation	Britain would almost certainly have to pay to access EU schemes and programmes, but it would allow them to take part in multinational projects, including those for science and research. Non-EU countries already have arrangements like this in place.
Healthcare access for UK and EU nationals	Under the reciprocal arrangements proposal, EU citizens should be able to access healthcare services in the UK.
Cooperation on health security	The importance of maintaining a common approach on health security issues is recognised. Ongoing work that helps respond to health threats that are by their nature cross-border would continue, including continued collaboration with European-wide networks and Committees.

PRIMARY CARE: GENERAL PRACTICE

General practice in England is not provided directly by the NHS. Unlike those working in hospitals, most general practitioners (GPs) are independent providers, who operate under contract with the NHS. It is a highly fragmented sector. Whilst there has been a move towards reducing the number of single-handed GP practices and moving towards larger models, such as GP Federations, in 2017 there were 7,613 GP practices with approximately 41,985 GPs. However, there are wider workforce challenges, and since 2015 the total amount of GPs in post has declined by nearly 1,000.

The sector is under pressure due to increasing demand and difficulties in recruitment and retention. In 2016, a policy initiative was introduced to increase the number of GPs by 5,000 by 2020/21, and funded a further 5,000 places for other practice staff. Trainee GPs are currently at record levels but still below what is required to hit recruitment targets. Plans to recruit 1,500 pharmacists to be placed in GP surgeries are on track.

General Practice accounts for 7.1% of total NHS spend. The 2016 GP Forward View pledged a £2.4bn increase in annual NHS expenditure on GP services by 2020/21, to bring up GP spending to 10% of the total NHS spend. However, the July 2018 announcement over a wider funding uplift to the NHS means that if this amount is not increased further, then overall spending on GPs will decrease as a proportion of total NHS expenditure.

PAYERS

NHS funding for general practice

In 2016/17 the NHS spent just over £10.2bn on general practice in England. The General Practice Forward View (GPFV) published in 2016 announced additional funding, which should bring annual funding to £12bn by 2020/21. This acknowledged that general practice had been neglected with funding directed towards ensuring sustainability in acute care and this needed to be rebalanced in view of the wider policy objectives. Although the funding package provided additional money for general practice, it was not new NHS funding. Instead it came from the overall NHS budget, which means that the money had to be redirected from other services' budgets to fund it.

It remains to be seen how much of the annual increase in NHS funding announced in June 2018 will be directed towards primary care. The Royal College of GPs has called for annual GP funding to be revised upwards to £14.5bn by 2020/21 to ensure that it reaches 10% of the overall budget. However, GPs were not mentioned in the Prime Minister's speech or in the Secretary of State's statement to parliament following the NHS funding settlement announcement. This suggests it may not be a viewed as a priority area. GPs and other providers involved in general practice are likely to have to wait until the 2018 Autumn Budget for more detail on future funding for the sector.

The Government announced in December 2014 that £1bn would be made available for improvements through a Primary Care Infrastructure Fund. This included specific funding for the development of the primary care estate and technology, available until 2019/20 via the Estate and Technology Transformation Fund. It can be used to extend existing buildings to grow capacity and/or expand services, building new facilities to support the delivery of hospital services in the community, or to introduce new IT systems that enable sharing patient records between various care professionals. However, there has been criticism that as little as £48m had reached frontline GP Practices by April 2017, and that NHS England had been siphoning money from the Primary Care Infrastructure Fund to pay for other policy commitments, such as supporting the introduction of 7-day working.

Commissioning trends

Under the Health and Social Care Act 2012, primary care commissioning responsibility sits centrally with NHS England. Since 2014/15 this has increasingly shifted to the local level, with NHS England delegating GP commissioning to Clinical Commissioning Groups (CCGs). This recognised that, as local commissioners, CCGs should have a better understanding of their population's needs and are better placed to commission GP services. As of April 2018, 178 CCGs out of 195 have delegated powers to commission general practice services.

GP Contract Reform

Discussions have started on a possible major reform of the 2004 NHS GP contract in 2019. Currently, there are three types of contracts:

- The General Medical Services (GMS) contract, agreed nationally
- The Personal Medical Services (PMS) contract, agreed locally
- The Alternative Provider Medical Services (APMS) contract, agreed locally and allowing independent providers to deliver primary care services

The reform's aim is to adjust the contracts to allow full realisation of changes in care provision and policy objectives. NHS England wants the new contract to address key areas around supporting the recruitment and retention of a multi-skilled workforce, expanding services through the creation of primary care networks (joining-up a range of community services from emergency care to care planning), new models of care, and delivering high-quality patient care.

The reform will also consider how payments should be adapted to digital primary care, as the success of the GP At Home service has highlighted significant limitations in the ability of the payment model to take into account people who chose to sign-up to digital services that are located outside of their local CCG. In August 2018, NHS England paused the expansion of the GP At Home service until these issues can be resolved.

The new contract will be negotiated between NHS England and the British Medical Association. Contract negotiation is never straightforward and is highly complex. According to the most recent discussions, the objective is to introduce the new contract on 01 April 2019.

POLICY AND LEGISLATION

Since 2016, policy objectives have focused on how to reduce the reliance on acute care by shifting some services out of hospitals into community settings and increasing prevention to avoid the escalation of health problems that require inpatient admission. Changes to the traditional model of general practice was regarded as central to achieving this objective.

General Practice Forward View

A progress review on the GPFV was published in April 2018. It sets a vision for the transformation of general practice services in England, recognising that they are increasingly the frontline of service delivery. The GPFV also formalised the objective of widening access to general practice services outside of normal working hours and introducing seven-day a week service provision. This is currently being implemented in local areas with GP practices designing solutions to meet local needs.

Multispecialty Community Providers

Multispecialty Community Providers (MCP) were introduced as part of the new care models agenda and offer a community model with primary care at the centre. Under the model, GPs practices work collaboratively across a local area, alongside other health and social care professionals to provide integrated services outside of hospitals. This policy direction is in line with the GPFV.

Over the past few years, MCPs have spread from the original vanguard sites, and models have been developed across the country. Whilst they vary in size, most of them tend to serve a patient population of 30,000-50,000 and there is an agreement that this is currently the ideal size, enabling these new models to focus on local needs, and to deliver care closer to home.

There are a number of systemic challenges that may hinder the success of the MCP model. It requires local buy-in from providers as well as a collaborative approach bridging public and private provision. An infrastructure challenge exists, as the model requires appropriate buildings and a multi-skilled workforce in place to ensure high-quality care is delivered to the patient.

WEST WAKEFIELD MCP – CASE STUDY

West Wakefield's MCP is made from a federation of six GP practices working alongside other services to collectively manage staff and resources. The MCP aims to provide care to over 150,000 patients. By creating connecting care hubs, the MCP looked to bring together GP practices with community nurses' voluntary organisations, and social care staff. The activity is focused on creating integrated care that is more responsive to people with long-term conditions who require complex care. The vanguard has also introduced prop-up primary care services to offer health checks, and assessments for cardiovascular disease risk, obesity screening and cholesterol tests.

REGULATION

Risk-based approach for NHS and independent providers

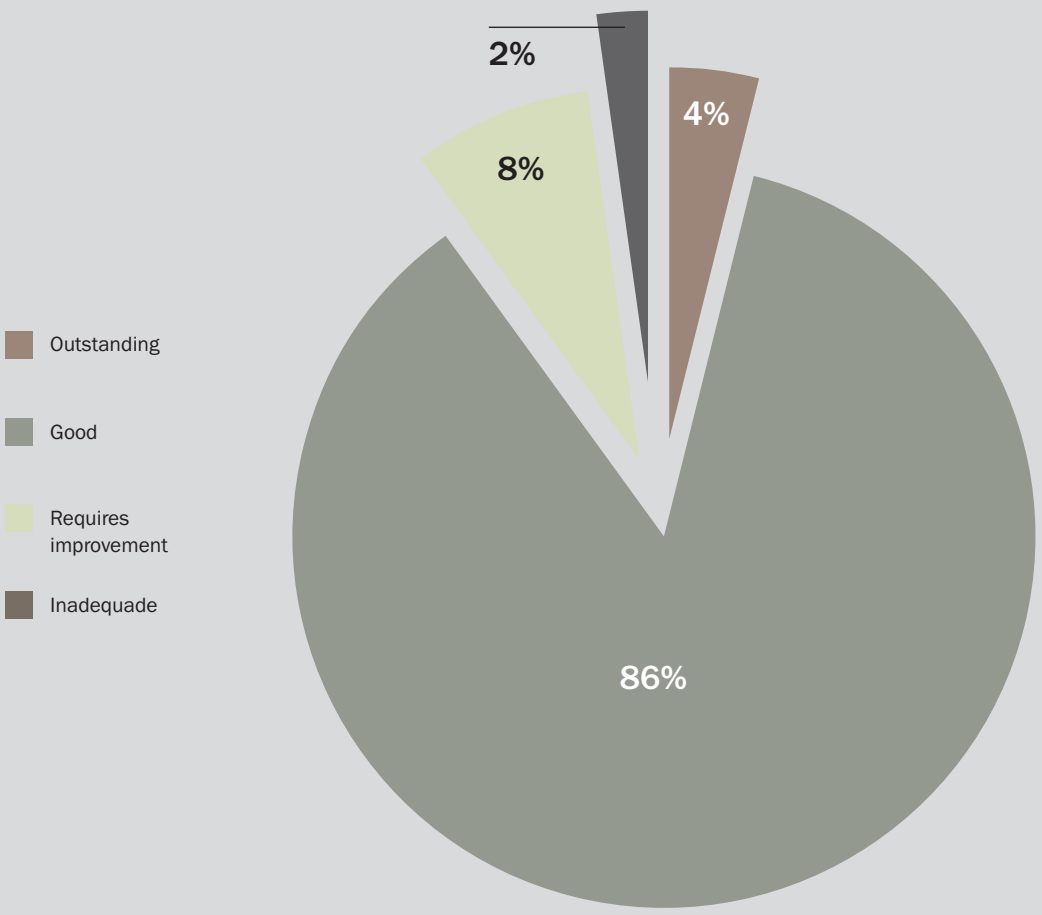
Traditional ways of regulating the general practice model are being challenged by new ways of working and the burgeoning use of digital technologies to deliver or facilitate the delivery of some services. CQC is in the process of adapting its regulatory framework to meet these new demands. The direction of the future regulatory framework was outlined in October 2017.

A key change is that CQC will move away from the comprehensive inspection approach, which took place between 2014 and 2017, and will increasingly rely on a risk-based approach. Under this approach, GP practices that have been rated good or outstanding by CQC's inspection teams will be inspected less frequently, with gaps of up to five years between inspections.

When inspecting better performing locations, inspections will increasingly focus on the well-led element. These changes are intended to allow CQC to direct more efforts and resources on the 10% of practices that require improvement or are rated as inadequate.

CQC RATINGS OF GP PRACTICES 2014-2017

Source: CQC



THE STATE OF CARE IN ONLINE PRIMARY HEALTH SERVICES

Between November 2016 and August 2017 CQC inspected 35 online providers of primary care services. These are defined as 'healthcare services that provide a regulated activity by an online means. This involves transmitting information by text, sound, images or other digital forms for the prevention, diagnosis or treatment of disease and to follow up patients' treatment'.

At the time, CQC had no powers to rate these services. However, it applied the five key questions during its inspection process. Findings show that whilst most are considered to be caring and responsive, there were major concerns around the issue of safety, with 15 out of the 35 online providers considered to be not safe. Highlighted concerns around safe care included prescribing companies failing to talk to patients when prescribing high volumes of opioids, antibiotics, and inhalers. Combined with failing to properly share patient information with GPs, serious concerns were raised over how medicines were being prescribed through online providers prescription habits.

Regulating new models of care

CQC's next phase of regulation acknowledges that the way general practices are working is changing. GPs are increasingly working in group practice, sometimes on a large scale through super-practices or federations. This poses several regulatory challenges, including questions about where accountability for quality of care lies, and how these models should be rated. The proposed changes outlined in 2017 do not fully address these issues.

Another challenge to CQC's traditional regulatory framework is the development of digital primary care. Whilst these solutions, which include online consultations and symptom checkers, make-up a very small part of GP services, they are expanding rapidly. This prompted CQC to think about the regulation of online providers followed by an announcement that it will inspect and make judgements about the quality and safety of these services. This led to the publication of the State of care in independent online primary health services in February 2018.

CQC has been granted legal powers to rate online providers. This is likely to be an area of focus, keeping with the regulator's objective to support new models of care and innovation and as the number of online providers grow.

Dental services provision in England primarily consists of independent, small or single-handed practices, alongside a few larger corporate groups that operate across multiple locations. Most dental practices offer a mixture of NHS and private-pay services, but some may focus on the pure-NHS or pure private pay sectors.

In 2016/17, 22.2 million adults saw one of the 24,007 NHS dentists, a slight increase on the previous year. The cost of NHS dentistry is split between the user – through a patient charge – and by NHS direct payments to dentist. Recent increases to the patient charge have averaged 5% per year, making-up a growing proportion of NHS dentists' revenue (from total revenue of 23% in 2011/12 to 28% to in 2016/17).

Dental policy rarely garners much political attention, and sector conversations are dominated by attempts to reform the 2006 NHS General Dental Service contract, which is very unpopular with the dental profession. Several models are being piloted across a small number of practices, but finding a workable and financially sustainable solution has proved difficult. This has led to delays in implementing a new contract, with little confidence that any national solution will occur before 2021.

PAYERS

The majority of dentists in England provide both NHS-funded and private-pay services. They are exposed to two payers; the NHS and individual private payments.

NHS funding trends

Unlike the majority of NHS services, dental services are not free at the point of need. Patients are required to contribute to the cost of services through a co-payment, known as the 'patient charge', unless they qualify for an exemption. This creates two separate payment elements to NHS-funded dental services:

1. Direct NHS payments
2. Patient charge (co-payment)

Direct NHS payments
Currently, direct NHS payments to dentistry amount to about £2bn each year representing 72% of the total NHS spend on dentistry in 2016/17. The amount paid varies year-on-year, but overall, between 2011/12 and 2016/17, direct NHS payments to dentistry have decreased by an annual average of 1.5%, reflecting wider pressures on NHS budgets and the fact that dentistry is not a key priority for policy-makers.

	TYPE OF TREATMENT	2018/19 PATIENT CHARGE
Band 1	Check-up, diagnosis, treatment planning and maintenance	£21.60
Band 2	Fillings, root canal, tooth extraction	£59.10
Band 3	Complex treatment that includes laboratory element	£256.50

Patient charge

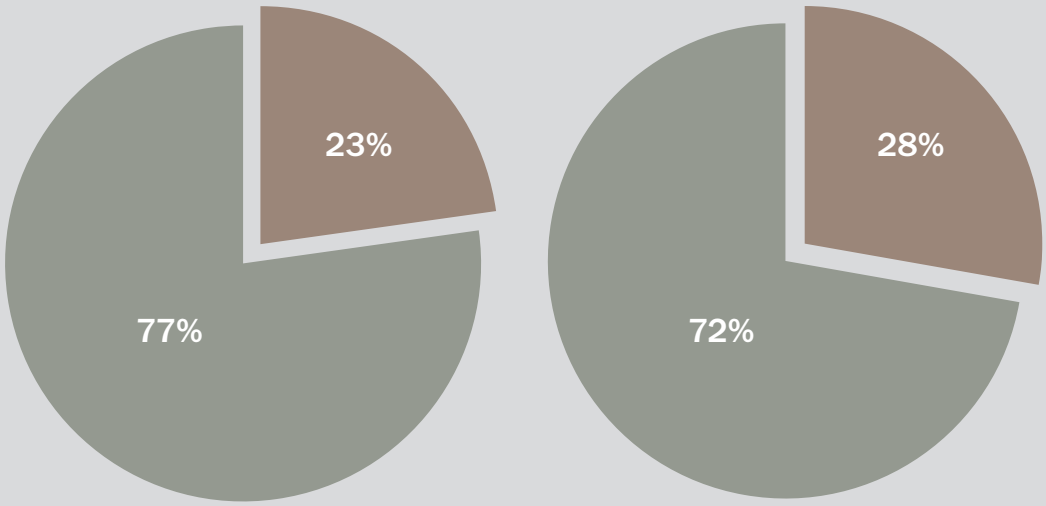
Patient charge revenue contributed to 28% of the total NHS spend on dentistry in 2016/17. There are three different levels of charge (known as 'bands'), depending on the type of treatment. In the past three years, patient charges have increased by about 5% per annum across all bands.

