NDPP National Service Specification

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1. Service Specifications

[These provisions may be subject to further amendment and/or refinement prior to contract award, as appropriate]

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<tr>
<th>Service Specification No.</th>
<th>1</th>
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<tbody>
<tr>
<td>Service</td>
<td>Provision of behavioural interventions for people with non-diabetic hyperglycaemia</td>
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<tr>
<td>Commissioner Lead</td>
<td>NHS England</td>
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<tr>
<td>Provider Lead</td>
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<td>Period</td>
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<td>Date of Review</td>
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2. Population Needs

2.1 National / local context and evidence base

2.1.1 Introduction to the NHS Diabetes Prevention Programme

The NHS Diabetes Prevention Programme (‘NDPP’) was announced in the NHS Five Year Forward View, published in October 2014, which set out the 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 new NHS Health Check.

The NDPP is a joint initiative between NHS England, Public Health England
and Diabetes UK which aims to deliver at a large scale services for people already identified with non-diabetic hyperglycaemia, and 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, improved diet and increased levels of physical activity.

2.1.2 Rationale for the Service

The rationale for procuring the Service on a national scale is as follows:

- A recent report published by the National Cardiovascular Intelligence Network (NCVIN) 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 and minority ethnic groups (and onset is often at a younger age in these groups), and prevalence increases with age and obesity.

- We know that demand for NICE recommended behavioural interventions outstrips supply for individuals identified by their GP as being at high risk of Type 2 diabetes. GPs commonly do not have an evidence based diabetes prevention service to refer into. Further, where diabetes prevention services do already exist, the quality and value of these services varies and they do not necessarily conform to the evidence of what is effective. Growing numbers of people at high risk of Type 2 diabetes are also being identified through the NHS Health Check; this is increasing demand for diabetes prevention services.

- A national procurement for the Service will allow the rapid roll-out and scale up of the NDPP whilst ensuring consistency in Service design and data collection, reducing existing inequalities in access and outcomes, and maintaining fidelity to the evidence base.

3. Outcomes

3.1 NHS Outcomes Framework Domains & Indicators

<table>
<thead>
<tr>
<th>Domain</th>
<th>Outcomes</th>
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<tbody>
<tr>
<td>Domain 1</td>
<td>Preventing people from dying prematurely</td>
</tr>
<tr>
<td>Domain 2</td>
<td>Enhancing quality of life for people with long-term conditions</td>
</tr>
<tr>
<td>Domain 3</td>
<td>Helping people to recover from episodes of ill-health or following injury</td>
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</tbody>
</table>

### Domain 4
Ensuring people have a positive experience of care

### Domain 5
Treating and caring for people in safe environment and protecting them from avoidable harm

#### 3.2 Local defined outcomes

##### 3.2.1 Public Health Outcomes Framework

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Description</th>
<th>X</th>
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<tbody>
<tr>
<td>Outcome 1</td>
<td>Increased healthy life expectancy</td>
<td>X</td>
</tr>
<tr>
<td>Outcome 2</td>
<td>Reduced differences in life expectancy and healthy life expectancy between communities</td>
<td>X</td>
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</tbody>
</table>

##### 3.1.2 NDPP outcomes
- Reduction in incidence of diabetes among Service Users
- Reduction in blood glucose parameters among Service Users
- Reduction in weight of Service Users

#### 4. Scope

##### 4.1 Aims and objectives of the Service

##### 4.1.1 Aims of the Service

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.

A tertiary aim of the Service is to establish sound data collection mechanisms to ensure that 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.
4.1.2 Objectives of the Service

The Provider must:

- provide the Service in the following geographical area – [insert definition of area];
- ensure that the number of Service Users who achieve Milestone 1 (as defined in Schedule 3A) does not exceed 1,970 during the Contract Term. This number is the "Intervention Cap" for the purposes of Schedule 3A;
- ensure that no Service User is invited to participate in the Service after a period of two (2) years has elapsed since the Effective Date. This period is the "Intervention Period" for the purposes of Schedule 3A;
- actively monitor the number of Service Users who achieve Milestone 1 throughout the Contract Term; and
- notify the Commissioner as soon as reasonably practicable after 75% of the number of Service Users indicated in the second bullet point above (the Intervention Cap) achieve Milestone 1.

