NHS England

Consultation on proposals to introduce supplementary prescribing by dietitians across the United Kingdom

Prepared by the Allied Health Professions Medicines Project Team

NHS England – February 2015

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Consultation on proposals to introduce supplementary prescribing by dietitians across the United Kingdom

The proposed changes to medicines legislation would apply throughout the United Kingdom. This consultation document has been developed in partnership with: the Northern Ireland Department of Health, Social Services and Public Safety; the Scottish Department of Health and Social Care; the Welsh Department of Health and Social Services; the Department of Health for England; and the Medicines and Healthcare Products Regulatory Agency.

Contents

Contents 4
1 Executive summary 6
2 Purpose of the document 8
2.1 Introduction to the consultation 8
3 Introduction to dietetics 9
3.1 General information 9
3.1.1 Dietitian/Specialist practitioner 10
3.1.2 Advanced dietitian 10
3.1.3 Consultant dietitian 10
3.2 Examples of dietetic roles 11
3.3 Where dietitians work 12
3.4 How dietitians are trained and regulated 13
3.4.1 Core modules underpinning dietetics 13
3.5 Current use of supply and administration of medicines by dietitians 14
3.6 Education programmes and continuous professional development for supplementary prescribers 15
3.7 Eligibility for training as a dietetic supplementary prescriber 15
3.8 Continuing professional development 16
3.9 Governance and safeguarding 17
3.9.1 Access to medical records 17
3.9.2 Updating the medical record 18
3.9.3 Clinical governance 18
3.9.4 Antimicrobial resistance 18
4 Benefits 19
5 Approach to the consultation 22
5.1 The case for change 22
5.2 Work to date 23
5.2.1 Scoping study 23
5.2.2 Developing the case of need 23
6 Proposal for the introduction of supplementary prescribing by dietitians 24
6.1 Scope of supplementary prescribing 24
6.2 Additional information 25
6.3 Supporting documents: impact assessment, practice guidance and education curriculum framework 25
6.3.1 Impact assessment 25
6.3.2 Practice guidance 25
6.3.3 Education curriculum frameworks 26
6.4 Equality 27
7 Consultation process 27
7.1 How to respond 28
7.2 Comments on the consultation process itself 28
8 Next steps 29
9 Appendices 30
9.1 Appendix A: Role of the professional body 30

9.2 Appendix B: The mechanisms for the prescribing, supply and administration of medicines 31
9.3 Appendix C: Contributors..... 33
9.4 Appendix D: Frequently asked questions 34
10 Glossary 41

1 Executive summary

This consultation concerns proposals to extend the existing legislation in respect of supplementary prescribing to advanced dietitians across the United Kingdom. This would be achieved primarily by changes to the Human Medicines Regulations (2012).

The proposed changes to medicines legislation would apply throughout the United Kingdom, in any setting in which dietitians work including the NHS, independent and voluntary sectors. Changes to NHS regulations to enable supplementary prescribing by dietitians within Scotland, Wales and Northern Ireland and the resultant focus and pace of this in each respective country are matters for each of the Devolved Administrations.

Supplementary prescribing is defined as: a voluntary prescribing partnership between the independent medical prescriber and the supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.

Supplementary prescribing can enable new ways of working to improve quality of care – delivering safe, effective services focussed on improving the patient experience. It facilitates partnership working across professional and organisational boundaries within commissioning/provider landscapes and with patients to redesign care pathways that are cost-effective and sustainable. It can enhance choice and competition, maximising the benefits for patients.

Supplementary prescribing by dietitians also has the potential to improve patient safety by reducing delays in care and creating clear lines of responsibility and accountability for prescribing decisions. The development of supplementary prescribing by dietitians is part of a drive to make better use of their skills and to make it easier for patients to get access to the medicines that will give them the most benefit.

An Allied Health Professions (AHPs) Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken in 2009 to establish whether there was evidence of service and patient need to support extending prescribing and medicines supply mechanisms available to AHPs. The project found there was evidence supporting a progression to supplementary prescribing for dietitians and that further work should be undertaken, when appropriate, to consider the need for supplementary prescribing by dietitians; a project was established in October 2014 to take the work forward.

The NHS England AHP Medicines Project Team, in partnership with the British Dietetic Association developed a case of need for enabling supplementary prescribing by dietitians based on improving the quality of care for patients in relation to safety, clinical outcomes and experience, whilst also improving efficiency of service delivery and value for money. Approval of the cases of need was received from NHS England's Medical and Nursing Directorates Senior Management Teams in May 2014 and from the Department of Health Non-Medical Prescribing Board in July 2014.

A number of supporting documents are provided alongside the consultation to inform consideration of the proposal to extend the existing legislation in respect of supplementary prescribing to dietitians; these include *Draft Practice Guidance in the Safe Use of Medicines for Dietetic Supplementary Prescribers*, a *Draft Outline Curriculum Framework for Education Programmes to Prepare Dietitians as Supplementary Prescribers* and a *Consultation Stage Impact Assessment*.

These documents will remain in draft format until the consultation closes after which amendments will be made in line with the consultation responses received and then final versions will be published as appropriate.

A summary of this consultation document is also available here and can be requested in alternative formats, such as easy read, Welsh language, large print and audio. Please contact: enquiries.ahp@nhs.net

The consultation seeks responses to the following questions:

Question 1: Should amendments to legislation be made to enable dietitians to supplementary prescribe?

Question 2: Do you have any additional information as to why the proposal for supplementary prescribing by dietitians SHOULD go forward?

Question 3: Do you have any additional information as to why the proposal for supplementary prescribing by dietitians SHOULD NOT go forward?

Question 4: Does the 'Consultation Stage Impact Assessment' give a realistic indication of the likely costs, benefits and risks of the proposal?

Question 5: Do you have any comments on the proposed practice guidance for dietetic supplementary prescribers?

Question 6: Do you have any comments on the 'Draft Outline Curriculum Framework for Education Programmes to Prepare Dietitians as Supplementary Prescribers'?

Question 7: Do you have any comments on how this proposal may impact either positively or negatively on specific equality characteristics, particularly concerning; disability, ethnicity, gender, sexual orientation, age, religion or belief, and human rights?

Question 8: Do you have any comments on how this proposal may impact either positively or negatively on any specific groups e.g. students, travellers, immigrants, children, offenders?

2 Purpose of the document

2.1 Introduction to the consultation

This consultation is in accordance with the Human Medicine Regulations (2012) concerning proposals to enable registered dietitians to practice as supplementary prescribers on completion of an approved training programme and annotation of their professional registration. This would be achieved primarily by amendment to the Human Medicines Regulations (2012) and consequential amendments to NHS regulations.

Supplementary prescribing is defined as: a voluntary prescribing partnership between the independent prescriber (a doctor) and the supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.

This consultation document has been produced by NHS England with support from The British Dietetic Association (BDA), the Medicines and Healthcare products Regulatory Agency (MHRA), the Department of Health, the Northern Ireland Department of Health, Social Services and Public Safety, the Scottish Department of Health and Social Care and the Welsh Department of Health and Social Services.

Application to England, Wales, Scotland and Northern Ireland
The proposed changes to medicines legislation would apply throughout the United Kingdom, in any setting in which dietitians work including the NHS, independent and voluntary sectors. Changes to NHS regulations to implement supplementary prescribing are matters for each of the Devolved Administrations.

The Professional Body
The British Dietetic Association (BDA) is the professional body representing the dietetic workforce including, practitioners, assistant practitioners, support workers and student dietitians in the United Kingdom. The role of the professional body is summarised in Appendix A for information.

Who can respond to this consultation?
Everyone is welcome to respond. We hope to hear from the public, patients/patient representative groups, carers, voluntary organisations, healthcare providers, commissioners, doctors, pharmacists, allied health professionals (AHPs), nurses, regulators, non-medical prescribers, the Royal Colleges and other representative bodies.

The consultation
Will run for eight weeks and will close on **24 April 2015**

3 Introduction to dietetics

3.1 General information

Dietitians are statutorily registered health professionals who are the only qualified health professionals that assess, diagnose and treat diet and nutrition problems at an individual and wider public health level. There are currently 8,476 (as of January 2015) dietitians in the UK registered with the HCPC.

Uniquely, dietitians use the most up to date public health and scientific research on food, health and disease, which they translate into practical guidance to enable people to make appropriate lifestyle and food choices.

Dietitians use their in-depth knowledge of food, in relation to its effect on normal body biochemistry and physiology in sickness and health, taking into account the patient's medical (including medicines), social and psychological circumstances. They help patients make food and lifestyle choices to ensure they eat sufficient energy and nutrients to maintain normal physiological functions, correct nutritional imbalances and help patients reach their potential, or maximize functioning and health.

Dietary modification is at the core of dietetic practice and requires enormous skill. People, and the factors affecting their lives, are infinitely variable and no two situations requiring dietetic intervention will ever be exactly the same. The skill of the dietitian lies in assessing a patient's needs, risks and problems and deciding how, in their particular circumstances, these may best be addressed.

Dietary modification may range from detailed guidance based on adjustment of food choice or complex manipulations necessitating artificial nutrition directly into the patient's vein. Whatever the intervention, it is important to ensure that alteration of one aspect of the diet does not inadvertently create other dietary imbalances, deficiencies or drug nutrient interactions that could create other health risks.