As the price of the patient charge has increased much faster than direct NHS payments to dentistry, the burden of funding NHS dental services has shifted towards patients. In 2011/12, patient charge revenue contributed to just 23% of the total dental revenue. In 2016/17 it was 28%. This is expected to continue in the next few years.

Private pay trends

Consumer demand for private services has been increasing, and the private pay market now has returned to levels not seen since 2011/12. The decline in private pay in this period reflected the impact of the economic recession combined with significant increases in funding in NHS dentistry.

Demand has re-emerged due to limited NHS funding, increased patient charges for dental treatment on the NHS, an increasing gap in the range of services available, and increasing interest in cosmetic treatments, such as tooth whitening. Most private payments are directly out-of-pocket as few private insurance plans cover dental services.



SOURCE OF SPEND IN NHS DENTISTRY

Source: NHS, Department of Health and Social Care

POLICY AND LEGISLATION

General Dental Contract reform

Issues with the 2006 General Dental Contract
The current NHS General Dental Services (GDS) contract was introduced in 2006. Resisted from the start by dentists, it has remained highly unpopular over the subsequent decade, and the British Dental Association view is that it is not fit for purpose. The activity-based payments system is blamed for dentists spending too much time chasing agreed activity targets and being incentivised to focus on treatment rather than preventive activity.

The Department of Health is in agreement that reform is needed. Patients may have benefited from a simplified payment system, but have found that procedures such as a single filling has become more expensive. This increased the risk that lower-income patients may delay their dental visits - in effect storing up dental problems - to access more treatment. This threatens the wider prevention agenda.

UNDERSTANDING NHS DENTAL PAYMENTS: UNITS OF DENTAL ACTIVITY

Dentists providing NHS services are currently reimbursed on the basis of the Units of Dental Activity (UDA) system. Each dental practice that provides NHS activity will have a contract specifying the volume of UDAs they should deliver annually. Treatments will be valued at between 1 and 12 UDAs. This is supposed to reflect the complexity and length of time different treatments will take. It aims to ensure dentists are not disincentivised to provide complex, lengthy treatments. Dentists earn between 1 and 12 UDAs depending on the type of treatment provided. The unit price of UDAs is agreed on a practice by practice basis, leading to variation between practices.

Under the current contract, dentists carry most of the financial risks. If a practice fails to achieve the volume of UDAs they committed to deliver, their NHS payments are adjusted to reflect lower volumes. However, there are no requirements on commissioners to fund over-delivery of UDAs. This balance is meant to ensure that dentists do not under-deliver to NHS patients by over-committing to private provision, but also allows NHS England to help manage the cost to the NHS by not rewarding over-delivery. When practices miss their UDA volumes for three consecutive years, NHSE may also reduce the contractual volume of UDAs a dental practice can deliver.

Reforming the Dental Contract: Pilots and prototypes

Recognising concerns with the 2006 contract, the government commissioned Professor Jimmy Steele to review the dental sector, and to consider options for improving the system. The Steele Report (2009) laid the foundations for reform and argued that the payment system should incentivise prevention rather than treatment.

In 2011, 70 practices were selected to pilot new clinical pathway and payment models, including capitated budgets. Concluding in 2014, the first phase of contract reform found that pilot sites were supportive in principle, but had experienced access issues as patient numbers fell in most locations. The second phase of reform was launched in November 2015. Initially being tested with 62 (now 76) practices, areas are testing two possible new remuneration systems. Both systems blend capitation and quality elements (prevention) with activity elements (treatment and repair).

- **Blend A**: Capitation as the basis of remuneration for oral health reviews and preventative care, and activity payments for routine and complex treatment

- **Blend B**: Capitation as the basis of remuneration for oral health reviews, preventative care and routine treatment, and activity payments are used for more complex treatment.

The most recent evaluation has suggested that after an initial decrease, patient numbers start recovering after a few years. However, establishing the precise impact of these reimbursement changes is complex. In view of these challenges, implementation of the new contract keeps being postponed. In the short-term, the UDA payment system is likely to remain for the majority of dental practices.

Prevention and access

Overall, dentistry is not a major priority in healthcare policy. Outside of the contract reform, there are limited policy initiatives, and these are mostly focused on increasing oral health prevention and ensuring access to services for priority groups. Achieving these two policy objectives is partly dependent on funding, which has been constrained, and efforts are prioritising children and the most deprived patients.

In the longer term, oral health across the nation is likely to continue the trajectory of the past 50 years, with gradual improvements linked to prevention policies and wider lifestyle changes. This will eventually alter the type of work dentists do and may require a different skill mix to respond to shifting demand and needs.

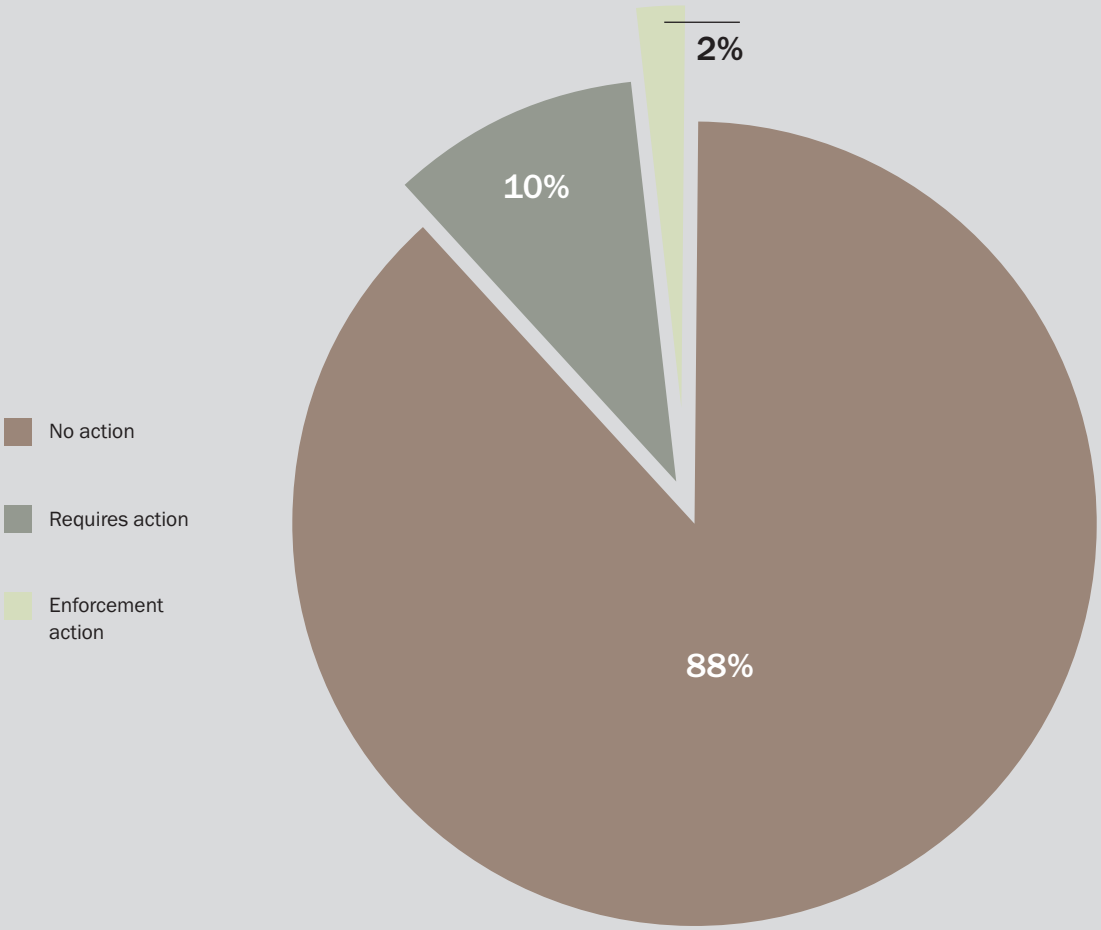
REGULATION

Compared to most healthcare services, the regulatory regime governing dentistry is light-touch. This is because CQC considers that dental services represent a low risk to patient safety. Since 2015, CQC has carried out comprehensive inspections of 10% of dental practices each year.

The latest State of Care report confirmed that dental practices deliver high quality services. 88% of services inspected in 2016/17 (1,131 practices) were considered safe and required no action. 10% of services needed to improve in specific areas and were rated as 'requiring action'. Enforcement actions were taken for 2% of the services inspected, meaning that they needed to significantly improve the quality of their services. This is in line with CQC's findings in 2015/16, suggesting quality is broadly stable across the sector.

CQC RATINGS OF DENTAL PRACTICES IN ENGLAND 2016/17

Source: CQC



ACUTE HOSPITAL CARE

The acute care (hospital) sector is dominated by NHS providers. Hospitals are operated by either NHS Trusts or NHS Foundation Trusts. These Trusts may operate multiple hospital sites. NHS Foundation Trusts have more flexibility and freedom to operate than NHS Trusts. There are 153 NHS Trusts or Foundation Trusts offering acute care provision. Services will vary across hospital location but will range across secondary care services including emergency care, surgery, medical non-surgical care, critical care, maternity, as well as outpatient services and diagnostic imaging.

The acute care sector is under significant strain due to the combination of below inflation funding growth, set alongside rapidly increasing demand. The Five Year Forward View (FYFV) identified a potentially £30bn funding gap by 2020/21, and generally feeling across the sector is that – despite significant innovation and efficiency savings – the outlook has worsened. The last four years has seen 4 in 10 Trusts end the financial year in deficit, and quality and access performance targets have fallen well below expected levels. In this landscape, the recently announced NHS funding uplift is essential but it remains to be seen where the money will go, what will be required to plug existing gaps, and what will be leftover for genuine service improvements.

Operating in parallel to the NHS, there is a small private acute sector. Providers are mostly located in and around London and other major urban areas. They provide mostly elective care services and can contract with NHS Trusts to deliver some NHS services, often to help the NHS reduce waiting lists.

PAYERS

Acute Trusts deficits

Over the past few years, the NHS acute sector has been under enormous financial pressure as NHS funding growth has not kept pace with increasing service demand. Despite emergency cash injections and social care funding targeted towards relieving some of the pressure on hospitals caused by delayed transfers of care, 2017/18 saw the sector record an overall deficit of £960m, with 44% of NHS Trusts ending the year in deficit. This was almost twice the projected deficit of £496m.

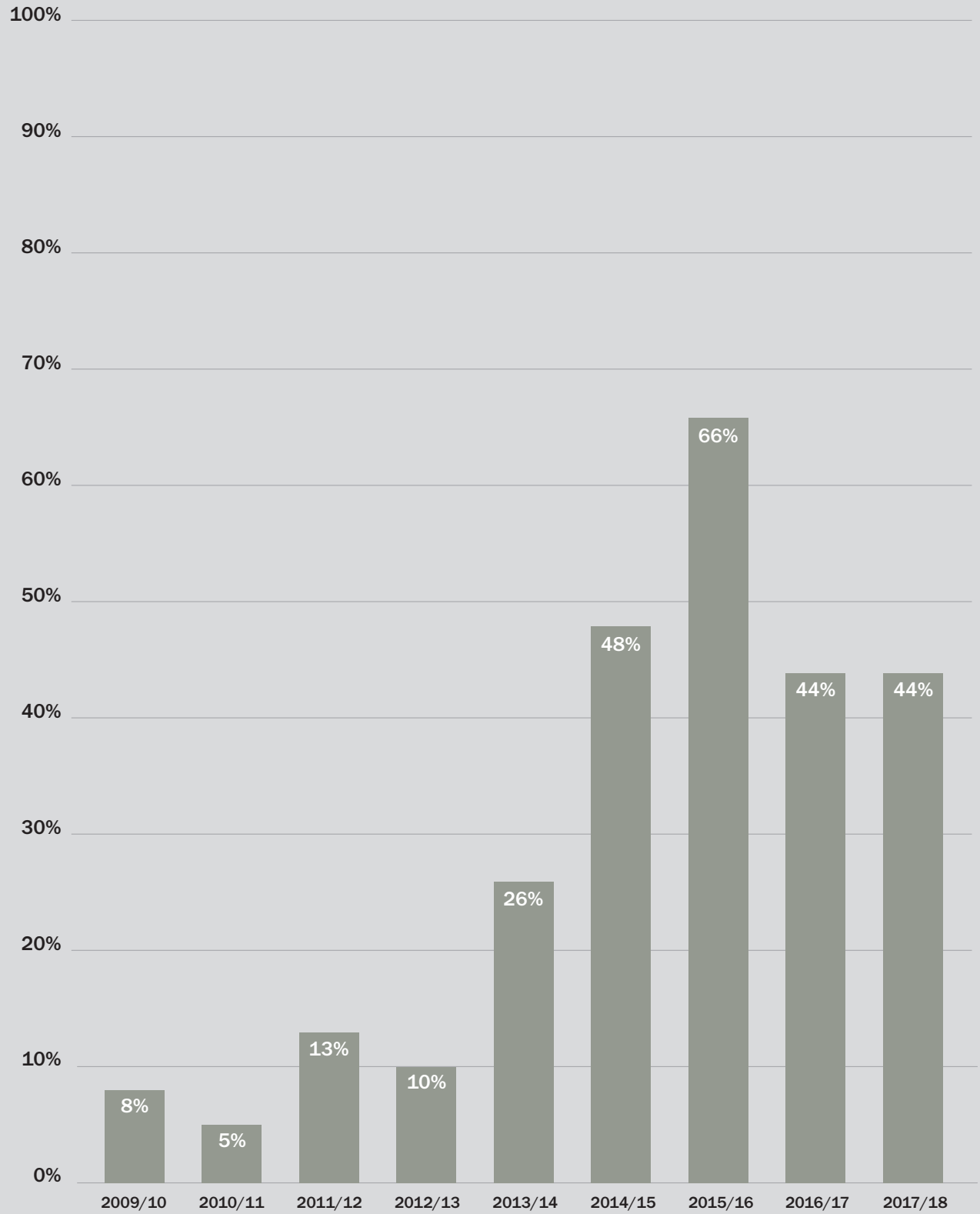
Financial problems in the NHS has a knock-on impact on private sector acute providers. Many rely on referrals from the NHS as a revenue stream, and in February 2018, several major private providers reported a decline in NHS revenue compared to the previous year. This suggests that NHS Trusts were looking to save money by letting their elective care waiting lists grow rather than outsource the work to private providers.

In 2018/19, the plan to address the financial deficits has been to introduce the £2.45bn Provider Sustainability Fund. This replaces the £1.8bn annual Sustainability and Transformation Fund and suggests a re-focusing of priorities towards improving the financial situation in 2018/19. It is unclear whether it will be continued beyond 2018/19 – particularly given the long-term NHS funding uplift announced in June 2018.

The Sustainability and Transformation Fund was meant to support system transformation by helping the development of new models of care, whilst ensuring that NHS Trusts maintained their financial sustainability. However the money has essentially been used to plug the gaps and address short-term pressure and had failed to deliver system transformation.

PROPORTION OF NHS TRUSTS REPORTING A FINANCIAL DEFICIT

Source: King's Fund



Additional NHS funding

In June 2018, the Prime Minister announced that, by 2023/24, the NHS in England would be receiving an additional £20.5bn funding annually. Demand for this additional funding will be high across the NHS, but it is likely that acute services will be the largest beneficiary. Elective care has come into focus recently, with current performance well below targets. Unlike A&E waiting times, which are impacted by the crisis in social care, it should be possible to improve elective performance purely by injecting money into the system and providing incentives for NHS Trusts to employ more staff, or to outsource demand to private providers.