Following receipt of such notification from the Provider, the Parties shall meet to review the activity levels under the Contract and the potential trajectory of Service User numbers. Following such meeting, the Commissioner may at its discretion either:

- propose a Variation to vary the Intervention Cap and/or the Intervention Period in accordance with General Condition 13.4 (and propose such consequential amendments to this Contract as may be necessary in accordance with General Condition 13); or
- notify the Provider that it will not vary the Intervention Cap and/or the Intervention Period.

If either the Parties do not agree a Variation to vary the Intervention Cap and/or the Intervention Period or the Commissioner notifies the Provider that it will not vary the Intervention Cap and/or the Intervention Period, 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 Schedule 3A, Part 1.

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.

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2 The relevant geographical area as referenced in the relevant prospectus (issued with the ITT documents) will be inserted here prior to contract award.
4.2 Service description / care pathway

4.2.1 Principles

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

- The Service must aim to reduce health inequalities and promote equality, targeting those with greatest need through a proportionate universalism approach and equality of access for people with protected characteristics under the Equality Act 2010;

- The Provider must ensure that the impact on existing primary care services of the Service is minimised, including (but not limited to) in terms of information requirements, data transfer into GP practices and requests for diagnostic tests;

- All individuals must be treated with courtesy, respect and an understanding of their needs;

- All potential Service Users participating in any aspect of the Service 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;

- Access to the Service will be matched to the diverse needs of the target population in terms of availability, accessibility and location, as far as possible;

- Identification of people with non-diabetic hyperglycaemia and referral on to 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 demonstrator phase 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).

- The Provider must provide the Services in accordance with this Schedule 2A and the Tender Response documents contained in Appendix 1 of this Schedule 2A.

- If there is any conflict or inconsistency between the provisions of Schedule 2A and the provisions of Appendix 1 to this Schedule 2A,
the provisions of Schedule 2A will prevail over the provisions of Appendix 1 of this Schedule 2A.

4.2.2 Invitation to participate

The Provider will send an invitation to participate in the Service to all eligible individuals who have been referred into the Service. The Provider will make first contact with all eligible individuals within 5 Operational Days of receipt of the referral inviting them to participate in the Service. The Provider will work with local health economies to set expectations around trajectory of referrals to be received by the Provider.

Where there is no response from the potential Service User the Provider will make additional attempts to contact the potential Service User. The Provider must make contact with potential Service Users via letter, phone call, text message or email. The commissioner considers that two contact attempts will be the minimum. Bidders will need to consider whether further attempts may result in the person joining the programme.

The invitation and all follow-up contact will contain basic, accessible information about Type 2 diabetes; information about how risk of developing Type 2 diabetes can be reduced. 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 to them by the Commissioner.

The Provider will ensure that eligible individuals who do not accept an invitation to enroll on the Service are given information about 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.

The Provider must also notify the eligible individual’s GP providing notification of “Discharge” from the Service. “Discharge” prior to participation in the Service must be defined by the Provider.

4.2.3 Individual assessments

Individual assessments form the first stage of the Service. The Provider will conduct assessments with all Service Users who accept their 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 Schedule 6A.

The initial assessment should be delivered face to face. Elements of the initial assessment other than weight measurement and blood test might be conducted through alternative channels other than face to face. However, given the need to accurately measure weight of participants at the initial assessment, this does assume a need for the assessment to be conducted face to face.
The Provider must establish a baseline blood glucose reading for:

- all Service Users whose blood result provided on referral is dated more than three months prior to attendance at this assessment; and
- all Service Users recruited directly by the Provider via the DR Service.

Please refer to section 3.2.4 for blood test specifications.

- If the blood test result confirms that a Service User has non-diabetic hyperglycaemia the Provider will invite the Service User to continue in the Service.

