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NHS Standard Contract 2023/24

Particulars (Full Length)

Contract title / ref: North East London ICS

Version 1, March 2023

Prepared by: NHS Standard Contract Team, NHS England
england.contractshelp@nhs.net
(please do not send contracts to this email address)

Contract Reference	C172428
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DATE OF CONTRACT	As per signature
SERVICE COMMENCEMENT DATE	1st June 2023
CONTRACT TERM	As set out in section 3.10 of Schedule 2A (Service Specification) subject to early termination
COMMISSIONERS	NHS England
CO-ORDINATING COMMISSIONER <i>See GC10 and Schedule 5C</i>	NHS England
PROVIDER	Oviva UK Limited Principal and/or registered office address: Runway East, 20 St Thomas Street, London, SE1 9RS Company number: 09667784

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CONTRACT

Contract title: NHS Type 2 Diabetes Path to Remission Programme Wave 1 (previously LCD) Lot 7 North East London

Contract ref: C172428

This Contract records the agreement between the Commissioners and the Provider and comprises

1. these **Particulars**, as completed and agreed by the Parties and as may be varied from time to time in accordance with GC13 (*Variations*);
2. the **Service Conditions (Full Length)**, as published by NHS England from time to time at: <https://www.england.nhs.uk/nhs-standard-contract/>;
3. the **General Conditions (Full Length)**, as published by NHS England from time to time at: <https://www.england.nhs.uk/nhs-standard-contract/>.

Each Party acknowledges and agrees

- (i) that it accepts and will be bound by the Service Conditions and General Conditions as published by NHS England at the date of this Contract, and
- (ii) that it will accept and will be bound by the Service Conditions and General Conditions as from time to time updated, amended or replaced and published by, NHS England pursuant to its powers under Regulation 17 of the National Health Service Commissioning Board and Clinical Commissioning Groups (*Responsibilities and Standing Rules*) Regulations 2012, with effect from the date of such publication.

IN WITNESS OF WHICH the Parties have signed this Contract on the date(s) shown below

SIGNED by [REDACTED]

For and on behalf of NHS England

SIGNED [REDACTED]

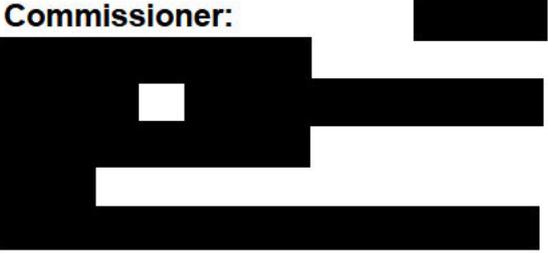
SIGNED by [REDACTED]

For and on behalf of Oviva UK Limited

SERVICE COMMENCEMENT AND CONTRACT TERM	
Effective Date <i>See GC2.1</i>	Date of Contract
Expected Service Commencement Date <i>See GC3.1</i>	1st June 2023
Longstop Date <i>See GC4.1 and 17.10.1</i>	30th June 2023
Contract Term	As set out in section 3.10 of Schedule 2A (Service Specification) subject to early termination
Commissioner option to extend Contract Term <i>See Schedule 1C, which applies only if YES is indicated here</i>	YES
Commissioner Notice Period (for termination under GC17.2)	<p>If the Commissioner exercises its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: 2 months</p> <p>If the Commissioner <u>does not</u> exercise its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: 6 months</p>
Commissioner Earliest Termination Date (for termination under GC17.2)	<p>If the Commissioner exercises its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: the Expected Service Commencement Date</p> <p>If the Commissioner <u>does not</u> exercise its right to terminate pursuant to paragraph 9 of Schedule 1C (Extension of Contract Term) below: 3 months after the Service Commencement Date</p>
Provider Notice Period (for termination under GC17.3)	6 months
Provider Earliest Termination Date (for termination under GC17.3)	3 months after the Service Commencement Date

SERVICES	
Service Categories	Indicate <u>all</u> categories of service which the Provider is commissioned to provide under this Contract. <i>Note that certain provisions of the Service Conditions and Annex A to the Service Conditions apply in respect of some service categories but not others.</i>
Accident and Emergency Services (Type 1 and Type 2 only) (A+E)	
Acute Services (A)	
Ambulance Services (AM)	
Cancer Services (CR)	
Continuing Healthcare Services (including continuing care for children) (CHC)	
Community Services (CS)	
Diagnostic, Screening and/or Pathology Services (D)	
End of Life Care Services (ELC)	
Mental Health and Learning Disability Services (MH)	
Mental Health and Learning Disability Secure Services (MHSS)	
NHS 111 Services (111)	
Patient Transport Services (non-emergency) (PT)	
Radiotherapy Services (R)	
Urgent Treatment Centre Services (including Walk-in Centre Services/Minor Injuries Units) (U)	
The Parties agree that the Services do not fall under any of the service categories above and therefore the only Service Conditions and provisions of Annex A that apply to the Services are those that are marked with "All".	
Service Requirements	
Prior Approval Response Time Standard See SC29.25	Not applicable
GOVERNANCE AND REGULATORY	
Nominated Mediation Body (where required – see GC14.4)	CEDR
Provider's Nominated Individual	Name: [REDACTED]
Provider's Information Governance Lead	Name: [REDACTED]

	Tel: [REDACTED]
Provider's Data Protection Officer (if required by Data Protection Legislation)	Name: [REDACTED]
Provider's Caldicott Guardian	Name: [REDACTED]
Provider's Senior Information Risk Owner	Name: [REDACTED]
Provider's Accountable Emergency Officer	Name: [REDACTED]
Provider's Safeguarding Lead (children) / named professional for safeguarding children	Name: [REDACTED]
Provider's Safeguarding Lead (adults) / named professional for safeguarding adults	Name: [REDACTED]
Provider's Child Sexual Abuse and Exploitation Lead	Name: [REDACTED]
Provider's Mental Capacity and Liberty Protection Safeguards Lead	Name: [REDACTED]
Provider's Prevent Lead	Name: [REDACTED]
Provider's Freedom To Speak Up Guardian(s)	Name: [REDACTED]
Provider's UEC DoS Contact	Not applicable
Commissioners' UEC DoS Leads	Not applicable
Provider's Infection Prevention Lead	Name: [REDACTED]
Provider's Health Inequalities Lead	Name: [REDACTED]
Provider's Net Zero Lead	Name: [REDACTED]
Provider's 2018 Act Responsible Person	Not applicable

Provider's Wellbeing Guardian (NHS Trusts and Foundation Trusts only)	Not applicable
CONTRACT MANAGEMENT	
Addresses for service of Notices <i>See GC36</i>	Commissioner:  
Frequency of Review Meetings <i>See GC8.1</i>	Quarterly
Commissioner Representative(s) <i>See GC10.3</i>	
Provider Representative <i>See GC10.3</i>	

SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

A. Conditions Precedent

The Provider must provide the Co-ordinating Commissioner with the following documents:

1. Evidence of appropriate Indemnity Arrangements
2. Evidence of CQC registration in respect of Provider and Material Sub-Contractors (where required) if required or evidence that CQC registration is not required
3. Evidence that the Provider has employed or engaged a Medical Director as required by section 3.2.12 of the Service Specification
4. Evidence that TDR products that the Provider intends to use comply with all relevant legislation and standards
5. Evidence of compliance with General Conditions 5.11 in relation to Enhanced DBS & Barred List Checks
6. Evidence of compliance with the final paragraph of section 3.2.12 of the Service Specification in relation to:
 - carrying out of Enhanced DBS & Barred List Checks in respect of all members of Staff engaged in the Service who are eligible for such checks;
 - not engaging any person in the Service who is barred from working with vulnerable adults or is otherwise unsuitable for working with vulnerable adults; and
 - ensuring that any Sub-contractor is subject to the same obligations as the two bullet points above

The Provider must complete the following actions:

Not applicable

**SCHEDULE 1 – SERVICE COMMENCEMENT
AND CONTRACT TERM**

B. Commissioner Documents

Date	Document	Description
Not Applicable		

SCHEDULE 1 – SERVICE COMMENCEMENT AND CONTRACT TERM

C. Extension of Contract Term

Extension of Contract Term

1. As advertised to all prospective providers before the award of this Contract, and as set out in section 3.10 of the Service Specification, the Commissioner may vary the Intervention Period (as defined in the Service Specification) which has the effect of extending the Contract Term.
2. If the Commissioner wishes to exercise the option to extend the Contract Term in this way, the Commissioner will give written notice to that effect to the Provider as set out in section 3.10 of the Service Specification.
3. If the Commissioner gives notice to extend the Intervention Period in accordance with paragraph 2 above, the Contract Term will also be extended and the Expiry Date will be deemed to be the day after which the Provider submits the data submission for the last Service User being provided with the Service who completed the Final Session or other such day as agreed in writing between the Parties.