The final funding settlement will not be known until the Autumn, when the 10-year plan for the NHS will be unveiled. However, it has already been noted how even undertaking the basics, such as getting performance back to target levels, clearing the provider deficit and funding the pay increase for staff already accounts for a large amount of the available ongoing funding, with little left over for service transformation and improvements.

Payment system

NHS acute services are primarily commissioned locally by CCGs. Providers are paid for activity delivered via a National Tariff System. The national tariff is a catalogue of activity-based prices for different acute services, classified under diagnosis-related groups (DRGs). This payment system is also known as 'payment by results' (PbR) and gradually replaced block contracts in the 2000s. The Tariff system is expected to be amended over the next few years, and Simon Stevens (Chief Executive of the NHS) has suggested ahead of this, that the PbR system is likely to be reviewed as part of the development of the NHS 10-year plan. It will likely build on NHS England and NHS Improvement's work since 2013 on the development of new payment approaches that enable more integrated care services. New payment systems include population-based capitated budgets. Some local areas are already trailing this approach, which intends to remove traditional budget barriers between acute, primary and community care. It also intends to improve patient outcomes. Given the current pressure and the emphasis on the fact that there is no 'one-size fits all' when it comes to transformation, the full roll-out of new payment models will take time and implementation will differ across local areas. In late Summer 2018, NHS England published a consultation on a draft Integrated Care Provider contract. This provides the first clear framework of what a future, local area, capitated payment system might look like.

There are a further 146 specialised service areas that are funded centrally by NHS England, where there is little financial value in commissioning at a local level. These are for rare conditions that often have low patient numbers but high-cost treatments. It can include highly innovative treatment options that are provided outside of England, such as Proton Beam Therapy, which until 2018 was delivered by clinics in the United States. The budget for specialist services was £16.6bn in 2017/18.

POLICY AND LEGISLATION

Efficiency and productivity

Given the growing demand for services, the efficiency challenge in the acute sector will likely continue. To address limited funding increases, the NHS has been expected to realise efficiencies of 2-3% per year, substantially above historic efficiencies in the NHS (0.8% per year). The 2016 Carter Review: Operational Productive and Performance in English NHS Acute Hospitals identified significant variation across NHS Trusts and suggested areas where efficiencies could be made. These include operational cost, procurement expenditure, workforce planning, and estates management. It found that addressing variation could deliver £5bn of efficiencies.

Progress towards achieving efficiency to date has been relatively slow and subject to local variation. Reports from the NAO and from a House of Lords inquiry have the need for more coordination and clear plans to achieve greater efficiency and minimise performance variation.

RELEASING EFFICIENCIES IN NHS PROCUREMENT

The scale of NHS as a buyer shouldn't be underestimated. The acute sector alone spends nearly £6 billion on goods and products every year. The Carter Review estimated that £700m could be released through more efficient procurement processes. To achieve this, the Future Operating Model has been established. This looks to centralise a far higher proportion of NHS procurement, shifting the balance from the current 40% to nearly 80% of all goods and products procured centrally in the future. The challenge is that without legislative change, which is not expected, NHS Trusts cannot be mandated to use centralised procurement, and hospitals will remain able to choose the procurement channels they use.

Waiting times

Discussions ahead of publication of the NHS 10-year plan have suggested that waiting time targets are likely to be reviewed. In July 2018, Simon Stevens publicly mentioned that the 4-hour wait target for accident and emergency (A&E) and the 18-week wait target for elective care were 'outdated'.

It is highly unlikely that targets will be removed entirely due to the political sensitivity that surrounds them. The last time it was suggested, Jeremy Hunt had to make a swift U-turn after a political and media backlash. However, senior NHS leaders are discussing waiting time importance within the context of a wider set of metrics. It suggests that the targets may be relaxed when taking a broader range of measures into account.

Workforce

The NHS acute sector is facing significant recruitment and retention issues. There have been difficulties recruiting to a permanent workforce, with a vacancy rate of around 8% across the NHS. This figure masks specific challenges recruiting to rural areas, and within particular medical specialities.

The prospect of Brexit has also added pressure on future recruitment with non-UK EU nurses registrations numbers falling significantly since the outcome of the referendum. 9.6% of NHS hospital doctors from the EU. They currently have full working rights in the UK and benefit from 'mutual recognition' of qualifications. This is likely to continue for those already working in the UK. The White Paper on Brexit states that the UK would seek to maintain such a mutual recognition system. This would form part of any deal negotiation , but would be advantageous for NHS and private employers.

NHS Trusts have often made use of agency staff to maintain staffing at a level that provides safe care. In recent years, NHS Improvement – the financial regulator for the NHS – has paid close attention to agency spend as part of an ongoing efficiency drive across the NHS. As a result, Trusts are subject to an overall cap on the amount they spend on agency staff every year, and a cap on the hourly rate for staff. This has led to a reduction in agency spend, with Trusts increasingly looking at encouraging staff onto permanent contracts and developing Staff Banks as an alternative flexible workforce model. However, in medical specialisms where there is a real skills shortage there has been limited success, as medical professionals are aware of competition for their services.

A Joint Health and Care Workforce Strategy is expected in Autumn 2018. This is expected to provide a long-term approach to a more sustainable staffing solution. This is likely to include the creation of new roles, such as associate nurses, which will enable quicker training pathways and clearer career pathways for lower skilled workers. It may also lead to workforce demand increasingly being viewed at a regional level, and in closer collaboration with the needs of the social care sector.

REGULATION

Quality regulation and financial oversight

NHS Acute Trusts (and independent acute providers delivering NHS services) are regulated by CQC. NHS Improvement also has financial regulatory powers over NHS Trusts, as it took on the regulatory functions of Monitor and the NHS Trust Development Authority following their merger.

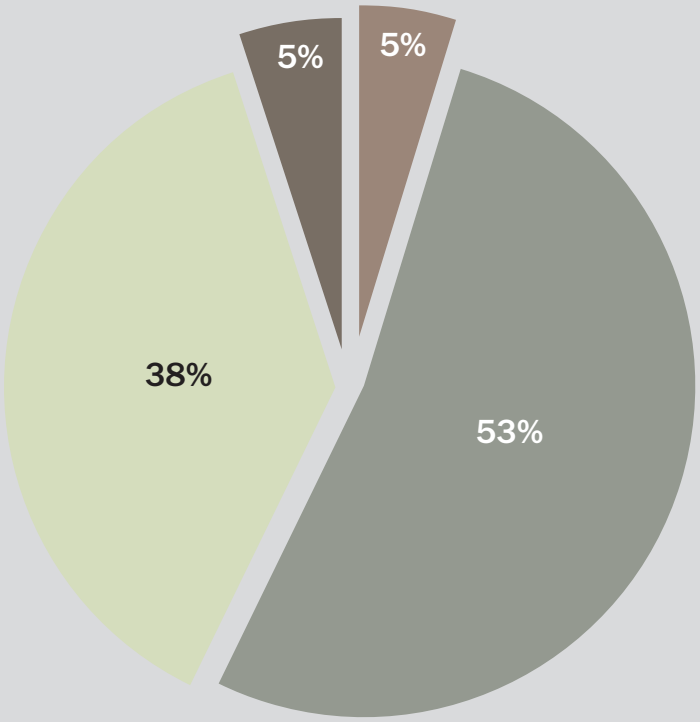
Care Quality Commission

CQC outlined its new approach to the regulation of the NHS acute sector in June 2017. This followed the completion of CQC's comprehensive inspections of the NHS acute sector carried out between September 2013 and June 2016. Whilst the five Key Questions remain, a more focussed approach means that less comprehensive inspections will be carried out. This means not all core services are liable to be inspected, and there may be targeted inspections around areas of interest. However Safe and Well-Led remain key parts of any CQC inspection – as they are seen as good barometers of the overall quality of a provider.

CQC also regulates private acute providers. Overall, the private sector performs better than the NHS sector, with 76% of private providers good or outstanding compared to 58% of NHS providers. However, it is difficult to provide a like for like comparison as NHS Trusts tend to offer a wider range of core services, including those that tend to receive poorer ratings (such as A&E).

CQC RATINGS OF NHS ACUTE TRUSTS' CORE SERVICES 2014-2016

Source: CQC



Outstanding

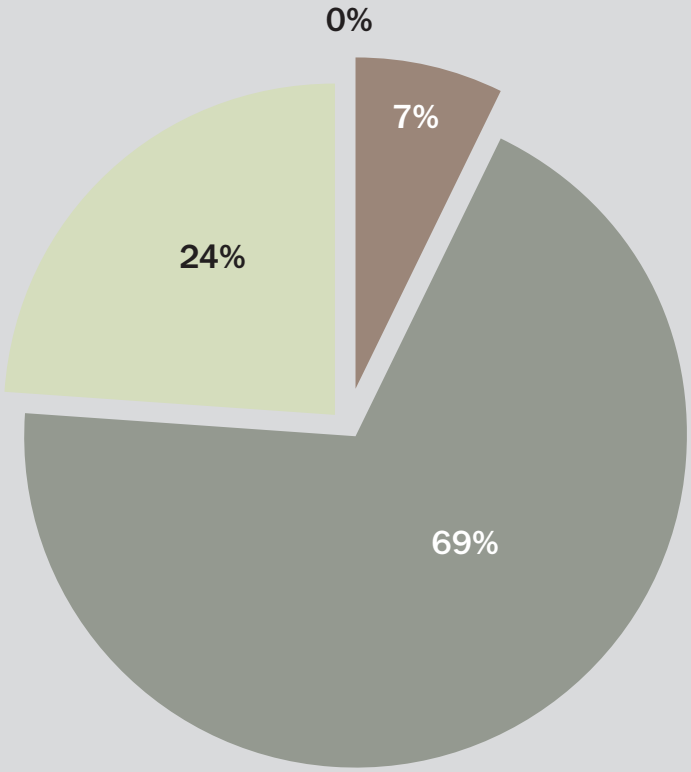
Good

Requires improvement

Inadequate

CQC RATINGS OF INDEPENDENT ACUTE TRUSTS' CORE SERVICES 2015-2018

Source: CQC



NHS Improvement

In England NHS Trusts are also regulated by NHS Improvement. NHS Improvement oversees financial sustainability. Performance is monitored on a quarterly basis, in accordance with the Single Oversight Framework (SOF), which was first introduced in September 2016 and updated in November 2017. The SOF does not apply to independent providers, even when they are contracted to deliver NHS services.

Use of Resources Assessments

NHS Improvement and CQC have been working together to develop a methodology to assess and rate how efficiently acute Trusts' use their resources. Since March 2018, 'use of resources' has become a sixth inspection criterion. CQC will rely on NHS Improvement's assessment and incorporate their Use of Resources rating into their judgement on a provider's overall quality.

MENTAL HEALTH

The mental health service landscape in England is complex. Care delivery is split between NHS Mental Health Trusts, and for-profit and not-for-profit independent providers. Services are often identified by their setting – either being viewed as 'inpatient' or 'community'. The majority of mental health provision is funded by the NHS, primarily through CCGs, although some specialised services (such as secure care) are funded by NHS England. There is a small private-pay market that covers both CQC-regulated activity (such as eating disorder or addiction services that do not target NHS patients) and some services that do not offer regulated activities (such as some self-styled Wellness Clinics).

Unlike many countries, mental health and learning disability services are split apart from a policy and reimbursement perspective. However, many providers will deliver services to both groups in the same locations. Demand for mental health services is increasing. Several drivers sit behind this, including campaigns to raise awareness about mental health issues that have led to more people trying to access support. These has also a rise in age- and lifestyle-related mental health conditions.

There has been a real-terms increase in mental health spending over the past three years; reaching £11.9bn in 2017/18. Many in the sector still argue that it is under-funded in comparison to acute care and point to figures suggesting that mental health accounts for 23% of total disease burden, but only receives 11% of the NHS total budget. There is some expectation that mental health may be an area to benefit from the wider NHS funding boost announced in June 2018.

PAYERS

NHS funding

The majority of NHS community and acute mental health services are funded locally by CCGs. NHS England funds specialised services, including secure services and eating disorder services. In 2017/18, the NHS spent £11.9bn on all mental health services, or about 11% of the total NHS budget.

Since 2016, when significant funding commitments were made to mental health, the overall funding trajectory for the sector has been broadly positive. A total of £3.9bn additional funding was made available between 2016/17 and 2020/21. Although some of this funding is spent directly by NHS England, the majority is reliant on CCG's finding the money from within their total budget allocation. To ensure that the money is made available, CCGs have been instructed to increase their spending on mental health by at least the same percentage as their annual global allocation increase. There is concern over whether this is being achieved, and 32 CCGs failed to hit this target in 2017/18. This is leading to a diverse funding picture at local level.

The June 2018 NHS settlement funding announcement is likely to strengthen mental health funding over the next five years. Whilst the details of the settlement and allocations to sub-sectors will not be published until November 2018, it is likely that mental health services will benefit from additional funding. This should ease the pressure on CCGs and stop them redirecting necessary funding from less well protected service areas.

Additional funding is likely to align to an ongoing policy focus at increasing service capacity within community settings, so as to reduce demand on inpatient provision and halt out-of-area placements. Some targeted funding towards more specialised

services is likely, with perinatal mental health, including mother and baby units, as well as children and adolescent mental health services (CAMHS), considered to be among the likely beneficiaries.

Mental health payments

The introduction of a tariff for mental health services has been under consideration for a long time. The objective was to move away from block contracts, which have historically been the default payment system for inpatient mental health services and introduce more transparency and consistency in the prices commissioners pay for mental health services. However, implementation has been slow, and in order to speed this up NHS Improvement designed two new payment approaches.

- Capitated payments: providers are paid to provide services for a population group. Payments are adjusted to reflect the population's mental health needs.

- Episodic payments: providers are paid a pre-defined amount to care for a patient for a certain duration. The price paid depends on the type of episode the patient is experiencing.

Both methods include an element of outcome-based payments, which mean that a proportion of payment is linked to achieving quality and other service improvement objectives. Providers and commissioners are allowed to choose from either of these approaches, and design them to reflect local circumstances and priorities. However, without direct national control, the majority of local areas have made use of a provision that allows them to design an 'alternate payment approach consistent with local pricing' to create models that primarily rely on the continued use of block contracts.

POLICY AND LEGISLATION

Mental Health Act Review

The Mental Health Act (1983 and amended in 2007) determines how someone with mental health problems can be sectioned (i.e. detained in hospital without consent for assessment or treatment) and their rights under section. Over the past ten years, the number of people sectioned under the Mental Health Act has increased significantly, with the number of detentions increasing by 26% between 2012/13 and 2015/16.

The increase in detentions has led to calls for its reform. The Conservative Party pledged to replace it with new legislation and commissioned an independent review to form reform recommendations. A final report is expected in November 2018 and is likely to offer recommendations on how to address increasing detention rates, the higher detention rate of ethnic minorities, and how to modernise the functioning of the Act. The government is expected to introduce legislation that acts on these recommendations.

However, reform attempts are likely to be contentious, and finding space in the Parliamentary calendar may prove difficult due to time taken up by Brexit-related discussions.

Mental health policy

Mental health has been a priority within wider healthcare policy for several years. Both David Cameron and Theresa May have shown interest in developing and improving mental health services.

In February 2016, the Mental Health Task Force published the *Five Year Forward View for Mental Health* (*FYFVMH*). It outlined a future vision of community-based mental health service provision focusing on early intervention and prevention. The FYFVMH was followed by an Action Plan in July 2016, a more strategic document outlining seven key priority areas within mental health to benefit from additional funding.

Expanding access to services is at the core of mental health policy, which focuses on preventative and early intervention services. The aim is to target mental health needs before they reach the point of crisis, increasingly manage ongoing mental health conditions within community settings and reduce the reliance on inpatient care. There will also be a need for some inpatient settings, but these should be focussed on individuals with the highest acuity needs.