Dietitians play a crucial role in patient pathways where dietary modification is fundamental to management of the condition or to reducing its progression. For example:

- Diabetes
- Cystic Fibrosis
- Gastrointestinal failure
- Renal Disease
- Cancer

The scope of dietetic practice is wide and covers a variety of physical, cognitive and similar interventions, including medicines use aimed at improving nutritional status, nutritional intake and disease management and progression. A dietitian's scope of practice will change over time because of experience, specialisation in a certain clinical area or with a particular client group, or a movement into roles in management, education or research.

A dietitian must undertake the necessary ongoing training and experience to demonstrate that they are capable of working lawfully, safely and effectively within their given scope of practice, and must not practise in areas where they are not proficient. The expectations which define the levels of clinical dietetic practice (graduate, practitioner, specialist, advanced and consultant) are clearly stated in the BDA guidance paper *Dietetic Career Framework*[1].

3.1.1 Dietitian/Specialist practitioner

At the point of registration a graduate in dietetics has the ability to work within the wide-ranging sphere of influence of dietetics. They work autonomously, with practice based on sound evidence, in therapeutic roles with individuals and more broadly, in health promotion and public health with both individuals and groups. The dietitian will demonstrate professional problem solving skills where there is considerable variation in the presentation and health needs of service users and the setting for care. They go on to develop deeper knowledge of dietetic practice within a specialism e.g. diabetes or gastroenterology. They actively seek to develop their own practice for the benefit of their service users, through integrating new knowledge obtained through reflection and evaluation, or from external sources. They will demonstrate flexibility in delivering care in complex and unpredictable contexts.

3.1.2 Advanced dietitian

Advanced dietitians roles function at the forefront of nutrition and dietetics research and practice across a variety of settings – clinical, public health, research, education, private practice, acute and community. They work collaboratively as integral members of multi-disciplinary teams.

An advanced dietitian demonstrates highly developed expert knowledge and skills within their field of practice, including outside traditional role boundaries, and will demonstrate originality and creativity in the application of these. The advanced dietitian will manage complex issues in situations where there is incomplete data, conflicting priorities (clinical, environmental, organisational, strategic, political or policy) and often no existing guidance. The advanced dietitian seeks to shape and influence the environment at different levels including local, regional, professional and national, in order to influence outcomes for their service users.

3.1.3 Consultant dietitian

The consultant dietitian demonstrates highly developed expert knowledge and skills within their field of practice. They deliver improved outcomes for service users with complex and multifactorial healthcare needs, through innovative service delivery and the development of practice and research.

Dietetic consultants work with senior medical, nursing and AHP colleagues across hospitals, community and primary care services in drawing up local and regional care and referral protocols. They also have a health improvement role and must work across organisational boundaries.

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[1] The British Dietetic Association (BDA) (2009) *Dietetic Career Framework*. Birmingham.

Consultant dietitians will have:

- Clinical expertise in a specialist area of dietetics
- Ability to demonstrate clinical strategic leadership
- Research expertise, experience and critical appraisal skills
- Competent engagement and collaboration with appropriate Higher Education Institutions (HEIs)
- Ability to develop and implement extended roles in dietetics
- Ability to influence at a local, national and international level

3.2 Examples of dietetic roles

The primary aim for clinical dietetic care is to empower patients to remain fit, well and self-managed, as far as possible, in their own homes - preventing emergency paramedic call out and hospital admission. Dietitians work across a broad spectrum of sectors including the NHS, private health care, public health, food and pharmaceutical industry; sports and fitness; and even media and TV, where they play a crucial role in health and disease management. Dietary modification is at the core of dietetic practice. The skill of the dietitian lies in assessing an individual's needs, risks and problems; and deciding how, in those particular circumstances, they may best be addressed.

Key pathways that dietitians are involved in include:

- Diabetes
- Cystic Fibrosis
- Gastrointestinal Disorders
- Renal Disease
- Cancer

Dietitians use a whole system approach to nutritional management from developing trust-wide nutritional policy, catering specifications, procurement and menu planning to staff development and training. They integrate professional knowledge and skills into evidence-based decision making for every patient referred to their service. Due to the complex interaction between nutrition and drugs; in sickness and in health, dietitians have a high level of pharmaceutical knowledge regarding the impact of a wide range of medications on nutritional status and the medical conditions they are used to treat. A dietitian is skilled at managing a patient's dietary intake alongside their prescribed medication. Diabetes, kidney disease and cystic fibrosis are only three examples of conditions where this interaction between dietary intake and medication is key to optimising treatment.

3.3 Where dietitians work

Dietitians predominantly work within the NHS, although there are a small percentage of dietitians employed by the private sector and commissioned or contracted by an NHS organisation to deliver NHS services. The BDA estimates that therapeutic dietitians are approximately (80%) NHS and 20% non- NHS. Examples of the wide-spectrum of sectors that dietitians work across are outlined below:

NHS (acute in patient, and community care/nursing homes)
Dietitians work across both acute and clinical community settings, delivering treatment and supporting disease management for long term conditions such as diabetes and kidney disease. Dietitians also develop and run training for healthcare professionals, individuals and carers.

Private health care
Dietitians are employed by private hospitals and clinics to deliver nutritional care to both in patients and outpatients. Dietitians also run their own clinics and can see clients who self-refer for conditions such as food allergy/intolerance, weight reduction and irritable bowel syndrome.

Public Health
Dietitians also work to promote good health and prevent disease by informing and teaching the public, health professionals and others about diet and nutrition. Dietitians help to promote healthy food choices and prevent disease by increasing awareness of the link between nutrition and health.

Food and Pharmaceutical Industry
Dietitians work with industry on product development such as gluten free foods, and also as product representatives providing specialist advice to healthcare professionals and patients. They will also interpret strict European legislation on food and nutritional products and food labelling on behalf of companies.

Media and TV
Dietitians provide factual, evidence based information, direction and comment on nutrition topics for the media. They will interpret nutritional science into simple safe and practical messages for the public.

Community dietetics
More recently, national policy is looking to integrate health and social care services to deliver healthier outcomes for communities and populations. Dietitians have always functioned at the point between the two sectors as diet/nutrition and lifestyle are inextricably linked. Dietitians are experts in rehabilitation, re-enablement, preventative care, health promotion and self-management. Dietitians are often the link that holds complex health and social care pathways together, especially for older people and those living with long-term conditions. They also work in schools supporting the implementation of healthy school meals.

3.4 How dietitians are trained and regulated

Dietetics is one of the Allied Health Professions, and the Dietetic profession is a statutorily regulated health profession under the terms of the Health and Social Work Professions Order (2001). The regulatory body is the Health and Care Professions Council (HCPC). Any person wishing to use the protected title 'dietitian' must be registered on the relevant part of the register.

The HCPC sets the standards that all dietitians have to meet in relation to their education, proficiency, conduct, performance, character and health. These are the minimum standards that the HCPC considers necessary to protect members of the public. Registrants must meet all these standards when they first register and complete a professional declaration every two years thereafter, to confirm they have continued to practise and continue to meet all the standards.

Registered dietitians are all degree qualified health professionals that assess, diagnose and treat diet and nutrition problems at an individual and wider public health level.

The threshold qualification for entry to the dietetic profession is a bachelor's degree with honours in dietetics/nutrition and dietetics or a BSc Hons in science with a substantial human science component such as biochemistry, physiology or nutrition together with a 2 year post graduate diploma or Masters Degree.

The practice of dietetics requires a broad range of knowledge. Dietetics is firmly based on an understanding of biological sciences; and the basic and applied sciences underpinning nutrition and dietetics are major components of pre-registration dietetics programmes. Knowledge of research methodology and ways in which practice needs to be evidence-based and developed, is also fundamental, supported by the necessary information technology. This is complemented by knowledge of social and behavioural sciences and the theories of communication in order to support the skills of dietetic practice.

Further development in specialist areas of practice is achieved via different routes; underpinned by performance review and personal development plans. This will include the use of competency base development programmes, formal and informal learning opportunities (including Masters and other higher level study and research), reflection on practice and practice supervision.

The profession has actively engaged with professional development encouraged and supported by the professional body. In more recent years this has included the BDA Professional Development Award, MSc in Advanced Dietetic Practice (2004) and the BDA Centre for Education and Development courses and resources.

3.4.1 Core modules underpinning dietetics

- Extensive critical, integrated and applied knowledge of dietetics for the prevention and treatment of disease
- Extensive, critical, integrated and applied knowledge and understanding of applied nutrition and food.
- Broad knowledge and understanding of food science, food skills and food systems management.
- Broad knowledge and understanding of Health Inequalities, Structure and Function of the NHS, Social and Health Policy, Public Health, and Public Health Nutrition
- Critical, integrated and applied knowledge and understanding of professional practice and leadership
- Extensive critical, integrated and applied knowledge of nutritional sciences; critical and applied knowledge of physiology and biochemistry and a broad knowledge & understanding of genetics
- Broad knowledge & understanding of immunology and microbiology
- Critical integrated and applied knowledge & understanding of clinical medicine, disease processes and pharmacology with respect to dietetic and nutrition interventions.
- Broad knowledge and understanding of psychology as applied to health
- Critical, integrated and applied knowledge of communication and educational methods
- Critical, integrated and applied understanding of the theories, concepts and principles of research and evidence informed practice.
- Broad knowledge & understanding of the use of technology in relation to dietetic practice.