Changes to Expected Service Commencement Date

4. The Provider acknowledges and agrees that the Commissioner will be entitled, in its absolute discretion, to:
 - 4.1 amend the Expected Service Commencement Date in accordance with paragraph 5 of this Schedule 1C below; and/or
 - 4.2 terminate this Contract before the then current Expected Service Commencement Date in accordance with paragraph 9 of this Schedule 1C below.
5. Subject to paragraph 6 of this Schedule 1C below, the Commissioner will be entitled to amend the Expected Service Commencement Date not less than 2 months before the Expected Service Commencement Date by notifying the Provider in writing.
6. The Commissioner will be entitled to amend the Expected Service Commencement Date pursuant to paragraph 5 of this Schedule 1C on more than one occasion but the Commissioner will only be entitled to amend the Expected Service Commencement Date to a date that is later than the then current Expected Service Commencement Date. For the avoidance of doubt, the Commissioner will not be entitled to amend the Expected Service Commencement Date if it does not notify the Provider in writing of the amendment at least 2 months before the then current Expected Service Commencement Date and will not be entitled to amend it to a date that is sooner than the then current Expected Service Commencement Date.
7. If the Commissioner amends the Expected Service Commencement Date in accordance with paragraph 5 of this Schedule 1C, the Longstop Date will also be amended accordingly to the day before the new Expected Service Commencement Date.
8. The amendment of the Expected Service Commencement Date and the Longstop Date by the Commissioner in accordance with this Schedule 1C will not constitute a Variation and the provisions of General Condition 13 (Variations) will not apply in relation to such an amendment.
9. The Commissioner will be entitled to terminate this Contract immediately without cause by giving written notice to the Provider not less than 2 months before the then current Expected Service Commencement Date (as it may have been amended in accordance with this Schedule 1C).
10. For the avoidance of doubt, termination under paragraph 9 of this Schedule 1C will be deemed to be termination in accordance with General Condition 17.2.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

All defined terms set out in this document reflect the definitions contained within the Contract unless defined in this Schedule 2A

Service Specification No.	1
Service	NHS Type 2 Diabetes Path to Remission Programme
Commissioner Lead	NHS England and NHS Improvement
Provider Lead	
Period	
Date of Review	

1. Overview

1.1 National context and evidence base

Type 2 diabetes represents a major burden on health and care services and its increasing prevalence poses a major risk to population wellbeing and the sustainability of the NHS. Helping people with Type 2 diabetes achieve significant weight loss and improve glucose regulation is likely to reduce the future risk of complications and associated impacts on wellbeing and healthcare costs.

The NHS Long Term Plan published in 2019 announced that a low calorie diet programme would be piloted, at scale, from 2020/21. This commitment built on the approaches of the Diabetes Remission Clinical Trial (DiRECT), and the Doctor Referral of Overweight People to Low Energy total diet replacement Treatment (DROPLET) Randomised Control Trials (RCTs), reflecting the evidence base developed by both of these trials.

Following the pilot phase of the programme, NHS England is making this intervention available to the eligible population across all of England.

Introduction to the NHS Type 2 Diabetes Path to Remission Programme

The NHS Type 2 Diabetes Path to Remission Programme (the “NHS T2DR Programme”) is a joint initiative between NHS England and Diabetes UK (Note: the name of the programme is subject to change). The NHS T2DR Programme involves a total diet replacement (TDR) approach that has been shown in RCTs to help some people with Type 2 diabetes achieve and maintain non-diabetic glycaemic levels off all diabetes medication (commonly referred to as remission).

The overall aim of this intervention is to promote weight loss in those that are overweight (BMI of 27 kg/m² or over in people from White ethnic groups, adjusted to 25 kg/m² or over in people from Black, Asian and other ethnic groups) and recently diagnosed with Type 2 diabetes, achieving remission wherever possible.

Service Users will follow a diet composed solely of nutritionally-complete TDR products, with total energy intake of 800-900 kilocalories a day, for 12 weeks, followed by a period of food reintroduction and subsequent weight maintenance support, with total duration of 12 months.

The Provider must offer a variety of TDR products such as soups, shakes and other suitable products. These must include the availability of varied flavours and textures to support Service User compliance and retention on the NHS T2DR Programme. The Provider must supply the appropriate TDR products to Service Users but must not supply any Service User with more than a four (4) week supply of TDR products at any one time. The Provider must ensure that, at all times during the Contract Term, all TDR products it supplies to Service Users adhere to all legislation and standards that apply to total diet replacement products. To avoid doubt, this includes any legislation and standards as they may be amended, extended or re-enacted from time to time and including any applicable subordinate or replacement legislation or standards. This includes but is not limited to The Foods Intended for Use in Energy Restricted Diets for Weight Reduction Regulations 1997 which provide the specific composition and labelling requirements of TDR products. The Provider will be responsible for procuring the TDR products that it supplies to Service Users. The Provider must consider the needs of a variety of potential Service Users, including offering suitable or alternative TDR products where possible for those with intolerances (e.g. lactose intolerance) which may impact on their ability to use certain products.

The identification and referral of people to the NHS T2DR Programme is undertaken by General Practice primary care services (see section 3.2.3). Eligible individuals will be aged 18 - 65 years, diagnosed with Type 2 diabetes within the last 6 years and have a BMI of 27 kg/m² or over in people from White ethnic groups, adjusted to 25 kg/m² or over in people from Black, Asian and other ethnic groups. Other eligibility criteria also apply and are considered necessary to ensure safety within the context of real-world implementation of this programme. Modelling suggests that 10-20% of those living with Type 2 diabetes would be eligible for the NHS T2DR Programme, once the eligibility criteria are applied (see section 3.2.2 for the full eligibility criteria).

The responsibility of identifying eligible individuals and referring them (once their consent has been obtained) to the NHS T2DR Programme sits with the individual's GP Practice and the Provider is required to verify eligibility with the individual confirming that exclusion criteria have not been met prior to commencement of the intervention in accordance with this Service Specification.

It is intended that, within a defined geographical area, a single provider will deliver the NHS T2DR Programme by offering to individuals the following choice of delivery models:

- One to one face-to-face (the "Face-to-Face Delivery Model");
- One to one digital support (the "Digital Delivery Model"),

References to "the Delivery Models" in this Service Specification are references to both delivery models.

References to "sections" in this Service Specification are references to sections of this Service Specification.

2. Outcomes

2.1 Expected outcomes of the NHS T2DR Programme

- Reduction in weight of Service Users and the maintenance of weight loss achieved;
- Reduced glycaemic parameters in Service Users and achievement of remission of Type 2 diabetes as a result of the intervention;
- Reduction in medication usage among Service Users in line with the intervention;
- Continue to build the evidence base around the effectiveness of a low calorie diet, total diet replacement programme, including evidence around impact of the intervention in different demographic groups.

3. Scope

3.1 Aims of the Service

In order to achieve the outcomes set out in section 2.1, the NHS T2DR Programme will aim to:

- Promote weight loss in those that are overweight (BMI \geq 27kg/m² in people from White ethnic groups, adjusted to 25kg/m² in people from Black, Asian and other ethnic groups) and recently diagnosed with Type 2 diabetes;
- Support Service Users to adopt a healthier lifestyle, having appropriate regard to achievement of dietary recommendations in England; and
- Maximise completion rates of Service Users, including across groups that share a protected characteristic.

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

3.2 Service description / care pathway

The Service will comprise:

- An individual assessment of a Service User;
- A period during which the Provider will provide TDR products to the Service User (the “TDR Phase”);
- A period during which the Provider will work with the Service User to reintroduce food into the Service User’s diet (the “Food Reintroduction Phase”); and
- A period during which the Provider will support the Service User in maintaining their weight (the “Weight Maintenance Phase”).

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 cultural context of Service Users and will be sensitive to different culinary traditions, including where possible for the TDR products themselves;
- The content of the sessions (or, for the Digital Delivery Model, engagement) with Service Users should aim to empower people with Type 2 diabetes to take a leading role in instituting and maintaining long-term behaviour changes;
- The Provider must endeavour to ensure equal access by all Service Users, 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;
- The Provider must monitor service performance and inequalities in outcomes and take appropriate corrective action to improve performance and reduce inequalities accordingly. Specific attention should be given to monitoring and improving performance relating to people with characteristics which have been associated with poorer outcomes in the pilots;
- Access to the 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 systems and community sector organisations) to deliver a relevant and inclusive programme;
- The Provider should maximise the flexibility (within the scope of this Service Specification) 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 design, evaluation and improvement of the Service;
- The Provider must engage proactively with GP practices whilst ensuring that the impact on workload for GP practices is minimised;
- All individuals must be treated with courtesy, respect and an understanding of their needs;
- The Provider must supply to GP practices adequate information on the benefits and risks of the Service, in a format which is accessible to potential Service Users and healthcare professionals. The Provider acknowledges that the purpose of providing this information is to support the GP practices' staff to provide information to patients, enabling patients to make an informed choice in accepting referral to the Service;
- All potential Service Users must be given adequate information on the benefits and risks of the Service, in a format which is accessible to them, once a referral has been made but before the Service User begins the Service to allow an informed decision to be made by Service Users before participating in the Service;
- All potential Service Users must also be given information (in compliance with data protection requirements) about how personal data will be used, who will have access to it, and patients' data protection rights (e.g. how to obtain a copy of personal records, rectification, objection, etc);
- All Service Users must be given unconstrained choice between the Face-to-Face Delivery Model and the Digital Delivery Model, with adequate information provided to allow for an informed decision to be made;
- The Provider must provide Service Users with appropriate support throughout the duration of participation in the Service;
- The Provider must ensure that persons referred to the Service are effectively integrated across a pathway including between the Provider of the Service and the GP practice with which the person is registered;
- The Provider must ensure safe, timely and appropriate communication with relevant GP practices for management of adverse or concurrent medical events and for ongoing management at time of discharge, disengagement or drop out from the intervention;
- The Provider must use the template letters to GP practices and Service Users supplied by the Commissioner at all times specified by the Commissioner (including, but not limited to, receipt of referral, notification of TDR start, completion of TDR phase, completion of the programme, discharge from programme). These must be used in the manner and form specified by the Commissioner;
- The Provider must ensure that any contact from GP practices (including, but not limited to, requests for advice on medication adjustments, questions about the referral process, questions about the programme, requests for updates on Service User progress) is responded to appropriately within 5 Operational Days (for avoidance of doubt, this timeline pertains to answering the query rather than simply providing acknowledgement of having receiving such contact)
- Improvements and adjustments to the delivery of the Service may be identified as new evidence emerges from national and international research and local evaluation of the

Service. The Provider acknowledges and agrees that the Service will 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);

- If the Provider identifies emotional wellbeing or mental health issues, the Provider should signpost the Service User to appropriate local services through a process agreed with the local health system prior to the Expected Services Commencement Date.
- If the Provider suspects or identifies behaviours that meet the threshold of an eating disorder during the course of the sessions, the GP practice should be notified and the Service User should be advised to seek care with their GP practice accordingly. In addition, identification of an active eating disorder should be recorded as an adverse event and the process for adverse events followed (as set out in Section 3.2.12).
- The Provider must actively encourage and respond to Service User feedback. This should be sought on all aspects of the Service including the curriculum, programme structure, frequency of support, TDR products, coaching, approach to meeting individual, cultural adaptation, support materials and functionality / usability of any digital tools. The Provider must have effective governance processes for collating and actioning such feedback as well as for responding to any complaints.