- If the blood test result 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 must conduct a confirmatory blood test to either confirm or disconfirm diagnosis. If the confirmatory blood test confirms a diagnosis of Type 2 diabetes, according to the WHO diagnostic criteria for Type 2 diabetes, the Provider must advise the Service User that their blood test indicates Type 2 diabetes and that they should see their GP or Practice Nurse to discuss this further. The Provider must provide to the GP the new blood glucose results and the new diagnosis of Type 2 diabetes within 3 Operational Days. The Provider will not invite the individual to continue in the Service.

- If the first blood test result performed or organized 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 who's blood glucose levels have risen rapidly requiring urgent/same day assessment by a GP, diabetologist or accident & emergency and the Provider must respond immediately and within the same Operational 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.

- If the blood test result suggests normal blood glucose levels, defined as HbA1c level of less than 42 mmol/mol (5.9% or less) or FPG level of less than 5.5 mmol/l, the Provider will invite the Service User to participate in the Service.

This blood test must be done or organized by the Provider and blood results should be fed back to general practice. Individuals must not be accepted

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onto the Service unless a blood test has been conducted and the blood result must demonstrate non-diabetic hyperglycaemia.

The Provider must ensure that their use of this approach does not have a significant impact on GP workloads unless there is agreement from the local GP. In particular, any blood tests undertaken by the Provider must be arranged with pharmacy or laboratory services, unless local GPs have explicitly agreed that they will arrange blood tests (and in such circumstances GPs should be appropriately remunerated for the service outside of their existing contracts with the NHS to provide primary medical services).

The Provider will offer all eligible Service Users a place on the Service, and those who accept this invitation to enroll on the Service will be considered sufficiently motivated to benefit from participation.

4.2.4 HbA1c and FPG testing

The Provider must use either an HbA1c test or an FPG test for assessing glycaemic status. The Provider must use the same test as was provided to them in the Service User’s referral. (nb. The same type of test needs to be conducted, but different methods can be used. For example, the GP may provide a laboratory-based test result but it is permissible for the provider to conduct a POCT provided it meets all of the requirements detailed in the service spec.)

In such circumstances where two test results are provided (both HbA1c and FPG) the HbA1c test result must be used and subsequent testing must involve HbA1c testing.

There are circumstances that result in HbA1c being less reliable for this assessment, and FPG must be used in those individuals where such circumstances arise. These circumstances include, but are not restricted to:

- Abnormal haemoglobins (variant haemoglobins)
- Anaemia
- Altered lifespan of the red blood cell.

The Provider may perform HbA1c testing using venous blood analysed on laboratory-based analysers or capillary whole blood measured on point-of-care testing (POCT) devices. Once selected, the Provider must use the same analyser (laboratory-based or POCT) for repeated measures in the same individuals.

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.

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.

The Provider must ensure that POCT devices meet the analytical performance criteria of laboratory-based methodologies as stipulated in expert guidance.\(^4,5\) POCT devices must function within an appropriate quality framework that ensures all parameters of MHRA stipulated guidance on POCT are met.\(^6\)

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.\(^7,8\) 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.

Point-of-care capillary blood glucose devices (including those meeting International Organisation for Standardisation 15197\(^5\)) do not currently meet the accuracy or quality assurance criteria required for diagnostic testing and therefore must not be used in this capacity.\(^9\)

The Provider must ensure that it, or its sub-contractor (as appropriate), is registered with the CQC for HbA1c and FPG testing.

4.2.5 Service aim

The primary focus 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 objectives set out in 3.1 above and with the aim of achieving three core goals:

- Weight loss, or the maintenance of a healthy weight;
- Achievement of UK dietary recommendations related to fibre, fruit and vegetables, oily fish, saturated fat, salt and free sugars;\(^10\) and
- Achievement of the England Chief Medical Officer’s (CMO) physical...
activity recommendations.\textsuperscript{11}

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.

