

## Service Specification

**NB this document serves as the service specification for the NHS Diabetes Prevention Programme under the 2019 Framework Agreement, which is procured on a national basis. Highlighted text on page 21 will be varied according to contract area and this document will form Schedule 2A of the Call-off Contract.**

**All defined terms set out in this document reflect the definitions contained within the Call-off Contract unless defined in this document**

<b>Service No.</b>	1
<b>Service</b>	Provision of behavioural interventions for people with non-diabetic hyperglycaemia
<b>Commissioner Lead</b>	NHS England
<b>Provider Lead</b>	
<b>Period</b>	
<b>Date of Review</b>	

### 1. Population Needs

#### 1.1 National / local context and evidence base

##### 1.1.1 Introduction to the NHS Diabetes Prevention Programme

The NHS Diabetes Prevention Programme ("**NDPP**"), publically branded as Healthier You; the NHS Diabetes Prevention Programme was announced in the NHS Five Year Forward View ("**FYFV**") published in October 2014. The FYFV set out an ambition to become the first country to implement at scale a national evidence-based diabetes prevention programme modelled on proven UK and international models, and linked where appropriate to the NHS Health Check.

Diabetes constitutes a major burden on public health and preventative action is necessary to prevent the onset of the condition for those at high risk. A report published by the National Cardiovascular Intelligence Network (NCVIN)<sup>1</sup> suggests that the average prevalence of non-diabetic hyperglycaemia in England is 10.7%, which equates to approximately five million people. The report describes how prevalence is higher among Black, Asian and Minority Ethnic groups (and onset is often at a younger age in these groups), and that prevalence increases with age and obesity.

The NDPP is a joint initiative between NHS England, Public Health England and Diabetes UK. It aims to deliver services at a large scale, for people already identified with non-diabetic hyperglycaemia who are therefore at high risk of developing Type 2 diabetes. High risk individuals will be offered a behavioural intervention (the "**Service**") to enable them to reduce their risk of developing Type 2 diabetes through weight loss, as a result of improved diet and increased levels of physical activity.

<sup>1</sup> National Cardiovascular Intelligence Network. 2015. NHS Diabetes Prevention Programme (NDPP) Non-diabetic hyperglycaemia. Public Health England.

In 2016 a framework agreement was implemented and mini-competitions initiated to implement a predominantly group based face-to-face service. Since then, contracts based on Sustainable Transformation Partnership ("**STP**") areas have been awarded covering the whole of England and the current framework agreement will expire in March 2019.

Rates of referral and the volume of interventions procured across current contracts have varied according to a variety of local factors. A modelling assumption of 500 referrals per 100,000 population was used to estimate referral generation under current contracts. Under the new Framework Agreement the distribution of contracted interventions will be based more explicitly on the prevalence of non-diabetic hyperglycaemia, subject to confirmation at mini-competition.

Between 36% and 55% of people referred into current face to face contracts decline the service. Of those who participate, a further cohort of between 26% and 50%, depending on the contract area, do not progress onto the group based sessions. The Commissioner recognises that for a range of individuals there are barriers to committing to and attending a face to face intervention. Whilst the evidence base for remote or digital diabetes prevention services is yet to be fully established, such services provide an opportunity to extend access to prevention services for those people who decline or do not progress onto the face-to-face service. Under the new Framework Agreement the Service may include a remote/digital service (the "**Digital Service**"), if required by the Commissioner, that complements the face to face service (the "**Face-to-face Service**").

Alternative, remote delivery channels have been tested in other countries, notably the United States. Reviews of this evidence suggest that remote programmes may be effective for diabetes prevention, and have key potential benefits in terms of increased coverage and equity of access. For this reason, the Center for Disease Control in the United States has recognized and commissioned remote diabetes prevention programmes which follow the same curriculum as its face to face service since December 2016.

Evidence from diabetes structured education management shows that people learn in different ways and offering more flexible ways to learn has been shown to increase engagement in self-management and to deliver increased knowledge and confidence (Kings Fund level 2 review, Diabetes UK 2016).

The overriding principles will be that:

- all persons referred to the Service are offered the Face-to-face Service in the first instance; and
- the Provider must also offer the Digital Service to persons in the circumstances specified in this Schedule unless the Commissioner has specified that the Digital Service is not, or no longer, to be offered – see paragraph 3.10 of this Service Specification for further information.

Where the Provider is providing the Digital Service, the term "Service" refers to both the Digital Service and the Face-to-face Service. Where the Provider is not providing the Digital Service, the term "Service" relates only to the Face-to-face Service.

## 2. Outcomes

### 2.1 Expected outcomes of the NDPP

- Reduction in incidence of diabetes among Service Users as a result of the intervention;
- Reduction in weight of Service Users where they are overweight or obese, and the maintenance of a healthy weight; and
- To reduce blood glucose parameters (HbA1c or Fasting Plasma Glucose (FPG)) in Service Users at 12 months from referral and beyond.

## 3. Scope

### 3.1 Aims of the Service

The primary aim of the Service is to prevent Type 2 diabetes. All aspects of the Service should be delivered by the Provider in accordance with the NDPP outcomes and with the aim of achieving three core aims:

- Support people to achieve a healthy body weight, having appropriate regard to achievement of UK dietary recommendations related to fibre, fruit and vegetables, oily fish, saturated fat, salt and free sugars;<sup>2</sup>
- Achievement of the England Chief Medical Officer's (CMO) physical activity recommendations and a reduction in sedentary behaviour; and
- To maximise completion rates of Service Users, including across groups that share a protected characteristic.

The above goals are for the Service as a whole, and at an individual Service User level goals must be tailored to suit individual Service User requirements.

A secondary aim of the Service is to ensure sound data collection mechanisms to ensure that the effectiveness of the Service in reducing the long term microvascular and cardiovascular complications of Type 2 diabetes, as well as to reduce the associated higher mortality risk, can be assessed over time. It is also to establish the evidence base for the effectiveness of the Service in delivering outcomes.

A tertiary aim is to continue to build the evidence base around the effectiveness of remote or digital approaches to diabetes prevention.

### 3.2 Service description / care pathway

#### 3.2.1 Principles

The Provider will deliver the Service in accordance with the following principles:

- The Provider must provide the Service in accordance with this Schedule 2A and the Annexes and Appendices to this Schedule 2A;
- Delivery of the Service will be tailored to the circumstances and culture of Service Users and will be sensitive to different culinary traditions;
- The content of the sessions should aim to empower people at risk of diabetes to take a leading role in instituting and maintaining long-term behaviour changes;
- The Service must aim to ensure equal access by all Service User groups, reduce health inequalities and promote inclusion, tailoring the Service to support and target those with greatest need through a proportionate universalism approach and equality of access for people with protected characteristics under the Equality Act 2010;
- Access to the Face-to-face Service will accommodate the diverse needs of the target population in terms of availability, accessibility, customs and location, as far as possible;
- The Provider must build relationships and work with relevant local stakeholders (including local health economies and community sector organisations) to deliver a relevant and inclusive programme;
- The Provider should maximise the flexibility of their offering in order to increase reach for all, including communities who face the most barriers to access;

- The Provider should ensure Service User involvement and engagement in the evaluation and improvement of the Service;
- The Provider must engage proactively with primary care services whilst ensuring that the impact on workload for existing providers of primary care services is minimised;
- All individuals must be treated with courtesy, respect and an understanding of their needs;
- All individuals invited to participate in the Service must be offered the Face-to-face Service. The Digital Service must be offered in the circumstances set out in this Schedule unless the Commissioner has specified that the Digital Service is not, or no longer, to be offered – see paragraph 3.10 of this Service Specification for further information. The Commissioner may require the Provider to offer the Digital Service under additional circumstances and the Provider will offer the Digital Service in such other circumstances as notified by the Commissioner;
- All potential Service Users must be given adequate information on the benefits and risks, in a format which is accessible to them, to allow an informed decision to be made before participating in the Service;
- Those referred onto the Service must be effectively integrated across a pathway including between different providers of the Service, the NHS Health Check, primary care and secondary care;
- Ongoing improvements and adjustments will be made to the delivery of the Service as new evidence emerges both from national and international research and local evaluation of the Service (for example, the evaluation of the digital pilots of the NDPP that is currently underway). The Provider acknowledges and agrees that the Service may be adjusted to respond to best available evidence, including (by way of example only) as a result of planned innovation-testing evaluation (e.g. a research project or time-limited pilot of a local innovation to improve the Service). Any such adjustments would be effected as a variation to this Contract in accordance with the variation procedure set out in General Condition 13 (Variations).

Subject to the bullet point immediately below, in the event and to the extent only of a conflict between any of the provisions of this Service Specification and Appendix 1 (Tender Response Document) and/or Appendix 2 (Local Service Requirements) of this Schedule 2A, the conflict shall be resolved in accordance with the following descending order of precedence:

- this Service Specification;
- Appendix 1 of Schedule 2A (Tender Response Document);
- Appendix 2 of Schedule 2A (Local Service Requirements).