3.5 Current use of supply and administration of medicines by dietitians

Due to the complex interaction between nutrition and drugs in sickness and in health, dietitians need to have a high level of pharmaceutical knowledge regarding the impact of a wide range of medications on nutritional status and the medical conditions they are used to treat.

Dietitians have been able to supply and administer prescription only medicines under PGDs and PSDs since 2003. However, they are of limited benefit due to the broad scope of dietetics and the narrow remit of PGDs.

The mechanisms by which registered dietitians access medicines are as follows (a full description of each mechanism can be found in Appendix B:

A Patient Group Direction (PGD) is a written instruction for the supply and/or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may not be individually identified before presenting for treatment. Each PGD must be signed by both a doctor and pharmacist; and approved by the organisation in which it is to be used.

A Patient Specific Direction (PSD) is a prescribers (usually written) instruction that enables a dietitian to supply or administer a medicine to a named patient.

The BDA has published practice guidance to support members in managing medicines under PGDs/PSDs[2]. In addition, dietitians have extensive experience of the safe and effective use of medicines, and they are professionally responsible for ensuring that they adhere to standards regarding supply and administration of medicines set by The National Institute of Clinical Excellence (NICE)[3].

Although dietitians do engage in short-term acute interventions they more commonly work as members of multi-disciplinary teams with patients who have long-term conditions. However, the National Institute for Health and Care Excellence (NICE) states that PGDs should not be used in the treatment of long-term conditions[3].

While the existing mechanisms have helped to improve the effectiveness of care for some patients, there is potential for dietitians to have a greater impact and additional benefits if they were enabled to practice with supplementary prescribing rights.

3.6 Education programmes and continuous professional development for supplementary prescribers

Currently, non-medical prescribing training is multi-professional and provided as an integrated programme for both independent and supplementary prescribers. It is the relevant legislative framework which defines the mechanism(s) available to each profession and thus the assessment of course participants. For example nurses, pharmacists, physiotherapists and podiatrists who successfully complete an approved programme are able to practice as both independent and supplementary prescribers whilst radiographers are only currently able to practice as supplementary prescribers. If legislation was to be amended in line with the current proposal, dietitians would only be annotated and able to practice as supplementary prescribers.

The HCPC will have the authority to approve education programmes for the provision of dietetic supplementary prescribing training. The *Draft Outline Curriculum Framework for Education Programmes to Prepare Dietitians as Supplementary Prescribers* has been developed and is available on the NHS England consultation hub website here.

3.7 Eligibility for training as a dietetic supplementary prescriber

Not all dietitians would be expected to train to become supplementary prescribers. The safety of patients is paramount and the strict eligibility criteria for acceptance on supplementary prescribing education programmes reflect this.

In line with other professions who are able to train as supplementary prescribers (e.g. nurses, pharmacists, optometrists, physiotherapists, podiatrists and radiographers), it is proposed that all dietitians entrants to the training programme would need to meet the following requirements:

- Be registered with the Health and Care Professions Council as a dietitian.
- Be professionally practising in an environment where there is an identified need for the individual to regularly prescribe.

[2] The BDA (2009) *Working With Patient Group Directions and Protocols - Information on Medicines Legislation.* Birmingham: BDA

[3] National Institute for Health Care Excellence (NICE) (2014) *Medicine Practice Guidelines – Patient Group Directive.* London: NICE http://www.nice.org.uk/guidance/mpg2/resources/guidance-patient-group-directions-pdf

- Be able to demonstrate support from their employer/sponsor including confirmation that the entrant will have appropriate supervised practice in the clinical area in which they are expected to prescribe.
- Be able to demonstrate medicines and clinical governance arrangements are in place to support safe and effective supplementary prescribing.
- Have an approved medical practitioner to supervise and assess their clinical training as a supplementary prescriber.
- Have normally at least 3 years relevant post-qualification experience in the clinical area in which they will be prescribing.
- Be working at an advanced practitioner or equivalent level.
- Be able to demonstrate how they reflect on their own performance and take responsibility for their own Continuing Professional Development (CPD) including development of networks for support, reflection and learning.
- Provide evidence of a Disclosure and Barring Service (DBS) check within the last 3 years.

Dietetic supplementary prescribers would be required to have an annotation on the HCPC register as a supplementary prescriber. This would require them to maintain their skills and competence in keeping with the HCPC *Standards for Prescribing*[4].

3.8 Continuing professional development

Once registered, dietitians must undertake continuing professional development (CPD) and demonstrate that they continue to practise both safely and effectively within their changing scope of practice, in order to retain their registration. Registrants are required to maintain a continuous, up to- date and accurate portfolio of their CPD activities, which must demonstrate a mixture of learning activities relevant to current or future practice. The portfolio would declare how their CPD has contributed to both the quality of their practice and service delivery, while providing evidence as to how their CPD has benefited the service user.

The British Dietetic Association supports the HCPC in its requirement for dietitians to engage in CPD and provides advice and opportunities to its members regarding CPD activities required to achieve the standards set by the regulator.

The HCPC randomly audits the CPD of 2.5% of each registered profession on a two year cycle of registration renewal. Those registrants who are chosen for audit must submit a CPD profile to show how their CPD meets the minimum standards of the regulator. If introduced, dietetic supplementary prescribers would have a similar responsibility to keep up-to-date with clinical and professional developments in medicines use. The British Dietetic Association also makes it very clear to dietitians that they are required to maintain their competence to practice. This is an individual professional requirement and the employing authority would have a role in monitoring that this is the case by, for example, undertaking annual appraisal interviews.
The National Prescribing Centre (now the Medicines and Prescribing Centre at NICE) has developed a *Competency Framework for Health Professionals Using PGDs*[5] as a source of information and as a tool to reflect on practice and identify CPD needs.

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[4] Heath and Care Professions Council (HCPC) (2012) *Standards for Prescribing*. London: HCPC http://www.hcpc-uk.org/assets/documents/10004160Standardsforprescribing.pdf

Dietitians should also undertake information governance training as prescribed by the Health and Social Care Information Centre's (HSCIC) Information Governance Toolkit using the NHS Information Governance Training Tool.

3.9 Governance and safeguarding

The role of the HCPC is to protect the public. It does this by setting standards for a dietitians conduct, competence, training, character and health. A dietitian must be registered with the HCPC to practice within the UK and must meet the standards set. The HCPC can take action to protect the public where dietitians do not meet the necessary standards, including removing them from practice where appropriate. The HCPC will set standards for supplementary prescribing and will also approve the educational programmes which deliver training in supplementary prescribing. An advanced practice dietitian working in an appropriate role would only be able to act as a supplementary prescriber if they successfully complete an educational programme and then have their entry on the HCPC Register 'annotated' as a supplementary prescriber. By setting standards, approving programmes and annotating the Register, the HCPC can make sure that supplementary prescribers meet the standards necessary for safe and effective prescribing practice.

All professionals registered with the HCPC, including dietitians must always practice within their 'scope of practice'. A dietitian's scope of practice is the area of nutrition and dietetic practice in which they have the knowledge, skills and experience to undertake their role safely and effectively. This requirement to practice within scope would also extend to a dietitians supplementary prescribing practice. This means that a dietitian must only prescribe where they have the appropriate knowledge, skills and experience to do so safely and in accordance with the Clinical Management Plan (CMP). If they prescribed outside their scope of practice the HCPC could take action against them to protect the public.

The National Prescribing Centre (now the Medicines and Prescribing Centre at NICE) has developed *A Single Competency Framework for all Prescribers*[6] that applies to all existing prescribers and any professions that are granted prescribing responsibilities going forward, including dietitians.

Employers will retain responsibility for ensuring adequate skills, safety and appropriate environments for dietetic supplementary prescribing. Employers would also be responsible for ensuring that there is a need for a dietitian to undertake supplementary prescribing responsibilities, before the dietitian embarks on training – as well as ensuring that there is a role to regularly undertake supplementary prescribing post-training. The same standards would apply regardless of whether the dietitian is working in the NHS, independent or other settings.

3.9.1 Access to medical records

In the interest of patient safety, if supplementary prescribing is implemented it is essential that dietetic supplementary prescribers ensure they have up-to-date, relevant

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[5] National Prescribing Centre provided by NICE (2014) *Competency framework for health professionals using PGDs* . London: NICE http://www.nice.org.uk/guidance/mpg2/resources/mpg2-patient-group-directions7

[6] National Prescribing Centre provided by NICE (2012) *A Single Competency Framework for all Prescribers*. London: NICE http://www.npc.co.uk/improving_safety/improving_quality/resources/single_comp_framework_v2.pdf

and proportionate information about a patient's medical history and their medicines. The most accessible way to obtain this information is by consulting the patients Summary Care Record physically, electronically or by liaising directly with the patient's own GP, or the individual holding this information. That access will normally be with implied consent as dietitians are part of the team providing the treatment or care in question. However, where the patient has refused access or the information is especially sensitive, explicit consent should be sought. Supplementary prescribers must assure themselves that they have all relevant information in relation to the safe treatment of and safe prescribing to the individual patient and if there is any doubt, further information should be sought before making a decision whether to prescribe or not to prescribe for the patient. When necessary it should be explained to patients that all or part of the treatment cannot be given unless they grant access to the further information.