PRIORITY AREAS	KEY POINTS
Perinatal mental health	Increase access to perinatal mental health for 30,000 women. This includes developing mother and baby units in hospital, and expansion of community-based mental health support.
Children and young people's mental health	Increase access to mental health for 70,000 children. This includes the development of new 'Mental Health Support Teams' and introducing access targets for services.
Adult mental health: common mental health problems	Increase access to psychological therapies as part of wider move to preventative solutions.
Adult mental health: community, acute and crisis care	Setting-up crisis resolution and home treatment teams throughout the country, in order to enable early interventions and prevent mental health needs escalating. For those who are required to be treated in an acute setting, then ensure it is close to home and eliminate out of area placements by 2020/21.
Adult mental health: secure care pathway	Pathway redesign with a focus on ensuring that patients are treated in the most appropriate and least restrictive setting of care.
Health and justice	Increase access to liaison and diversion services, which allow comprehensive assessments between police, justice, and health services.
Suicide prevention	CCGs to develop suicide prevention plans involving all relevant local partners.

REGULATION

Regulation of independent mental health providers

As far as possible, CQC regulation of private providers mirrors the regulation of NHS providers, with some slight variation to reflect specific circumstances. The July 2018 CQC guidance on monitoring, inspection and regulation for independent healthcare providers clarified the regulatory approach for independent mental health services.

Data quality has been an ongoing concern within the mental health sector, and CQC confirmed that it would start introducing CQC Insight for private providers of inpatient mental health services from October/ December 2018. CQC Insight – already a staple of CQC's NHS Acute Hospital monitoring – is a tool that allows CQC to have an ongoing view of a providers' quality.

Providers will be required to collect and share information on a range of quality indicators, for instance inpatient mental health providers will be required to provide specific information on substance misuse and services for people with a learning disability.

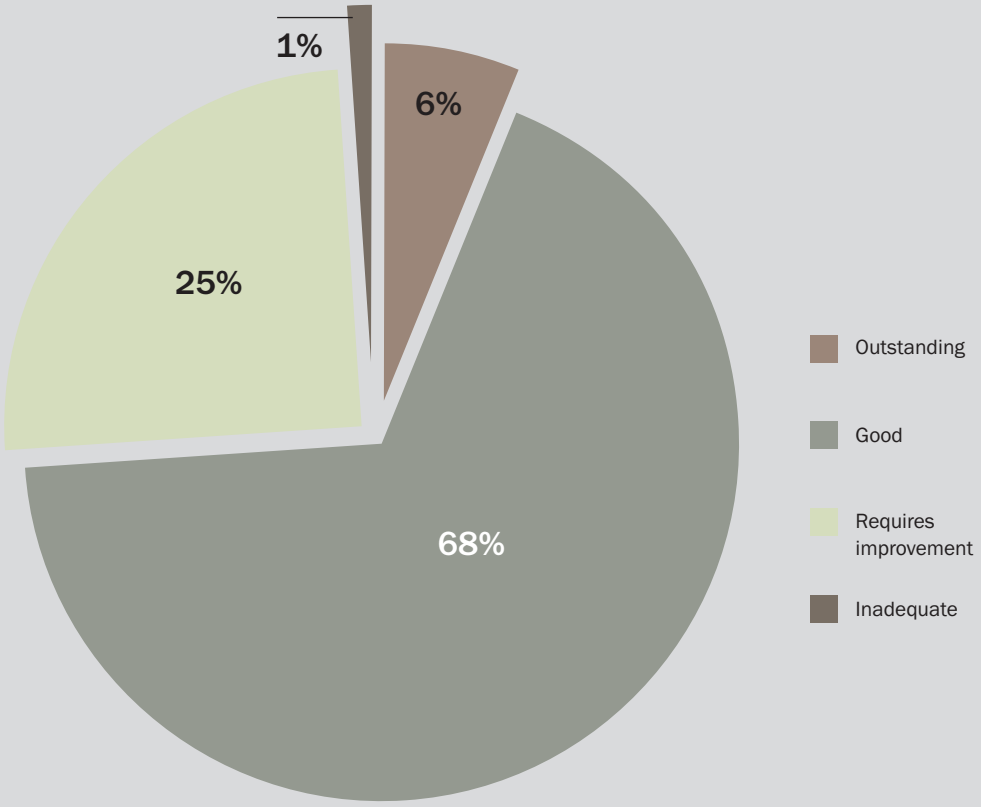
CQC will allow longer inspection intervals for private providers that have been rated 'good' or 'outstanding'. This will allow CQC to focus its regulatory efforts on lower quality providers that 'require improvement' or are 'inadequate'. CQC also intends to carry out more unannounced inspections. However, it has acknowledged that the nature of mental health conditions means that notice needs to be given to providers. This will generally be 48 hours.

RATING	MAXIMUM INTERVAL BETWEEN INSPECTIONS
Outstanding	Up to five years
Good	Up to three and a half years
Requires Improvement	Up to two years
Inadequate	Up to one year

State of mental health care services

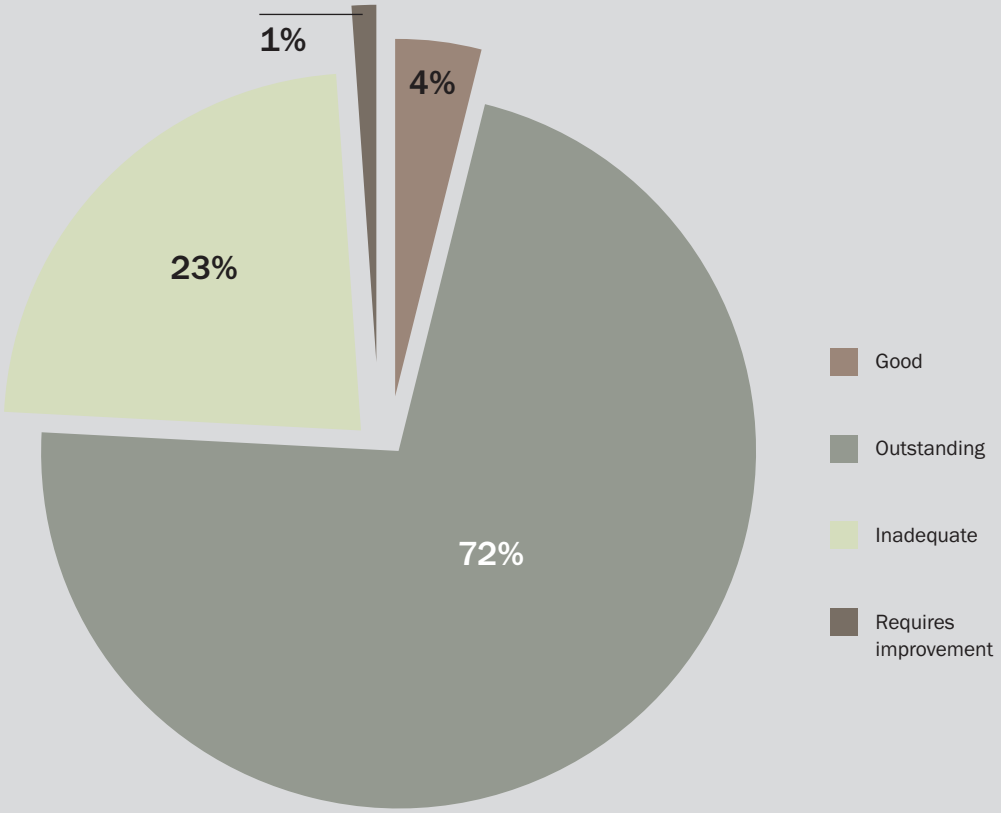
In April 2018, CQC published The state of care in mental health services 2014 to 2017. The report follows the completion of the first wave of comprehensive inspection of specialist and acute mental health services in England. These services are provided by 54 NHS Trusts and 221 independent providers. Overall, CQC found that the majority of services were good or outstanding and notes that community mental health services performed particularly well.

Common themes among those performing poorly, include patients being located a long way from their home, effectively cutting them off from local family and friend support networks. CQC expressed concerns about out-of-area placements, which are estimated to have increased by 39% between 2014/15 and 2016/17. The report also outlines safety as a key area for improvement, including making sure that buildings are fit for purpose with appropriate sightlines, no ligature points, and secure access to stairwells.



CQC RATINGS OF NHS MENTAL HEALTH TRUSTS' CORE SERVICES 2014-2017

Source: CQC



CQC RATINGS OF INDEPENDENT MENTAL HEALTH PROVIDERS' CORE SERVICES 2014-2017

Source: CQC

Complex care services cover a wide range of conditions which require high levels of ongoing support. This includes advanced neurological conditions, serious brain injuries, and palliative care. Whilst many patients can be older, complex care services also deal with younger adult patients. The diverse nature of conditions captured under complex care means that treatment may occur in a variety of care settings. It can include highly specialised care in acute hospitals through to ongoing therapy in community rehabilitation centres, or support for needs in the home. Acute services tend to be delivered by NHS providers, whilst community services are provided by a broader mix of NHS and Independent Providers.

Care provided in hospital, or as part of a treatment package, is available to eligible individuals under standard NHS processes. However, people may also have long-term, potentially ongoing, healthcare needs. In these situations, they may be eligible for NHS continuing healthcare funding, which covers all care costs outside of hospital. The overall spend is estimated at more than £3bn per year, and has been increasing in recent years.

PAYERS

NHS Continuing Healthcare funding

The majority of long-term complex care is funded by NHS Continuing Healthcare (CHC). CHC is a comprehensive package of NHS-funded care intended to support individuals with high and complex needs outside of hospital settings. CHC funding often supports individuals suffering from neuro-degenerative diseases such as advanced multiple sclerosis or Parkinson's disease, or those impacted by the consequences of acquired brain injuries or strokes. However, having one of these conditions does not guarantee funding eligibility. Funding eligibility is determined through a needs assessment and is managed by local CCGs. In recent years, spending on CHC has grown quickly, driven by increased demand. Spending in 2015/16 was 16% higher than in 2013/14.

This has led to CHC becoming a source of budgetary pressure for CCGs, as patients may have high acuity needs leading to expensive care packages, and it can be difficult to anticipate how many packages will be required and for how long.

However, there are inconsistencies in CCGs' decisions to fund packages of care and therefore access to funding varies across local areas. Whilst the average CCG spending on CHC represents about 4% of their total budget, it varies between 1% and 10% across individual CCGs.

Given the wider funding pressure on healthcare, NHS England has requested CCGs make £855m savings on CHC spending by 2020/21. Some of these savings are expected to come from administrative improvements to the assessment process. However, this alone is unlikely to cover the full amount of savings required. This creates a tension between CCGs' statutory obligation to provide CHC funding to those eligible and centrally-driven saving targets. In view of the risk of legal challenges against too restrictive decisions that potentially lead to lead legal challenges demanding retrospective payments, CCGs are likely to approach the need for balancing funding CHC with the need to make savings carefully.

NHS funded nursing care

Those who are not eligible for CHC funding and live in a nursing home may alternatively be supported by NHS funded nursing care. All CCGs are required to pay a weekly standard rate, which is set at £158.16 in 2018/19. Payments are made directly to providers and are intended to cover some of the individual's nursing care costs.

CHC ASSESSMENT DECISIONS: THE 'PRIMARY HEALTH NEEDS' CONCEPT

CCGs are legally required to provide CHC funding to anybody who is eligible. Eligibility is determined following a needs assessment which establishes whether the individual presents a 'primary health need'.

The concept of primary health need is not defined in primary legislation. But the concept has been developed to mean care needs that mostly fall under the responsibility of the NHS (i.e. needs that go beyond social care, which is the responsibility of local authorities).

A primary health need is subject to a degree of interpretation by those carrying out CHC assessments. National guidance has been published to support local commissioners and harmonise the assessment process.

POLICY AND LEGISLATION

Reviews of the efficacy of Continuing Healthcare Funding

In July 2017, the National Audit Office (NAO) published a report investigating the efficiency of CHC assessment process and eligibility. The NAO found assessment decisions were taking too long and they raised concerns at the lack of processes to ensure consistent decision-making both between and within CCGs.

The House of Commons' Public Accounts Committee (PAC) carried out its own inquiry into CHC, and published its recommendations in January 2018. It found unacceptable variation in the number of people being found eligible for CHC funding, and that this was due to inconsistency in interpreting the assessment criteria. It also found significant variation in the length of time people were waiting for assessments, with over a third of people waiting for more than 28 days.

The Government fully endorsed the PAC recommendations, and the new National CHC framework looks to further refine the definition of a primary health need to reduce national variation whilst still leaving local CCGs responsible for determining eligibility.

National CHC framework update

The Department of Health and Social Care is responsible for determining the legal framework, including setting criteria for assessing eligibility for CHC. They do this through the publication of a national framework. The next national framework will come into force on 01 October 2018. Key changes include:

- Further clarifying the concept of 'primary health need'. The new framework states that an individual is considered to have a primary health need if 'it can be said that the main aspects or majority part of the care they require is focused on addressing and/or preventing health needs'. This defines the element of care that the NHS is responsible for funding.

- The majority of assessments should take place in an individual's usual place of residency (i.e. at home or in a care home) in order to assess the level of needs with more accuracy. Whilst assessments can take place in a care home, individuals should not normally be discharged directly from hospital into long-term care.

- CCGs will be asked to develop their own dispute resolution processes to deal with disagreements at a local level, and as quickly as possible.

CCGs will continue to be responsible for determining an individual's eligibility for CHC and for commissioning appropriate services.

Wider complex care policy

Despite the recent focus on CHC, complex care does not gather significant policy interest. Whilst the government is aware of the growing demand for complex care, there are no specific strategies managing this element of healthcare provision. Part of the reason for this is that complex care services cover a wide range of conditions, and relevant policy announcements tend to be fragmented across a number of different strategies, such as mental health or learning disability. This can reduce national visibility on key issues affecting those with complex needs.

REGULATION

Regulation of independent complex care providers

As far as possible CQC regulates private providers and NHS providers equally, with some slight variation to reflect specific circumstances. The July 2018 CQC guidance on monitoring, inspection and regulation for independent healthcare providers clarified the regulatory approach for independent complex care services. The only notable reference to complex care is a clarification that inspections of these providers are likely to involve a mix of regulatory experts, including community and mental health care professionals, as well as acute and specialist practitioners.

Patients receiving long-term, complex care can be found across a range of services. These include community rehabilitation services, palliative care services, or specialist community centres. Higher acuity services will likely be registered as a healthcare location and regulated as an independent healthcare provider. However, for lower acuity support delivered in a person's home or in a care home, the provider may be registered as either a care home or a domiciliary care provider.

OLDER PEOPLE'S CARE

Older people care services in England refer to services supporting individuals over-65 years old in their activities of daily living. Where required, this may include an element of nursing care. Care provision is delivered mostly by private providers; either within an individual's home (domiciliary care) or in residential or nursing care homes. It is estimated that there are 5,500 care home providers operating 11,300 homes, and around 8,500 domiciliary care providers.

Social care provision is the responsibility of local authorities. They are statutorily responsible for ensuring appropriate service levels in their areas, carrying out needs assessments on individuals to determine their requirements, and signposting people to appropriate services. However, unlike most NHS services, older people social care services are not free at the point of need. Most individuals are required to either fully or part-fund the cost of their care.

The total value of older people's care commissioned by local authorities is estimated to amount to £17.5bn in 2016/17.

PAYERS

Local authority and private funding

Overview of funding for older people

There are two main payers for older people's care in England: local authorities and individuals. This is because social care services are not necessarily free at the point of need. People who require social care services and are looking to access publicly funded support are subject to both a needs assessment and a means assessment. The needs test is carried out by local authorities in accordance to national criteria, and they are responsible for determining whether the individual meets the eligibility threshold.

Once needs have been established, a means assessment takes place. To be eligible for local authority funded social care, an individual must have less than £23,250 in assets and savings. For domiciliary care, this does not include the value of their house. For care home services (nursing or residential), the value of an individual's house is taken into account. In practical terms, this means that a person will be required to pay for their own care until they have reached a point where their assets and savings reach the level where they qualify for local authority funded care.