Where Appendix 1 of Schedule 2A (Tender Response Document) or Appendix 2 of Schedule 2A (Local Service Requirements) contains provisions which are more favourable to the Commissioner in relation to the Service Specification and/or Appendix 1 of Schedule 2A (Tender Response Document) as relevant, such provisions of Appendix 1 of Schedule 2A (Tender Response Document) or Appendix 2 of Schedule 2A (Local Service Requirements) shall prevail.

The Commissioner shall in its absolute and sole discretion determine whether any provision in Appendix 1 of Schedule 2A (Tender Response Document) or Appendix 2 of Schedule 2A (Local Service Requirements) is more favourable to it in relation to the Service Specifications and/or Appendix 1 of Schedule 2A (Tender Response Document) as relevant.

### **3.2.2 Population covered**

The Service is limited to individuals aged 18 years or over who have 'non-diabetic hyperglycaemia', defined as having an HbA1c of 42 – 47 mmol/mol (6.0 – 6.4%) or an FPG of 5.5 – 6.9 mmol/l within the 12 months prior to the date of referral into the Service.

Where both HbA1c and FPG are provided on referral, if all readings are NDH the individual is eligible for the programme. Where any reading is in the diabetic range (HbA1c  $\geq 48$  mmol/mol or FPG  $\geq 7$  mmol/l) the individual is not eligible for the programme and should be referred back to their GP for further diagnostic clarification. Where one reading is normal and the other is in the non-diabetic hyperglycaemic range the individual is eligible for the Service.

Oral Glucose Tolerance Testing (OGTT) is rarely used now clinically for diagnosis of hyperglycaemia outside pregnancy; in pregnancy it is used to assess for gestational diabetes. However, it is acknowledged that there may be circumstances where impaired glucose tolerance has been identified in an individual through OGTT (2 hour post 75 gram glucose load glucose value  $\geq 7.8$  and  $< 11.1$  mmol/l), and such individuals should be eligible for the Service.

### 3.2.3 Acceptance

The Provider must accept the following individuals onto the Service:

- Individuals who have already been identified as having non-diabetic hyperglycaemia in the past 12 months via GP systems and/or who have been included on a GP register of patients with non-diabetic hyperglycaemia; and / or
- Individuals who have already been identified as having non-diabetic hyperglycaemia in the past 12 months via the NHS Health Check programme.

The Provider will develop and agree detailed referral protocols with local health economies. Additional referral routes may be established with the agreement of the local health economy.

### 3.2.4 Exclusion criteria

The following individuals must be excluded from the Service:

- Individuals on referral who do not meet the eligibility criteria as defined in paragraph 3.2.3 above;
- Individuals aged under 18 years; and/or
- Pregnant women.

If a Service User becomes pregnant whilst participating in the Service, the Provider should tailor the Service accordingly, following the specification set out in NICE Guideline PH27, for example adjusting any weight loss goals. This guidance stipulates recommendations for diet, physical activity and weight management during pregnancy.

### 3.2.5 Invitation to participate

Subject to the Intervention Cap and Intervention Period (referred to in paragraph 3.10 of this Service Specification), the Provider will invite all referred, individuals to participate in the Face-to-face Service. The Provider will initiate contact with all individuals directly referred to them, within 5 Operational Days of receipt of the referral, inviting them to participate in the Face-to-face Service. The Provider will work with local health economies to manage the trajectory of referrals in line with the volume of contracted interventions available within the cap and work together with the local economy and with the Commissioner to match supply and demand across the duration of the Contract.

The invitation and all follow-up contact will contain basic, accessible information about Type 2 diabetes and information about how to reduce the risk of developing Type 2. All contact made with potential Service Users must be grounded in theory and evidence from behavioural insights and the Provider must make use of templates provided by the Commissioner.

Where there is no response from the initial invitation to the potential Service User, the Provider must make additional attempts to contact the potential Service User via at least two of the following methods: letter, phone call, text message or email; within a period of one calendar month from the date of referral into the Service.

### **Where contact has not been established after one month**

If it has not been possible to make contact after a minimum of three attempts and through different channels after one calendar month, the individual should be discharged back to their GP. A discharge notice to the individual should also be communicated, signposting them to NHS Choices website pages related to weight management, physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and physical activity.

### **Where contact has been established**

Where contact has been established but an individual indicates that they do not accept an invitation to participate in the Face-to-face Service, then the Provider must offer the Digital Service, subject to:

- the Commissioner not specifying that the Digital Service is not to be offered; and
- the Digital Service Cap (as defined in paragraph 3.10 below) not being reached.

All further references in this Service Specification to the Provider offering the Digital Service to individuals is subject to the two points above.

NHS England may require the Provider to use an approved script for this purpose in which case NHS England will notify the Provider of the script and the Provider shall use that script. This also applies to all further references in this Service Specification to the Provider offering the Digital Service.

Where contact has been established and an individual accepts an invitation to participate in the Face-to-face Service, the Provider must offer a choice of dates, times and appropriate venues to attend an Individual Assessment (as set out in paragraph 3.2.6 below). If the individual declines on three separate occasions, the Digital Service should be offered. Where the individual refuses the Digital Service, they should be discharged back to their GP.

The Provider must notify GPs where contact has been made with the Service User and they have taken up a place on the Service. The Provider must comply with any template letters or discharge communication content that the Commissioner notifies the Provider must be used.

The Provider must comply with relevant clinical codes associated with data items and include clinical codes in all notifications as specified by the Commissioner under the Contract.

The Provider will work closely with local health economies to identify and implement a feasible and locally appropriate mechanism for ensuring data is fed back to the GP in read coded format and can be integrated within GP clinical systems; ideally by electronic transfer. The Provider will also work with the local health economies to ensure that there is a monthly update on referral and uptake rates, waiting list size and outcomes at CCG level.

Additionally the Commissioner may require the Provider to notify GPs about progression of Service Users through the Service. The Commissioner will notify the Provider if this is required and the Provider shall comply with such notification.

Where contact has been established but an individual indicates that they do not accept the Face-to-face Service or the Digital Service (if the Provider was required to offer the Digital Service), then the individual should be discharged back to their GP. A discharge notice to the individual should also be communicated, signposting them to NHS Choices website pages related to weight management, physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and physical activity.

### **3.2.6 Individual assessments**

Individual assessments ("Individual Assessments") form the first stage of the Service. The Provider will conduct Individual Assessments with all Service Users who accept the invitation to participate in the Service. The Provider will use Individual Assessments to confirm whether Service Users are eligible for the Service and to gather baseline data as specified in Schedule 6A. Data must be gathered at all points of Service delivery in accordance with the requirements of this Service

Specification and Schedule 6A. The Provider will also use the Individual Assessment to deliver a brief intervention in line with NICE guidelines (see NICE PH38 and PH49).

Elements of the Individual Assessment might be conducted through remote or digital channels. However, weight measurements need to be taken through calibrated and objective mechanisms.

If an individual has previously accepted the Face-to-face Service but fails to attend a scheduled and agreed Individual Assessment, the Provider must make at least two further attempts to offer an Individual Assessment as part of the Face-to-face Service at times and venues appropriate to the individual. If the individual does not attend any of the offered Individual Assessments, the Provider must offer the Digital Service.

If an individual who has previously accepted the Digital Service has not completed the Individual Assessment within 2 months of first being offered the Digital Service, the Provider must make a second attempt to offer the Digital Service.

If the person subsequently declines the Digital Service or does not complete the Individual Assessment in the Digital Service within a further 2 months, the Provider must discharge the individual back to their GP, sign posting the individual to the NHS Choices website pages related to weight management, physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and physical activity.

If, following the Individual Assessment as part of the Face-to-face Service, a Service User:

- does not attend the first group session after the Provider has offered the first group session on 3 separate occasions at times and venues appropriate to the Service User;
- defers attendance at the first group session after the Provider has offered the first group session on 3 separate occasions at times and venues appropriate to the Service User; or
- declines the Face-to-face Service,

the Provider must offer the Service User the Digital Service.

The Provider must record details about the number of contact attempts made to offer the Face-to-face Service, including date and method of contact as set out in this paragraph prior to offering the Service User the Digital Service. The Provider is not required to record all of this information under Schedule 6A but must share this information with the Commissioner if requested.

The Commissioner may, from time to time, require the Provider to offer a person the Digital Service in other circumstances. Where the Commissioner so requires, it shall notify the Provider in writing and the Provider shall offer persons the Digital Service in the indicated circumstances always subject to the Digital Service Cap.

#### Participants who smoke

The Provider must conduct a very brief intervention (very brief advice) with Service Users who are smokers, as detailed in guidance provided by the National Centre for Smoking Cessation and Training. This will involve the following steps: i) Ask – if the Service User smokes (yes/no); If yes, ii) Advice – the best way to quit is with a combination of medication and support. Would you be interested in this? If yes: Act – refer to stop smoking service. The Provider will establish an appropriate referral mechanism with local health economies and systems. The Provider must maintain a record about Service Users who were screened for smoking, offered advice and referred to stop smoking services.