3.9.2 Updating the medical record

It is essential that any prescribing activity by dietitians is known to other healthcare professionals caring for the same patient, such as the patient's GP, and the patient is made aware or when necessary is made aware that this information will be shared. All prescribers are expected to update a patient's notes with their prescribing decisions contemporaneously if possible and in any event within 48 hours of the episode of care. This may be done electronically where possible, via secure email or electronic update to the GP's office where the patient's notes are held, or by fax to the GP's surgery, ensuring good information governance procedures are taken for its safe transfer. The Health and Social Care Information Centre have produced a detailed *Information Governance Toolkit*[7] regarding the safe transfer of patient data which list the most commonly used methods of communication along with the minimum standards required for safe and secure data transfer, which should be followed.

3.9.3 Clinical governance

Part of the assurance to be put in place for satisfying local clinical governance requirements will be the development of a non-medical prescribing policy that is approved according to local arrangements and frequently monitored and reviewed.

3.9.4 Antimicrobial resistance

Healthcare workers have a vital role to play in preserving the usefulness of antimicrobials by controlling and preventing the spread of infections that could require

[7] Health and Social Care Information Centre: *IG Toolkit*. https://www.igt.hscic.gov.uk/

antibiotic treatment. In line with all other prescribers, dietitians will also be required to consider antimicrobial stewardship and follow local policies for antibiotic use. The local policy is required to be based on national guidance and should be evidence-based, relevant to the local healthcare setting and take into account local antibiotic resistance patterns. The local policy should also cover diagnosis and treatment of common infections and prophylaxis of infection. The 2013 Public Health England (PHE) / Advisory Committee on Antimicrobial Resistance and Healthcare Associated Infection (ARHAI) *Antimicrobial Prescribing and Stewardship Competencies*[8] should be used by any prescriber to aid their professional development in relation to prescribing antimicrobials.

4 Benefits

[8] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies* https://www.gov.uk/government/publications/antimicrobial-prescribing-and-stewardship-competencies

Supplementary prescribing by dietitians can improve outcomes for patients, whilst also providing greater cost-effectiveness and increasing choice for patients and commissioners. Organisations would use supplementary prescribing where this would facilitate more effective care for the patient where supplementary prescribing would prevent deterioration in a patient's health, and where the appropriate use of medicines would improve outcomes for the patient.

Supplementary prescribing is intended for ongoing care and is therefore ideally suited for use by dietitians who work as part of the multi-disciplinary team in treating patients with conditions such as diabetes, renal disease, gastrointestinal disease and cancer.

For example:

Chronic Kidney Disease (CKD)

Renal consultants refer their patients to an advanced dietitian as the most appropriate healthcare professional to assess the patient's diet and advise on the optimum phosphate binder medication and dosage in relation to this. Poor phosphate management results in a higher risk of fractures in weakened bones and a hardening of the blood vessels (cardiovascular disease), leading to heart failure.

The frustration amongst doctors and patients alike is that the current system requires the patient's consultant or GP to initiate and adjust medicines as advised by the dietitian in a separate additional appointment/consultation. As such, there can be several days delay between the dietitian's appointment, and obtaining the prescription from the consultant or GP. Due to the need for additional appointments, patients often wait for their next routine review appointment with the consultant to get their prescription. This results in a continuation of suboptimal treatment and risk of further deterioration in the condition.

With supplementary prescribing rights the dietitian would be able to advise the patient on their diet, and supply the patient with a more tailored and timely prescription against an agreed clinical management plan (CMP), for dispensing at a local pharmacy without the need to refer back to a prescribing physician. This saves hospital/GP appointments, streamlines the patient pathway and improves the patient experience of coordinated seamless management.

Cystic Fibrosis (CF)

Patients with CF are required to take prescribed digestive enzymes from birth to help them digest food and get the nutrients they need, with every meal and snack. They also need to take vitamin supplements. Some of the symptoms of poorly managed CF are abdominal cramping, pain, nausea, constipation and diarrhoea and can lead to hospital admissions to manage the symptoms.

Advanced CF dietitians can manage patients who require pancreatic enzyme replacement therapy (PERT) and vitamins, however, a doctor is required to prescribe the PERT/vitamin preparations and any associated changes necessary as the condition progresses. The long term nature of CF means that patients will require regular review by the advanced CF dietitian. Adjustment of PERT medication is common to treat CF and manage acute symptoms. Currently the dietitian needs to request a prescription from the GP which can lead to delays in treatment, further exacerbation of symptoms and hospital admission.

Under supplementary prescribing, a clinical management plan would be developed at diagnosis, and the advanced dietitian could manage the PERT medication in relation to the patient's diet and lifestyle more timely and accurately. The benefits include prompt resolution to a particularly sensitive set of symptoms as well as preventing hospital admissions.

Intestinal Failure

Patients with intestinal failure (IF) do not have adequate bowel function to absorb enough fluid and nutrition to survive and rely on parenteral nutrition (PN). PN is a type of nutrition which is infused into the bloodstream to prevent dehydration and malnutrition and correct imbalances. Many patients will only require PN until the medical condition can be resolved, whilst others will require PN at home for life.

The advanced nutrition support dietitian completes a clinical and nutritional assessment, calculates the nutritional requirements including fluid, energy, nitrogen, electrolytes and duration of infusion, and according to the patient's blood results requests a prescription for PN to be made up in a pharmacy compounding unit.

Currently the dietitian needs to access an independent prescriber (usually a doctor) to generate the prescription advised by the dietitian. Getting the PN prescription signed is frequently a time limiting step to making the changes required, which can put the patient at risk of metabolic complications including malnutrition, dehydration/fluid overload and electrolyte abnormalities and deterioration in liver function.

If the advanced nutrition support dietitian could supplementary prescribe, a clinical management plan would be developed with the independent prescriber and agreed with the patient, which included the initiation and adjustments of the PN. This would mean the patient receives the correctly formulated PN for their needs, without unnecessary delay.

5 Approach to the consultation

5.1 The case for change

The development of non-medical prescribing by a wider range of healthcare professionals is part of a drive to make better use of their skills and to make it easier for patients to get access to the medicines that they need. Supplementary prescribing is an important part of developing health professionals' roles in delivering frontline care and patient-centred services.

The original policy objectives for the development of non-medical prescribing from 2000 related to the principles set out in *The NHS Plan: a plan for investment, a plan for reform*[9] including; improvements in patient care, choice and access; patient safety; better use of health professionals' skills; and more flexible team working across the NHS. In working towards these objectives, the NHS embarked on a graduated move to increase the scope and responsibilities of non-medical prescribing.

Non-medical prescribing continues to support the achievement of a number of current ambitions across the UK:

In England

The proposal to introduce supplementary prescribing by dietitians supports the achievement of ambitions set out in *Equity and Excellence: Liberating the NHS*[10], the *Urgent and Emergency Care review: end of phase 1 report*[11] and the *NHS Five Year Forward View*[12].

In Scotland

The Introduction of supplementary prescribing by dietitians will support the delivery of *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision* [13] and *Improving Outcomes by Shifting the Balance of Care: Improvement Framework*[14].

In Wales

Supplementary prescribing by dietitians supports the achievement of ambitions set out in *Together for Health: A Five Year Vision for the NHS in Wales*[15] and *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales*[16]

In Northern Ireland

The proposal supports the delivery of *Transforming Your Care: A Review of Health and Social care in Northern Ireland*[17] and *Transforming Your Care: Strategic Implementation Plan*[18]

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[9] Department of Health (2000) *The NHS Plan: a plan for investment, a plan for reform, London*
[10] Department of Health (2010) *Equity and Excellence: Liberating the NHS*, London
[11] NHS England (2013) *Urgent and Emergency Care Review: End of Phase 1 Report*, London
[12] NHS England (2014) *Five Year Forward View*, London
[13] NHS Scotland (2011*) Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision,* Edinburgh
[14] NHS Scotland (2009) *Improving Outcomes by Shifting the Balance of Care: Improvement Framework,* Edinburgh
[15] NHS Wales (2011) *Together for Health: A Five Year Vision for the NHS in Wales,* Cardiff
[16] NHS Wales (2012) *Achieving Excellence: The Quality Delivery Plan for the NHS in Wales,* Cardiff
[17] Northern Ireland Department of Health, Social Services and Public Safety (2011) *Transforming Your Care: A Review of Health and Social Care in Northern Ireland,* Belfast
[18] Northern Ireland Department of Health, Social Services and Public Safety (2013) *Transforming Your Care: Strategic Implementation Plan,* Belfast

5.2 Work to date

5.2.1 Scoping study[19]

An Allied Health Professions (AHPs) Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken in 2009 to establish whether there was evidence of service and patient need to support extending prescribing and medicines supply mechanisms available to AHPs.