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 Eligible population

Individuals who satisfy all the following eligibility criteria may be referred to the Service:

- Aged 18 to 65 years;
- Diagnosed with Type 2 diabetes within the last 6 years;
- A BMI of 27kg/m² or higher in people from White ethnic groups, adjusted to 25kg/m² or higher in people from Black, Asian and other ethnic groups.
 - BMI obtained from self-measured weight by a Service User is acceptable for referral. If this cannot be obtained, a clinic-measured value within the last 12 months may be used, provided there is no concern from the referrer that the Service User's weight may have reduced since last measured such that the individual would not be eligible for the Service at present;
- A HbA1c measurement taken within the last 12 months, with values as follows:

- If on diabetes medication, HbA1c 43 to 87 mmol/mol; or
- If not on diabetes medication, HbA1c 48 to 87 mmol/mol;

provided there is no concern from the referrer that the Service User's HbA1c may have changed since last measured such that the individual would not be eligible for the Service at present; and

- Have attended for monitoring and diabetes review when this was last offered, including retinal screening, and commit to continue attending annual reviews, even if remission is achieved. (For avoidance of doubt, if a Service User is newly diagnosed then there is no requirement to wait for retinal screening to take place before offering referral)

Individuals who meet any of the following exclusion criteria must not be referred to the Service and must not be accepted by the Provider. The Provider must confirm that the individual is eligible and so does not meet any of the following exclusion criteria prior to the individual's commencement of the intervention:

- Current insulin user;
- Pregnant or planning to become pregnant within the next 6 months;
- Currently breastfeeding;
- Discharged in the last 12 months from the NHS Type 2 Diabetes Path to Remission Programme after having commenced the programme (for clarity, this does not apply to people previously referred to the programme but who dropped out or declined prior to commencing the TDR Phase);
- Has at least one of the following significant co-morbidities;
 - active cancer;
 - heart attack or stroke in last 6 months;
 - severe heart failure (defined as New York Heart Association grade 3 or 4);
 - severe renal impairment (most recent eGFR less than 30mls/min/1.73m²);
 - active liver disease other than non-alcoholic fatty liver disease (NAFLD) (i.e. NAFLD is not an exclusion criterion);
 - active substance use disorder;
 - active eating disorder (including binge eating disorder);
 - porphyria; or
 - known proliferative retinopathy that has not been treated (this does not exclude individuals who are newly diagnosed and have not yet had the opportunity for retinal screening);
- Has had bariatric surgery; or
- Health professional assessment that the person is unable to understand or meet the demands of the NHS T2DR Programme and/or monitoring requirements (due to physical or psychological conditions or co-morbidities).

At time of referral to the Service, the referrer is responsible for discussing and agreeing any relevant medication changes with the potential Service User. The Provider must take steps to ensure that referrers can obtain advice from the Provider regarding medication changes and the Provider must ensure that communication in this regard is facilitated between referrers and the Provider's Medical Director (or another suitably experienced registered medical practitioner within the meaning of Schedule 1 of the Interpretation Act 1978 with an MRCP or MRCPGP). Any requests for advice should be responded to with appropriate advice within 5 Operational Days. The Provider acknowledges that

clinical responsibility for an individual's medication changes remains with general practice at all times that the individual is associated with the Service.

It should be made clear by the referrer to the potential Service User that these changes should only be enacted on the first day of starting the TDR intervention. The Provider must be aware of whether any potential Service User has a medication change or not. The Provider must ensure that it has received in writing from the referrer either details of medication changes or confirmation that no medication changes are required. The Provider must ensure the potential Service User is also aware of the medication changes proposed (or that no medication changes are required) although there is no requirement for this to be submitted to the Service User by the referrer in writing. The Provider must ensure that, prior to the first day of TDR Phase, the Service User understands the specific medication changes which are required (or that no medication changes are required). The referrer should also confirm with the Service User that, should they proceed on the NHS T2DR Programme, the Service User:

- Agrees to continue attending yearly diabetes review appointments at their GP practice, regardless of whether remission is achieved;
- Will contact their GP practice or urgent care service as appropriate if they have any unexpected or concerning symptoms which are considered urgent; and
- Will notify their GP practice if they disengage or drop out before the end of their intervention.

The Provider is required, as set out in more detail in section 3.2.5, to confirm that it and the Service User have been provided with information relating to medication changes prior to commencement of the intervention.

3.2.3 Referral and Acceptance

The Service will commence when the Provider begins to accept referrals from the local health systems. As set out in General Condition 3 of the Contract, the date the Provider is required to commence the Service (and so accept referrals) is the later of:

- the Expected Services Commencement Date; and
- the day after the date on which all Conditions Precedent are satisfied.

The Provider and the Commissioner may agree to substitute the Expected Services Commencement Date with any earlier date in which case the Contract will be varied in accordance with its provisions.

The Provider will develop and agree detailed referral protocols with local health systems prior to receiving referrals to the Service. Referrals will come from GP practices. If there is agreement by the Provider, the local health system and the Commissioner, the Parties may agree to amend this Service Specification to include other referral routes.

All individuals who satisfy the eligibility criteria and are not excluded in accordance with section 3.2.2 will be invited by the Provider to participate in the Service as further detailed in section 3.2.4.

The first communication sent by the Provider to the relevant Service User's GP practice on receipt of a referral should make clear that any changes in eligibility to participate in the Service or medication changes (including in particular (but not limited to) new glucose-lowering agents / BP-lowering agents) should be communicated urgently to the Provider. The Provider will confirm with the relevant Service User, prior to starting the TDR Phase, that they have not started any new medications (including in particular (but not limited to) glucose-lowering or blood pressure-lowering medications) since medication changes to take place on the first day of TDR were agreed with their referrer. Where there is concern such changes may have occurred and may require re-consideration of medication changes (e.g. if new glucose-lowering agents / BP-lowering agents have been started), the Provider should contact the GP practice for confirmation that it remains appropriate for the Service User to proceed with the TDR Phase and to request an update on medication changes to take place on the first day of TDR (these would need to be agreed by the referrer and Service User).

3.2.4 Invitation to participate

Subject to the Intervention Cap and Intervention Period (referred to in section 3.10), the Provider will invite all eligible, referred individuals to participate in the Service.

The Provider will initiate contact with each individual directly referred to them (where there is no evidence for ineligibility), within five Operational Days of receipt of the referral, inviting the individual to participate in the Service. The individual must be provided with adequate information about the Delivery Models to allow for an informed, unrestricted choice about which Delivery Model would better suit their needs and individual context.

The Provider will work with local health systems to manage the trajectory of referrals in line with the volume of contracted interventions and work together with the local health system and with the Commissioner to match supply and demand across the duration of the Contract.

The invitation and all follow-up contact will contain accessible information about Type 2 diabetes, the potential to achieve remission, the nature of the intervention and the requirements for Service Users. All contact made with individuals should be grounded in behavioural insight theory and evidence.

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

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 at least two different channels after one calendar month, the Provider must discharge the individual back to their GP practice. The Provider must also communicate a discharge notice to the individual and signpost the individual to the NHS website pages related to weight management, appropriate physical activity and healthy lifestyles and to any other locally available resources for supporting weight loss, healthy eating and appropriate 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 Service, then the Provider must discharge that individual back to the GP practice. The Provider must communicate a discharge notice to the individual's GP practice and the individual and signpost that individual to the NHS 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 and an individual accepts an invitation to participate in the Service, the Provider must offer as much choice of dates and times (and, for Face-to-Face Delivery Models, appropriate venues) as logistically possible, where applicable, to attend or participate in an Individual Assessment (which is explained further in 3.2.5 below) provided that the dates and times offered by the Provider are within a period of one calendar month of the date the Provider established contact with the individual and the individual accepted the invitation to participate in the Service. If driven by Service User choice and a decision to defer starting the TDR Phase to a more suitable time, Individual Assessment may occur within 90 days of the referral.

At the point the individual accepts the offer to attend or participate in the Individual Assessment, that individual is considered to be a Service User.

The Provider must comply with any template letters or discharge communication content that the Commissioner notifies the Provider must be used. The Provider must ensure sound data collection mechanisms are in place to support evaluation of the Service in achieving defined outcomes and enable the assessment over time of progress relating to diabetes remission and reductions in the long term complications of Type 2 diabetes and associated morbidity and mortality.