### **3.2.7 Intensity and duration of the Face-to-face Service**

The Provider must deliver the Face-to-face Service in accordance with the following requirements:

- The Service must consist of a series of 'sessions' as opposed to minimal ('one-off') contact;
- The Service must be spread across a minimum of 9 months' duration;

- 13 sessions must be provided to each Service User; each session should last between 1 and 2 hours;
- The minimum total contact time must be 16 hours;
- Additional contact outside of the 13 sessions and minimum of 16 hours, to further engage and support Service Users, to encourage retention and, where a Service User has missed sessions, to re-engage them to attend face to face is encouraged, particularly through remote channels. The Provider should consider how it ensures that Service Users are given appropriate individual support, including dedicated 1:1 time as required;
- The Provider will ensure that sessions are delivered in a format and at times that are appropriate to a range of diverse groups in the community and should include evening and weekend sessions to facilitate access for working people. Sessions must be offered at a range of times, days and venues and in accessible locations in order to maximise access to (and therefore uptake of) the Service, particularly for those of working age, BAME groups and more socially deprived communities;
- The design of the Service should allow Service Users to make behavioural changes gradually;
- The Individual Assessment does not count towards intervention hours but the final session does. The Individual Assessment is counted outside of the minimum 13 sessions. Weigh-ins do not count towards session time in isolation although they could be part of a session.

### **3.2.8 Underpinning theory and approach for both the Face-to-face Service and the Digital Service**

- The Provider must ensure that the Service is grounded in and delivered in accordance with behavioural theory. The Provider must be explicit regarding the behavioural change theory and techniques that are being used, and the expected mechanism of action of their intervention.
- The Provider must utilise a behavior change framework which is evidence based, such as the COM-B model - see Michie et al (2011a)<sup>3</sup>.
- The Provider must demonstrate which behavior change techniques from the Behaviour Change Technique Taxonomy Michie et al (2011b)<sup>4</sup> are met by their intervention. As a minimum the intervention should include all the behaviour change techniques set out in NICE PH38 recommendations 1.9.2, 1.9.3 and 1.9.4.
- The Provider must ensure that all sessions and communications incorporate clear, targeted, and high quality communication of risk, which optimise understanding of the risk of developing Type 2 diabetes and how this can be prevented. Application of behavioural insights approaches to behaviour change must be demonstrated; particularly in relation to promoting recruitment and retention/reengagement of Service Users, and session attendance. The Provider must comply with any materials and templates provided by the Commissioner.
- The Provider must be explicit about the intended action expected of Service Users in response to non-face-to-face contact (marketing, invitation letters, leaflets, referral forms, text messages etc.) and the mechanism of action by which that is expected to occur (with reference to behavioural change frameworks as described above). Evidence and best

<sup>3</sup> Michie, S., et al. (2011a). "The behaviour change wheel: A new method for characterising and designing behaviour change interventions." *Implementation Science* : IS 6: 42-42.

<sup>4</sup> Michie S, Ashford S, Snihotta FS, et al. (2011b). A refined taxonomy of behaviour change techniques to help people change their physical activity and healthy eating behaviours: The CALORE taxonomy. *Psychology and Health*, 26 (11), 1479 – 1498.

practice must be considered and described by the Provider when producing these materials and communication channels.

- The Provider must ensure that family or peer support is accommodated where this would be helpful to a Service User.

### **3.2.9 Content of Sessions for the Face-to-face Service and the Digital Service**

- The Provider must develop detailed content for sessions.
- The sessions must cover information about Type 2 diabetes and the risk factors, and provide information and practical tools on nutrition, physical activity and weight management based on National Guidance set out below and detailed more fully in Annex 1 of this Service Specification.
- The content should consider the social and psychological support needed to support people to implement behaviour changes in environments which promote unhealthy behaviours.
- The Provider should consider the extent to which the intervention is delivered in a logical progression in line with behavioural change techniques as described in paragraph 3.2.8 above.
- The programme material for the Digital Service should be designed to allow Service Users with different levels of knowledge and different approaches to learning to progress at different paces. This should include promoting self-directed learning.

### **3.2.10 Delivery of sessions for the Face-to-face Service**

- The Provider must ensure that the Service is delivered using predominantly group sessions designed to be delivered to up to 20 Service Users in each group. Individual contact, in addition to the 13 sessions (either in person or remotely) may also be included to enhance delivery and retention. Larger group sizes may be used by exception (for example, a group exceeds 20 people where a Service User is bringing a family member or carer or where a Service User from another group has missed a session and attends to catch up). A record of group numbers should be kept and made available on request by the Commissioner.
- Group sessions, within the required 13 sessions, will be delivered face-to-face (in person).
- If a group size diminishes as the programme progresses due to non-attendance, there is no minimum group size; a Service User who wishes to continue on the programme (if they haven't already attended the final session) should be allowed to do so regardless of group size. However, the Provider may introduce mechanisms for joining together groups if numbers of attendees in a group are small.
- Service Users should be offered a choice of dates and times for each and any session to encourage attendance and also to offer the opportunity to catch up where they have missed a session. This choice should be available throughout the duration of the intervention. The Provider should consider the extent to which the intervention is delivered in a logical progression.

### **3.2.11 Delivery of Sessions for the Digital Service**

The Provider must deliver the Digital Service in accordance with the following minimum requirements:

- Engagement with the Service by the Service User shall be monitored and reported to the Commissioner. Engagement shall be characterised by the interest and subjective experience of using the intervention, combined with the amount, frequency, duration and depth of usage. Examples of engagement might include: viewing materials, completing any active elements, engaging directly with human coaches, inputting self-monitoring data, or participating in moderated group sessions. Engagement would not include passive receipt of emails and other communications unless it could be demonstrated that these have been actively read through Service User feedback mechanisms embedded into the

communication. Schedule 3A sets out the specific types of engagement methods that the Provider must ensure are used for payments to be claimed and this may include engagement methods proposed by the Provider where this is agreed with the Commissioner.

- The Provider must be able to demonstrate that their curricula/modules are designed to deliver engagement of Service Users for a minimum of nine months and should aim to deliver the same objectives and the same course content as the Face-to-face Service.
- To ensure engagement is spread over nine months, the Provider must ensure there is engagement activity each month. Payment for the Digital Service is dependent on monthly engagement. Schedule 3A (Local Prices) sets out the specific requirements that need to be met for payment.
- Subject to this paragraph 3.2.11, access to the Digital Service should be flexible to accommodate Service User preferences about accessing the Digital Service at a time of their choosing and to work through content flexibly at their own pace.
- The Provider should consider how it ensures that Service Users are given appropriate individual support, including dedicated 1:1 time as required.

### **3.2.12 Training and Competencies for Face-to-face Service and Digital Service**

- The Provider will ensure that the Service is delivered or, where there is no human coaching element, developed, by suitably trained and competent individuals who are trained in delivery of behaviour change. The Provider will specify the type and level of qualification, training and / or competence to be required aligning with, for example, the Association for Nutrition 'wider workforce' training, the Register of Exercise Professionals training, City & Guilds qualifications, and the Royal Society of Public Health qualifications. The Provider needs to demonstrate that these qualifications will ensure that front-line staff are trained to deliver interventions in line with NICE PH49 for both overall behaviour change and for group based delivery.
- The Provider must ensure that all individuals involved in the delivery of the Service have sufficient and appropriate training and competencies required to deliver the actions and content of the Service and to manage confidential and sensitive personal identifiable data. This must include training in delivery of the Service. The Provider must also consider the creation of apprenticeships as a means of developing and maintaining skills. Training must be routinely monitored and updated as necessary, and suitable continued professional development strategies must be in place.
- The Provider will ensure that all Staff adopt a person-centred, empathy-building approach in delivering the Service. This includes finding ways to help Service Users make gradual changes by understanding their beliefs, needs and preferences and building their confidence over time.
- The Provider must ensure that a multi-disciplinary team of health professionals or specialists relevant to the core components of the Service (i.e. diabetes, behaviour change, weight loss, diet and physical activity) is involved in development of the Service. These should include; for example, a registered dietitian / nutritionist, a registered health psychologist trained in the application of the COM-B model and a qualified (e.g. to level 4) physical activity instructor.
- There is not a requirement for health professionals to deliver content of group sessions, nor be involved in every session. In discussions about physical activity it would be beneficial to involve a qualified physical activity instructor who will have been trained in understanding and communicating risk.
- The Provider must ensure that the Service is delivered in a way which is culturally sensitive to local populations, and flexible enough to meet the needs of Service Users with diverse needs.

- Staff delivering the Service will reflect the diversity of the population accessing the Service.