4.2.6 Intensity and duration

The Provider must deliver the Service in accordance with the following minimum 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;
- At least 13 sessions must be provided to each Service User, spread across a minimum total of 16 hours’ contact time;
- Each session must last between 1 and 2 hours. Shorter sessions must only be provided on prior agreement between the Commissioner and the Provider and a strong rationale must be provided (for example, 20 minute telephone-based sessions in between longer group sessions or 50 minute sessions to slot sessions into lunch breaks for those in employment).
- Very brief and brief interventions may be classified as a session delivered when they are over and above the 13 sessions of 1-2 hours. For example, the provider may wish to deliver 13 face-to-face sessions of 1-2 hours with 4 brief or very brief interventions as an addition, totalling 17 sessions.
- 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 may include evening and weekend sessions to facilitate access for working people. Sessions must be offered at a range of times, days and venues in order to maximise access to (and therefore uptake of) the Service;
- The Provider must allow sufficient time between sessions for Service Users to make behavioural changes gradually.
- The initial assessment does not count towards intervention hours but the final session does. The initial assessment is counted outside of the minimum 13 sessions service specification. Weigh-ins do not count towards session time in isolation although they could be part of a session.

4.2.7 Underpinning theory and approach

\textsuperscript{11} 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.
• The Provider must ensure that the Service is grounded in behavioural theory. The Provider must be explicit regarding the behavior change theory and techniques that are being used, and the expected mechanism of action. The Provider must utilise a known framework (for example, Mitchie et al (2011)\textsuperscript{12}) in their detailing of behaviour change theory and techniques.

• 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 behavior change must be demonstrated; particularly in relation to promoting recruitment and retention of Service Users, and session attendance. The Provider must comply with materials and templates provided. Templates are provided as Annexes to this document.

• The Provider must be explicit about the intended action expected by 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 behaviour change frameworks as described above). Evidence and best 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.

4.2.8 Delivery, training and competencies

• The Provider must ensure that the Service is delivered using predominantly group sessions with a maximum of 20 people in each group. Individual sessions (either in person or remotely) may also be included to enhance delivery. Larger group sizes must only be used on prior agreement between the Commissioner and the Provider and a strong rationale must be provided (for example, a group exceeds 20 people where some Service Users are bringing a family member). The Provider must ensure that group sessions are delivered face-to-face (in person). An alternative approach (for example, online delivery) must only be used on prior agreement between the Commissioner and the Provider and a strong rationale and / or local drive for an alternative approach must be detailed (for example, remote communities are unable to attend regular face-to-face sessions). Where an alternative approach is agreed and adopted it must be part of rigorous evaluation or based on new evidence that

did not form part of Public Health England’s published meta-analysis 13 and this evidence or evaluation must be described.

• 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 commissioner would be prepared to consider proposals for the amalgamation or joining together of groups if numbers of attendees in a group are small (subject to maximum group size of 20).

• The Provider will ensure that the Service is delivered by health professionals or other suitably trained and competent individuals. 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 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.

• Training in delivery of the Service must incorporate training in the delivery of very brief advice for smoking cessation, provided free of charge online by the National Centre for Smoking Cessation and Training. 14

• The Provider will ensure that all Staff adopt a person-centered, 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, behavior change, weight loss, diet and physical activity) is involved in development and delivery of the Service; for example, a registered dietitian / nutritionist, a registered health

14 www.ncsct.co.uk/publication_very-brief-advice.php
psychologist and a qualified physical activity instructor and their expertise will be drawn upon relevant to their respective areas of expertise.

- There is not a requirement for health professionals to deliver content of group sessions, nor be involved in every session, but the Provider should consider involving health professionals in aspects of delivery of the Service. For example, in discussions about physical activity it would be beneficial to involve a qualified physical activity instructor who will have been trained in understanding 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.

4.2.9 Content of sessions

The Provider must develop detailed content for sessions. Certain topics must be covered including (but not limited to) information about Type 2 diabetes and risk factors for Type 2 diabetes, weight loss, and dietary and physical activity information set out below and detailed more fully in Annex 1 of this document.

The Provider must deliver the sessions in a logical progression, for example starting out with information about risk for Type 2 diabetes and a discussion of the risks and benefits of lifestyle changes.