In addition to use of the template letters, the Provider will work closely with the local health system to identify and implement any further locally appropriate mechanisms for ensuring data about a Service User is communicated to the GP practice with which the Service User is registered (using

SNOMED codes where appropriate) and that such data can be integrated within GP clinical systems; ideally by electronic transfer. The Provider will also work with the local health systems to ensure that there is a monthly update on referral and uptake rates, waiting list size and outcomes at locally-agreed levels; e.g. at the level of individual GP practices, Primary Care Networks (PCNs) or ICSs.

The Provider must highlight to the Commissioner and the local health system any issues in relation to referrals and uptake into the Service and any deviation from the expected referral and uptake numbers (as agreed with the local health system).

Additionally, the Provider must notify GP practices about progression of Service Users through the Service through use of the template letters provided by the Commissioner in addition to any further locally agreed means.

3.2.5 Individual assessment

The Provider will conduct individual assessments with all Service Users who accept the invitation to participate in the Service ("Individual Assessment").

The Provider will use Individual Assessments to:

- verify the eligibility of the Service User;
- explain in detail the rationale and requirements of the Service; and
- determine whether the Service User wishes to continue with the Service.
- confirm the Service User's choice of Delivery Model.

If the Service User chooses to proceed to the TDR Phase, the Provider will set a mutually-agreeable start date with the Service User and confirm matters relating to any medication changes that will be enacted by the Service User on this same date as set out in this Service Specification.

The Individual Assessment may be undertaken remotely in the Face-to-Face Delivery Model providing this does not restrict the Individual Assessment process in any way and allows for the required information to be obtained and eligibility to be verified. (It is expected that all Individual Assessments will occur remotely in the Digital Delivery Model).

Following the Individual Assessment, confirmation of the Individual Assessment must be sent to the Service User's GP practice. This should include:

- notification regarding whether the Service User intends to proceed to the TDR Phase;
- details of the mutually-agreed start date of the TDR Phase;
- confirmation of any medication changes which will be enacted on the first day of the TDR Phase (or that no changes are required) (as communicated to the Service User and supplied in writing to the Provider by the referrer); and
- confirmation that the Service User:
 - agrees to continue attending yearly diabetes review appointments at their GP practice, regardless of whether remission is achieved;
 - will contact their GP practice or urgent care service as appropriate if they have any unexpected or concerning symptoms which are considered urgent; and
 - will notify their GP practice if they disengage or drop out before the end of the intervention.

Data must be gathered at all points of Service delivery in accordance with the requirements of this Service Specification and Schedule 6A. If a specific data item is indicated in Schedule 6A to be gathered at a specific point of Service delivery, the Provider will gather such data item.

If a Service User has previously accepted the Service but fails to attend or participate in a scheduled and agreed Individual Assessment, the Provider must make at least two further attempts to offer an Individual Assessment at times appropriate to the Service User provided that such times are within one calendar month of the date the Service User failed to attend or participate in the scheduled and agreed Individual Assessment, but no later than 90 days following referral. If the Service User does not complete an Individual Assessment during this time, the Service User should be discharged back to their GP practice, signposting the Service User to the NHS 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, a Service User:

- does not attend or participate in the first session (or, in the Digital Delivery Model, the first episode of engagement) within 90 days of Individual Assessment;
- does not attend or participate in the first session (or, in the Digital Delivery Model, the first episode of engagement) after the Provider has offered the first session (or, in the Digital Delivery Model, the first episode of engagement) on three separate occasions at times, and for the Face-to-Face Delivery Model, venues, appropriate to the Service User;
- defers attendance at or participation in the session (or, in the Digital Delivery Model, the first episode of engagement) after the Provider has offered the first session (or, in the Digital Delivery Model, the first episode of engagement) on three separate occasions at times, and for the Face-to-Face Delivery Model, venues, appropriate to the Service User; or
- declines the Service,

the Service User should be discharged back to their GP practice, signposting the Service User to the NHS 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 offer the first session (or, in the Digital Delivery Model, the first episode of engagement) within 30 days of the Individual Assessment. For the Face-to-Face Delivery Model, this must be at a venue appropriate to the Service User. If driven by Service User choice and a decision to defer starting the TDR Phase to a more suitable time, the first session may occur within 90 days of the Individual Assessment.

If the Provider cancels any booked session (or, in the Digital Delivery Model, any booked episode of engagement) for any reason at any time during a Service User's participation in the Service, the Provider must promptly reschedule the Service User's session (or, in the Digital Delivery Model, the episode of engagement).

The Provider must record details about the number of contact attempts made to offer the Service, arrange Individual Assessments and rearrange sessions (or, in the Digital Delivery Model, episodes of engagement) including date and method of contact as set out in this section. The Provider is required to record all of this information under Schedule 6A and must share this information with the Commissioner in accordance with the requirements of this Contract and, if relevant, at any other time requested by the Commissioner.

Intervention commencement

Following the Individual Assessment, if the Service User has decided to proceed with the TDR Phase, the Provider must notify the Service User's GP practice of the agreed start date of the TDR Phase. This must be within 90 days of the Individual Assessment. Although necessary medication changes, if applicable, should have been discussed at time of referral, any changes must not be enacted by the Service User until the first day of the TDR Phase. The Provider must, prior to the first day of the TDR intervention:

- ensure that the Provider and the Service User understand the specific medication changes which are required (or that no medication changes are required) and the Provider has

received details of changes (or confirmation that no change is necessary) in writing from the referrer;

- confirm that no additional glucose-lowering or blood pressure-lowering medications have been started since medication changes were last agreed (including if the recommendation was for no medication changes to take place) and specified in writing to the Provider and communicated to the Service User); and
- confirm with the Service User that they will not be taking sulphonylureas, meglitinides or SGLT2 inhibitors as of the first day of the TDR intervention.

If the Provider:

- cannot confirm that the Provider and the Service User have been provided with confirmation from the referrer of the specific medication changes which are required (or that no medication changes are required); and/or
- cannot confirm that no additional glucose-lowering or blood pressure-lowering medications have been started since medication changes were last communicated by the referrer (including communication of no medication changes to be made); and/or
- cannot confirm with the Service User that they will not be taking sulphonylureas, meglitinides or SGLT2 inhibitors (if applicable) as of the first day of the TDR intervention,

then the Provider must defer the Service User's TDR Phase start date and take such action as it necessary to ensure that the above matters are confirmed. Once the matters above have been confirmed, the Provider must promptly arrange the Service User's commencement of the TDR Phase.

3.2.6 Intensity and duration of the Service

The Provider must deliver the Service in accordance with the requirements set out in this section.

TDR Phase

- The TDR Phase begins from the first day the Service User starts taking TDR products and lasts for 12 weeks.
- An individual should not start taking TDR products and/or commence the TDR Phase or a rescue package (as defined later in this Specification) at any time if they are taking sulphonylureas, meglitinides or SGLT2 inhibitors.
- If the Service User cannot confirm to the Provider that they are not taking sulphonylureas, meglitinides or SGLT2 inhibitors during the TDR Phase or at the commencement of a rescue package or the recommencement of the TDR Phase following a planned pause, the Provider should contact the Service User's GP practice to obtain confirmation as to whether the Service User is or is not taking sulphonylureas, meglitinides or SGLT2 inhibitors. An individual should not start taking TDR products and/or commence or re-commence the TDR Phase or a rescue package (as defined later in this Specification) at any time unless it is confirmed that they are not taking sulphonylureas, meglitinides or SGLT2 inhibitors.
- If the Service User confirms to the Provider that they are taking sulphonylureas, meglitinides or SGLT2 inhibitors during the TDR Phase or at the commencement of a rescue package, the Provider must advise the Service User to cease taking TDR products immediately and the Provider must refer the Service User to their GP practice.
- The Provider must provide TDR products to each Service User for the duration of that Service User's participation in the TDR Phase. The Provider must offer a variety of TDR products such as soups, shakes and other suitable products. These must include the availability of varied flavours and textures to support Service Users' compliance and retention on the Service. The Provider must not supply any Service User with more than a four (4) week supply of TDR products.