The scoping project report found that AHPs use prescribing and medicines supply and administration mechanisms safely and effectively to improve patient care in clinical pathways where the application of the mechanisms are suited to the needs of patients.

The project also found that extension of prescribing and medicines supply for certain AHPs would improve the patient experience by allowing patients greater access, convenience and choice. The project found a strong case for extending independent prescribing to physiotherapists and podiatrists and a project was established to take the work forward, with amendments to legislation being made in 2013 to enable independent prescribing by appropriately trained physiotherapists and podiatrists.

The scoping project also found there was evidence supporting a progression to supplementary prescribing for dietitians and that further work should be undertaken, when appropriate, to consider the need for supplementary prescribing by dietitians; a project was established in October 2014 to take the work forward.

5.2.2 Developing the case of need

Following the recommendation in the 2009 Department of Health (DH) *Allied Health Professionals Prescribing and Medicines Supply Mechanisms Scoping Project Report*[19] that further work be undertaken, when appropriate, to consider the need for supplementary prescribing by dietitians, in October 2013 a AHP Medicines Project Team was established within NHS England to take this work forwards.

The British Dietetic Association had already established a Medicines Supply and Administration Group and this group helped gather the evidence from current clinical practice, in collaboration with clinical specialists in long term conditions, which was necessary to support the case of need. The NHS England AHP Medicines Project Team, in partnership with the British Dietetic Association developed a case of need for the progression to supplementary prescribing by dietitians based on improving quality of care for patients in relation to safety, clinical outcomes and experience, whilst also improving efficiency of service delivery and value for money. Approval of the cases of need was received from NHS England's Medical and Nursing Directorates Senior Management Teams in May 2014 and from the DH Non-Medical Prescribing Board in July 2014. Following this ministerial approval was received to commence preparation for a public consultation on the proposal for dietitians to supplementary prescribe.

[19] Department of Health (2009). *Allied Health Professionals Prescribing and Medicines Supply Mechanisms Scoping Project Report*. London: DH www.dh.gov.uk

6 Proposal for the introduction of supplementary prescribing by dietitians

The proposal in this consultation is to introduce supplementary prescribing by advanced dietitians who have successfully completed the appropriate training and education.

Supplementary prescribing is defined as: a voluntary prescribing partnership between the independent prescriber (usually a doctor) and the supplementary prescriber, to implement an agreed patient-specific clinical management plan with the patient's agreement.

Supplementary prescribing was introduced in April 2003 for nurses and pharmacists. It was extended to physiotherapists, chiropodists/podiatrists, radiographers and optometrists in May 2005.

6.1 Scope of supplementary prescribing

There are no legal restrictions on the clinical conditions which supplementary prescribers may treat. As supplementary prescribing requires a prescribing partnership and clinical management plan for the patient before it can begin, it is likely to be most useful in dealing with long-term medical conditions or long-term health needs. However, it will be for the independent prescriber with the supplementary prescriber to decide, in drawing up the clinical management plan, when supplementary prescribing will be appropriate. Unlike independent prescribing, there is no specific formulary or list of medicines for supplementary prescribing.

In the NHS, provided medicines are prescribable by the independent prescriber at NHS expense and are referred to in the patient's clinical management plan, supplementary prescribers are able to prescribe:

- All general sales list (GSL) medicines, pharmacy (P) medicines, appliances and devices, foods and other borderline substances approved by the Advisory Committee on Borderline Substances.
- All prescription only medicines (see below for specific provisions in relation to controlled drugs).
- Medicines for use outside of their licensed indications, i.e. 'off label' prescribing, 'black triangle' drugs and drugs marked 'less suitable for prescribing' in the 'British National Formulary' (BNF).
- Unlicensed medicines.

Amendments to the Home Office's Misuse of Drugs Regulations (2001), which came into force in March 2005, allow supplementary prescribers to prescribe all controlled drugs listed in a CMP, except those listed in Schedule 1 of the (2001) Regulations, which are not intended for medicinal use.

Question 1: Should amendments to legislation be made to enable dietitians to supplementary prescribe?

6.2 Additional information

The following questions invite additional information relevant to this proposal.

Question 2: Do you have any additional information as to why the proposal for supplementary prescribing by dietitians SHOULD go forward?

Question 3: Do you have any additional information as to why the proposal for supplementary prescribing by dietitians SHOULD NOT go forward?

6.3 Supporting documents: impact assessment, practice guidance and education curriculum framework

6.3.1 Impact assessment

Impact assessments (IA) are an integral part of the policy making process; the purpose of an IA is to focus on why intervention is necessary, what impact the policy change is likely to have, highlighting costs, benefits and risks. *The Consultation Stage Impact Assessment* is available on the NHS England consultation hub website here and contains the available evidence of the actual (where available) and estimated costs and benefits of the introduction of supplementary prescribing by dietitians. The consultation is an opportunity to gather additional evidence to further inform the costs, benefits and risks of the proposal.

Question 4: Does the 'Consultation Stage Impact Assessment' give a realistic indication of the likely costs, benefits and risks of the proposal?

6.3.2 Practice guidance

The proposed *Practice Guidance in the Safe Use of Medicines for Dietetic Supplementary Prescribers* has been developed by the British Dietetic Association and provides information which should underpin the decision-making and actions of dietitians who are annotated with the HCPC as supplementary prescribers. The proposed practice guidance can be accessed on the NHS England consultation hub website here.

This document is 'guidance'. Guidance is information which a dietitian has a duty to consider and is expected to take into account as part of their decision making process. The practice guidance document also provides advice on the behaviours and conduct expected of dietetic supplementary prescribers. A dietetic supplementary prescriber will be expected to justify any decision to act outside the guidance.

The consultation is an opportunity to acquire feedback and comments on the guidance developed and therefore the practice guidance document will remain in draft form until the consultation closes, when amendments will be made in line with the responses received and final versions published as appropriate.

Question 5: Do you have any comments on the proposed practice guidance for dietetic supplementary prescribers?

6.3.3 Education curriculum frameworks

The British Dietetic Association have worked in partnership with several other AHP professional bodies to develop a draft outline curriculum aimed at education providers intending to develop education programmes and individuals interested in education programmes for; dietitians to fulfil the requirements for annotation on the HCPC register as supplementary prescribers. *The Draft Outline Curriculum Framework for Education Programmes to Prepare Dietitians as Supplementary Prescribers* can be accessed on the NHS England consultation hub website here.

The alignment of the outline curriculum framework with the *Single Competency Framework for All Prescribers*[20] provides clear and consistent competencies for education providers in the development of supplementary prescribing education programmes. The programmes will be subject to approval and monitoring by the HCPC against the standards that it sets. Dietitians who successfully complete an approved programme are able to apply for annotation on the HCPC register as a supplementary prescriber.

The consultation is an opportunity to gain feedback and comments on the outline curriculum framework which will remain in draft form until the consultation closes, when amendments will be made in line with the responses received and final versions published as appropriate.

Question 6:	Do you have any comments on the 'Draft Outline Curriculum Framework for Education Programmes to Prepare Dietitians as Supplementary Prescribers'?

[20] National Prescribing Centre provided by NICE (2012) *A Single Competency Framework for all Prescribers*. London: NICE http://www.npc.co.uk/improving_safety/improving_quality/resources/single_comp_framework_v2.pdf

6.4 Equality

Dietitians have a responsibility to contribute to equality in healthcare by working towards eliminating discrimination and reducing inequalities in care. The BDA communicates clear values and principles about equality and fairness. All members of the dietetic workforce are required to work within the HCPC standards of conduct performance and ethics, and the BDA Code of Professional Conduct which makes clear these expectations.

Discussions held with key stakeholders including the professional bodies, regulators, MHRA, DH, clinicians, pharmacists, allied health professionals, service managers, educationalists, commissioners and service users highlighted the potential for supplementary prescribing by dietitians to improve access to medicines for groups within the community or home and in particular within rural areas and for vulnerable groups such as the homeless and travellers. The introduction of supplementary prescribing also has the potential to streamline care for other groups including for older people and those with disabilities.

At present dietitians are restricted by the requirement for a doctor to agree and prescribe the medicines a patient requires. This can result in additional appointments and delays in patients receiving the required medications. This is particularly problematic in rural and remote communities where access to a GP or doctor may not be practical. The introduction of supplementary prescribing by dietitians will enable innovative care pathway redesign. A dietetic supplementary prescriber would be able to treat patients directly and prescribe the required medications (in line with the patient's clinical management plan) at the time, reducing cost, time and travel for patients. This will be particularly beneficial for groups in rural and remote locations, travellers, small community hospitals or specialist clinics or services.

Specific groups such as older people and people with disabilities can benefit through avoiding the need for additional appointments to obtain a prescription. Vulnerable groups such as homeless people may not be registered with a GP. Dietitians working as supplementary prescribers can play a role in delivering services for such groups.

As autonomous practitioners, dietetic supplementary prescribers would be able to work in a much more flexible way. As the proposed changes to regulations will increase flexibility of access to services and the way in which services can be delivered it is assumed that there will be a benefit to any existing inequalities. However, raising awareness of clinicians in considering equality characteristic groups in the development of service re-design would ensure that groups are not inadvertently disadvantaged. Within a local context service providers and commissioners can use service redesign to address specific characteristics of equality and the needs of specific groups.