### 3.2.13 Weight Loss

In relation to weight loss:

- The Service must involve collecting weight data for all Service Users. For the Face-to-face Service this should include a weigh-in at every session.
- Data collection of weight measurements must be objective (should not be self-reported) and taken using appropriately calibrated scales (see PHE standard evaluation framework for weight management interventions (a) for details of measurement of height and weight. Scales should meet Class III scales for levels of accuracy as per UK weighing federation guidance) and (b):

[https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/685545/SEF\\_weight\\_management\\_interventions.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685545/SEF_weight_management_interventions.pdf)

<http://www.ukwf.org.uk/res/medicalguidancenotes.pdf>

- For Service Users undertaking the Digital Service, the Provider should encourage Service Users to use regular weigh-ins as part of self-monitoring and for these, self-reported weight is acceptable. However, baseline, 3 month, 6 month and 9 month weigh-ins must be taken objectively. It is the Provider's responsibility to establish how this weight measure is organised (e.g. through calibrated digital scales or weigh in at a local Face-to-face Service location).
- The Provider must ensure that achievable goals for weight loss (for those who are overweight or obese) are agreed for different stages of the Service for example, within the first few weeks, at three months and at completion of the Service.
- The Provider should, wherever possible, work with Service Users to assess their dietary intake and support Service Users to plan sustainable dietary changes, aligned with the balance of food groups in the Eatwell Guide (refer to paragraph 3.2.14 below for further information), to achieve weight loss and help with weight maintenance.
- The Provider must design approaches to support individuals who are overweight or obese at baseline (as defined in Annex 2) to reduce their calorie intake. A calorie limit of no more than 1,900kcal for men and 1,400kcal for women should support weight loss at a rate of 0.5kg-1kg each week. Weight loss of 5-10% of baseline weight should be used to support individuals who are overweight or obese to understand how much weight loss is required to achieve health benefits and to set achievable targets. Approaches need to support longer term sustainable behaviour change in order to maintain target weight.
- The Provider must design approaches to support individuals who are a healthy weight at baseline to maintain a healthy weight in line with NICE Guideline NG7.

### 3.2.14 Dietary content

The design and delivery of the syllabus must be underpinned by the UK Government dietary recommendations as detailed in the Eatwell Guide<sup>5</sup> and support weight loss for Service Users who are overweight or obese, or the maintenance of a healthy weight in Service Users of healthy weight. The Eatwell Guide shows the proportions on the main food groups that form a healthy balanced diet. This involves increased intake of fibre, fruit and vegetables and oily fish, and decreased intake of saturated fat, sugar, salt and energy:

- Eat at least 5 portions of a variety of fruit and vegetables every day;

<sup>5</sup> Information about the Eatwell Plate can be accessed at [www.nhs.uk/Livewell/Goodfood/Pages/eatwell-plate.aspx](http://www.nhs.uk/Livewell/Goodfood/Pages/eatwell-plate.aspx).

- Base meals on potatoes, bread, rice, pasta or other starchy carbohydrates; choosing wholegrain versions where possible;
- Have some dairy or dairy alternatives (such as soya drinks); choosing lower fat and lower sugar options;
- Eat some beans, pulses, fish, eggs, meat and other proteins (including 2 portions of fish every week, one of which should be oily);
- Choose unsaturated oils and spreads and eat in small amounts;
- Drink 6-8 cups/glasses of fluid a day;
- If consuming foods and drinks high in fat, salt or sugar have these less often and in small amounts.

The Provider must support Service Users towards achieving the Government's dietary recommendations:

- Use dietary approaches that are evidence based and sustainable in the longer term;
- Service Users should be encouraged to set tailored achievable short, medium and long term goals which help them to achieve their aims.
- Service Users should be supported to consume wholegrain and higher fibre starchy carbohydrates in line with the Eatwell Guide (about a third of food eaten).
- For Service Users who are overweight or obese and therefore need to lose weight through calorie reduction, the Provider should ensure that this is achieved through the promotion of the balance of food groups as set out in the Eatwell Guide.
- Dietary advice should reflect the culinary traditions of the communities in which the Service is being provided.

### 3.2.15 Physical activity content

- The Provider will support Service Users to aim to become active daily and minimize time spent being sedentary, ultimately working towards meeting or exceeding the England CMO recommendations.<sup>6</sup> The Provider will tailor the support provided as part of the Service to meet the needs, goals and capabilities of individual Service Users and care should be taken to set achievable goals.
- The Provider will take a graded and structured approach to setting, monitoring and reviewing goals to ensure that those who have a very low baseline level of physical activity are supported to attain the CMO recommendations within a personalized timeframe.
- The Provider will support Service Users to reduce the amount of sedentary activity in their leisure and working time, by promoting and demonstrating the use of breaks after a prolonged period of sitting or other sedentary activity.
- The Provider will support Service Users to incorporate active travel into their daily routine either through walking or cycling skills and group activities; the Provider could use tools which encourage the incorporation of walking into daily routines such as those applied through the PACE-UP trial<sup>7</sup> or the Public Health England Active 10 app which promote minimum and graded increases, and ways to encourage brisk walking;

<sup>6</sup> Department of Health. 2011. Start Active, Stay Active: A report on physical activity for health from the four home countries' Chief Medical Officers. Department of Health

<sup>7</sup> Harris, T., et al. (2017). "Effect of a Primary Care Walking Intervention with and without Nurse Support on Physical Activity Levels in 45- to 75-Year-Olds: The Pedometer And Consultation Evaluation (PACE-UP) Cluster Randomised Clinical Trial." PLoS Med 14(1): e1002210.

- The Provider is required to measure physical activity for both the Face-to-face Service and the Digital Service using a standard self-reporting tool as determined by the Commissioner and when required by the Commissioner. This will be confirmed in due course, however the Recent Physical Activity Questionnaire<sup>8</sup> ("RPAQ") is currently proposed.
- The Provider must encourage self-monitoring of physical activity by regularly liaising with Service Users about the number of steps undertaken in the previous week using objective measurement such as use of pedometers, activity trackers, or smart phone step counters. Data on absolute step counts will be required over a measurement period of the previous seven days.
- The Provider will be required to provide data on physical activity including calculation and reporting of step counts, e.g. by calculating percentage change, to allow comparison of Service User and Provider physical activity changes relating to the Service as determined by the Commissioner and as notified by the Commissioner to the Provider.
- The Service may include supervised exercise and when used must build gradually to increase exercise capacity of the Service User. It is the Provider's responsibility to ensure that Staff providing supervised exercise are suitably qualified.
- For the Digital Service, self-monitoring and reliable data capture to understand individual-level change in weight, diet, and physical activity are key behavior change techniques. The Digital Service should include methods to allow Service Users to accurately and regularly self-monitor their diet and physical activity behaviours. Methods may include the provision of, or integration with, wearable devices.

The Provider must ensure that content of the Service is regularly reviewed and adjusted to stay up to date with government recommendations and new evidence.

### 3.2.16 Final session

The "Final Session" is defined as the last session delivered by the Provider as part of the planned Service (for those Service Users still attending).

As part of the Final Session, the Provider must conduct a post intervention assessment of (objective) weight, wellbeing and achievement of individual goals for all Service Users who attend. BMI must also be calculated and arrangements for collection of Service User feedback / customer satisfaction survey should be agreed. Details of the data to be reported are provided in Schedule 6A.

The Commissioner may require the Provider to carry out blood testing as part of the Service (the "**Blood Testing Service**"). If the Commissioner so requires, it shall notify the Provider that it requires the Provider to provide the Blood Testing Service and shall indicate from when and on whom blood testing should be undertaken. The Provider shall provide the Blood Testing Service in accordance with paragraph 3.2.17 below on the Service Users in accordance with the Commissioner's notification.

The Provider must again ensure that links are made with local or national activities and services, in order to provide support for Service Users to continue with improvements made to dietary and physical activity behaviours and weight loss.

The Provider must ensure that participants are reminded about key sources of information and advice, such as NHS Choices.

The Provider should make available support and advice post intervention to Service Users to encourage the maintenance of improved lifestyles.

### 3.2.17 Blood Testing Service

Rationale for the Blood Testing Service

<sup>8</sup> <http://www.mrc-epid.cam.ac.uk/wp-content/uploads/2014/08/RPAQ.pdf>

As indicated in section 3.1.1 above, the primary aim of the NDPP, and therefore the Service, is to reduce the incidence of Type 2 diabetes in individuals referred onto the Service (Service Users) (all of whom will have non-diabetic hyperglycaemia).

The secondary aims are:

- To reduce blood glucose parameters (HbA1c or Fasting Plasma Glucose (FPG)) in Service Users at 12 months and beyond;
- To reduce weight of Service Users at 12 months and beyond; and
- To maximise completion rates of Service Users.

The Blood Testing Service allows achieves two objectives in areas where it is implemented:

- to assess changes in HbA1c or fasting glucose levels at the first session and discharge from the Service so that Service Users can assess their progress through the intervention and the Commissioner can evaluate the effectiveness of the intervention in reducing glycaemic parameters at 9 months and beyond;
- to provide information on glycaemic parameters to support GPs in the provision of ongoing care and support to discharged Service Users.

Establishing eligibility in primary care

Eligibility to the NDPP is dependent on blood glucose levels being within certain parameters ie. HbA1c of 42 – 47 mmol/mol (6.0 – 6.4%) or an FPG of 5.5 – 6.9 mmol/l.