- The Contract requires the Provider to perform all its obligations under this Contract in accordance with the Law (as set out in Service Condition 1.1). This requires the Provider to comply with all applicable legislation in relation to the TDR products. The Provider is also required to ensure all TDR products provided to a Service User comply with all standards that are applicable to total diet replacement products. To avoid doubt, this includes any legislation and standards as they may be amended, extended or re-enacted from time to time and including any applicable subordinate or replacement legislation or standards.
- Subject to the three bullet points immediately following this bullet point, TDR products must be provided to replace all daily meals from the first session (or, in the Digital Delivery Model, the first episode of engagement) of the TDR Phase for 12 weeks, with support to ensure that Service Users can adhere to the regimen. Total energy intake should be 800 – 900 kilocalories daily.
- If during the TDR Phase or during the use of a rescue package, the BMI of the Service User has decreased below 21 kg/m² in people from White ethnic groups or below 19 kg/m² in people from Black, Asian and other ethnic groups, the Provider must cease TDR for the Service User and move the Service User to the Weight Maintenance Phase.
- Where Service Users are unable to comply with full TDR and are at high risk of dropping out of the NHS T2DR Programme, they may, at any point, introduce firstly a single meal of non-starchy vegetables. If they remain at high risk of disengagement, they may further substitute a single TDR meal for a nutritionally appropriate meal of no more than 300 calories. The Provider must set out the point at which Service Users start to replace TDR products with an alternative meal.
- If an individual Service User has specific needs that can't be addressed due to a lack of any compliant TDR product then consideration can be given to alternative approaches for that individual Service User.
- All Service Users must receive fibre supplements from the Provider prior to starting the TDR Phase (and any subsequent periods of TDR such as rescue packages) and the Provider will advise Service Users that they should start taking these from the first day of TDR. The dose provided will equate to 7g per day (usually issued in 2 x 3.5g portions of Ispaghula Husk/Psyllium Husk/Fybogel) during the TDR Phase (and during any rescue packages). Service Users will continue to receive these supplements from the Provider until the relevant Service User advises the Provider that these are no longer necessary. Service Users may be able to stop the fibre supplement on re-introducing meals in the food re-introduction phase. After stopping or decreasing fibre supplementation, if a Service User subsequently indicates a need for further fibre supplementation, the Provider will provide the Service User with further fibre supplements and will continue to provide these.
- If the Service User becomes pregnant, the Provider must immediately discharge the Service User from the Service to the care of the Service User's GP practice.
- If an adverse event occurs, the Provider's Medical Director will decide whether it is appropriate for the Service User to continue with the Service without any changes, or whether appropriate modifications may be made, or to stop the Service User's participation in the TDR Phase but enable the Service User to continue participation in the Service within the requirements of the Service Specification, or whether the Service User should be discharged. If the Provider's Medical Director decides that it is appropriate to enable the Service User to continue with the Service despite the adverse event, the Service User will progress to the Food Re-introduction Phase and then to the Weight Management Phase in accordance with this Service Specification unless any relevant variations to this Service Specification are agreed in relation to that Service User in advance by the Commissioner. However, if it is established that the Service User cannot tolerate the TDR products within the first 2 weeks of the TDR Phase, the Provider must discharge the Service User from the Service to the care of the Service User's GP practice.

- The Provider must ensure that Service Users receive appropriate advice, tools and support in preparation for the Food Re-introduction Phase and the transition to healthy eating. This includes healthy dietary plans appropriate to their preferences and culinary traditions.

Food Re-introduction Phase

- This phase immediately follows the 12 week TDR Phase and lasts for 6 weeks.
- Service Users will gradually re-introduce food using a stepped approach.
- At the latest, the Service User should have ceased using TDR products by the end of 18 weeks following commencement of the TDR Phase.
- During this Food Re-introduction Phase the focus is on the transition from TDR to a balanced diet.
- The Provider must support the Service User to achieve appropriate calorie intake and nutritional balance from food, with targets set according to the Service User's preference for maintaining their weight or aiming for further controlled weight loss and improved diet quality through nutritional and behaviour change support.
- Advice and dietary plans should be tailored to the Service User's individual needs, preferences and culinary traditions.

Weight Maintenance Phase

- This phase follows the Food Reintroduction Phase and comprises the remainder of the programme. The programme is 52 weeks in total.
- During this Weight Maintenance Phase the focus is per Service User preference, for maintaining a steady weight or aiming for further controlled weight loss (except that if the BMI of the Service User has decreased below 21 kg/m² in people from White ethnic groups or below 19 kg/m² in people from Black, Asian and other ethnic groups as set out in the section under TDR Phase above, the Provider must not support further weight loss) and ensuring changes are embedded for the longer term.
- The Provider must support the Service User to set tailored achievable short, medium and long term dietary and physical activity goals.
- The Provider must support the Service User to ensure appropriate energy intake, and steady increases in appropriate physical activity to meet their individualised weight maintenance goals.
- If a Service User regains 2kg or more, with reference to the lowest weight recorded for that Service User since the completion of the TDR Phase, at any time during the Weight Maintenance Phase, the Provider must offer Service User a relapse management protocol, also referred to as a "rescue package", which includes the reintroduction of TDR for a period of 4 weeks with weekly support sessions.
- The Provider must ensure that the default offer for the rescue package is full TDR for a period of 4 weeks and the Provider must encourage the Service User to accept full TDR. If, however, full TDR is declined by the Service User, a partial rescue package may be offered, consisting of 2 meals replaced with TDR products for a period of 4 weeks. Regardless of whether the rescue package is full or partial, the Provider must ensure there are weekly support sessions during the period of the rescue package;
- The Provider shall not put in place more than one rescue package for any Service User and shall not put in place a rescue package for any Service User after the end of week 42 (as calculated in accordance with the "Minimum session/engagement requirements" section below).

- The Provider will closely monitor and support the Service User during the rescue package. This should be in line with the monitoring requirements of the TDR Phase, with blood glucose and weight measurements taken weekly. Where a Service User is on medication(s) that affects blood pressure (this may include medications used for other purposes such as diuretics for heart failure or alpha-blockers for BPH), the Service User should return to weekly blood pressure monitoring during the rescue package.
- The Provider must put in place an individualised plan for each Service User for food re-introduction for that Service User following a rescue package being implemented. The food re-introduction plan may be up to 6 weeks in duration.

Minimum session/engagement requirements

For the Face-to-Face Delivery Model, the Service must consist of defined sessions.

For the Digital Delivery Model the Service must consist of defined contacts or episodes of engagements between the Provider and the Service User. The minimum requirements of these defined contacts or episodes of engagement are set out in sections 3.2.8 and 3.2.9. Engagement methods that are relevant to the different Milestones are set out in Schedule 3C.

These episodes of engagement or contacts, that comply with the minimum requirements set out in section 3.2.8 and 3.2.9 (as applicable) and as referred to in Schedule 3C are referred to simply as episodes of engagement in this Service Specification.

The minimum defined episodes of engagement are set out below.

Additional sessions (or, in the Digital Delivery Model, episodes of engagement) may be provided to support engagement, retention and achievement of intended outcomes.

The Provider must provide the following minimum sessions (or, in the Digital Delivery Model, episodes of engagement) with a Service User during the Service, constituting an overall minimum of 20 sessions (or, in the Digital Delivery Model, episodes of engagement):

- minimum of 8 sessions (or, in the Digital Delivery Model, episodes of engagement) in the first 12 weeks – these must take place weekly for weeks 1 – 4 (or more frequently at the discretion of the Provider), and fortnightly in weeks 5 – 12 (or more frequently at the discretion of the Provider);
- minimum of 4 sessions (or, in the Digital Delivery Model, episodes of engagement) in weeks 13-18 – these must take place weekly for weeks 13 – 14 (or more frequently at the discretion of the Provider), and fortnightly in weeks 15 – 18 (or more frequently at the discretion of the Provider); and
- minimum of 8 sessions (or, in the Digital Delivery Model, episodes of engagement) in weeks 19 – 52 (these must occur monthly or more frequently at the discretion of the Provider)
- weekly sessions (or more frequently at the discretion of the Provider) during a rescue package after week 19 (i.e. during the Weight Maintenance Phase). The Provider expressly acknowledges that the all of the minimum requirements set out in the three preceding bullet points still comply even where a rescue package is put in place.

For the avoidance of doubt, week 1 begins on the first day of the TDR Phase.

The first session of (or, in the Digital Delivery Model, the first episode of engagement within) the TDR Phase must not be undertaken at the same time as the Individual Assessment.

The Provider's achievement of Milestone 1 will be subject to the relevant Service Achievement Criteria, as set out in Part 1 of Schedule 3C.

The planned participation of a Service User in the Service should be 52 weeks in total from the first day of the TDR Phase.

Additional contact outside of the minimum sessions (or, in the Digital Delivery Model, episodes of engagement) to further engage and support Service Users, to encourage retention is encouraged.

If a Service User has missed a session (or, in the Digital Delivery Model, an episode of engagement), additional contact to explore any barriers to engagement, re-engage them and cover missed content is encouraged.

The Provider should consider how it ensures that Service Users are given appropriate support which is aligned to their needs, preferences and individual circumstances, including cultural context.

Service Users should be made aware of the availability of peer support throughout the intervention. If the Service User accepts the offer of peer support, this should be facilitated by the Provider.

Sessions (or, in the Digital Delivery Model, episodes of engagement) must be offered at a range of times and days (and, for the Face-to-Face Delivery Models, venues) and where logistically possible in accessible locations to maximise access to (and therefore uptake of) the Service, particularly for those of working age, from ethnic minority groups and from more socially deprived backgrounds.

Planned Pauses

If otherwise at risk of disengagement from the programme due to life circumstances or external factors, a planned pause by a Service User of up to 4 weeks can take place during any phase of the programme after the start of the TDR Phase. Where a pause is arranged, the Provider must share the details of the pause with the Service User's GP practice. If the Service User is not able to re-start the programme within 4 weeks of commencing the pause, the Service User should be discharged.

If, following discharge, the individual subsequently requests to re-start the programme, the Provider must inform the individual that they will need to be re-referred by their GP practice. If they had previously commenced the TDR Phase of the programme, they should be informed that they will not be accepted on to the programme until a period of 12 months has elapsed since the date that individual was discharged.

Where a Service User restarts the programme within 4 weeks after an agreed planned pause, the calculation of:

- that Service User's progression on the programme;
- the Milestone 2 Period; and
- the Milestone 3 Period,

must not take into account the period of the pause. For example, if a Service User commences an agreed planned pause at the end of week 14 and the pause lasts 2 weeks, on re-starting the programme, the Service User should be treated as starting week 15 of the programme.

Where a Service User commences an agreed planned pause during a rescue package, the rescue package is treated as having ended on the commencement of the pause.