Weight loss:

- The Service must involve a ‘weigh in’ at every session for those Service Users who are overweight or obese, as defined in Annex 2.

- 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.

Dietary content:

- The syllabus must include the broader UK dietary recommendations as detailed in the Eatwell plate.\textsuperscript{15} This involves (for some) increased intake of fibre, fruit and vegetables and oily fish, and decreased intake of saturated fat, sugar, salt and energy;

- The Provider must support Service Users to aim to meet as many of the dietary recommendations as possible. Service Users should be encouraged to set achievable goals within identified areas for

\textsuperscript{15} Information about the Eatwell Plate can be accessed at \url{www.nhs.uk/Livewell/Goodfood/Pages/eatwell-plate.aspx}. The Eatwell plate is currently under review and pending revision in January 2016.
improvement.

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. 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 support Service Users to incorporate active travel into their daily routine either through walking or cycling skills and group activities; and

- 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.

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.

The Provider is required to take additional HbA1c/FPG test at 6 months for all those individuals that remain on the programme.

It is included at Session 8 in the Data Output Specification (contained in Schedule 6A) however this should be collected at whichever session takes place 6 months in to the programme. Session 8 does not have to take place at 6 months in to the programme.

4.2.10 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 Services departments within Local Authorities, NHS Choices, and local Exercise on Referral schemes.

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 person 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 mechanism with local health economies and systems.

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16 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
17 www.ncsct.co.uk/publication_very-brief-advice.php
### 4.2.11 Final session

The “Final Session” is defined as the last session delivered by the Provider as part of the planned Service (for those participants still attending). As part of the Final Session the Provider must conduct a post-intervention assessment of weight, HbA1c (or FPG for those Service Users in whom HbA1c cannot be used) and wellbeing for all Service Users who attend. Body mass index must also be calculated. Details of the data to be collated and reported for these assessments is provided in Schedule 6A.

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.

### 4.2.12 Notification of Discharge from the Service

The Service User is “Discharged” from the Service following completion of the Final Session (or once the Final Session has been delivered), or when a Service User misses three consecutive sessions for no known reason. The Provider must provide each Service User’s GP with notification of Discharge via letter. The Annexes to this document contain a template letter and the Provider must comply with this and the Discharge information requirements set out in Schedule 6A. Once the Final Sessions is completed then the Service User is discharged automatically regardless of the number (or percentage) of sessions attended.

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 must also comply with the template structure in which this information should be provided as specified by the Commissioner in Schedule 6A.

The Provider must ensure that the letter to the GP referred to in this section 4.2.13 advises 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 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.

### 4.2.13 Marketing of the Service

The Provider must undertake marketing and promotional activity to advertise the existence of the NDPP, with a view to raising awareness about the availability and benefits of the Service amongst people in the geographical area.
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.

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.

4.2.14 Intellectual Property

For the avoidance of doubt, notwithstanding General Condition 1.2, the Parties expressly agree that this paragraph 3.2.14 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.

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 3.2.14 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 3.2.14 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.

“Participating Commissioner” in this paragraph 3.2.14 means a clinical commissioning group or local authority in relation to whose geographical area the Services are delivered.

“Provider IPR” in this paragraph 3.2.14 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 infringement (including the defence of such infringement or alleged 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.

4.2.15 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.

4.2.16 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 the NHS South, Central and West Commissioning Support Unit and 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. Such meeting records will be reviewed at Review Meetings.

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. Such meetings shall be held in addition to Review Meetings (which shall be held on a quarterly basis).

4.3 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
referral onto the Service.

4.4 Any acceptance and exclusion criteria

4.4.1 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.

4.4.2 Exclusion criteria

The following individuals must be excluded from the Service:

- Individuals with blood results confirming a diagnosis of Type 2 diabetes
- Individuals with a normal blood glucose reading on referral to the Service
- Individuals aged under 18 years
- 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.)

4.5 Direct to consumer advertising

In certain circumstances the Provider may recruit Service Users directly onto the Service, in which case such services will be provided in line with the requirements set out in Service Specification No. 2 (Direct Recruitment onto Behavioural Interventions by Providers) set out in Schedule 2A.