Local health economies and their clinicians are responsible for the appropriate categorisation of their patients, and referral onto suitable lifestyle interventions such as the NDPP. NDPP providers are **not** responsible for re-assessing eligibility, when taking baseline blood tests.

The majority of Service Users will be referred to the Service from primary care following a venous blood test. This is because there are currently no published guidelines suggesting use of POCT measured HbA1c for diagnosis of either Type 2 Diabetes or non-diabetic hyperglycaemia.

Tracking change in blood glucose

To assess the NDPPs progress against its aim of reducing glycaemic parameters at 9 months and beyond and also provide information to Service Users on their progress through the programme, the Commissioner requires blood tests to be undertaken on Service Users at completion of the programme. The Commissioner is exploring options to work with local health economies to arrange for primary care to undertake this function, however, it may be that some or all local health economies decide that they cannot undertake this function locally.

The Commissioner may therefore require the Provider to undertake blood testing as part of the Service, on all Service Users by Milestone 1 (as defined in Schedule 3A) where a Point of Care Testing ("POCT") device is used (subject to the Provider indicating in the Tender Response Document that it will carry out POCT) for blood testing) and again at or around the Final Session (subject to the timescales set out in this paragraph 3.2.17) for those who reach that stage.

HbA1C POCT devices may be used, subject to the quality criteria set out below. Where POCT devices are used all Service Users will need to have a baseline test and a test at completion to ensure that the results are comparable. The same type of device must be used for both tests.

Where a venous test is conducted (either HbA1C or FPG) (subject to the Provider indicating in the Tender Response Document that it will carry out venous tests) the Provider will only need to

conduct a blood test at completion (subject to the timescales set out in this paragraph 3.2.17), as this venous result will be comparable with the venous test result at the point of referral.

The Provider will:

- Use one testing modality for a Service User (i.e. a different testing approach cannot be used at completion to the one used at baseline);
- Where POCT devices are used, ensure that the same type of device is used for the baseline test and test at completion;
- Conduct, or arrange, blood tests for all Service Users at the first session NDPP, where a POCT device is being used by the Provider to undertake the blood test;
- Conduct, or arrange, blood tests for all Service Users that reach the Final Session;
- As part of the first session (where a POCT device is being used) and Final Session, make arrangements with the Service User to receive a blood test;
- Conduct this as part of the first session (where a POCT device is being used) and or around the final session (subject to the timescales set out in this paragraph 3.2.17) ; and
- Use either an HbA1c test (or an FPG test) for assessing glycaemic status.

The timescales for conducting blood tests are:

- If using POCT devices, at the sessions detailed; and
- If using venous testing, as close as possible to the sessions detailed but in any event no later than 10 Operational Days from the date of the relevant session.

#### Principles

Where the Commissioner requires the Provider to provide the Blood Testing Service, the Commissioner will notify the Provider no less than 12 weeks before the date the Provider is required to commence blood tests.

The Provider will;

- be responsible for conducting a HbA1C or FPG blood test for all Service Users as part of the first session (where a POCT device is being used) and at or around the Final Session (subject to the timescales set out in this paragraph 3.2.17); and
- conduct blood tests in accordance with the approach set out in the Tender Response Document.

The Provider may deliver the blood testing through their own staff or through sub-contracted arrangements, subject to the quality requirements set out in this paragraph 3.2.17.

If the Provider uses sub-contractors to perform or undertake the Blood Testing Service, any references in this paragraph 3.2.17 to a requirement on the Provider in relation to blood testing should be read as a requirement for the Provider to ensure the relevant subcontractor complies with that requirement.

#### Quality requirements – Venous Testing

- The Provider may perform HbA1c testing using venous blood analysed on laboratory-based analysers.
- The Provider must ensure that HbA1c testing using laboratory-based analysers is undertaken in UK Accreditation Service accredited laboratories, using methods that are directly traceable to the International Federation of Clinical Chemistry reference measurement procedure.
- If FPG testing must be used instead of HbA1c testing, the Provider must ensure that FPG testing is performed according to local standard operating procedures compatible with best practice guidance. FPG must be measured on venous blood on analysers with standardised methodologies that are directly traceable to the reference measurement procedure. The Provider will ensure that these assays are performed in UK Accreditation Service accredited laboratories demonstrating appropriate quality control and quality assurance.
- Use of existing testing facilities, e.g. local phlebotomy services, would be acceptable provided adequate arrangements had been made with that local facility, and the person or organisation to provide the testing facilities has agreed to do so.
- Blood tests may be measured on venous blood on analysers with standardised methodologies that are directly traceable to the reference measurement procedure. The Provider will ensure that these assays are performed in UK Accreditation Service accredited laboratories demonstrating appropriate quality control and quality assurance.

#### Quality requirements – Point of Care testing

To date, UK guidance has not supported the use of POCT HbA1c for diagnosis of diabetes or categorisation of people in high risk states, only for tracking response of HbA1c to an intervention. Guidance has suggested that POCT HbA1c should only be considered where performance of these devices is comparable to laboratory assays, and delivery must be implemented within an appropriate quality framework. The Commissioner will not recommend a device or devices.

Recognising the expanding repertoire of POCT analyses, devices, provision outside of laboratories and potential pitfalls of incorrect implementation, the Medicine and Healthcare products Regulatory Agency (MHRA) produced guidance on the management of in vitro POCT devices<sup>9</sup>. It is clear from this guidance and the ISO standards covering POCT (ISO standard ISO15197:2013) that there are a number of processes, systems and steps that need to be in place to ensure POCT is managed appropriately and a quality service is delivered.

These points collectively form the quality framework and are fully explained in the MHRA document.

If POCT devices are used, the Provider shall comply with the points below:

- There must be clear messaging in place to advise Service Users that POCT devices are not necessarily as accurate as venous tests and that some variation in results from different devices and over different timeframes is feasible. Further that where a Service User receives a result in the normo-glycaemic range on a particular occasion they should be aware that their lifetime risk of developing diabetes remains high, although making and sustaining lifestyle changes can help to reduce this risk. This is to help ensure that baseline readings indicating normo-glycaemia do not lower Service User motivation to continue engaging with the Service.

<sup>9</sup> [MHRA: Management and use of IVD point-of-care test devices. 2013. [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/e/371800/In\\_vitro\\_diagnostic\\_point-of-care\\_test\\_devices.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/e/371800/In_vitro_diagnostic_point-of-care_test_devices.pdf)]

- All POCT HbA1c devices must have a clear process for internal quality control and be enrolled into an external quality assessment programme (EQA). This means that disposable devices are not suitable.
- Procurement of HbA1c POCT devices should only be considered in collaboration with a UKAS accredited pathology laboratory. A service level agreement with the UKAS accredited pathology laboratory should be in place to ensure adequate support at every stage during device selection, procurement, evaluation, implementation and thereafter to help initiate, advise on and maintain the quality framework.
- Advice, and guidance, from the UKAS accredited pathology laboratory should relate to the minimum analytical performance criteria, published studies on device performance, local laboratory experience and external quality assessment data.
- The Commissioner reserves the right to request copies of the service level agreement in addition to evidence of advice and guidance received by the Provider from the UKAS accredited pathology laboratory.
- All parameters of the MHRA stipulated quality framework must be in place prior to implementation of POCT HbA1c devices.
- Potential hazards associated with the handling and disposal of bodily fluids, sharps and waste reagents outside of a laboratory setting should be considered.
- Staff who use POCT devices must be trained. Only staff whose training and competence has been established and recorded should be permitted to carry out POCT. Which staff review the results should be considered, staff should be appropriately qualified and cited on the Service User's history.
- Standard operating procedures (SOPs) which must include the manufacturer's instructions for use, are developed. Particular attention should be paid to any storage and handling requirements of the machine and cassettes.
- Quality assurance must be addressed, through implementation of quality control (QC) procedures, including internal QC and EQA, which provide assurance that the system is working correctly. A QC record should be in place for each machine and each individual machine must be enrolled into an EQA programme, with on-going satisfactory results. In addition, adequate procedures must be in place to address poor performance of IQC or EQA.
- Record keeping is essential and must include patient results, test strip lot number and operator identity.
- Maintaining devices according to the manufacturer's guidance is essential to ensure that they continue to perform accurately.

#### Reporting

- The Provider must report blood test results to the Commissioner using the reporting mechanisms detailed in Schedule 6A.
- The Provide must also report blood test results to primary care at discharge following the Final Session. This reading should be communicated to primary care within 5 Operational Days from receipt of blood results by the Provider and no later than 20 Operational Days after the blood has been taken from the Service User. Should the reading indicate progression to Type 2 diabetes, the Provider will make sure that this is explicit in any communication back to primary care.
- Blood test results at first session do not need to be reported back to primary care, except where this indicates potential Type 2 diabetes (reading above HbA1c 47 mmol/mol or FPG

above 6.9 mmol/l). Where a blood reading indicates potential Type 2 diabetes notification should be communicated to primary care in 5 working days from the point of collection.