3.2.7 Content of sessions/episodes of engagement

The sessions (or, in the Digital Delivery Model, episodes of engagement) must support behaviour change, supporting compliance with TDR during the TDR Phase or during a rescue package. During the Food Re-introduction Phase and the Weight Maintenance Phase, the sessions (or, in the Digital Delivery Model, episodes of engagement) must provide information and practical tools on nutrition, behaviour change and weight management based on current national guidance as set out in section 4.1.

The content must consider the social and psychological support needed to support people to implement behaviour changes in environments which promote unhealthy behaviours.

The Provider must consider the relationship between the dietary treatment and the behavioural support as described in section 3.2.10 to ensure a coherent programme with logical progression.

For the Digital Delivery Model, the programme material should be designed to allow Service Users with different levels of knowledge and different approaches to learning to progress at different paces, with an appropriate reading age to optimise accessibility. This should include promoting self-directed learning.

The Provider must emphasise to Service Users the importance of continuing to attend for diabetes reviews at their GP practice, regardless of the outcome achieved with the Service.

3.2.8 Delivery of Sessions for the Face-to-Face Delivery Model

Where the Provider delivers the Face-to-Face Delivery Model to a Service User, it must comply with this section.

The Provider's service model must ensure that all of the minimum sessions set out in section 3.2.6 are delivered one to one, face-to-face in-person between a Service User and the Provider if the Service User so chooses. The Provider must ensure that the opportunity to have all minimum sessions provided one to one face-to-face in-person is made expressly clear to all Service Users.

Where there is evidence that it will support delivery and participant engagement, and where the Service User:

- declines a one to one face-to-face in-person session; or
- cannot attend a scheduled one-to-one, face-to-face in-person session; or
- expresses a clear preference (unaffected by any influence of the Provider) for a session to be delivered in a manner other than one-to-one, face-to-face in-person,

a session may be delivered through other delivery mechanisms that involve Provider and Service User contact (options include, but are not limited to, telephone calls or video calls). Any such delivery through other delivery mechanisms must be driven by Service User choice. The Provider must not seek to influence the Service User's choice of delivery mechanism for any session. Where a Service User chooses or prefers one-to-one, face-to-face delivery, the Provider must not require a Service User to have a session delivered through other delivery mechanisms. Whichever mode of delivery is used, the requirements for monitoring and recording weight, blood glucose and, where applicable, blood pressure, remain (although it is acceptable for such readings to be obtained through self-measurement if a session is not delivered face-to-face in-person). Regardless of whether a Service User chooses that one or more sessions are delivered through other mechanisms, the Provider must ensure that for each Service User, the majority of the minimum sessions are delivered one-to-one, face-to-face and in-person.

Further individual contact, in addition to the minimum sessions set out in section 3.2.6, may also be included to enhance engagement and retention. Where requested by the Service User, the Provider should support attendance by a family member or carer.

Service Users should be offered a choice of dates and times for sessions to encourage attendance and also to offer the opportunity to catch up where they have missed a session. This choice should be available throughout a Service User's participation in the Service. The Provider should consider the extent to which the intervention is delivered in a logical progression.

References to delivery of a session "in-person" in this section 3.2.8 means the session will be delivered with the Service User and the Staff delivering the session being physically present at the same location. The Commissioner may notify the Provider that all or some of the sessions must be delivered remotely i.e. with the Services User and the Staff delivering the session not being physically present at the same location but having contact through a suitable online platform such as MS Teams, Zoom or Skype or other similar platform ("Remote Delivery").

At any time during the Contract Term, on one or more occasions the Commissioner may at its absolute discretion require the Provider to change the method of delivery of the sessions to Remote Delivery or back from Remote Delivery to the in-person delivery, as the case may be.

If the Commissioner requires the Provider to change the method of delivery of the sessions to Remote Delivery, the Commissioner will notify the Provider in writing and the Provider will change

the method of delivery of the sessions as soon as reasonably practicable following receipt of the notification and in any event in accordance with any timescales specified in the notification. If the Commissioner requires the Provider to change the method of delivery of the sessions from Remote Delivery to in-person delivery, it shall give the Provider notification in writing and the Provider will change the method of delivery of the sessions no later than 3 months following receipt of the notification.

The Provider will ensure that at all times during the Term it has all necessary premises and equipment available to provide in-person delivery and Remote Delivery of the sessions and it will provide Service Users with such equipment if necessary to change the method of delivery of the sessions to Remote Delivery.

If the Commissioner requires the Provider to change the method of delivery of the sessions, the Provider will notify all affected Service Users of the change in writing as soon as reasonably practicable, including details of how they can attend/access sessions under the new method of delivery. If a Service User's first session is held via in-person delivery and the Commissioner requires the Provider to change the method of delivery of the sessions to Remote Delivery, the Provider will ensure that all Service Users that are affected by the change are given the option to continue to attend/access the sessions via Remote Delivery even if the Commissioner subsequently requires the Provider to change back to in-person delivery. If a Service User's first session is held via Remote Delivery following a requirement from the Commissioner that the Provider changes the method of delivery, the Provider will continue to provide the Service to that Service User via Remote Delivery for the duration of that Service User's participation in the Service even if the Commissioner subsequently requires the Provider to change the method of delivery to in-person Delivery.

For the avoidance of doubt, the Provider's consent is not required for the Commissioner to require the Provider to change the method of delivery of the sessions and General Condition 13 does not apply to such a change.

The Service Price (as defined in Schedule 3C) will not be varied as a result of the Commissioner requiring the Provider to change the method of delivery of the sessions.

3.2.9 Delivery of episodes of engagement for the Digital Delivery Model

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

- The Provider must ensure that, in complying with the minimum engagement requirements detailed in section 3.2.6, there is contact between the Service User and Staff of the Provider at each episode of engagement.
- In addition to one-to-one episodes of engagement with the Service User, engagement may also be characterised by the interest and subjective experience of using the intervention, combined with the amount, frequency, duration and depth of usage. Such engagement might include: viewing materials, completing an education module or educational materials via a digital application or digital platform, completing a quiz, completing any active elements, use of tracking technology with associated data logged in the digital platform or application and, inputting self-monitoring data. For clarity, such engagement is in addition to one-to-one episodes of engagement and may not be used as a replacement for human coaching.
- 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 3C sets out the specific types of engagement methods that the Provider must ensure are used for payments to be claimed.
- The Provider must be able to demonstrate that their curricula/modules are designed to deliver engagement of Service Users for a minimum of twelve months.
- To ensure engagement is spread over twelve months, the Provider must ensure there are episodes of engagement at the frequency indicated in section 3.2.6. Schedule 3C (Local Prices) sets out the specific requirements that need to be met for payment.

- Subject to this section 3.2.9, access to the Service should be flexible to accommodate Service User preferences about accessing the Service at a time of their choosing and to work through content within the required frequency flexibly at their own pace.

3.2.10 Underpinning theory and development of approach

The Provider should be explicit regarding the behavioural change theory and techniques that are being used, and the expected mechanism of action of their intervention (Evans et al, 2022¹).

This must utilise a behaviour change framework which is evidence based such as those from the Public Health England Behaviour Change Guide: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/738214/adult_weight_management_changing_behaviour_techniques.pdf.

The Provider must ensure that family, carer and/or household support is accommodated where this would be preferred by a Service User. The Provider should facilitate peer support for Service Users who have a preference for this.

The Provider must ensure that a multi-disciplinary team of health professionals or specialists relevant to the core components of the Service (i.e. Type 2 diabetes, behaviour change, weight loss, diet) is involved in development of the Service. These should include, as a minimum; a registered dietitian and registered health professional with specialist diabetes knowledge.

3.2.11 Training and Competencies for the Service

The Provider will ensure that the Service is delivered 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 expected. The Provider needs to demonstrate that these qualifications will ensure that front-line Staff are trained to deliver interventions in line with [NICE PH49](#) (as set out in section 4.1) for overall behaviour change.

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, recognise individual needs and provide appropriate support including advice, techniques and signposting to other services. The Provider must manage confidential and sensitive personal identifiable data. This must include training in delivery of the Service. 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 changes by understanding their beliefs, needs and preferences and building their confidence.

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. This includes adaptation of dietary advice and plans to the Service User's preferences and culinary traditions. Where reasonable and appropriate, the Provider will provide Services in languages to suit the needs of the local population.

Ideally staff delivering the Service will reflect the diversity of the population accessing the Service.

3.2.12 Clinical Training and Competencies for the Service

There is not a requirement for health professionals to deliver content of sessions (or, in the Digital Delivery Model, episodes of engagement), nor be involved in sessions (or, in the Digital Delivery Model, episodes of engagement). In discussions about physical activity taking place during the Weight Maintenance Phase, it would be beneficial to involve a qualified physical activity instructor trained in behaviour change in the design of the Service.

All Staff required to undertake weight, blood pressure and finger-prick blood testing must be appropriately trained to do so.

¹ <https://pubmed.ncbi.nlm.nih.gov/36045887/>

All Staff delivering the Service must be trained to appropriately recognise adverse events, including those relating to blood pressure or blood glucose levels, and safely respond where able and appropriate to do. Those delivering the intervention are required to promptly seek advice from the Provider's appointed Medical Director. This will include a requirement to appropriately interpret results and feedback to GP Practices if there is concern.

The Provider must have a Medical Director, who is available at all times, relevant to the delivery of the Service, to advise Staff and provide guidance on appropriate courses of action particularly in the case of an adverse event. The Medical Director must be a registered medical practitioner within the meaning of Schedule 1 of the Interpretation Act 1978 and must have an MRCP or MRCGP.