4.6 Interdependence with other services/providers

The Service needs to function within the broader prevention and primary care systems. The Provider must establish systems that allow local GP practices and NHS Health Check providers (where these are not part of a GP practice) to make referrals into the Service with clear protocols in place.
about how they do this. The Provider must send information about participation in the Service for Service Users and the outcomes they achieve to the relevant GP practice in a way that is consistent with NHS information governance principles and the provisions of General Condition 21 of the Contract.

The Provider must promote the Service to local GP practices and to NHS Health Check providers to ensure that there is good awareness locally of the Service and the methods for referring people into it.

4.6.1 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.

4.7 Information Governance

The Provider will submit the "Data Output Specification" document and the "Direct Recruitment Data Requirements" 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 a proportion of participants to agree to be contacted for the purpose of service evaluation and record their consent where given. The Commissioner will specify this proportion of participants 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.

5. Applicable Service Standards

5.1 Applicable national standards (eg 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)
- 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 PH 8 Physical activity and the environment (2008)
- 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)

6. Applicable Quality Requirements

6.1 Applicable Quality Requirements

The Quality Requirements applicable to the Service are set out in Schedule 4.
6.2 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.
## Service Specification No 1 - Annexes

### Annex 1: Government recommendations for diet and physical activity

<table>
<thead>
<tr>
<th>Topic</th>
<th>Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diet</strong></td>
<td></td>
</tr>
<tr>
<td>Carbohydrates(^{18,19})</td>
<td>Approximately 50% of total dietary energy(^{20})</td>
</tr>
<tr>
<td>Free sugars(^{1})</td>
<td>No more than 5% of total dietary energy</td>
</tr>
<tr>
<td>Sugar-sweetened drinks(^{1})</td>
<td>Consumption should be minimised</td>
</tr>
<tr>
<td>Fat(^{21})</td>
<td>No more than 35% of food energy(^{22}) (33% total dietary energy)</td>
</tr>
<tr>
<td>Of which saturated fat</td>
<td>No more than 11% of food energy(^{22}) (10% total dietary energy)</td>
</tr>
<tr>
<td>Salt(^{23})</td>
<td>No more than 6g for adults</td>
</tr>
<tr>
<td>Fibre(^{1}) (AOAC)</td>
<td>30g per day for adults</td>
</tr>
<tr>
<td>Fruit &amp; vegetables(^{24})</td>
<td>At least 5 portions of a variety per day</td>
</tr>
<tr>
<td>Fish(^{25})</td>
<td>At least 2 portions (2 x 140g) a week, one of which should be oily</td>
</tr>
</tbody>
</table>

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\(^{19}\) SACN’s recommendations for carbohydrates were set as a percentage of ‘total dietary energy’ only

\(^{20}\) Total dietary energy includes energy from food and alcohol


\(^{22}\) Food energy excludes energy from alcohol


<table>
<thead>
<tr>
<th>Red and processed meat&lt;sup&gt;26&lt;/sup&gt;</th>
<th>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)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Topic</strong></td>
<td><strong>Recommendation</strong></td>
</tr>
<tr>
<td>Physical activity</td>
<td>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 bouts of 10 minutes or more – one way to approach this is to do 30 minutes on at least 5 days a week. 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. Adults should also undertake physical activity to improve muscle strength on at least two days a week. All adults should minimise the amount of time spent being sedentary (sitting) for extended periods.</td>
</tr>
</tbody>
</table>

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<sup>26</sup> Red and processed meat – SACN (2011) Iron and Health
Annex 2: BMI classifications for overweight and obesity

<table>
<thead>
<tr>
<th>Classification</th>
<th>BMI (kg/m²)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Underweight</td>
<td>&lt; 18.5</td>
</tr>
<tr>
<td>Healthy weight</td>
<td>18.5 – 24.9</td>
</tr>
<tr>
<td>Overweight</td>
<td>25 – 29.9</td>
</tr>
<tr>
<td>Obesity</td>
<td>≥ 30</td>
</tr>
</tbody>
</table>
Service Specification No 1 – Annexes

Annex 3 - Template Documents

[Template letters to be inserted prior to call-off contract award]
1. Overview

1.1. Service Specification No. 1, set out in Schedule 2A, requires the Provider to market and promote the Service (i) to local healthcare professionals; and (ii) to the public to raise awareness about the availability of the Service in areas where it is operating.