Question 7: Do you have any comments on how this proposal may impact either positively or negatively on specific equality characteristics, particularly concerning; disability, ethnicity, gender, sexual orientation, age, religion or belief, and human rights?

Question 8: Do you have any comments on how this proposal may impact either positively or negatively on any specific groups e.g. students, travellers, immigrants, children, offenders?

7.1 How to respond

You can respond in one of the following ways:

- By completing the **online consultation** here
- Download and print a copy of the consultation response form here. Send your responses to George Hilton, AHP Medicines Project Team, NHS England, 5W20, Quarry House, Leeds, LS2 7UE
- Alternatively, you may request a copy of the consultation response form to be posted to you. Please contact: enquiries.ahp@nhs.net

A summary version of this consultation document is also available here and can be requested in alternative formats, such as easy read, Welsh language, large print and audio. Please contact enquiries.ahp@nhs.net

This consultation remains open for eight weeks and responses should be sent to arrive no later than **24 April 2015.**

7.2 Comments on the consultation process itself

If you have any concerns or comments which you would like to share relating specifically to the consultation process itself please contact -

Address*: George Hilton
AHP Medicines Project Team
NHS England
5W20, Quarry House
Leeds
LS2 7UE

e-mail: enquiries.ahp@nhs.net

***Please do not send consultation responses to this address**

8 Next steps

Following the close of the consultation, the Commission on Human Medicines (CHM) will be asked to consider the proposals in the light of the comments received. CHM's advice will be conveyed to Ministers. Subject to the agreement of Ministers, the Medicines and Healthcare products Regulatory Agency (MHRA) will then make the necessary amendments to medicines legislation.

It is estimated that if all elements of the proposal were approved and all relevant organisations are in a position to complete their elements of the work at the earliest possible point without delay, the first intake of dietitians on a supplementary prescribing education programme could be in 2016.

Part of the drive to enable supplementary prescribing by dietitians is the opportunities it gives for service re-design to improve patient centred practice. NHS England will be working with partners including the Devolved Administrations, and in particular, commissioners to steer the necessary changes.

9 Appendices

9.1 Appendix A: Role of the professional body

The British Dietetic Association (BDA) is the only body in the UK representing the whole of the dietetic workforce. It has 7985 members, representing 80% of the dietetic workforce in membership. It shapes the healthcare agenda and leads opinion on a wide range of professional issues, as well as setting standards and developing policies that are adopted internationally. It is also the professional body representing the professional, educational, public and workplace interests of its members. The BDA communicates in the best interests of dietitians to national organisations, stakeholders and partners, and to influence and lobby government policy.

The BDA has a commitment to assist its members in upholding the highest standards of professional practice, and to develop themselves continually throughout their working lives, by providing CPD opportunities, courses, guidance, nutrition& dietetic texts and the Journal of Human Nutrition and Dietetics.

Membership is open to anyone working in dietetics, in nutrition, or who has an interest in diet or food, throughout the world. The BDA represents the whole of the dietetic workforce - practitioners, researchers, educators, support workers and students. The BDA works in non-commercial partnership and alliances with other professional bodies, consumer groups, health charities, food interest groups and the food industry

The BDA also provides its members with Professional Indemnity Insurance for their day to day practice. This cover, alongside robust industrial relations support through the Trade Union ensures completely independent and personalised support and cover

The BDA strives to push the boundaries of nutrition and dietetics for the benefit of dietitians and their service users, and ensures that its members work in a safe and fair environment.

https://www.bda.uk.com

9.2 Appendix B: The mechanisms for the prescribing, supply and administration of medicines

The mechanisms available for the prescribing, supply and administration of medicines are:

- **Patient Specific Directions** (PSDs)
- **Patient Group Directions** (PGDs)
- **Specific Exemptions** covering supply or administration - as defined in medicines legislation applicable to chiropodists/podiatrists, midwives, optometrists and paramedics
- **Supplementary prescribing** by nurses, pharmacists, optometrists, physiotherapists, radiographers and chiropodists/podiatrists
- **Independent Prescribing** – doctors, nurses, pharmacists, optometrists, physiotherapists and podiatrists only

Patient Specific Direction (PSD)

A Patient Specific Direction is the traditional written instruction, from a prescriber, for medicines to be supplied or administered to a named patient after the prescriber has assessed the patient on an individual basis. The majority of medicines are still supplied or administered using this process.

All allied health professionals (AHPs) including dietitians can supply or administer a medicine following a patient-specific direction from a prescriber.

Patient Group Directions (PGDs)

A Patient Group Direction (PGD) is a written instruction for the supply or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may, or may not, be individually identified before presenting for treatment. This should not be interpreted as indicating that the patient must not be identified; patients may or may not be identified, depending on the circumstances.

A PGD is signed by a doctor and a pharmacist and must meet certain legal criteria. Each PGD must be approved by the organisation in which it is to be used. PGDs can also be developed in specific non-NHS settings such as independent hospitals and clinics registered with the Care Quality Commission and prisons.

PGDs can be used for the supply or administration of medicines by a number of regulated healthcare professions including dietitians.

Specific Exemptions Covering Supply or Administration

A number of health professions – for example, midwives, podiatrists, optometrists and paramedics – have specific exemptions in medicines legislation to sell, supply or administer medicines. An exemption enables the relevant health professional to sell or supply the specific medicine listed in the exemption without a prescription. For example, registered podiatrists have exemptions under medicines legislation for parenteral administration of a number of prescription only medicines (POMs), including local analgesias and some painkillers. There are currently NO Exemptions that apply to dietitians.

Supplementary Prescribing

Supplementary prescribing is a voluntary prescribing partnership between the independent prescriber (doctor or dentist) and supplementary prescriber, to implement an agreed patient-specific written clinical management plan (CMP), with the patient's agreement.

Following documentation within the CMP, the supplementary prescriber may prescribe any medicine for the patient that is referred to in the plan, until the next review with the independent prescriber. There is no formulary for supplementary prescribing, and no restrictions on the medical conditions that can be managed under these arrangements. It can be appropriate for example, in the management of long-term conditions.

Supplementary prescribing was introduced in April 2003 for nurses and pharmacists. It was extended to physiotherapists, chiropodists/podiatrists, radiographers and optometrists in May 2005.

Independent Prescribing

Independent prescribing means that the prescriber takes responsibility for the clinical assessment of the patient, establishing a diagnosis and the clinical management required, as well as prescribing where necessary and the appropriateness of any prescription.

From 1 May 2006 Nurse Independent Prescribing (formerly Extended Formulary Nurse Prescribing) was expanded. This change enabled nurses to prescribe any licensed medicine for any medical condition that a nurse prescriber is competent to treat, including some Controlled Drugs. It allows virtually any licensed medicine in the British National Formulary (see part XVIIB (ii) of the Drug Tariff) to be prescribed.

Pharmacist Independent Prescribing was also introduced on 1 May 2006 and enables pharmacists to prescribe any licensed medicine for any medical condition that a pharmacist prescriber is competent to treat, this allows access to virtually the whole of the British National Formulary.

Further changes to legislation in 2009 allowed nurse and pharmacist independent prescribers to prescribe unlicensed medicines.

Legislation to enable optometrists to train as independent prescribers came into force in June 2008 and more recently changes to legislation were made in August 2013 to allow physiotherapists and podiatrists to train as independent prescribers

9.3 Appendix C: Contributors

Membership of NHS England Allied Health Professions Medicines Project Board

Representative	Organisation
Lesley-Anne Baxter	Allied Health Professions Federation
Charlotte Beardmore	Society and College of Radiographers
Jan Beattie	Scottish Government
Sarah Billington	Care Quality Commission
Julie Bishop	MHRA
Rebecca Blessing	Department of Health
Sara Bordoley	NHS England
Nicole Casey	Health and Care Professions Council
Bill Davidson	Patient and public representative
Hannah-Rose Douglas	NHS England
Anne Duffy	Department of Health, Social Services & Public Safety *(Northern Ireland)*
Catherine Duggan	Royal Pharmaceutical Society
Gerry Egan	College of Paramedics
Sue Faulding	Health and Social Care Information Centre
Katherine Gough	Dorset Clinical Commissioning Group
Linda Hindle	Public Health England
Barry Hunt	College of Paramedics *(advisory)*
Steve Irving	Association of Ambulance Chief Executives
Cathryn James	Association of Ambulance Chief Executives
Elisabeth Jelfs	Council of Deans
Sue Kellie	British Dietetic Association
Helen Marriott (Project Lead)	NHS England
Rowena McNamara	British and Irish Orthoptic Society
Shelagh Morris	NHS England
Graham Prestwich	Patient and public representative
Suzanne Rastrick (Co-Chair)	NHS England
Patricia Saunders	Health Education England
Alison Strode	Welsh Government
Duncan Stroud	NHS England
Bruce Warner (Co-Chair)	NHS England
Hazel Winning	Department of Health, Social Services & Public Safety *(Northern Ireland)*

9.4 Appendix D: Frequently asked questions

1. What is non-medical prescribing?

Over recent years, changes to the law have permitted a number of professions, other than doctors and dentists to play an increasing role in prescribing and supply of medicines for their patients without the authority of a doctor or dentist. Non-medical prescribers are professions other than doctors and dentists that have a level of prescribing responsibilities. This includes nurse, pharmacist optometrist, physiotherapist and podiatrist independent prescribing and radiotherapy supplementary prescribing. There are now over 25,000 qualified nurse independent prescribers and around 2,000 qualified pharmacists' independent prescribers.