It is the role of the Provider's Medical Director in relation to adverse events, to:

- Respond appropriately to all adverse events;
- Respond and give advice about non-serious adverse events and side effects; and
- Appropriately record all adverse events, liaise with the relevant Service Users' GP practices as appropriate, and notify the Commissioner within the next regular monthly report of adverse events and side effects (unless the Provider's Medical Director considers the individual circumstances of the event necessitate earlier reporting).

Staff must also have undergone information governance training and have confidentiality clauses in their contracts of employment.

The Provider acknowledges and agrees that the Service involves training, teaching, instruction, assistance, advice and guidance provided wholly or mainly for adults receiving healthcare. The Commissioner therefore considers the Service to be regulated activity for the purposes of regulations governing the use of Enhanced DBS & Barred List Checks and the Provider must carry out Enhanced DBS & Barred List Checks in respect of all members of Staff engaged in the Service who are eligible for such checks and must not engage any such person in the Service who is barred from working with vulnerable adults or is otherwise unsuitable for working with vulnerable adults. The Provider must ensure that any Sub-contractor is subject to similar obligations.

3.2.13 Weight Loss

It is anticipated that the majority of the weight loss will be attained during the TDR Phase.

The Provider must, following the TDR Phase or any further period of TDR, i.e. rescue packages, work with Service Users to assess their dietary intake and support planning of sustainable dietary changes, to achieve a healthy balanced diet as set out in the current national guidance. If the BMI of the Service User has decreased below 21 kg/m² in people from White ethnic groups or below 19 kg/m² in people from Black, Asian and other ethnic groups as set out in section 3.2.6 under the heading "TDR Phase" above, the Provider must not support further weight loss.

Following the TDR Phase or any further period of TDR, i.e. rescue packages, the Provider must design approaches to support Service Users to maintain a healthier weight in line with [NICE Guideline NG7](#).

3.2.14 Dietary content

Following the TDR Phase or any further period of TDR, i.e. rescue packages, the design and delivery of the curriculum must be underpinned by the UK Government dietary recommendations, acknowledging the findings of the Scientific Advisory Committee on Nutrition consultation (May 2021)². The current recommendations are detailed in the Eat Well Guide³. The Eat Well Guide shows the proportions of the main food groups that form a healthy balanced diet. It promotes a diet high in fibre, fruit and vegetables and low in saturated fat, sugar and salt.

² [SACN report: lower carbohydrate diets for type 2 diabetes - GOV.UK \(www.gov.uk\)](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/90422/sacn-report-lower-carbohydrate-diets-for-type-2-diabetes.pdf)

³ Eatwell Guide can be accessed at <https://www.nhs.uk/live-well/eat-well/the-eatwell-guide>

The Provider must support Service Users to achieve the Government's dietary recommendations, using dietary approaches that are evidence based and sustainable in the longer term.

The Commissioner may vary the requirements in this section 3.2.14 if there is a change in the national guidelines. 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.

Service Users should be supported to set individualised weight maintenance goals following the TDR Phase which may include setting tailored achievable short, medium and long term dietary and physical activity goals which help them to achieve their aims.

Dietary advice should reflect the culinary traditions of the populations in which the Service is being provided wherever possible (information on the populations is set out in the Local Service Requirements in Appendix 2 of this Schedule 2A).

3.2.15 Physical activity content

During the TDR Phase it is not recommended that additional physical activity is actively encouraged. However, following TDR, the Provider will support Service Users to undertake regular physical activity and aim to minimise or break-up extended periods of being sedentary, ultimately working towards achieving the UK Chief Medical Officer's physical activity recommendations: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/832868/uk-chief-medical-officers-physical-activity-guidelines.pdf.

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 in being active.

The Provider may incorporate into the Service, methods for self-monitoring to enable the Service User to capture individual-level change in weight, diet and physical activity. Methods may include the provision of, or integration with, wearable devices once the TDR Phase is complete.

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/Episode of Engagement

The "Final Session" (or, in the Digital Delivery Model, the "Final Episode of Engagement") is defined as the last session or episode of engagement delivered by the Provider as part of the planned Service (for those Service Users still attending or participating).

As part of the Final Session or Final Episode of Engagement, the Provider must conduct a post intervention assessment of weight, wellbeing, and achievement of individual goals for all Service Users who attend or participate. 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 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 body weight.

The Provider must ensure that Service Users are reminded about key sources of information and advice, such as the NHS website.

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

3.2.17 Service User measurements through the Programme

Blood pressure

For Service Users who are prescribed medication which may lower blood pressure at the time of referral, blood pressure must be monitored by the Provider as follows;

- Blood pressure monitoring should be undertaken at every session (or, in the Digital Delivery Model, episode of engagement) with the Provider.
- Where the Face-to-Face Delivery Model is being delivered and a session is occurring face-to-face in-person, all required readings will be taken by the Provider at that face-to-face in-person session. If a session is being delivered through other mechanisms, all required readings may be obtained remotely e.g. through self-measurement
- For the Digital Delivery Model or where the Face-to-Face Delivery Model is subject to Remote Delivery, readings should be taken remotely using devices provided by the Provider, submitted to the Provider and reviewed as set out in this section.
- If Service Users go onto a rescue package the Provider must ensure weekly blood pressure monitoring over the duration of the rescue package.

The thresholds for action should be applied as follows:

- 89/59 mmHg or lower (systolic and/or diastolic) or postural symptoms – the Provider must contact the Service User's GP practice team. If symptoms are interfering with daily activities, same-day contact with the GP practice must be made (the Provider must contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day);
- Between 90/60 and 159/99 mmHg – no additional action required, continue intervention;
- Between 160/100 and 179/119 mmHg (systolic and/or diastolic) over two sessions (or, in the Digital Delivery Model, two episodes of engagement) – the Provider must contact the Service User's GP practice;
- 180/120 mmHg or higher (systolic and/or diastolic) – there must be same-day contact with the Service User's GP practice (the Provider should contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day);
- For avoidance of doubt, if a blood pressure reading could fit into two of the categories described above (such as 181/118 mmHg), action should be taken in line with the category prompting the most rapid response (in this case, same-day contact with the GP practice).

For the Digital Delivery Model, and any sessions being delivered as part of the Face-to-Face Delivery Model but which are not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), blood pressure measurement may be arranged at venues or services nearby and convenient to Service Users or self-measurement may be used (with relevant equipment, training and support provided to the Service User by the Provider at the Provider's cost).

The Provider must use a validated device for the type of testing that they propose, and ensure that their workforce has received appropriate training to use the devices as specified, providing quality measurements. Guidance on appropriate monitors can be found here <https://bihsoc.org/bp-monitors/>.

Weight

Weight measurements must be taken at every session.

Where the Face-to-Face Delivery Model is being delivered and a session is occurring face-to-face in-person, all required readings will be taken by the Provider at that face-to-face in-person session.

For the Digital Delivery Model, and any sessions being delivered as part of the Face-to-Face Delivery Model but which are not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), all required readings may be obtained remotely e.g. through self-measurement.

The baseline weight and height measurement should be recorded by the Provider at the first session (or, in the Digital Delivery Model, episode of engagement) of the TDR Phase.

BMI will be calculated at baseline and every time a weight measurement is taken. As set out in section 3.2.6, TDR should be stopped, with no further advice directed at weight loss, if BMI falls below 21kg/m² in people from White ethnic groups or below 19kg/m² in people from Black, Asian and other ethnic groups.

Data collection of weight measurements in face-to-face in-person sessions must be taken using appropriately calibrated scales (see PHE standard evaluation framework for weight management interventions for details of measurement of height and weight: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/685545/SEF_weight_management_interventions.pdf).

Scales used to measure weight where Face-to-Face Delivery Models are being used should meet Class III scales for levels of accuracy as per UK weighing federation guidance): <http://www.ukwf.org.uk/res/medicalguidancenotes.pdf>.

For the Digital Delivery Model, and where a session is being delivered as part of the Face-to-Face Delivery Model but which is not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), the Provider will provide at its own cost scales to each Service User and home scale readings must be shared by Service Users with the Provider. Measurements must be taken at all sessions (or, in the Digital Delivery Model, episodes of engagement) as specified in this Service Specification, on the same device consistently (as appropriate). For all devices provided to Service Users by the Provider, the Provider must ensure that the device adheres to the error margins for Class IV scales (set out in Table 1 of the UKWF Guidance). The Commissioner acknowledges there may be limited options on the market for certified Class IV scales (particularly digital scales that are certified Class IV in the UK), so confirmation from the manufacturer that the scales adhere to the error margins for Class IV scales (set out in Table 1 of the UKWF Guidance) is acceptable, in place of the official certification.

If Service Users go on a rescue package at any stage during the Service, the Provider must ensure weekly weight measurement recording and reporting for the duration of the rescue package.

Blood glucose testing

For all Service Users, finger prick capillary blood glucose testing should be monitored by the Provider as follows;

- Finger prick capillary blood glucose testing should be undertaken at every session with the Provider;
- Where the Face-to-Face Delivery Model is being used and a session is occurring face-to-face in-person, all required readings will be taken by the Provider at the relevant session. For the Digital Delivery Model, and where a session is being delivered as part of the Face-to-Face Delivery Model but which is not being delivered in-person (whether due to Service User choice or Remote Delivery required by the commissioner), all required readings will be submitted by the Service User to the Provider and reviewed as set out in this section;
- If Service Users go onto a rescue package the Provider must ensure weekly blood glucose monitoring over the duration of the rescue package.