1.2. In addition, the Commissioner may choose to purchase the DR Service whereby the Provider directly identifies and recruits people with non-diabetic hyperglycaemia onto its programme.

2. Background

2.1. The effect of direct recruitment by providers onto behavioural interventions is unknown. On the one hand it could support the objective of delivering evidence based behavioural intervention programmes to 100,000 people per year. On the other it could be the case that demand could exceed supply, or that people from some communities, or some groups in local communities would be more likely to respond to attempts to recruit them onto programmes than others and thereby exacerbating health inequalities.

2.2. It is therefore desirable to introduce direct recruitment by the Provider within the Service in a controlled way to enable the impact of the approach to be evaluated.

2.3. Type 2 Diabetes is strongly associated with ethnicity, with those from black and minority ethnic groups more likely to develop it at a younger age and with a lower BMI. Direct recruitment by the Provider could potentially help the programme to engage with people from minority groups through targeted marketing and therefore help to reduce future health inequalities. Therefore, where it is introduced there must be a specific focus on recruitment of people from BME groups and other groups in the community which may be less likely to access existing services.

3. Direct Recruitment by Providers

3.1. Objectives – The objectives in commissioning direct recruitment
into the Service by the Provider are:

3.1.1. To increase the number of people accessing evidence based diabetes prevention programmes;

3.1.2. To expand the evidence base around the effectiveness of direct recruitment onto diabetes prevention programmes by providers (particularly the extent to which recruitment by providers has the potential to impact on health inequalities); and

3.1.3. Improving take up by groups in the community which are potentially less likely to participate in a diabetes prevention programme i.e. targeting “hard to reach” groups, including those groups included in the Commissioner's equality and health inequality obligations.

3.2. Principles – The following principles have informed the Commissioner's approach in relation to direct recruitment by the Provider:

3.2.1. As the evidence base for direct recruitment of people onto programmes by providers has yet to be established, such approaches must be introduced in the first instance in a limited and controlled way and must be subject to an evaluation;

3.2.2. the Commissioner may at its discretion require the Provider to provide the DR Service at any time during the Contract Term by providing at least 30 days’ written notice to the Provider. The Commissioner may at its discretion serve such notice on the Provider to commence delivery of the DR Service on multiple occasions during the Contract Term. The Provider will commence delivery of the DR Service from the date of expiry of such notice period and shall continue to deliver the DR Service until such date as may be specified by the Commissioner in the notice or such other date as the Commissioner may reasonably notify the Provider in writing (the “DR Provision Period”). For the avoidance of doubt, notwithstanding General Condition 1.2, the Parties agree that:

a) this paragraph 3.2.2 shall take precedence over General Condition 17.2 in respect of any termination of the DR Service; and
b) General Condition 18 does not apply where the Commissioner terminates the DR Service in accordance with this paragraph 3.2.2.

3.2.3. In serving the notice referred to in paragraph 3.2.2, the Commissioner may at its absolute discretion require the Provider:

a) To introduce the DR Service in some local CCG or local authority areas, but not in others;
b) To introduce the DR Service at a timing of its choosing;
c) To introduce the DR Service at different times in different places; and/or

d) To introduce the DR Service for a limited period of time only, such period to be set out in the notice referred to in paragraph 3.2.2.

3.2.4. Any approach to direct recruitment of people with non-diabetic hyperglycaemia onto the Service must particularly target groups in the community which are currently less likely to access existing services, or which are at a disproportionately higher risk of developing diabetes with a view to reducing health inequalities.

3.2.5. Direct recruitment will only be required by the Commissioner where local organisations involved in the programme are supportive of the DR Service being introduced.