2. What are the current arrangements for allied health professionals?

The arrangements currently in place are complex. Independent prescribing training is available to appropriately physiotherapists and podiatrists. Supplementary prescribing training is available to appropriately trained physiotherapists, podiatrists and radiographers. Patient Group Directions for the supply and administration of medicine are available to all Allied Health Professionals, with the exception of art therapists, music therapists and drama therapists. Exemptions are used by podiatrists and paramedics and all the professionals can supply and administer medicines under Patient Specific Directions.

3. What is supplementary prescribing?

Supplementary prescribing is a voluntary partnership between a doctor or dentist, a supplementary prescriber and a patient to implement an agreed patient-specific clinical management plan (CMP). This process is specific to the patient and professionals named on the CMP.

4. What is a clinical management plan (CMP)?

Before supplementary prescribing can take place, it is obligatory for an agreed CMP to be in place (written or electronic) relating to a named patient and to that patient's specific condition(s) to be managed by the supplementary prescriber. This will be developed with the Medical Prescriber, agreed with the patient and included in the patient record.

Regulations specify that the CMP must include the following:

- The name of the patient to whom the plan relates
- The illness or conditions which may be treated by the supplementary prescriber
- The date on which the plan is to take effect, and when it is to be reviewed by the doctor or dentist who is party to the plan
- Reference to the class or description of medicines or types of appliances which may be prescribed or administered under the plan
- Any restrictions or limitations as to the strength or dose of any medicine which may be prescribed or administered under the plan
- Relevant warnings about known sensitivities of the patient to, or known difficulties of the patient with, particular medicines or appliances

Also the arrangements for notification of:

- Suspected or known reactions to any medicine which may be prescribed or administered under the plan, and suspected or known adverse reactions to any other medicine taken at the same time as any medicine prescribed or administered under the plan.
- Incidents occurring with the appliance which might lead, might have led or has led to the death or serious deterioration of state of health of the patient
- Circumstances in which the supplementary prescriber should refer to, or seek the advice of, the doctor or dentist who is party to the plan.

5. Why extend supplementary prescribing responsibilities to dietitians?

Dietitians have been able to supply and administer prescription only medicines under PGDs and PSDs since 2003. However, they are of limited benefit due to the broad scope of dietetics and the narrow remit of PGDs. These existing arrangements for supply and administration of medicines do not best support the needs of patients, particularly those with long term conditions, where frequent change and adjustment of medicines and dosages are required. Supplementary prescribing is therefore the most appropriate mechanism, and provides greater benefit for patient care. With supplementary prescribing, the creation of innovative new care pathways will be supported which will result in improved outcomes for patients by reducing delays in care, improving compliance in taking medicines, and improving patient experience through increasing access, convenience, choice and improving productivity.

6. Why introduce supplementary prescribing rights for dietitians now?

In 2009, the Allied Health Professions (AHPs) Prescribing and Medicines Supply Mechanisms Scoping Project was undertaken to establish whether there was evidence of service and patient need to support extending prescribing and medicines supply mechanisms available to AHPs. The project found there was evidence supporting a progression to supplementary prescribing for dietitians and that further work should be undertaken, when appropriate, to consider the need for supplementary prescribing by dietitians. The work was not progressed to a public consultation at that time primarily due to capacity and resource issues. A project team was established within NHS England in October 2013 to take the work forward.

7. What training will dietitians receive?

Comprehensive and stringent education programmes will be put in place to ensure that dietitians are competent, confident and educated to supplementary prescribe medicines. A *Draft Outline Curriculum Framework for Education Programmes to Prepare Dietitians as Supplementary Prescribers* has been developed for the training of supplementary prescribers and can be accessed on the NHS England website here. Non-medical prescribing is targeted at advanced practitioners only– not all advanced dietitians will meet the entry requirements for training as supplementary prescribers.

8. Is it safe to allow dietitians to become supplementary prescribers?

Patient safety is of paramount importance. Dietitians have a long relationship with medicines. Due to the complex interaction between nutrition and drugs in many disease states, dietitians need to have a high level of pharmaceutical knowledge regarding the impact of a wide range of medications on nutritional status and the medical conditions they are used to treat. Dietitian supplementary prescribers would be advanced practitioners employed in roles relevant to supplementary prescribing, with knowledge and skills specific to their clinical role. Continuing professional development would include activities relevant to ensuring safe use of medicines including prescribing within their role enabling them to retain their specific registration with the HCPC. Under current medicines legislation, dietitians already safely supply and administer a range of medicines under Patient Group Directions and Patient Specific Directions. Increasing access to prescribing has the potential to improve patient safety by reducing delays in care, improving the use of medicines and creating clear lines of professional responsibility.

9. What is advanced practice in dietetics?

Advanced dietitians roles function at the forefront of nutrition and dietetics research and practice across a variety of settings – clinical, public health, research, education, private practice, acute and community. They work collaboratively as integral members of multi-disciplinary teams.

An advanced dietitian demonstrates highly developed expert knowledge and skills within their field of practice, including outside traditional role boundaries, and will demonstrate originality and creativity in the application of these. The advanced dietitian will manage complex issues in situations where there is incomplete data, conflicting priorities (clinical, environmental, organisational, strategic, political or policy) and often no existing guidance. The advanced dietitian will strive to shape and influence the environment at different levels including local, regional, professional and national, in order to influence outcomes for their service users.

10. On the entry requirements for the education programmes, the Disclosure and Barring Service (DBS) requirement is to "*provide evidence of a DBS check within the last 3 years*" Why is this?

The Criminal Records Bureau (CRB) and the Independent Safeguarding Authority (ISA) have merged to become the Disclosure and Barring Service (DBS). The DBS enables organisations in the public, private and voluntary sectors to make safer recruitment decisions by identifying candidates who may be unsuitable for certain work, especially that involve children or vulnerable adults.

Entry requirements for nurses and pharmacists undertaking courses to become supplementary and/or independent prescribers include the need to provide proof of a DBS check undertaken within the last three years and so this requirement will bring dietitians into line with that which is demanded of nurses and pharmacists.

11. How will dietetic supplementary prescribers undertake CPD and maintain their competency in prescribing?

Dietitians are required to undertake CPD relevant to their practice to maintain and demonstrate continuing competence. To maintain registration with the HCPC, dietitians must sign a professional declaration once every two years to confirm that they continue to meet the HCPC's standards of proficiency for safe and effective practice and that they meet the HCPC's standards for continuing professional development. Dietitian supplementary prescribers are required to demonstrate their continuing professional competence with regard to their prescribing practice.

Examples of CPD activities for dietitian supplementary prescribers will include attending and presenting at conferences and study days, Subscribing to MHRA and NICE alerts and receiving updates of information from local pharmacy. Other examples are attending regular meetings with medical and non-medical prescribers, being part of local multidisciplinary non-medical prescribing (NMP) group and attending local NMP update days and undertaking self-reflection, peer reviewing, supervising and teaching.

12. Will prescribing costs increase?

This is not anticipated. There is no general evidence to indicate that prescribing by other professionals, e.g. nurses and pharmacists, has increased prescribing costs.

13. Will dietitians working outside the NHS, for example, in private practice or voluntary organisations be able to become supplementary prescribers?

Yes. Provided they meet the entry requirements of the education programme, including demonstrating they have appropriate governance arrangements in place for their role as a supplementary prescriber.

14. Will a dietitian working in one clinical area as a supplementary prescriber be able to supplementary prescribe if they move to a new clinical area?

The dietitian would need to meet the HCPC standards for continued registration which includes that with any move outside current scope of practice the dietitian must be certain that they are capable of working safely and effectively including undertaking any necessary training and experience. If the new clinical area requires the dietitian to work as a supplementary prescriber then the organisation and the dietitian would need to ensure that all local clinical governance arrangements are in place before the dietitian works as a supplementary prescriber.

15. Will dietitian supplementary prescribers be able to prescribe medicines to be mixed prior to administration?

The law defines "mixing" as the combination of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient. Dietitian supplementary prescribers will be able to prescribe medicines to be mixed prior to administration as long as they are included on the Clinical Management Plan, developed in agreement with the medical prescriber.

16. Will dietitian supplementary prescribers be able to prescribe unlicensed medicines?

When two licensed medicines are mixed together they produce a medicine that is unlicensed. This is common in parenteral nutrition where the individual elements that are necessary to meet the patients daily nutritional requirements, e.g. carbohydrates, lipids, amino acids, vitamins and minerals, are licensed individually, but must then be mixed to create an unlicensed bag for intravenous administration to the patient. Dietitian supplementary prescribers will be able to prescribe medicines to be mixed prior to administration provided the elements to be mixed are listed on the CMP, and developed in agreement with the medical prescriber.