Since local authorities are the primary public payers, the changes in local authority funding since the start of the decade has had a significant impact on the funding landscape for older people's services. Successive governments have reduced national funding for local authorities by nearly 60% since 2010. Whilst there have been moves to offset this by giving councils more freedom over local revenue raising – the introduction of the social care precept, and the ability to retain a greater proportion of business rate revenue – these changes do not meet the shortfall driven by reductions in central allocations.

In recent months, Northamptonshire has declared effective bankruptcy, and East Sussex has recently discussed stripping back its service offering to near the statutory minimum. Against this backdrop and taking into account demographic changes and rising care needs, the Local Government Association have estimated that without further reforms, there will be a £3.56bn shortfall in social care funding by 2025.

COUNCIL TAX AND THE SOCIAL CARE PRECEPT

Council tax has historically been one of the primary levers available to local authorities to control their revenue. However, in 2012, the Government introduced a cap of 2% on annual council tax increase. Local authorities wanting to introduce higher council tax increases were required to hold a local referendum. Given the backdrop of austerity, local authorities did not try to push through these increases, recognising its likely failure if put to a public vote – and the potential damage it would do to their political reputation.

In recognition of the pressure on social care funding, central government has slowly been releasing the levers of control and allowing local authorities more flexibility over revenue raising.

- In 2016/17, the social care precept was introduced. This granted local authorities the right to apply an additional 2% annual increase to council tax. Any revenue raised this way must be spent on social care.
- In 2017/18, the social care precept maximum increase rose to 3%
- In 2018/19, the maximum council tax uplift (without a referendum) was set at 3%.

These adjustments have meant that total council tax bills could grow by up to 6% in 2018/19. The majority of local authorities have made full or close to full use of this increased flexibility.

Domiciliary care services

In 2015, at least 465,000 adults in England received domiciliary care services in England, with 273,000 of those being funded by local authorities. It is estimated that local authorities spent approximately £2.6bn on providing services, whilst individual self-funders spent a further £623m. Since 2009/10 there has been a continued decrease in both overall local authority expenditure on domiciliary care services, and in the total number of those receiving local authority funded care in England. Alongside this has been a rise in the number of self-funders.

Private providers delivering local authority contracts have been under pressure due to the constrained funding environment, alongside rising organisational costs driven by national living wage uplifts and a growing proportion of the client base with higher acuity needs. This has led to increasing numbers of domiciliary care contracts being handed back to local authorities.

Care home services

Estimations put local authorities spending on care home services at around £5bn (65% of the total elderly care spend) in 2015/16. In 2016, there were nearly 5,500 care home providers in the UK, operating a total of 11,300 care homes. Bed provision is split between residential and nursing services with a total capacity in England of around 380,000. Just over half (53%) are in nursing homes.

Approximately 40% of the care home market consists of those who pay for their own care (Self-funders). However, this is subject to regional variation with more self-funders in the south of England. Care home fees are significantly greater for self-funders than the rates paid to local authorities to provide care for those who eligible for state support. The average fee for local authority-commissioned residential care is £588 per week whilst nursing care costs an average of £741 per week, but this masks significant variation across regions. In comparison,

ADDITIONAL DEDICATED ADULT SOCIAL CARE FUNDING	DISTRIBUTION OF FUNDING (PER YEAR)		
	2017/18	2018/19	2019/20
2015 Spending Review	£105m	£825m	£1,500m
2017 Statement on additional funding	£1,010m	£674m	£337m
Total	£1,115m	£1,499m	£1,837m

the cost to self-funders £846 per week on average. Fees for both local-authority and self-funded care tends to be cheaper in the north of England.

Additional funding for social care

Whilst the sector is under significant pressure, the outlook has slightly improved due to the Government committing an additional £2bn to the sector. This is a one-off payment, and so does not address the ongoing issues in how to sustainably fund social care in the longer-term. However, it does protect the sector against collapse in the short-term. The funding was announced in March 2017. Local authorities will receive the money between 2017/18 and 2019/20. This money is ring-fenced and must be allocated to social care services. It was released in addition to the funding previously announced in the 2015 Spending Review.

As the funding is allocated to local authorities directly, they are responsible for deciding how it should be spent. However, they must be able to demonstrate that spending has been efficient and is contributing to wider policy objectives. In particular, it should support reducing the length of hospital stays and help the discharging of elderly patients into the most appropriate care setting. A specific focus has been placed on providing extra domiciliary care services, to help older people staying in their own home as long as possible.

POLICY AND LEGISLATION

In recent years, there has been an increased policy focus on social care and increased political recognition of the need to provide a sustainable funding solution. There is also a clear message from both the NHS and social care about the need to recognise the additional costs to the NHS of failing to resolve problems with older people's care.

The challenge is that solving the problem is likely to require a financial solution, and the experiences of the Conservative Party at the last election in trying to introduce social care reform policies will have made political parties wary of suggesting the radical change that the sector may require. The Social Care Green Paper that was due to be introduced by Summer 2018 (already delayed from December 2017) is now expected in time for the Budget Announcement in Autumn 2018.

The advantage of the delaying publication is that policy objectives can be aligned with wider plans for the NHS. This may lead to benefits, such as considering a joint health and care workforce strategy, which may help align sector needs. However, there is concern that the delay, and the dominance of the NHS, will lead to social care proposals that are too health-focussed and ignore with wider challenge of finding a sustainable funding solution for adult social care.

FINDING A SUSTAINABLE SOLUTION TO SOCIAL CARE

Although there is a political consensus that the system needs reform, there is significant disagreement on the method for achieving this. There is the additional problem that achieving a sustainable, equitable solution will require members of the public to pay more – either directly for their own care, or through funding mechanisms that raise more in revenue nationally. This makes it a highly political debate, and liable to attract significant criticism from opposition parties, backbench MPs, and the national press.

The attempt by the Conservative Party to introduce proposed changes in their 2017 election manifesto is widely credited with being a major factor in Theresa May losing her parliamentary majority. As a result, making it is difficult to imagine the introduction of wide scale reform within the lifetime of the Parliament.

Conservative proposals would have introduced capital floor of £100,000 under which local authorities would have had to fund an individual's social care needs. This raised it significantly from the current floor of £23,250, and so potentially protected a much higher proportion of a person's income.

However, home value was not to be included in the means test for domiciliary care, aligning it with the current process for residential care. This would mean people in cash-poor households but with high total assets due to the value of their home being liable to pay for their own domiciliary care. The media labelled it the 'dementia tax' and it was highly criticized by the Labour Party.

Labour policy on social care refers to plans to build a 'national care service'. They intend to increase social care budgets by £8bn over the lifetime of the Parliament, including an additional £1bn in the first year. This money would be used to place a maximum cap on personal contributions to care costs and raise the current asset threshold. They do not set out specific plans for how this would be funded.

Social Care Green Paper

The Social Care Green Paper is the core policy focus for older people's social care. It is now expected to be published in Autumn 2018, and work is underway to ensure that any proposals are aligned with the NHS 10-year plan, and the joint health and care workforce strategy.

In March 2018, the then Secretary of State for Health and Social Care, Jeremy Hunt, outlined seven principles for social care.

1. Quality
2. Whole-person integrated care
3. Greater individual control over care
4. Workforce
5. Supporting families and carers
6. A sustainable funding model for social care
7. Security for all

Early insights have suggested that there will be a greater policy focus on keeping individuals in their own homes. This may

involve developing new models of housing to fit the needs of the elderly and enable them to stay in a home setting. Two key challenges to achieving this will be funding availability and accessing an appropriate workforce. The speech did not give detail on how the funding challenge would be addressed.

The workforce challenge is expected to be addressed in the Autumn 2018 Health and Social Care Workforce Strategy, which will look at options to address recruitment and retention issues in health and social care. This should include ways to make the profession appear more attractive to workers, and the development of new career pathways for social care staff. This is of particular importance to the sector as it currently experiences high turnover and vacancy rates, and may be impacted by Brexit due to the large number of lower skilled workers employed from EU countries. Brexit may mean it becomes harder for employers to recruit among non-UK EU workers in the future due to possible future restrictions on freedom of movement.

The intersection between health and care is likely to be an important area, including ensuring swift hospital discharges. This reflects the substantial variation across the country in relation to overall lengths of stay, delayed transfers of care, and in the number of older people who are required to go back into hospital after discharge. These aspects of care quality highlight the importance of ensuring that any proposals are aligned with the policy direction established in the NHS 10-year plan. There may be a key role for care home providers in embedding improvements in the discharge pathway.

Next Steps on the Care Act 2014

Progress on personal budgets

The Care Act 2014 has failed to deliver on its objective to increase the number of individuals in receipt of a personal budget. Personal budgets were expected to increase individual choice. However, the uptake in direct payments decreased by 6% between 2014 and 2016. Whilst direct payments are only one type of personal budget, this trajectory suggests that use of personal budgets remains low overall. In addition, there have been concerns that local authorities are actually directing individual choice. Therefore, the push towards personal budgets has had a mixed impact on individuals' ability to make their own care choices.

Progress on market oversight and preventing provider collapse

The Care Act also introduced a new market oversight role for CQC. From April 2015, CQC became responsible for monitoring the financial sustainability of social care providers that local authorities would find difficult to replace if they were to close. This is separate to their core quality regulatory function and was introduced to prevent another major provider collapse similar to that of Southern Cross in 2011.

CQC's Market Oversight Team focuses on providers who either have a large national profile, or those that hold a large presence in a particular geographic region. It includes both domiciliary care and care home providers. They will work closely with providers and local areas in the event of any concerns over a provider's status.

REGULATION

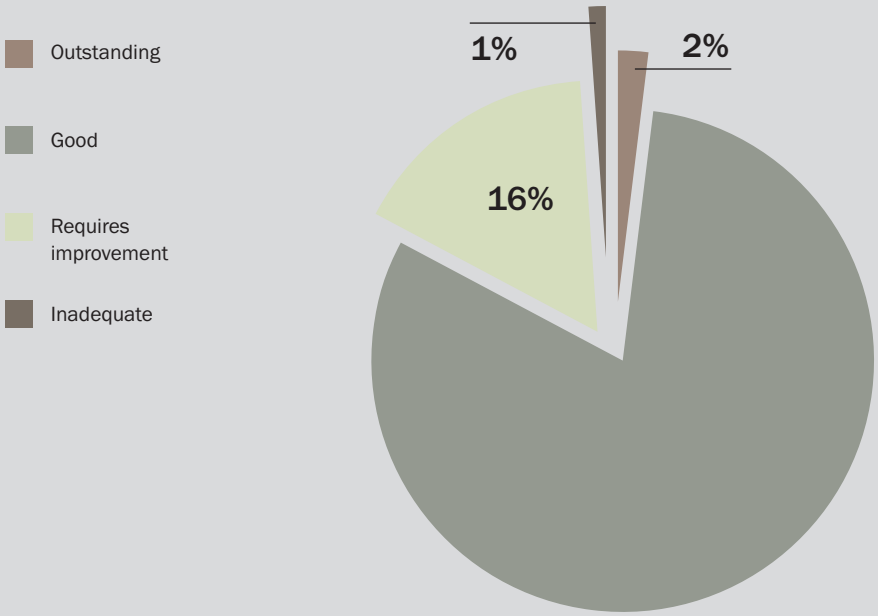
Quality regulation

CQC is responsible for regulating adult social care services. Its main function is to register, inspect and monitor providers. They have recently consulted on changes to its regulatory approach, and in recognition on the pressure facing providers, have announced that their inspections will be increasingly targeted at poorer performers, with outstanding and good providers given a greater gap between inspections. CQC retains the right to carry out comprehensive inspections at any time if they believe there is a risk to the safety or wellbeing of users.

RATING	FREQUENCY OF INSPECTION
Outstanding / Good	Within 30 months
Requires Improvement	Within 12 months
Inadequate	Within 6 months

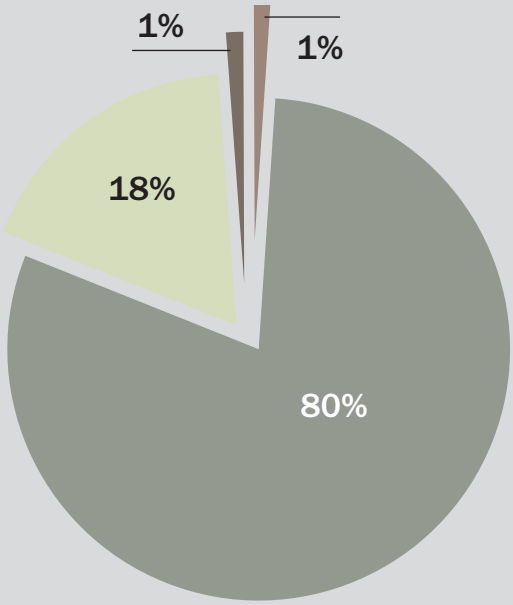
Between October 2014 and February 2017, CQC completed its first wave of comprehensive inspections of adult social care services, inspecting a total of 24,000 services. They found that overall 77% of adult social care services were rated as Good. Despite the pressure on providers, only a very small minority were found to be Inadequate.

However, CQC has stated that it remains concerned about the number of providers rated as Requires Improvement, and those that do not improve on re-inspection, as these are locations where people are continuing to receive care of a quality lower than they should expect.



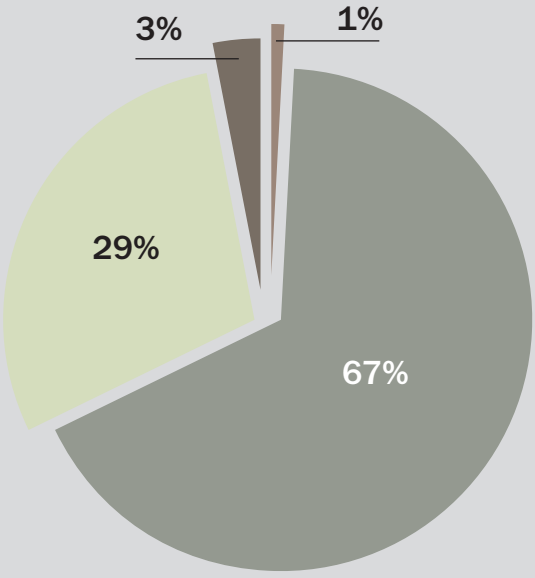
CQC RATINGS OF HOMECARE PROVIDERS 2014-2017

Source: CQC



CQC RATINGS OF RESIDENTIAL CARE PROVIDERS 2014-2017

Source: CQC



CQC RATINGS OF NURSING CARE PROVIDERS IN ENGLAND 2014-2017

Source: CQC

CMA care home market study

The Competition and Markets Authority (CMA) published the findings of their study on the residential and nursing care homes market in November 2017. The study was triggered by ongoing concerns that lack of transparency, information and advice for care home users was impacting consumers' rights.

It examined how well the care home market is working for those that pay for their own care (self-funders) and for those individuals whose care is paid for by the state.

It produced three key recommendations:

- Create an independent body to provide advice on local authority fee levels to improve investor confidence
- There should not be forced equalisation in pricing between local authority-funded and self-funded care within care homes
- Care homes should be given guidance around consumer protection laws, but tougher action is planned for providers who do not comply (see box).

In March 2018, the government accepted the recommendations in principle. However, any action taken in response is not expected to be announced before the publication of the Social Care Green Paper.

CMA INVESTIGATION OF CARE HOME PROVIDERS: CONSUMER PROTECTION

As early findings on the care home market emerged, the CMA opened a formal investigation into a number of care home providers charging upfront fees to self-funders and requiring their families to continue paying fees after a resident's death. This move has led some of these providers to amend their contracts' terms and conditions to remove these requirements. In addition, on 09 May 2018, the CMA announced that a major care home group had agreed to pay £2m compensation to users, or their families, who had been charged upfront fees as part of the T&Cs for using their care homes.