3.2.6. The Contract sets out the maximum number of interventions to be completed by the Provider at paragraph 3.1.2 of service specification of this Schedule 2A (the "Intervention Cap"). The Provider should be aware that direct recruitment could generate an increased level of recruitment onto programmes such that the Intervention Cap is reached earlier than where direct recruitment is not permitted. This is a risk that the Provider will be expected to manage.

3.2.7. The Provider must give priority with regards access to the Service to persons referred by GPs or NHS Health Check providers over those directly recruited by the Provider.

4. Scope

4.1.1. The Provider must develop proposals for generating interest in the programme – for example, this could be through advertising, direct marketing to consumers, use of digital marketing (roadshows) etc.

4.1.2. Any marketing undertaken by the Provider with a view to recruiting people directly onto its programmes must include a particular focus on people from BME groups and other hard to reach groups within the community. This may, for example, involve developing promotional materials in a number of languages and the use of interpreters.

4.1.3. Where seeking to recruit people onto the Service directly a Provider must use a validated risk assessment tool (in line with NICE guidelines), such as the Leicester or Diabetes UK ‘Diabetes Risk Score’ self-assessment tools to avoid subjecting people to unnecessary blood tests”.

4.1.4. Where a person is identified as being potentially at risk of diabetes on the basis of a validated risk assessment tool, then the
individual must be invited for a blood test (HbA1C or FBG) to be arranged by the Provider and paid for by the Provider, to confirm the presence of non-diabetic hyperglycaemia. Refer to paragraph 3.2.3 and 3.2.4 of Service Specification No. 1 for the requirements relating to blood tests.

4.1.5. Where the blood test indicates that the person is eligible for the Service, the Provider recruits the person onto one of its programmes and the Service described in Service Specification No. 1 will be provided to that person in line with the Provider’s standard procedures.

4.1.6. The Provider must collaborate closely with CCGs and local authorities to ensure that Service Users recruited onto the Service, as well as those who are deemed ineligible, are provided with advice and assistance to access other services available locally.

4.1.7. Where a Service User is recruited onto the Service directly by the Provider, the Provider must request from that Service User their NHS Number. The Provider should ask the individual to find out their NHS number and bring this to the assessment, or subsequent session, so that it can be added to the individual record. Where an individual has been recruited through direct recruitment and there is no NHS number the Provider would not fail the data validation.

5. Evaluation

5.1.1. An evaluation of the impact of any direct recruitment by the Provider will be commissioned centrally as part of the overall approach to developing the NDPP. The DR Service will only be required by the Commissioner where the Commissioner is satisfied that there is a system in place to monitor the impact of the DR Service locally.

5.1.2. Data and Reporting – The Provider is required to provide the data on activities linked to the delivery of the DR Service as set out in Schedule 6A. The Provider is required to comply with the Local Quality Requirements set out in Schedule 4C. For the avoidance of doubt, once a person is directly recruited by the Provider onto the Service, the requirements of Service Specification No. 1 including the reporting requirements set out in Schedule 6A will apply to the provision of the Service to that person.

6. Payment for the DR Service

6.1.1. To the extent that the Commissioner requires the Provider to provide the DR Service in accordance with paragraph 3.2.2, the Commissioner will pay the Provider for the provision of the DR Service in accordance with Part 1A of Schedule 3A (Local Prices) during any DR Provision Period.
6.1.2. Once a person is directly recruited onto the Service, the payment provisions in Part 1 of Schedule 3A will apply in relation to the provision of the Service to that person.
Schedule 2A – Appendix 1

Local Service Requirements

[Note to bidders: The Commissioner may populate this schedule with requirements from the relevant local prospectus (included in the ITT documents) prior to each call-off Contract award]
Schedule 2A
Schedule 2A – Appendix 2
Tender Response Document
[Bidder tender response to be inserted prior to each call-off Contract award]
Schedule 2A
Schedule 2A – Appendix 3
Provider IPR
[To be inserted prior to each call-off Contract award]