17. Will dietitian supplementary prescribers be able to prescribe oral nutrition supplements (ONS)?

Yes dietitians who become supplementary prescribers will be able to prescribe ONS to manage disease related malnutrition. However, management of malnutrition using ONS is an entry level skill and not limited to advanced practice. As such, advanced practitioners will only prescribe ONS as an adjunct to their core practice in medicines for long term conditions. It is anticipated that ONS, currently managed by dietitians from entry level onwards, will be primarily supplied to the patient through other supply and administration frameworks.

18. How will we ensure supplementary prescribing by dietitians will not increase antimicrobial resistance and contribute to over prescribing of medication?

Healthcare workers have a vital role to play in preserving the usefulness of antimicrobials by controlling and preventing the spread of microbes. All dietetic supplementary prescribers will be required to work within their scope of practice and the PHE/ARHAI *Antimicrobial Prescribing and Stewardship Competencies*[21], and are professionally responsible for ensuring that they adhere to standards of supply and administration of all medicines, as set by the MHRA and NICE. They will also be required to follow local policies for antimicrobial use. There is a specific competence included in the *Draft Outline Curriculum Framework for Education Programmes to Prepare Dietitians as Supplementary Prescribers* which the HCPC will use to approve training programmes. Prescribing is not an activity that occurs in isolation so dietitian supplementary prescribers will communicate with other practitioners involved in the care of patients.

19. How will a dietitian communicate their prescribing decisions to other practitioners involved in a patients care?

Dietitian supplementary prescribers will need to communicate effectively with other practitioners involved in the care of patients within and across the boundaries of NHS and private practice and use the most appropriate media available. When sending patient data, it is vital that the data is secure, and that the risk of data loss (including misdirection) is minimised.

[21] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies* https://www.gov.uk/government/publications/antimicrobial-prescribing-and-stewardship-competencies

The Health and Social Care Information Centre gives detailed guidance on information security[22], and detailed and regularly updated information security requirements are set out in the HSCIC's *Information Governance Toolkit*[23].

20. Why is the consultation for introducing supplementary prescribing by dietitians only running for 8 weeks?

Before supplementary prescribing can take place, it is obligatory for an agreed CMP to be in place. As such there is less professional autonomy than a practitioner using an independent prescribing mechanism. It was therefore recommended by the Medicines and Healthcare Regulatory Agency (MHRA) that an 8 week consultation period was appropriate.

21. What happens next?

Following close of the consultation, responses received will be collated and analysed. The CHM and the MHRA will evaluate the responses and make recommendation(s) to Ministers. If the recommendation(s) is/are to amend legislation to enable dietitians to train as supplementary prescribers and Ministers agree to the recommendation(s), MHRA will take forward work to make the relevant amendments.

22. When will this legislation come into effect?

Due to the procedures involved in achieving the necessary changes to legislation, it is not possible at this stage to give a definitive timeframe for these changes and for the subsequent training programmes to be developed. The first intake of dietitians on a supplementary prescribing programme would not be before 2016. We will, however keep people informed of the progress of the project as it develops.

23. Why was an equality analysis NOT undertaken for this public consultation?

The general equality duty that is set out in the Equality Act (2010) requires public authorities, in the exercise of their functions, to have due regard for the need to:

- Eliminate unlawful discrimination, harassment, victimisation and other conduct prohibited by the Act
- Advance equality of opportunity between people who share a protected characteristic and those who do not
- Foster good relations between people who share a protected characteristic and those who do not

Under the previous public sector equality duties (for race, disability and gender), public bodies sometimes took unnecessary, inappropriate, disproportionate or counter-productive action in the name of equality. The new Equality Duty aims to reverse the overly-bureaucratic and burdensome approach often used under the previous duties, so that the focus is on performance, not process and therefore does not impose a legal requirement to conduct an Equality Impact Assessment, nor is there any practical need to conduct one. Compliance with the Equality Duty (2010) involves consciously thinking

[22] Health and Social Care Information Centre: *Principles of information security* http://systems.hscic.gov.uk/infogov/security

[23] Health and Social Care Information Centre: *IG Toolkit*. https://www.igt.hscic.gov.uk/

about the three aims of the Equality Duty as part of the process of decision-making and has been an integral part of the development of this consultation and all of the supporting documentation. The responses to the equality questions posed in this consultation will feed into the ongoing equality analysis that will in turn inform the policy decisions made.

10 Glossary

Term	Definition
Allied health professions:	Allied Health Professions are a group of professionals who work in health and social care. They prevent disease, diagnose, treat and rehabilitate patients of all ages and all specialities. Together with a range of technical and support staff they deliver patient care, rehabilitation, treatment, diagnostics and health improvement to restore and maintain physical, sensory, psychological, cognitive and social functions. Dietitians, orthoptists, paramedics and radiographers are Allied Health Professionals
British Dietetic Association (BDA):	The British Dietetic Association (BDA) is the professional body representing the dietetic workforce including, practitioners, assistant practitioners, support workers and student dietitians in the United Kingdom.
Commissioners:	NHS commissioners and Clinical Commissioning Groups (CCGs) are responsible for planning and purchasing healthcare services for their local population. They work with local providers to organise and deliver healthcare services which better meet the needs of patients.
Commission on Human Medicines (CHM):	The CHM advises ministers on the safety, efficacy and quality of medicinal products.CHM is an advisory non-departmental public body, sponsored by the Department of Health.
Controlled drugs:	Drugs that are listed in the United Kingdom Misuse of Drugs Act 1971 which can be prescribed to patients for medicinal purposes – e.g. morphine for pain relief.
Department of Health (DH) England:	The Department of Health England helps people to live better for longer. They lead, shape and fund health and care in England, making sure people have the support, care and treatment they need, with the compassion, respect and dignity they deserve.
Department of Health, Social Services and Public Safety (Northern Ireland):	It is the Department's mission to improve the health and social well-being of the people of Northern Ireland. It endeavours to do so by: • Leading a major programme of cross-government action to improve the health and well-being of the population and reduce health inequalities. This includes interventions involving health promotion and education to encourage people to adopt activities, behaviours and attitudes which lead to better health and well-being. The aim is a population much more engaged in ensuring its own health and well-being.

- Ensuring the provision of appropriate health and social care services, both in clinical settings such as hospitals and GPs' surgeries, and in the community through nursing, social work and other professional services.

Dietitian: Dietitians assess, diagnose and treat diet and nutrition problems at an individual and wider public health level. They ensure patients dietary intake has sufficient energy and nutrients to maintain normal physiological functions; correct nutritional imbalances; and advise on nutritional intake that best protects against the risk, or progression, of disease.

Exemptions: Exemptions permit certain listed medicines to be sold, supplied and/or administered to patients by certain health professional groups. Exemptions are distinct from prescribing which requires the involvement of a pharmacist in the sale or supply of the medicine

Health and Care Professions Council (HCPC): The regulator of 16 different health and care professions including the allied health professions. It keeps a register of health and care professionals and is responsible for setting the standards of training, conduct, and competence for these professionals.

Independent prescriber: An independent prescriber is a practitioner responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for decisions about the clinical management, including the prescription of medicines.

Licensed medicines: A medicine must be granted a licence by the appropriate body before it can be widely used in the UK. A licence indicates all the proper checks have been carried out and the product works for the purpose it is intended for

MHRA: The Medicines and Healthcare Products Regulatory Agency (MHRA) is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. The MHRA is an executive agency of the Department of Health

Mixing of medicines: The combination of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient.

Non-Medical Prescribing (NMP): NMP is prescribing by specially trained health care professionals who are not doctors or dentists. They include nurses, pharmacists, physiotherapists, podiatrists and radiographers. They work within their clinical competence as independent and/or supplementary prescribers.

Patient Group Direction (PGD):	A written instruction for the supply and/or administration of a licensed medicine (or medicines) in an identified clinical situation, where the patient may not be individually identified before presenting for treatment. Each PGD must be signed by both a doctor and pharmacist; and approved by the organisation in which it is to be used.
Patient Specific Direction (PSD):	A prescribers (usually written) instruction for medicines to be supplied and/or administered to a named patient after the prescriber has assessed the patient on an individual basis.
Scottish Government Health and Social Care Directorate:	The Scottish Government Health and Social Care Directorate aims to help people sustain and improve their health, especially in disadvantaged communities, ensuring better, local and faster access to healthcare. The Directorate also allocates resources and sets the strategic direction for NHS Scotland, and is responsible for the development and implementation of health and social care policy.
Supplementary prescribing:	A voluntary prescribing partnership between the independent prescriber and the supplementary prescriber, to implement an agreed patient specific clinical management plan with the patient's agreement.
Welsh Department of Health and Social Services:	Is the devolved Government for Wales - working to help improve the lives of people in Wales and make the nation a better place in which to live and work. The aim is to promote, protect and improve the health and well-being of everyone in Wales by delivering high quality health and social care services, including funding NHS Wales and setting a strategic framework for adult and children's social care services. Where there are inequalities in health, work takes place across Government to tackle the social, economic and environmental influences that affect health and well-being.