- If a blood test result performed or organised by the Provider falls within the diagnostic category for Type 2 diabetes, defined as HbA1c level of 48 mmol/mol (6.5%) or above or an FPG of 7 mmol/l or above, the Provider will identify the occasional Service User whose blood glucose levels have risen rapidly and who require urgent/same day assessment by a GP, diabetologist or accident & emergency and the Provider must respond immediately and within the same working day. Examples include: young people under the age of 30, symptoms suggesting type 1 diabetes (any age), short duration diabetes symptoms, patients at high risk of diabetes who are acutely ill, patients taking medication that may cause rapid glucose rise, e.g, corticosteroids, anti-psychotics, and acute pancreatic damage/pancreatic surgery.

#### Payment

- Payment for the Blood Testing Service will be dependent on a HbA1C or FPG reading being reported to the Commissioner and primary care and as set out in Schedule 3A of this Contract.

#### CQC Registration

The Provider must ensure that it, or its sub-contractor (as appropriate), is registered with the CQC for venous testing.

Where POCT is used, the CQC's diagnostic and screening procedure confirms that non-ambulatory blood pressure monitoring, and blood tests carried out by means of a pin prick test are excluded from the CQC registration requirement. However, the Provider is required to satisfy itself as to whether CQC registration is required for any action that it undertakes.

#### **3.2.18 Discharge from the Service**

The Service User is "Discharged" from the Service in the following circumstances:

- If after the Provider contacts an individual following referral, the individual does not respond to the Provider after one calendar month from referral provided that the Provider has made a minimum of three attempts to contact the individual, and used various different communications channels as set out in paragraph 3.2.5 above;
- If, after the Provider contacts an individual following referral, the individual indicates that they do not accept the Face-to-face Service, provided that the individual has been offered the Digital Service (subject to the Digital Service Cap) and the individual has indicated that they do not accept this;
- If, after the Provider contacts an individual following referral, the individual indicates that they accept the Face-to-face Service, and have either declined, deferred or did not attend an Individual Assessment and/or a first intervention session where the Provider has offered the session on 3 separate occasions at times and venues suitable to the individual, and who have subsequently also declined an offer of the Digital Service (subject to the Digital Service Cap);
- When a Service User misses three consecutive Face-to-face Service sessions for no known reason and the Provider has made a minimum of three attempts to contact the Service User since the last attended session, using at least two of the following means of communication: letter, phone call, text message or email;
- For the Digital Service, where there is no recorded activity for three consecutive calendar months. The Provider should also notify the Service User's GP that the Service User participated in the Service for a specified period of time but has been recorded as having been inactive for three consecutive months;

- When a Service User informs the Provider that they no longer wish to participate in the Service; and/or
- On completion of the Final Session (or once the Final Session has been delivered). Once the Final Session is completed then the Service User is discharged automatically regardless of the number (or percentage) of sessions attended.

### **Discharge Requirements**

The Provider must provide each Service User's GP and the Service User themselves, with notification of Discharge via letter. Where an individual is discharged in accordance with the first three bullet points above, the discharge requirements are set out in paragraphs 3.2.5 and 3.2.6 of this Specification. Where an individual is discharged in accordance with the last four bullet points above:

- the letter of Discharge should encourage the Service User to contact their GP to confirm a date for their annual review, including a blood test to confirm whether HbA1c or FPG levels have reduced; and
- the letter of Discharge to the GP must advise that clinical guidelines recommend follow up of people with non-diabetic hyper-glycaemia every 12 months, where follow up includes measurement of weight and HbA1c, as well as assessing and addressing cardiovascular risk consistent with standard clinical practice.

The Provider must comply with any template letters or discharge communication content that the Commissioner notifies the Provider must be used.

The Provider must comply with relevant clinical codes associated with data items and include clinical codes in all notifications as specified by the Commissioner under the Contract.

The Provider will work closely with local health economies to identify and implement a feasible and locally appropriate mechanism for ensuring data is fed back to the GP in read coded format and can be integrated within GP clinical systems; ideally by electronic transfer. The Provider will also work with the local health economies to ensure that there is a monthly update on referral and uptake rates, waiting list size and outcomes at CCG level.

### **3.2.19 Links to other services**

The Provider must ensure that links are made with existing local networks and partnerships (for example, physical activity providers) throughout the development and delivery of the Service. This could include, for example, leisure and public health services, departments within Local Authorities, NHS Choices, and local "Exercise on Referral" schemes.

### **3.3 Marketing of the Service**

The Provider must undertake marketing and promotional activity in conjunction with the local health economy to advertise the existence of the Face-to-face Service and the Digital Service, with a view to raising awareness about the availability and benefits of the Service amongst local primary care and to people in the geographical area covered by the Contract who may benefit from participating in a diabetes prevention programme. Any marketing or promotional activity must be designed to target groups in the community which are currently less likely to access services, or which are at a disproportionately higher risk of developing diabetes encouraging them to find out more about the Service.

In marketing the Service, the Provider must conform to any guidelines on social marketing of the Service under the Contract, for example to ensure alignment of messaging with any wider social marketing campaigns being undertaken in relation to diabetes, or health promotion more generally. This includes using any branding guidelines developed by the Commissioner specifically for the NDPP.

### **3.4 Intellectual Property**

For the avoidance of doubt, notwithstanding General Condition 1.2, the Parties expressly agree that this paragraph 3.4 shall take precedence over General Condition 22 in respect of Intellectual Property.

Except as set out expressly in this Contract, no Party will acquire the IPR of the other Party.

The Provider grants the Commissioner a fully paid-up non-exclusive licence to use Provider IPR for the purposes of the exercise of its functions and obtaining the full benefit of the Services under this Contract, which will include the dissemination of best practice to commissioners and providers of health and social care services.

The Commissioner grants the Provider a fully paid-up non-exclusive licence to use Commissioner IPR under this Contract for the sole purpose of providing the Services.

In the event that the Provider or the Commissioner at any time devise, discover or acquire rights in any Improvement it or they must promptly notify the owner of the IPR to which that Improvement relates giving full details of the Improvement and whatever information and explanations as that Party may reasonably require to be able to use the Improvement effectively and must assign to that Party all rights and title in any such Improvement without charge.

Any IPR created by the Commissioner in the exercise of its licence rights under this Contract will be owned by the Commissioner.

The Provider must disclose all documents and information concerning the development of Best Practice IPR to the Commissioner at Review Meetings and must grant the Commissioner a fully paid-up, non-exclusive perpetual licence to use Best Practice IPR for the purpose of the exercise of its functions together with the right to grant sub-licences to Public Health England and any Participating Commissioner for the purpose of the exercise of their respective functions.

"Best Practice IPR" in this paragraph 3.4 means any IPR developed by the Provider including Improvements to such IPR in connection with or as a result of the Services.

"Improvement" in this paragraph 3.4 means any improvement, enhancement or modification to Commissioner IPR, Provider IPR or Best Practice IPR (as the case may be) which cannot be used independently of such IPR.

"IPR" in this paragraph 3.4 means inventions, copyright, patents, database right, domain names, trade marks, module names, rights in computer software, database rights, rights in get-up, goodwill and the right to sue for passing off, designs and confidential know-how and any similar rights anywhere in the world whether registered or not, including applications and the right to apply for any such rights.

"Participating Commissioner" in this paragraph 3.4 means a clinical commissioning group or local authority in relation to whose geographical area the Services are delivered.

"Provider IPR" in this paragraph 3.4 means any IPR owned by or licensed to the Provider (other than by the Commissioner) that will be used by the Provider in the delivery of the Services (as set out in Appendix 3 of this Schedule 2A), including Improvements to such IPR.

The Provider shall ensure and procure that the availability, provision and use of the Service and the performance of the Provider's responsibilities and obligations hereunder shall not infringe any Intellectual Property Rights of any third party.

The Provider shall during and after the Contract Term indemnify the Commissioner against all Losses incurred by, awarded against or agreed to be paid by the Commissioner (whether before or after the making of the demand pursuant to the indemnity hereunder) arising from an IPR Claim. An IPR Claim is defined as any claim of infringement or alleged or threatened infringement by a third party (including the defence of such infringement or alleged or threatened infringement) of any IPR, used to provide the Services or as otherwise provided and/or licensed by the Provider (or to which the Provider has provided access) to the Commissioner in the fulfilment of its obligations under this Contract.

If an IPR Claim is made, or the Provider anticipates that an IPR Claim might be made, the Provider may, at its own expense and sole option, either:

- procure for the Commissioner the right to continue using the relevant IPR which is subject to the IPR Claim; or
- replace or modify the relevant deliverable with non-infringing substitutes provided that:
  - the performance and functionality of the replaced or modified deliverable is at least equivalent to the performance and functionality of the original deliverable; and
  - there is no additional cost to the Commissioner.