LEARNING DISABILITY SERVICES

There are estimated to be around 1.2m people with a learning disability in England, over 900,000 of whom are aged 18 or older. This is projected to grow by 10% by 2027. There is a wide range in the type and provision of learning disability services available, reflecting the varying level of need experienced by people with a learning disability. Provision can cover anything from high acuity inpatient beds through to supported living and community services. They are delivered through a mixture of private, public and not-for-profit providers.

The learning disability landscape in England is still marked by the Winterbourne View scandal in 2011. This shone a spotlight into care failings and accelerated the momentum to close inpatient unit and move individuals into community-based settings of care, closer to their families. This objective continues to be the main catalyst reshaping the provider landscape.

Despite the wider period of austerity, spending on learning disabilities has been comparatively well protected. Whilst overall spend on all adult social care, which includes learning disability funding, fell between 2010/11 and 2016/17, the learning disability element actually increased in real-terms. By 2016/17, spending on people with a learning disability had reached £5.9bn, with the majority of spending directed towards those ages 18-64.

PAYERS

The three primary payers for learning disability service are NHS England, CCGs, and local authorities. NHS England and CCGs are responsible for funding most inpatient services, whilst local authorities finance community services. With national policy initiatives focussing on moving individuals with learning disabilities out of hospital into community settings, local authorities are increasingly responsible for a higher proportion of overall spend on learning disability provision.

Local authority social care budgets have been under pressure since 2010, whilst the number of adults identified with a learning disability has risen substantially. As providing appropriate learning disability services is a statutory responsibility, this has placed pressure on local authority budgets. This is likely to continue as the number of young adults with learning disability is projected to rise by 72.5% between 2015 and 2040. It is important to note that funding pressures are subject to regional variation, such as in the prevalence of learning disabilities among the local population, and different approaches in how services are provided.

To support the move towards community care, the Transforming Care Programme was established in 2015. It intends to keep the total sum of money payers spend on learning disabilities the same, but reallocating it to incentivise the shifting of care from inpatient to community settings. To encourage commissioners to change how they commission services, a ‘dowry’ system has been developed for particularly high-cost individuals. In these cases, the money will follow the individual. This would support a long-term budgetary shift from NHS to local authority expenditure for a small number of people with learning disabilities with higher levels of need.

POLICY AND LEGISLATION

Transforming Care Programme

In recent years, learning disability policy has been focussed on a shift from inpatient to community service provision. To facilitate this transition, 48 regional Transforming Care Partnerships (TCP) were established across England. Consisting of representatives from CCGs, NHS England's specialised commissioners, and local authorities, the role of a TCP is to oversee and implement the vision outlined in the Transforming Care Programme.

The initial objective of the Transforming Care Programme was to close 35% to 50% of inpatient beds by 2019. The scale and implementation of the transformation towards community care varies significantly by local authority, and across regions, with those in the North expected to see most of a change due to a greater reliance on inpatient beds, and the planned closure of a specialist learning disability hospital. However, slow progress has meant it is unlikely that 50% of inpatient beds will be closed by 2019. At this point, the lower-end 35% target seems the more realistic one. The issue has been kept in the public eye due to continued criticism from Norman Lamb, a former Health Minister and leading Liberal Democrat politician, who played a key role in designing learning disability policy reform.

Initially, NHS England provided Transforming Care Partnerships (TCPs) with short-term support of £30 million over three years from April 2016, and £100 million of capital investments over five years for housing infrastructure. However, this funding has not enabled expected changes, and in July 2017, NHS England announced that an additional £76m will be spent on the programme to accelerate the development of community learning disability services and increase service capacity. This isn't all 'new' funding, as it includes £53m released through the decommissioning of specialist inpatient services. The announcement is recognition that progress on closing inpatient services has been slower than expected, in part due to difficulties in redirecting inpatient funding towards the development of community services.

LEARNING DISABILITY 'DOWRY' PAYMENTS

The concept of a 'dowry' payment is an innovation in funding high cost individuals. Local authorities may be unwilling to push through with policy objectives if it means taking funding responsibility for extremely high-cost individuals. The 'dowry' aims to mitigate this by attaching funding directly to the individual. This means that once a person is transferred out of CCG-funded inpatient care into local authority-funded community care, the money to pay for their care should transfer with them. It is estimated that there are approximately 900 high-cost individuals who will qualify under the dowry payment system.

Remuneration of sleep-in shifts

In July 2018, the Court of Appeal published an important ruling on the long-standing and complex issue of back-pay for sleep-in shifts (i.e. when employees are present on the premises in case their help is needed by residents, but they are otherwise allowed to sleep). It ruled in favour of Mencap (Royal Mencap Society v Tomlinson-Blake), and stated that employers were not liable for paying National Minimum Wage payments whilst the worker was asleep.

The appeal had been brought by Mencap, a charity provider of learning disability services. Mencap successfully challenged an Employment Appeal Tribunal ruling of April 2017 that sleep-in shifts should be considered as work. This decision created retrospective payment issues for employers who had been following official HMRC guidance that suggested that, under the National Minimum Wage regulations, sleep-in shifts should be remunerated at a flat rate of about £30 for an 8-hour shift, unless employees are required to wake-up, in which case they should be paid the hourly minimum wage rate.

The Court of Appeal ruling is a key decision for the wider sector, which had been facing total liability bills of over £400 million to fund backpay to care workers, and large increases to future salary projections. Many providers, in a sector with a large voluntary presence, had argued that this would be unaffordable.

However, this may not be the end of the story, as Unison has lodged permission to appeal to the Supreme Court. It will likely take at least two months for the Supreme Court to determine whether to hear the case. Given the tight financial constraint on the sector, and the potential future wage inflation if the decision against Mencap is reversed, it remains an area that providers and payers continue to keep a close eye on.

Personal Budgets

The Care Act 2014 promoted individual choice and responsibility in care and entitled individuals to a direct funding allocation to allow them to have more control over decisions about their care. Personal budgets can be managed by a local authority, the users themselves, or a third party.

In 2014/15, 500,000 social care users had their care paid for through personal budgets. However, local authorities have been accused of providing narrow criteria for what these budgets can be used for, leading to claims that restrictions over spending habits prevent individuals properly managing their own care. There are additional difficulties for adults with learning disabilities, as many may require greater support to personalise their care, and there is evidence that many local authorities are failing to provide adequate support for this.

REGULATION

Out of Area Placements

The ending of out of area placements, used to describe the placement of individuals outside their local area for treatment, is a clear government policy objective. NHS Trusts are now required to record data the number of patients they send out of area for treatment as part of a government effort to eliminate out of area placements in mental health services (including learning disabilities) for adults within acute inpatient care by 2020-21. Critics say that out of area placements cost more to the NHS and have a negative impact on the person receiving care. However, the failure to place an individual within their local area is usually the result of a lack of available appropriate local capacity. This highlights that commissioners often must balance competing policy objectives; the requirement to provide timely services to those in need, but also not to use out-of-area placements, which may be all that is available at that moment in time.

Quality of care improvements

Following the Winterbourne View scandal, regulatory scrutiny of learning disability services increased significantly. The scandal, which involved serious patient mistreatment, highlighted the over-reliance on inpatient settings and strengthened the view that individuals would be better served in community settings of care.

In 2012, CQC undertook a review of 150 services that provided learning disability care. NHS services, independent healthcare services, and adult social care services involved in providing care to people with a learning disability were inspected. Results were collected based on a service being rated either as compliant or non-compliant. 68% of NHS services were rated as compliant, followed by 33% of independent services and 47% of adult social care services.

TYPE OF PROVIDER	LEARNING DISABILITY SPECIALISM?	INADEQUATE	REQUIRES IMPROVEMENT	GOOD	OUTSTANDING
Community Social Care	With specialism	<0.5%	8%	89%	3%
	Without Specialism	1%	14%	84%	1%
Domiciliary Care Agencies	With specialism	<0.5%	9%	87%	3%
	Without Specialism	1%	18%	79%	2%
Residential homes	With specialism	1%	10%	88%	1%
	Without Specialism	2%	22%	75%	1%
Nursing homes	With specialism	1%	14%	83%	1%
	Without Specialism	3%	29%	66%	1%

Source: CQC

The transformation of CQC's regulatory approach has meant that direct comparison with previous inspections is not possible. However, now that CQC have inspected all providers of learning disability services it is possible to take a view on overall sector quality. Across NHS and private provides, inpatient wards for people with a learning disability were rated as 73% Good or Outstanding whilst 27% were rated as Requiring Improvement. In adult social care, providers that had been registered as having a learning disability specialism outperformed those that did not.

CQC inspection of learning disability providers is not particularly joined up for the independent sector. Inpatient learning disability services are captured as part of CQC's mental health inspection activity, whilst learning disability services being delivered through residential, nursing or domiciliary care are inspected by CQC's adult social care directorate. This can lead to a fragmented regulatory experience for providers operating across health and adult social care.

Building and registering suitable accommodation for people with learning disabilities

Building the right support (October 2015) set out a national service model for learning disability services. It reinforced the objective to move people out of institutional care models into more appropriate accommodation. It includes specifications for new buildings that NHS England would be prepared to fund out of capital budgets.

Since these buildings are highly likely to contain regulated activities, it is also necessary that they satisfy CQC that they would provide quality care. To support providers, CQC published Registering the right support, which sets out CQC's approach to registering services for people with learning disability or autism.

The guidance confirmed that CQC would take a flexible approach to registration, following provider feedback suggested a hard-line approach around the 'six-bed rule' set out in the national service model would not be sustainable in the current funding context. CQC confirmed that they would consider registrations on a case-by-case basis to confirm whether they are appropriate to the needs of the people using the service. Key aspects that will be considered include:

- Whether the facility supports genuinely innovative care models
- Evidence that an individual placed in the service would benefit from person-centred care
- Providers are expected to have had discussions with local commissioners to make sure facility meets identified local need

CQC remain unlikely to support applications for campus style settings as they do not align with underpinning principles of *Building the Right Support*.

A tribunal found in favour of CQC's policy on campus style settings, following a care provider appeal against CQC's decision to refuse an extension of existing care facility.

4

Since 2010, NHS spending on pharmaceuticals has increased faster than increases to overall NHS funding. This has meant that over the last eight years, pharmaceuticals have accounted for a growing proportion of the NHS budget. Branded drugs make-up the majority of this expenditure, and the increasing cost of new branded drugs have driven increases in spend. In 2016/17, the NHS spent about £11.6bn on branded drugs.

As a result, payers have explored cost containment measures, and a number of changes are taking place in 2018/19. However, attempts to contain overall expenditure on pharmaceuticals has been challenged by the arrival of new innovative high-cost drugs.

Over the past 20 years, major advances in genome sequencing and microbiology have paved the way for the development of personalised medicines. These innovative therapies often use gene, or cell-based products to offer treatment, or disease management opportunities, to patients who suffer from rare genetic diseases. They can provide significant quality of life extensions for those with some terminal illnesses.

There is a clear value proposition in these products; their benefits are understood by patients, clinicians, and policy-makers. It is unsurprising that this is an area that has caught the interest of pharmaceutical companies, developers and investors. However, they currently face funding and regulatory challenges, and require policy and political support over the medium-term to fully realise their potential.

PAYERS

Pricing

Pricing decisions shifting to NHS England

Pricing of branded drugs is set individually, on a drug by drug basis. The Department of Health and Social Care (DHSC) has traditionally been the key decision-maker on pricing and is seen as the first point of contact for companies wanting to bring a new drug to the British market. However, recently some pricing decisions have been made by NHS England, mostly for drugs whose price has proved difficult to agree. NHS England's increased role in drug pricing was also reflected in the Commercial Medicines Unit, which manages most tenders for NHS drugs (drugs used in hospital settings), moving from DHSC to NHS England.

It is a rational move, since NHS England already has responsibility for allocating the majority of the NHS healthcare budget, and this shift helps to bring pricing decisions closer to service delivery. For developers and pharmaceutical companies, this will require some adaptation in terms of managing price negotiations and defining the right value proposition to NHS England.

Medicines Value Programme

Launched in January 2018, NHS England's Medicines Value Programme aims to optimise the value and use of medicines. It suggests that to achieve this, NHS England should further develop the framework that governs medicine pricing and consider introducing outcome-based payment schemes. This would involve developing new commercial arrangements for innovative products.

INNOVATIVE DRUGS AND THE REIMBURSEMENT CHALLENGE

National policy makers have signalled their intention to ensure innovative drugs are made available on the NHS, but there continues to be difficulties in finding pricing models acceptable for both those selling, and those buying, the product. Recent developments provide grounds for optimism but some barriers remain in place.

In April 2018, NHS England announced that discussions are currently under way to make CAR-T therapy available to NHS patients, if an "affordable" price can be agreed with the manufacturer. There are several CAR-T therapies currently under regulatory evaluation by the European Medicines Agency (EMA), which could be made available in England under an early access scheme or accelerated access.

Agreeing pricing is likely to be the main challenge. Simon Stevens has called on developers to offer "fair prices" to the NHS. This reflects the concern that some available therapies are well above the prices that the NHS can afford. In September 2018, the NHS agreed to fund the CAR-T therapy, Kymriah, for young cancer patients, where earlier treatments have failed. This is estimated at £282,000 per patient per treatment. A price has not been agreed for the use in adults.

Spending controls

PPRS negotiations

The total spending on existing branded drugs (those introduced before 01 January 2014) is regulated by the Pharmaceutical Pricing Regulation Scheme (PPRS). The PPRS is a multi-annual agreement between the pharmaceutical industry, represented by the Association of British Pharmaceutical Industries (ABPI) and the DHSC. The current scheme expires on 31 December 2018 and negotiations are currently under way to agree the next PPRS for the period 2019-2022.

Whilst negotiations are confidential, there have been changes to the DHSC's approach. For the first time, the DHSC specifically recruited an industry expert to lead the negotiations instead of entrusting the task to a civil servant. This should strengthen the DHSC's expertise and help their understanding of the pharmaceutical industry. Whilst this may help the DHSC maximise spending controls, it may also facilitate more constructive discussions with the ABPI.

The new scheme is likely to be built on the principles of the existing PPRS. The current scheme introduced a cap on NHS' pharmaceutical spending for branded drugs, by setting annual spending limits, with the pharmaceutical industry having to repay excess expenditure. The repayment amount is calculated as a percentage of the value of a company's sales to the NHS. By the end of December 2017, the industry had repaid just over £2bn to the DHSC. It should be noted that this position was originally agreed against the backdrop of wider economic austerity, and severe pressure on NHS funding.

	2014	2015	2016	2017	2018
PPRS expenditure growth	0%	0%	1.8%	1.8%	1.9%
Industry re-payment (%)	3.74%	10.3%	7.8%	4.75%	7.8%

The overall cap on NHS spending on the PPRS is likely to remain. Significantly diverging from this principle would be surprising given that spending controls under the statutory scheme (which covers companies that decide not to opt-in to the PPRS) have been recently aligned with the current PPRS. However, both parties will have learned from the past five years and will seek to improve recognised shortcomings with the process. A key issue has been that the PPRS payment amounts have been difficult to foresee, creating issues for both the industry and the DHSC.

NICE's cost-efficiency assessment

The National Institute for Health and Care Excellence (NICE) is responsible for assessing the cost-efficiency of medicines in the UK and provides recommendations for whether they should be reimbursed by the NHS. A key element of this appraisal is the measurement of a medicine's cost per Quality-Adjusted Life Years (QALY) resulting from using the treatment. The QALY takes into account both the length and quality of life. Generally, a cost of £20,000 - £30,000 per QALY is deemed to be cost-effective by NICE and should lead to a product being reimbursement on the NHS.

In 2009, NICE increased the QALY to £50,000 for end-of-life treatments and in April 2017, it introduced another threshold for very rare disease treatments, which may have a QALY of £100,000 -£300,000. Subsequently, in October 2017, NICE recommended that the high-cost gene therapy product, Strimvelis, be made available for NHS reimbursement. A feature of Strimvelis that makes it even more unusual is that patients would access the treatment in Italy, rather than on-site in an NHS facility.

However, with an eye on containing potentially escalating costs, NICE introduced a new threshold for expensive drugs. If a drug costs more that £20m per year in the first three years, a commercial discussion automatically takes place between the company and NHS England, with the aim of mitigating the financial impact on the wider NHS budget. This not only reflects the scarcity of financial resources in the NHS, but also the increasing price tag of new treatments. Whilst NICE claims that the £20m annual cost is not a cap, and that products exceeding the threshold could still be reimbursed, it may be viewed an additional reimbursement hurdle for innovative therapies.

POLICY AND LEGISLATION

Legislative changes to the Statutory Scheme

About 80% of pharmaceutical companies selling branded drugs to the NHS are covered by the PPRS. The remaining 20% that have decided not to join the PPRS fall under the statutory scheme by default. The mechanisms underpinning NHS spending on statutory scheme companies are changing following the adoption of the *Health Service Medical Supplies* (Costs) Act in 2017.

The Act introduced provisions to align the statutory scheme spending controls with the PPRS. Before the introduction of the Act, expenditure on the statutory scheme was controlled through DHSC through cutting list prices for products. The Act now means price control is through a similar system to PPRS, with Companies operating under the statutory scheme liable to make repayments of 7.8% of their NHS sales to the DHSC. The reason for the change is that since list prices could be set much higher than actual prices (the price that the NHS paid for drugs once distributor discounts were taken into account), cuts sometimes had little impact on overall expenditure. This situation had led to some companies voluntarily exiting the PPRS to gain better financial conditions under the statutory scheme.

Life Sciences Strategy

The UK policy landscape is overall favourable to the development of new drugs. Increasingly, this is focused towards innovative therapies. The Life Sciences Strategy (November 2017) makes some specific references to the importance of cell and gene therapies. It recommends that the government accepts the conclusions of the Advanced Therapies Manufacturing Taskforce to foster investment in the commercial manufacture of cell and gene therapies in the UK. The government has already confirmed its intention to support the industry ahead of Brexit. Whilst this is positive, implementation actions are unlikely to start before the end of 2018. The Autumn 2018 Budget announcement may shed some light on the government's approach to innovative therapies and unveil further financial support.

The policy focus on cancer and increasing survival rates which remain lower than many other European countries also supports the development of innovative therapies. These opportunities exist through funding support in the Cancer Drug Fund, the NHS Cancer Strategy, and the announcement that from, October 2018, new cancer patients would be subject to DNA tests to help doctors determine the best treatment. This builds on the 100,000 Genome Project, which started in 2012 and is sequencing 100,000 genomes from around 70,000 people suffering from rare diseases or cancer. This project places the UK at the forefront of genetic medicine research.

REGULATION

Overview

Recent and upcoming regulatory changes are most likely to impact on new drugs or drugs under development, rather than existing branded drugs under patent. The majority of regulatory changes are taking place at the EU level, meaning that there is some uncertainty on their application due to Brexit. However, if the UK does come to an agreement on its withdrawal from the EU, the Government has indicated its intention to align regulatory frameworks closely with the EU and explore options for remaining in cross-EU research networks.

Marketing authorisations for innovative therapies

Since 2008, the assessment and regulatory approval of innovative cell and gene therapies is the responsibility of the EMA. This was agreed to avoid the duplication of regulatory frameworks across Europe and ensure consistency. This move greatly simplified the approach for developers wanting to bring their innovative treatments to European countries, even though it can still be difficult to gain an EMA marketing authorisation.

Given the small number of innovative therapies approved since 2008, the EMA is currently streamlining its regulatory framework. It has developed a fast track approval scheme, called PRIME. Under this scheme, eligible drugs can go through a shorter assessment and are more likely to gain marketing approval.

The future of marketing authorisations in the UK is tied to the outcome of Brexit. A no-deal exit may mean that innovative drug developers must apply for two marketing authorisations, one with the EMA and another with the Medicines and Healthcare Products Regulatory Agency (MHRA). Whilst there may be regulatory alignment with the EMA, this would still duplicate activity. Should there be an agreement, the EU Withdrawal Act (July 2018) stipulates that the UK would seek to remain a member of the EMA. Under this scenario, there would be limited changes to the way marketing authorisations currently work and authorisations granted by the EMA would be valid in the UK. However, as currently implemented, EMA members can only be EU or EEA members.

Clinical trials regulation

Before gaining a marketing authorisation, innovative therapies must complete the clinical trials process. Clinical trials are regulated at EU level, with a new Clinical Trial Regulation due to come into force in 2019. The new Regulation seeks to harmonise the rules for conducting clinical trials throughout the EU and simplify the clinical trial submission and assessment process when trials are conducted in multiple EU member states. This is particularly relevant to innovative therapies addressing rare diseases as patient populations will, by definition, be small. The EMA will be tasked with setting-up an EU portal and database to facilitate this cross-border collaboration.

The government has agreed to align the future regulatory framework for clinical trials to the EU's and seek access to the database. This is broadly positive for developers based in the UK, as they should continue to be able to work on a pan-European basis and access necessary patient pools to conduct their clinical trials.

OVERVIEW OF THE CLINICAL TRIALS PROCESS

	Phase I	Phase II	Phase III	Phase IV
Type	Human Pharmacology	Therapeutic Exploratory	Therapeutic Confirmatory	Post-Approval
Goal	Safety and tolerability "First in human trial"	Therapeutic effect Dose optimization Proof of concept Safety (toxicity)	Confirmation of efficacy and safety	Pharmacovigilance Real-life data
Size	Usually very small numbers of patients (<10)	May involve up to several hundred patients	May involve up to several thousand patients	Very large patient numbers

GENERIC DRUGS

Generic drugs are copies of originator branded drugs which have lost their patent protection. They are usually substantially cheaper than their branded competitor – although the margin can vary substantially depending on the level of competition. In 2016/17, the NHS spent about £4.3bn on generic drugs. The majority of this expenditure (£3.5bn) occurs in primary care, with funding being the responsibility of local CCG budgets. Since 2010/11, there has been a significant rise in primary care spending on generic drugs (total expenditure has increased by £1bn, or approximately 40%). However, purchasing generics is estimated to save the NHS £13.5bn a year due to the fact that generic drugs are overall cheaper than their branded equivalents.

Policies and pricing mechanisms rely on market dynamics to incentivise competition among generic companies. This has created a favourable environment for the generics industry because unlike many European countries, there are no automatic price reductions imposed on generic drugs over time and no direct price cuts. It is estimated that over 80% of medicines sold in the UK are generics, one of the highest proportion in Europe. However, a number of high profile cases involving pharmaceutical companies applying extremely large price increases to certain generic drugs have led to payers, regulators and policy-makers increasingly focusing on addressing this issue.

PAYERS

Generic drug price setting

Companies are free to set their own prices for generic drugs sold in the UK. However, to counter excessive pricing, government policy encourages market entry to foster competition and ensure that prices decrease rapidly and remain low. The NHS Drug Tariff is used to establish the level at which pharmacies are reimbursed for the provision of medicines in primary care. This aims to incentivise generic companies or wholesalers to sell generic drugs to pharmacies at a lower price than the Drug Tariff. There are three categories of medicines in the Drug Tariff, and the Tariff price for a drug is dependent on which category it is placed in.

The increasing cost of generic medicines in primary care

In June 2018, the National Audit Office (NAO) published a report into NHS spending on generic medicines in primary care. Its investigation was triggered by a substantial increase in the number of 'concessionary' requests made by pharmacies in 2017. Concessionary prices may be approved when pharmacies cannot purchase a medicine at the Drug Tariff's price or below, and so are often indicative of price increases of generics. The concessionary approvals resulted in £315m additional costs on CCGs.

According to the Department of Health and Social Care (DHSC), there are three possible reasons for the increase; medicine shortages, currency fluctuations, and increases in wholesalers' margins. The NAO investigation stops short of providing a view on how DHSC should react to future price increases, but it does note that the Secretary of State now has statutory powers to directly control generic drug prices.

The NAO's role is to scrutinise public spending on behalf of Parliament and support government in making efficient spending decisions. Unlike the Competition and Markets Authority (CMA), the NAO has no power to impose price reductions or fines on pharmaceutical companies. However, its conclusions are often investigated further by the Public Account Committee (PAC) of the

CATEGORY	DESCRIPTION	DRUG TARIFF
A	Drugs which are competitively available, including popular generics	Calculated monthly based on a weighted average of the prices from 2 wholesalers and 2 generic manufacturers
C	Drugs which are not competitively available (often branded drugs)	Set by manufacturer or supplier
M	Drugs which are competitively available	Calculated by the DHSC based on information submitted by manufacturers. Reviewed every 3 months

House of Commons. The PAC has already opened a follow-up inquiry into generic drug pricing and will issue recommendations to the government by early 2019.

POLICY AND LEGISLATION

Price control powers and information provision

The *Health Service Medical Supplies* (Costs) Act was adopted in 2017. This legislation gives power to the Secretary of State to intervene directly on generic pricing by formally requesting companies to reduce prices. The Act also formalises information sharing between generic drugs companies and the DHSC. Regulations implementing the provisions in the Act came into force in July 2018 and companies will now have to provide pricing information on a quarterly basis.

The legislation was introduced in September 2016 following political and media pressure as a result of well-publicised cases of price increases by generic drug companies. In some cases, price increases were in the region of several hundred percent, and in rare cases over a thousand percent.

To date, it appears that the Secretary of State has not used their price control power to request direct price reductions. This may be because the information provision regulations have only just come into force, and so high quality pricing information is only recently available. Alternatively, it is possible that confidential discussions have taken place between the DHSC and generic drug companies. If the CMA's current regulatory action against generic drug companies is unsuccessful, the new Secretary of State, Matt Hancock, may prove willing to use the powers.

Guidance to CCGs on drugs that should no longer be prescribed

Generic drug price increases, coupled with wider NHS funding pressure and the ongoing requirement to find cost-savings from within the NHS budget, led to the establishment of a working group to identify pharmaceutical products that should no longer be prescribed. In November 2017, guidance was published outlining seven generic products, that had been subject to 'excessive' price inflation and should no longer be prescribed because there are more cost-efficient alternatives.

The guidance is not binding on CCGs. They are free to develop their own formularies, which outline which drugs are available for prescription, taking into account clinical efficiency and price. However, given the level of financial pressure CCGs are under, it would be surprising if they did not use the guidance as an easy way to generate savings. This could lead to products listed as second or third line items, or removed from individual CCGs' formularies.

If GPs want to issue a new prescription for a product that is not on their CCG's formulary, they need to place a special request. In the medium to long-term, these changes are likely to see prescriptions for these products decrease, as new patients will be prescribed alternative treatments.

The working group's interest goes beyond generic drugs that are strictly available upon prescription. Guidance issued in March 2018 identified several drugs for minor conditions available over the counter but sometimes prescribed by GPs on the NHS, which should no longer be prescribed. This suggests that the working group is likely to continue monitoring NHS drug spending overall, including generic drug pricing, and may publish additional guidance in the future.

Biosimilar policy

Biosimilar drugs are non-branded versions of biological drugs. It is estimated that increasing the use of biosimilars could save the NHS £200-300m per year by 2020/21. Given their cost-saving potential, it is unsurprising that they have attracted policy makers' attention. However, biosimilars are only highly similar – not identical - to the originator biological drug. This means that they cannot be automatically substituted.

In September 2017, NHS England, NHS Improvement and NHS Commissioners published a guidance document Commissioning framework for biological medicines (including biosimilar medicines). This document supports commissioners in making decisions on biosimilars. It clearly states that all CCGs should be proactive in identifying the opportunities from biosimilars. The guidance recommends adopting a collaborative approach, involving clinicians, patients, providers (such as NHS Trusts) and CCGs.

REGULATION

Investigations into generic drug pricing

The CMA has taken an active interest in the pharmaceutical sector, in particular concerns around generic drug price increase, over the last few years. Between May 2016 and October 2017, the CMA formally opened seven investigations into generic drug companies for suspected unfair pricing. They were launched after it became evident that some companies had substantially increased the price of selected older generic drugs. In many cases, they used a 'de-branding' strategy, moving the drug from the PPRS to the Drug Tariff (category C), in order to benefit from the pricing freedom that the Drug Tariff allowed.

ABUSE OF A DOMINANT POSITION: PFIZER, FLYNN PHARMA, AND THE CMA

The issues concerning Pfizer and Flynn Pharma date back to May 2013, and it is viewed by many as a key test battle over the ability of the CMA to demonstrate 'abuse of market' over generic price increases.

In 2012, Pfizer and Flynn Pharma undertook a 'de-branding' strategy. Pfizer sold the rights of Epanutin (the brand name of phenytoin sodium capsules) to Flynn Pharma while retaining manufacturing. Epanutin was subsequently 'de-branded'– effectively making it a generic that did not have any competitors. This allowed them to move from the PPRS to become a Category C Drug on the Drug Tariff. This allowed free pricing, and in the absence of any competitor products, the product was increased in price by 2,600%.

Following over three years of investigation, the CMA published its final infringement decision in December 2016. The CMA found that Pfizer and Flynn Pharma abused their dominant position to charge the NHS 'unfair' prices. The companies were fined a record total of £89.4m, including the maximum penalty for Flynn (10% of its global turnover). The CMA also instructed them to decrease the price of phenytoin sodium capsules.

Pfizer and Flynn appealed the CMA's decision to the Competition Appeal Tribunal (CAT). In June 2018, the CAT partly dismissed the CMA's decision due to a failure to demonstrate that the companies had charged excessive or unfair prices to the NHS. The CAT has now referred the case back to the CMA.

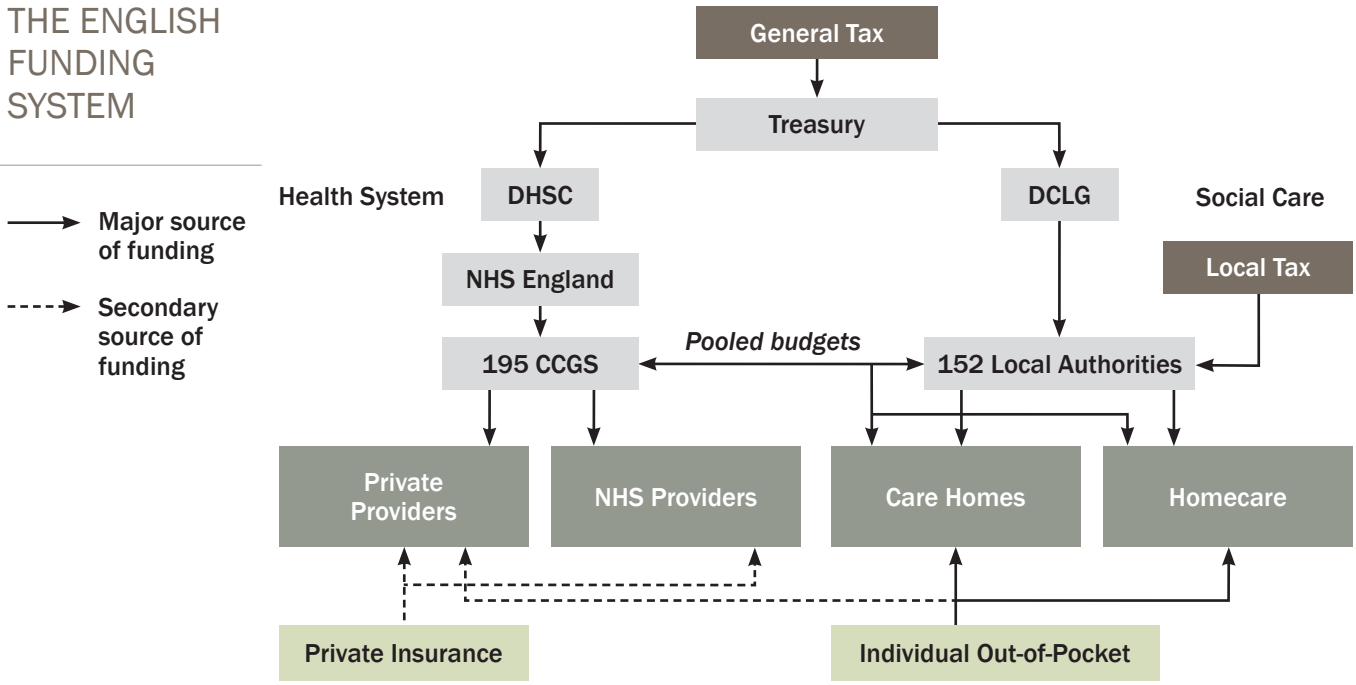
Although it remains possible for the CMA to demonstrate that unfair pricing took place, the CAT's judgement is likely to slow down other CMA investigations into generic drug pricing. Decisions on these cases are likely to be delayed and their outcome will depend on the CMA's ability to address its approach's shortcomings. In addition, it is unlikely that the CMA will open new cases until its views on Pfizer and Flynn Pharma are upheld.