If the Provider elects to procure a licence or to modify or replace a deliverable pursuant to the provision above but this has not avoided or resolved the IPR Claim, then:

- the Commissioner may terminate this Contract by written notice with immediate effect; and
- without prejudice to the indemnity set out above, the Provider shall be liable for all reasonable and unavoidable costs of the substitute deliverables and/or services including the additional costs of procuring, implementing and maintaining the substitute deliverables.

### 3.5 Cyber Essentials

The Provider has and will maintain certification under the HM Government Cyber Essentials Scheme (basic level) until such time as the Provider obtains Cyber Essentials Plus certification in accordance with the provision below.

The Provider shall, as soon as is reasonably practicable after the Services Commencement Date, obtain certification under the HM Government Cyber Essentials Scheme to the level of Cyber Essentials Plus and maintain such certification for the Contract Term

### 3.6 Digital Assessment Questionnaire

The Provider must ensure that the Digital Service is compliant with the requirements of the Digital Assessment Questionnaire ("DAQ") and ensure that the Digital Service is updated if requirements of the DAQ are updated.

### 3.7 Identity Verification and Authentication Standard for Digital Health and Care Services

If the Provider's Digital Service is by its nature a service to which NHS Digital's "Identity Verification and Authentication Standard for Digital Health and Care Services" applies, then the Provider is required to ensure it adheres to this standard. Please refer to the Standard for applicability: <https://digital.nhs.uk/data-and-information/information-standards/information-standards-and-data-collections-including-extractions/publications-and-notifications/standards-and-collections/dcb3051-identity-verification-and-authentication-standard-for-digital-health-and-care-services>.

The Provider agrees to provide evidence of adherence to the standard to the Commissioner on request.

### 3.8 Links to Tier 2 Weight Management Services

Tier 2 weight management services form part of the obesity pathway. Many exist across England and they are commissioned locally, mainly by local authorities. Typically, Tier 2 weight management services are multi-component lifestyle interventions that include diet, physical activity and behavior change components, delivered in group settings over 12 weeks. These services target overweight individuals, defined as having a BMI >25, although variation does exist across local authorities.

The eligibility for the Service is different from eligibility for existing weight management services as a measure of glycaemic status is required. Whilst many people eligible for the Service will be overweight, some will have a BMI of <25. Similarly, it is likely that a large proportion of those within

the overweight category will have normal blood glucose levels, and will not therefore be eligible for the Service. The Provider must therefore ensure that the Service interacts and aligns with tier 2 weight management services.

Aligning with a Tier 2 Weight Management Service (Tier 2) may include, but is not limited to: i) referring those who are still overweight following participation in the Service and who may benefit from further participation in a programme on to the T2 service, ii) working with local health economies to ensure that the pathway into T2 versus the Service is clearly defined.

The Service is more intensive than most existing weight management services. Where an individual has been identified as having non-diabetic hyperglycaemia but is also eligible for a Tier 2 weight management service, they will be referred into the Service.

### 3.9 Information Governance

The Provider will submit the "Data Output Specification" document in Schedule 6A to the commissioning support service specified by the Commissioner and in the manner specified by the Commissioner.

The Provider will invite all individuals they have contacted following referral and all Service Users to agree be contacted for the purpose of service evaluation and record their consent where given. The Commissioner will specify this proportion of Service Users and also the timing and manner of the invitation.

The Provider will respect any request by a Service User not to disclose information that identifies them in the documents indicated above.

For the avoidance of doubt, the requirements above are in addition to the information governance requirements set out elsewhere in this Contract.

### 3.10 Additional Service Delivery Requirements

The Provider must:

- provide the Service in the following geographical area – [to be defined at call-off]
- ensure that the number of Service Users who achieve Milestone 1 (as defined in Schedule 3A) does not exceed [number to be defined at call-off] during the Contract Term. This number is the "Intervention Cap" for the purposes of Schedule 3A;
- work with the Local Health Economy to agree and implement a strategy for managing demand within the Intervention Cap;
- ensure that no Service User is invited to participate in the Service after a period of [to be defined at call-off] years has elapsed since the Effective Date. This period is the "Intervention Period" for the purposes of Schedule 3A;
- ensure that the number of Service Users who have achieved Milestone 1 (as defined in Schedule 3A) and are participating in the Digital Service does not exceed a figure that is equal or more than [number to be defined at call-off]. This figure is the "Digital Service Cap" for the purpose of the Contract. For the avoidance of doubt, the Provider must not offer the Digital Service to a person once the number of Service Users who have achieved Milestone 1 (as defined in Schedule 3A) and are participating in the Digital Service is equal to or more than the Digital Service Cap.
- actively monitor and report to the Commissioner and Local Health Economies, the number of Service Users who achieve Milestone 1 via both the Face-to-face Service and the Digital Service throughout the Contract Term; and
- notify the Commissioner as soon as reasonably practicable where the number of Service Users achieving Milestone 1 (as defined in Schedule 3A) is predicted to exceed either the Digital Service Cap and / or the Intervention Cap.

The Commissioner may at its discretion either:

- vary the Intervention Cap and/or the Intervention Period;
- vary the Digital Service Cap; and/or
- notify the Provider that it will not vary the Intervention Cap and/or the Intervention Period.

Where the Commissioner varies the Intervention Cap, Intervention Period and/or Digital Service Cap, it will notify the Provider and the Provider shall comply with the variation.

For the avoidance of doubt:

- the Provider's consent is not required for such variations and General Condition 13 does not apply to such variations; and
- varying the figures for the purpose of this paragraph 3.10 includes increasing or decreasing the relevant figure.

The Provider will not be paid for the Service provided to any additional Service Users:

- invited to participate in the Service once the Intervention Cap has been reached in accordance with paragraph 2 of Part 1 of Schedule 3A;
- invited to participate in the Service once the Intervention Period has expired in accordance with paragraph 2 of Part 1 of Schedule 3A; and/or
- offered the Digital Service in the scenarios set out in this Schedule 2A once the Digital Service Cap has been exceeded.

The Contract Term will be the period from the Effective Date to the day after which the Provider submits the data submission for the last Service User on the programme who completed the Final Session or other such day as agreed in writing between the Parties.

### 3.11 Transition

This Contract may require the Provider to provide the Service in an area where, at commencement of this Contract, there is an existing provider providing services under a contract that the Commissioner has previously called off. In such a situation, there will be a period during which the Provider is commencing delivery of the Service and the existing provider is winding down its delivery of services (i.e. it will not be accepting any new referrals to its service).

Prior to expiry or termination of this Contract, the Provider may be required to provide the Service in an area where there is a new provider preparing to deliver services under a contract that the Commissioner has newly called off. In such a situation, there will be a period during which the Provider is winding down its delivery of services (i.e. it will not be accepting any new referrals to its service) and a new provider is commencing delivery of their service.

These periods are referred to as "Transition Periods". This paragraph 3.11 sets out obligations on the existing provider and/or the incoming provider. During a Transition Period, the Provider may be the existing provider or the incoming provider depending on the nature of the Transition Period. Where the Provider is the existing provider or the incoming provider, the Provider will comply with the relevant obligations set out below.

The aim during the Transition Period is that:

- Primary care engagement is maintained and a steady flow of referrals into NDPP service continues;
- A high quality of service is provided to service users regardless of which provider's service they are referred to, or enrolled on; and

- There is an orderly wind down by the existing provider and mobilisation and commencement of delivery of the service by the incoming provider.

The existing provider is responsible for delivering the full intervention to all service users who have reached milestone one as defined in that contract, within the intervention cap and the intervention period specified in that contract. The existing provider needs to maintain high levels of engagement of service users throughout the Transition Period, and ensure that there is a sustainable workforce and delivery model to manage the Transition Period.

During the Transition Period, there will likely be individuals who have been referred to the existing provider but who have not yet progressed to milestone one as defined in that contract prior to the Intervention Period expiring. Such individuals will be transferred, in compliance with the Data Protection Legislation, by the existing provider to the incoming provider and the incoming provider must offer such individuals the service in the same way the incoming provider offers the Service to those referred to the Service by their GP.

The incoming provider must ensure that the approach adopted to enable such transfers between programmes is agreed with the local health economy and the existing provider. The incoming provider and the existing provider are responsible for complying with relevant data protection legislation and the duty of confidentiality throughout this process.

The existing provider shall provide to the incoming provider details on waiting lists of individuals and current session delivery locations to support sustainability of service delivery and the incoming provider is required to attend joint planning meetings through the Transition Period to support operational delivery. The existing provider will continue to provide data to the local health economy and will provide an operational point of contact until all service users being provided with the service by the existing provider have either completed the programme or have been discharged.

The incoming provider must ensure it is able to provide the service to persons referred by the existing provider as if such persons were referred to the service by their GP and in accordance with all requirements in this Schedule 2A.

The incoming provider must support the local health economy and the existing provider in the delivery of a communications and engagement approach across local stakeholders to support a smooth transition of patient flow and service delivery.