5

The English healthcare system is a tax-funded system, mostly free at the point of need. Co-payments are required for a small number of services, including dentistry and medicines. A minority of the population holds private health insurance. By contrast, the social care system is not free at the point of need and many individuals must pay privately to receive services.

POPULATION	AREA	CAPITAL	LIFE EXPECTANCY
53.0m	130,279km^2	London	**W** 83.1 | **M** 79.5

THE ENGLISH FUNDING SYSTEM

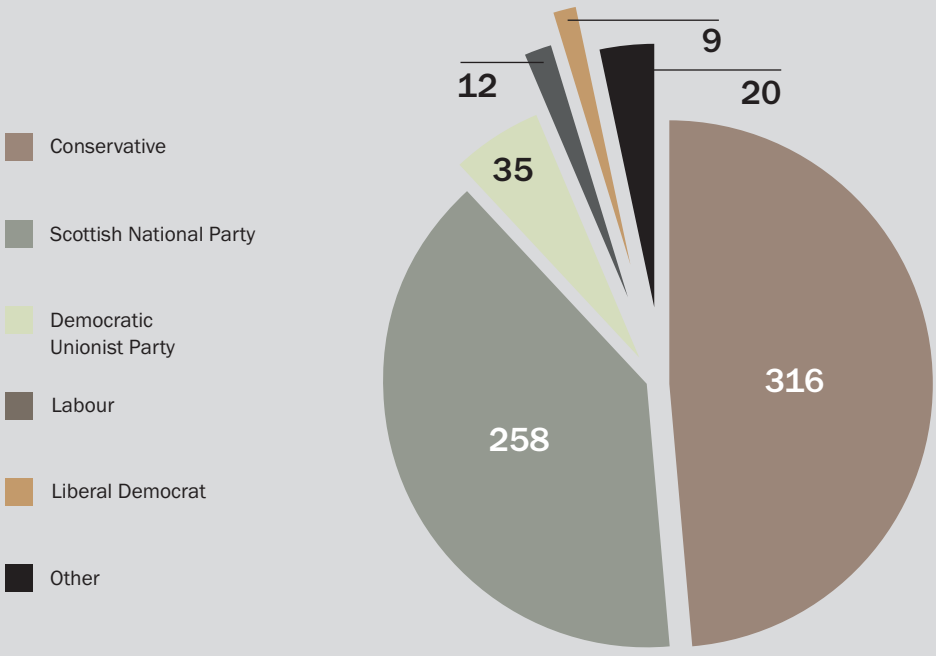


POLITICAL CONTEXT

The United Kingdom (UK) is a constitutional monarchy with a population of over 66 million. It is governed by a bicameral parliament, formed of the House of Lords and the House of Commons. 650 Members of Parliament (MPs) sit in the House of Commons and are elected every five years. The leader of the party that gathers the most MPs becomes Prime Minister (PM) and appoints the government. The last general election took place on 08 June 2017 and resulted in a 'hung' Parliament in which none of the parties have a majority of seats. However, the Conservative Party remained the largest party and its leader, Theresa May, has been PM since 2016.

General elections are held every five years. Thus, the next general election will take place no later than 22nd May 2022.

COMPOSITION OF THE HOUSE OF COMMONS



HEALTH AND SOCIAL CARE - GOVERNANCE AND REGULATION

Governance

Health and social care in England are shaped by different decision makers at the national and local levels.

	HEALTHCARE	SOCIAL CARE
National	- Department of Health - NHS England	Department of Health and Department for Communities and Local Government
Local	195 Clinical Commissioning Groups (CCGs)	152 local authorities (LAs)

Health and social care policy is devolved in the UK. This means that the devolved administrations of Wales, Scotland and Northern Ireland are responsible for health and social care policy in their respective jurisdictions. In England, the Secretary of State for Health and Social Care is accountable for the Department of Health and Social Care and provides strategic leadership for health and social care policy.

Healthcare

The Health and Social Care Act 2012 provided the legislative basis for the reorganisation of the NHS in England. The main changes included:

- Shifting many of the responsibilities historically located in the Department of Health to NHS England
- Replacing former Primary Care Trusts (PCTs) by Clinical Commissioning Groups (CCGs), formed of GPs and clinicians, responsible for planning and commissioning healthcare services at local level
- The creation of Public Health England (PHE) whose aim is to protect and improve the nation's health
- Allowing healthcare market competition in the best interests of patients

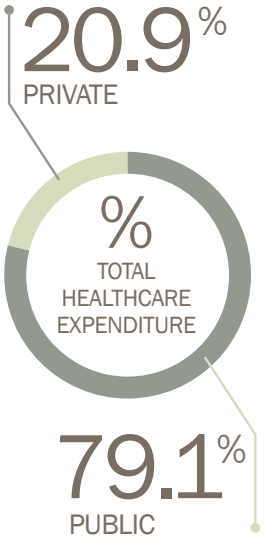
The national direction of healthcare policy is driven by the Secretary of State, supported by the Department of Health and Social Care. The Secretary of State is also responsible for negotiating the overall healthcare budget with the Treasury. The operational direction and priorities of the National Health Service (NHS) are delegated to NHS England, a public body. At local level, 209 Clinical Commissioning Groups (CCGs) implement NHS England's policy directions. Through their commissioning decisions and the requirement to meet local needs, CCGs play an important role in shaping the healthcare landscape in England.

Social Care

The Care Act 2014 formed the basis of the biggest changes to the social care sector since its establishment in the 1940s. The Act introduced legal duties to Local Authorities (LAs) to signpost individuals towards appropriate care and support. The main changes include:

- Introduction of deferred payments
- Extension of the government safety net
- Introduction of a capped cost model of care
- Introduction of LA information duties

152 LAs are responsible for organising social care services and have a significant influence on shaping policies and determining priorities locally. The overall direction of social care policy is determined at national level by the Department of Health and Social Care and the Department for Communities and Local Government.



REGULATION

In England, the regulation of health and social care services is the responsibility of several independent regulatory bodies. These bodies ensure that services are compliant with a range of standards, including quality, financial, sustainability and competition. Some of them are relevant to all health and social care services, while others focus on a particular sub-sector.

Quality regulation of both health and social care services is overseen by the Care Quality Commission (CQC). CQC is responsible for registering, monitoring, inspecting and rating a wide range of providers. CQC can take enforcement action when providers fail to comply with quality and safety standards.

NHS Improvement is responsible for overseeing the financial sustainability and leadership of NHS Foundation Trusts (FTs), NHS Trusts and independent providers who deliver NHS-funded hospital care. NHS Improvement ensure that competition rules are applied.

Historically, the governance of healthcare policy has been mostly centralised and separate to that of social care. However, this is changing. Greater Manchester and London have obtained 'devolution deals' from central government that has given them greater responsibility for health and social care, including some budgetary discretion. In other areas, developing integrated care systems are bringing local authorities together with healthcare partners.

HEALTHCARE – FINANCING AND STRUCTURE

Healthcare Financing

Healthcare Financing Context

Healthcare expenditure in England is mostly public. Although there are no specific figures for England only, in 2016, public expenditure accounted for 79.1% (or £122.5bn) of total healthcare expenditure in the UK. The remainder is made up of private spending, mostly in the form of co-payments for a small number of services and, to a lesser extent, through out-of-pocket payments and Private Health Insurance (PHI). It is estimated that 10.6% of people subscribe to PHI in the UK, a figure that has remained stable over the past five years.

Between 2009/10 and 2015/16, annual public healthcare expenditure increased by 1.4% on average. This is particularly slow in comparison to annual average increase of about 4% between the late 1940s and late 2000s. The pace of expenditure increase was particularly high under the last Labour government, from 1997-2010. In June 2018, additional funding for the NHS was announced. This will see annual expenditure on the NHS increase so that by 2023/24 it receives an additional £20.5bn every year.

Healthcare Financing Flows

The Treasury provides funds to the DHSC based on the Spending Review, a multi-annual plan outlining how public funding will be allocated. The money filters down through NHS England, where about a third of funding is used by NHS England directly to purchase certain services. The remaining budget is allocated to the 209 CCGs on a weighted capitation basis. The CCGs' total budget for 2017/18 is just over £72bn. CCGs are then responsible for allocating funding to an extensive range of local services, including secondary (hospital) care, non-specialist mental health, and, increasingly, general practice services.

Healthcare System Structure

Services

Primary and secondary healthcare services are mostly free at the point of need. In 2017, there were 7,613 general practices, 153 NHS Trusts (acute hospitals) and 54 mental health trusts.

Payers

NHS England purchases some services nationally, such as specialised services, military and veteran services, offender services, and primary care, including GP and dental services. However, in certain cases, the commissioning of specialised services and GP services has been delegated CCGs. CCGs were created by the Health and Social Care Act 2012. They are clinically-led statutory NHS bodies composed of local GPs and other clinicians (such as nurses and secondary care consultants) and are responsible for commissioning local services, namely emergency care, hospital care, mental health and community health services.

Providers

Services are provided by a mix of public and private providers.

Primary care providers include independent GPs, dentists, community pharmacists and opticians. GPs provide the majority of primary care services and are the first point of contact for most patients. GPs increasingly work in group practices and a growing number are salaried.

The secondary care provision landscape is mainly composed of public hospitals (trusts). Services are provided by consultants (specialist doctors), nurses and other healthcare professionals, such as radiotherapists and physiotherapists employed by the trusts. There are two types of trusts: NHS Foundation Trusts, and NHS Trusts. NHS Foundation Trusts have more flexibility and freedom to operate than NHS Trusts. There are a small number of private providers delivering acute elective care, as well as private provision of mental health, learning disability, and secure services.

ADULT SOCIAL CARE - FINANCING AND STRUCTURE

Adult Social Care Financing

Adult Social Care Financing Context

Social care services are funded primarily via public sources, through 152 Local Authorities (LAs), whose budgets are made up of a complex mix of national and local taxation. However, social care services are not free at the point of need. LA expenditure only provides a safety net and many people must pay for their own care privately. Individuals contribute towards the cost of their care if their personal wealth exceeds the thresholds set out in the means-test (see below). In 2016/17, LA expenditure on adult social care was £17.5bn. In real-terms, this equates to an 8% reduction compared to 2009/10.

Adult Social Care Financing Flows

Social care financing flows are complex. Expenditure is not ring-fenced and LAs must allocate social care expenditure from their global budgets, alongside other local services such as transport or housing. There are two sources of revenue for LAs. Some of their funds are allocated by the Treasury to the Department of Communities and Local Government, which in turns allocates some of it to LAs based on a complex formula. The rest of the funds are raised at local level directly by the LAs, mainly through council tax, levied on individual households, and business rates, levied on business activities. Since 2010, the balance between central allocations and local

revenue has shifted towards the latter. The Spending Review 2015 continued this trend. It sought to balance revenue by giving LAs the freedom to increase council tax to fund social care (the social care 'precept'). In addition, a complex reform of business rates retention is ongoing. The objective is to allow LAs to retain 100% of the business rates they raise, instead of pooling them nationally. Whilst this was to be achieved by 2020, the objective has been revised down. By 2020, all local authorities should retain 75% of business rates.

Adult Social Care System Structure

Services

Social care services are not free at the point of need. There are a wide range of services available to support different levels of need.

Services in support of activities of daily living are available through homecare (or domiciliary care) services. They are delivered by carers who go to an individual's house for a certain period of time to help them with daily tasks such as cooking, cleaning, or getting dressed.

When individuals' needs increase, care home services are available. They may include nursing for those with the highest level of need.

In addition, in England, learning disability services are mostly the responsibility of LAs and fall under social care provision. These services include day centres, residential care and home support.

Payers

The main public payer for social care services are local authorities. LA funding acts as a safety net in which individuals apply for funding and are assessed against a national set of needs and means criteria. The Care Act 2014 introduced several changes to the organisation and governance of social care. It placed a new responsibility on LAs to assess the needs of any individual who appears to have care needs and provide information and assistance to those who have been assessed as needing care. LAs continue to carry out financial assessments to determine whether an individual is eligible for public funding, but the Act extends the lower and upper thresholds for means-testing.

To be eligible for LA funded social care, an individual must have less than £23,250 in assets and savings. Where individuals are receiving homecare services, the value of their house is not taken into account. Where individuals are moving into a care home permanently, the value of their house will be taken into account. Individuals who do not qualify for LA support become private payers.

LAs agree on contracts with local providers, which are negotiated every year. In recent years, LA prices have mostly decreased, or at best, increased by about 1% annually for care homes, but they have not kept pace with the increase in costs. This increase is due in part to the introduction of the National Living Wage from April 2016. In addition, as social care is not free at the point of need, there is a substantial proportion of private payers who cover the full or partial cost of their care. Providers charge higher prices for them, and, increasingly, this revenue is used to make up for low LA prices. There has been a big reduction in the numbers of older people receiving LA-funded social care from more than 1.1 million in 2009 to 853,615 in 2013-14 – a fall of 26%.

Providers

Social care services are provided mainly by private operators as LAs offer very limited direct provision. Private operators of social care services typically provide a range of care homes (nursing and residential) and homecare services. These services can vary both in the size and types of services and care provided.

GLOSSARY: COMMON ACRONYMS IN HEALTH AND SOCIAL CARE

A&E: Accident and Emergency

ABPI: Association of British Pharmaceutical Industries

APMS: Alternate Provider Medical Services

BDA: British Dental Association

BMS: British Medical Association

CAMHS: Children and Adolescent Mental Health Services

CAT: Competition Appeal Tribunal

CCG: Clinical Commissioning Group

CHC: Continuing Health Care

CMA: Competition and Markets Authority

CMU: Commercial Medicines Unit

CQC: Care Quality Commission

DCLG: Department of Community and Local Government

DHSC: Department of Health and Social Care

DRG: Diagnosis Related Groups

EMA: European Medicines Agency

EU: European Union

FYFV: Five Year Forward View

FYFVMH: Five Year Forward View for Mental Health

GDS: General Dental Contract

GMS: General Medical Services

GP: General Practitioner

GPFV: General Practice Forward View

HMRC: Her Majesty's Revenue and Customs

ICS: Integrated Care System

LA: Local Authority

LGA: Local Government Authority

MCP: Multispeciality Community Providers

MHRA: Medical and Healthcare Products Regulatory Agency

NAO: National Audit Association

NHS: National Health Service

NHS FT: NHS Foundation Trust

NHSI: NHS Improvement

NICE: National Institute for Health and Care Excellence

NMC: Nursing and Midwifery Council

NMW: National Minimum Wage

PAC: Public Accounts Committee (House of Commons)

PACS: Primary and Acute Care System

PbR: Payment by Result

PCT: Primary Care Trust

PHE: Public Health England

PHI: Private Health Insurance

PMS: Primary Medical Services

PPRS: Pharmaceutical Pricing Regulation Scheme

PRIME: Priority Medicines Scheme

QALY: Quality -Adjusted Life Years

SOF: Single Oversight Framework

STP: Sustainability and Transformation Partnerships

TCP: Transforming Care Partnerships

TDA: (NHS) Trust Development Authority

UDA: Units of Dental Activity

Contact us

For more information on any of the content in this publication or to learn more about Marwood Group's advisory capabilities, we encourage you to please contact us.

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