### **3.12 Review meetings**

Review meetings between the Provider and the Commissioner in accordance with General Condition 8 of this Contract shall be conducted on behalf of the Commissioner by any person nominated by the Commissioner to act on its behalf. References to the "Commissioner" in the context of Review Meetings shall be construed accordingly.

The Provider shall attend monthly meetings (whether in person or by telephone) with the Commissioner Representative to discuss progress of the delivery of the Services and any key issues arising. The matters to be discussed at such meetings shall be as agreed between the Provider and the Commissioner Representative. Such meetings shall be held in addition to Review Meetings (which shall be held on a quarterly basis). The Provider shall agree a written record of the key outputs from such meetings with the Commissioner Representative and provide a copy of such record to the Commissioner Representative within one month of the relevant meeting.

Unless agreed otherwise by the Parties, at least one week in advance of these meetings the Provider will deliver to the Commissioner the performance reports detailed in Schedule 6A, in the format described.

The Provider shall attend monthly meetings (whether in person or by telephone) with local lead partner organisations, in whose areas the Services are delivered, to review any specific local issues relating to the delivery of the Services including the level of referrals to the Services and any other matters as either the Provider or the relevant local partner organisations considers relevant to the Services. The Provider shall agree a written record of the key outputs from such meetings with the local partner organisations and provide a copy of such record to the Commissioner Representative within one month of the relevant meeting. Such meeting records will be reviewed at Review Meetings between the Provider and the Commissioner.

At least one week in advance of these meetings, the Provider will deliver to the local lead partner, the data and performance reports detailed in Schedule 6A, in the format described.

### **3.13 Evaluation and Quality Assurance**

The Provider will participate fully in any Quality Assurance processes as defined by the Commissioner and co-operate in undertaking ad-hoc audits and reviews as requested by commissioners in a timely manner. This will include the submission to commissioners of:

- Agreed data and reports from external quality assurance schemes
- Self-assessment questionnaires / tools and associated evidence.

The Provider will also participate in evaluations of the Service commissioned by or approved by the Commissioner.

## **4. Applicable Service Standards**

### **4.1 Applicable national standards (e.g. NICE)**

The Provider will deliver the Service in accordance with all relevant clinical guidelines and other guidance and publications published nationally, in particular:

- NICE PH38 Preventing Type 2 Diabetes: risk identification and interventions for individuals at high risk (2012 and updated 2017)
- NICE PH 42 Obesity: working with local communities (2012)
- NICE PH 6 Behaviour change: the principles for effective interventions (2007)
- NICE PH 49 Behaviour change: individual approaches (2014)
- NICE NG90 Physical activity and the environment NICE CG 43 Obesity: Guidance on the prevention of overweight and obesity in adults and children (2006 and updated 2015)
- NICE CG 189 Obesity: identification, assessment and management of overweight and obesity in children, young people and adults (2014)
- NICE PH 53 Managing overweight and obesity in adults – lifestyle weight management services (2014)
- NICE PH 46 BMI: preventing ill health and premature death in black, Asian and other minority ethnic groups (2013)
- Healthy Lives, Healthy People: A call to action on obesity in England (DH 2011)

## **5. Applicable quality requirements**

### **5.1 Applicable Quality Requirements**

The Quality Requirements applicable to the Service are set out in Schedule 4.

### **5.2 Equity and access**

- In the delivery of the Service the Provider must comply with the obligations placed on the Commissioner by section 13G of the NHS Act 2006 (due regard to the need to reduce health inequalities) and section 149 of the Equality Act 2010 as if those obligations applied directly to the Provider;

- The Provider must promptly provide such co-operation to the Commissioner as the Commissioner reasonably requests regarding the Commissioner's discharge of its duties under section 13G of the NHS Act 2006 and section 149 of the Equality Act 2010; and
- The Provider will complete an annual Equality and Health Inequalities Impact Assessment (E&HIIA) and action plan to challenge discrimination, promote equality, respect Service Users' human rights and to reduce health inequalities in access to services and outcomes. The E&HIIA and action plan shall be provided to the Commissioner on the Effective Date and each anniversary of the Effective Date. Progress against the action plan will be reported by the Provider to the Commissioner on a Quarterly basis at the relevant Review Meeting.

The Provider must at all times adhere to all relevant health and safety and security Law in providing the Services.

## Schedule 2A Service Specification

### Annex 1

#### Government recommendations for diet and physical activity

Topic	Recommendation
<u>Diet</u>	
Carbohydrates <sup>10,11</sup>	Approximately 50% of total dietary energy <sup>14</sup>
Free sugars <sup>12</sup>	No more than 5% of total dietary energy
Sugar-sweetened drinks <sup>13</sup>	Consumption should be minimised
Fat <sup>15</sup>	No more than 35% of food energy <sup>16</sup> (33% total dietary energy)
<i>Of which saturated fat</i>	<i>No more than 11% of food energy (10% total dietary energy)</i>
Salt <sup>17</sup>	No more than 6g for adults
Fibre <sup>18</sup> (AOAC)	30g per day for adults
Fruit & vegetables <sup>19</sup>	At least 5 portions of a variety per day
Fish <sup>20</sup>	At least 2 portions (2 x 140g) a week, one of which should be oily
Red and processed meat <sup>21</sup>	For adults with relatively high intakes of red and processed meat (i.e. over 90g/day) to consider reducing their intake to the population average (about 70g/day)
Topic	Recommendation
<u>Physical activity</u>	Adults should aim to be active daily. Over a week, activity should add up to at least 150 minutes (2½ hours) of moderate intensity activity in

<sup>10</sup> Carbohydrates, free sugars, sugars-sweetened drinks and fibre – SACN (2015) Carbohydrates and Health. [www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/445503/SACN\\_Carbohydrates\\_and\\_Health.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/445503/SACN_Carbohydrates_and_Health.pdf)

<sup>11</sup> SACN's recommendations for carbohydrates were set as a percentage of 'total dietary energy' only

<sup>12</sup> As for footnote 10 above

<sup>13</sup> As for footnote 10 above

<sup>14</sup> Total dietary energy includes energy from food and alcohol

<sup>15</sup> Total fat, saturated fat – COMA (1991) Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. London: HMSO.

<sup>16</sup> Food energy excludes energy from alcohol

<sup>17</sup> Salt – SACN (2003) Salt and Health

[www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/338782/SACN\\_Salt\\_and\\_Health\\_report.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/338782/SACN_Salt_and_Health_report.pdf)

<sup>18</sup> As for foot note 10 above

<sup>19</sup> World Health Organisation (1990) Diet, nutrition and the prevention of chronic diseases.

[http://www.who.int/nutrition/publications/obesity/WHO\\_TRS\\_797/en/index.html](http://www.who.int/nutrition/publications/obesity/WHO_TRS_797/en/index.html)

World Health Organisation (2003) Diet, nutrition and the prevention of chronic diseases.

<http://www.who.int/dietphysicalactivity/publications/trs916/download/en/>

<sup>20</sup>SACN (2004) Advice on Fish Consumption: benefits and risks.

[www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/338801/SACN\\_Advice\\_on\\_Fish\\_Consumption.pdf](http://www.gov.uk/government/uploads/system/uploads/attachment_data/file/338801/SACN_Advice_on_Fish_Consumption.pdf)

<sup>21</sup> Red and processed meat – SACN (2011) Iron and Health

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/339309/SACN\\_Iron\\_and\\_Health\\_Report.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/339309/SACN_Iron_and_Health_Report.pdf)

	<p>bouts of 10 minutes or more – one way to approach this is to do 30 minutes on at least 5 days a week.</p> <p>Alternatively, comparable benefits can be achieved through 75 minutes of vigorous intensity activity spread across the week or combinations of moderate and vigorous intensity activity.</p> <p>Adults should also undertake physical activity to improve muscle strength on at least two days a week.</p> <p>All adults should minimise the amount of time spent being sedentary (sitting) for extended periods.</p>
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**Schedule 2A Service Specification**

**Annex 2**

**BMI classifications for overweight and obesity**

<b>Classification</b>	<b>White European populations</b>	<b>Asian populations</b>
<b>Underweight</b>	<18.5 kg/m <sup>2</sup>	<18.5 kg/m <sup>2</sup>
<b>Healthy weight</b>	18.5–24.9 kg/m <sup>2</sup>	18.5-23.4 kg/m <sup>2</sup>
<b>Overweight</b>	25–29.9 kg/m <sup>2</sup>	23.5-27.4 kg/m <sup>2</sup>
<b>Obese</b>	30 or more kg/m <sup>2</sup>	27.5 kg/m <sup>2</sup> or more

**Schedule 2A Service Specification**

**Appendix 1**

**Tender Response Document**

**[Bidder tender response to be inserted prior to each call-off Contract award]**

**Schedule 2A Service Specification**

**Appendix 2**

**Local Service Requirements**

**[A populated prospectus is included in the procurement documentations for the Call-off Contract. It will be added here on contract award and will constitute the Local Service Requirements of that Contract.]**

**Schedule 2A**

**Appendix 3**

**Provider IPR**

**[To be inserted prior to each Call-off Contract award]**