The thresholds for action should be applied as follows:

- Under 15 mmol/l – no additional action required, continue intervention;
- Between 15.0 - 19.9 mmol/l over 2 Sessions – the Provider must contact the Service User's GP practice;
- 20.0 mmol/l or higher – there must be same-day contact with the Service User's GP practice team (the Provider must contact the GP practice directly and the Service User must also be advised to contact their GP practice same-day).

Finger prick blood glucose testing may be arranged at venues or services nearby and convenient to Service Users or self-measurement may be used for the Digital Delivery Model, and where a session is being delivered as part of the Face-to-Face Delivery Model but which is not being delivered face-to-face in-person (whether due to Service User choice or Remote Delivery required by the commissioner), with relevant equipment, training and support provided to the Service User by the Provider at the Provider's cost.

When selecting blood glucose meters the Provider should ensure that the selected meter meets current International Organization for Standardization (ISO) standards for blood glucose meters

(ISO15197)⁴ and that choice is aligned with locally agreed provision of blood glucose meters on the NHS.

The CQC's guidance on the diagnostic and screening procedure regulated activity confirms that non-ambulatory blood pressure monitoring and blood tests carried out by means of a pin prick test are excluded from the registration requirements for this regulated activity. However, the Provider must 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 communications channels as set out in section 3.2.4 above;
- If, after the Provider contacts an individual following referral, the individual indicates that they do not accept the Service;
- If, after the Provider contacts an individual following referral, the individual indicates that they accept the Service, and do not complete an Individual Assessment within 90 days of referral;
- If, after the Service User has accepted the Service but fails to attend or participate in a scheduled and agreed Individual Assessment, an Individual Assessment has not been completed within one calendar month of the date the Service User failed to attend or participate in the scheduled and agreed Individual Assessment;
- If, following an Individual Assessment the individual:
 - does not attend or participate in a first session (or, in the Digital Delivery Model, episode of engagement) where the Provider has offered the session (or, in the Digital Delivery Model, episode of engagement) on three separate occasions at times (and for the Face-to-Face Delivery Model, venues) suitable to the individual; or
 - does not attend the first session (or, in the Digital Delivery Model, episode of engagement) within 90 days of the Individual Assessment;
- If, during the TDR Phase, it is established that the Service User is not complying, or unable to comply, with the requirements of the Service;
- If, whilst participating in the Service, an adverse or concurrent event occurs of sufficient severity that it would no longer be appropriate for the Service User to continue on the Service;
- If a Service User becomes pregnant whilst participating in the Service, the Service User should be discharged from the Service to the care of her GP practice. It must be made clear to pregnant women that weight loss or dieting during pregnancy is not advised;
- When a Service User informs the Provider they no longer wish to participate in the Service;
- If, during the first 2 weeks of the TDR Phase, it is established that a Service User cannot tolerate the TDR products;
- If, during the first four weeks of the TDR Phase, a Service User misses a session (or, in the Digital Delivery Model, episode of engagement) (or there is no recorded engagement for one week) without prior notification to the Provider and the Service User does not make contact within one week; or the Service User is not successfully contacted by the Provider within one week and the Provider has made a minimum of three attempts to contact the

⁴ <https://www.iso.org/standard/54976.html>

Service User using at least two of the following means of communication: letter, phone call, text message or email;

- If, during the TDR Phase after the first four weeks or during a rescue package, a Service User misses a session (or, in the Digital Delivery Model, episode of engagement) (or there is no recorded engagement for two weeks) without prior notification to the Provider and the Service User does not make contact within two weeks, or is not successfully contacted by the Provider within two weeks following a minimum of three attempts to contact the Service User using at least two of the following means of communication: letter, phone call, text message or email;
- If, after planned pause agreed in accordance with section 3.2.6, a Service User does not re-start the programme within 4 weeks of commencing the pause;
- If, during the Food Reintroduction and Weight Maintenance Phases, if a Service User misses a session (or, in the Digital Delivery Model, episode of engagement) (or there is no recorded engagement for four weeks) without prior notification to the Provider and the Service User does not make contact within four weeks, or is not successfully contacted by the Provider within four weeks following a minimum of three attempts to contact the Service User using at least two of the following means of communication: letter, phone call, text message or email;
- If a Service User does not submit measurements of the same type (weight, blood glucose, or blood pressure if applicable) at two consecutive sessions set out in section 3.2.17 where the Service User is required to submit them and the Provider has made a minimum of three attempts to contact the Service User to obtain each such measurement using at least two of the following means of communication: letter, phone call, text message or email;
- On completion of the Final Session or Final Episode of Engagement (or once the Final Session or Final Episode of Engagement has been delivered). Once the Final Session or Final Episode of Engagement is completed then the Service User is discharged automatically regardless of the number (or percentage) of sessions attended or episodes of engagement participated in.

The Provider must notify the Service User's GP practice that the Service User has been discharged. The length of time the Service User participated, the stage of the intervention reached, and the initial and most recent weight measurements should be communicated, as well as the reason for discharge. If the Service User has been discharged during the TDR Phase and any medication changes were made on the first day of TDR, the GP practice must be asked to arrange review to consider restarting medication using the template letters provided by the Commissioner.

Where an individual has previously started TDR and has subsequently been discharged from the programme for any reason, the Provider will not accept a re-referral of that individual until at least 12 months have elapsed since the date they were previously discharged.

Discharge Requirements

If a Service User had started the TDR Phase but is discharged before the TDR Phase is completed, the Provider must provide the Service User and the GP practice with a letter of discharge in accordance with the template letters provided by the Commissioner. Unless otherwise specified in these template letters, if any medication were stopped on the first day of TDR, the letter should advise the Service User to make contact with their GP practice within two Operational Days to arrange a review to discuss the potential need to restart medication (determination of the required urgency of such a review will be up to the GP practice), or if no medications were stopped on the first day of TDR, the letter should advise the Service User to make contact with their GP practice within 4 weeks for a routine review. Similarly, the letter of discharge to the GP practice must reflect this advice.

Unless otherwise specified in the template letters, if discharge occurs once the TDR Phase has been completed, the letter of discharge must advise the Service User to make contact with their GP practice within 4 weeks for consideration of a repeat blood tests and a routine review. Similarly, the

letter of discharge to the GP practice must advise the GP practice to consider repeat blood tests and a routine review.

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.

3.2.19 Links to other services

The Provider must ensure that links are made with existing local networks and partnerships throughout the development and delivery of the Service. This could include, for example, leisure and public health services, departments within Local Authorities, the NHS website, 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 system to advertise the existence of the Service, with a view to raising awareness of the eligibility criteria and the availability and benefits of the Service amongst local GP Practices and to people in the geographical area covered by the Contract and eligible for the service who may benefit from participating in the NHS T2DR Programme. Any marketing or promotional activity must be designed to target groups in the community which are currently less likely to access services and encourage them to find out more about and attend or participate in 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 this Service.

Providers must NOT use personal information provided to them by GP practices to target individuals directly.

3.4 Intellectual Property

For the avoidance of doubt, notwithstanding General Condition 1.2, the Parties expressly agree that this section 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 section 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 section 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 section 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 section 3.4 means a clinical commissioning group or local authority in relation to whose geographical area the Services are delivered.

“Provider IPR” in this section 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 Technology Assessment Criteria

The Provider must ensure that the Service, when provided via the Digital Delivery Model complies with the requirements of the Digital Technology Assessment Criteria ("**DTAC**") and ensure that the Service is updated if requirements of the DTAC are updated.

3.7 Government Digital Service Technology Code of Practice

The Provider must ensure that the Service adheres to the requirements of the Government Digital Service Technology Code of Practice, which is currently available at:

<https://www.gov.uk/government/publications/technology-code-of-practice/technology-code-of-practice>

3.8 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.

3.9 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 – **North East London ICS**
- ensure that the number of Service Users who achieve Milestone 1 (as defined in Schedule 3C) does not exceed 500 during the Contract Term. This number is the "Intervention Cap" for the purposes of Schedule 3C;
- work with the local health system 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 two years has elapsed since the Effective Date. This period is the "Intervention Period" for the purposes of Schedule 3C;

- actively monitor and report to the Commissioner and local health systems, the number of Service Users who achieve Milestone 1 on the 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 3C) is predicted to exceed the Intervention Cap.

The Commissioner may at its discretion either:

- vary the Intervention Cap and/or the Intervention Period; 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 and/or Intervention Period 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 section 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 3C; and/or
- invited to participate in the Service once the Intervention Period has expired in accordance with paragraph 2 of Part 1 of Schedule 3C.

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 being provided with the Service who completed the Final Session or Final Episode of Engagement or other such day as agreed in writing between the Parties.

3.11 Transition

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

This period is referred to as a "Transition Period". This section 3.11 sets out obligations on the Provider who is winding down its delivery of the Service. During a Transition Period the Provider will comply with the relevant obligations set out below.

The aim during the Transition Period is that:

- General Practice engagement is maintained and a steady flow of referrals 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 Provider and a smooth mobilisation and commencement of delivery of the service by the incoming provider.

Subject to the other requirements of this section 3.11, the Provider is responsible for delivering the Service to all Service Users who have been invited to participate as defined in this Contract, within the Intervention Cap and the Intervention Period specified in this Contract. The Provider must

maintain high levels of engagement with 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 Provider but who have not yet been invited to participate prior to the Intervention Period expiring. Such individuals will be transferred, in compliance with Data Protection Legislation, by the Provider to the incoming provider. Individuals who have not achieved (or who are unlikely to achieve, in the opinion of the Provider) Milestone 1 by the 2 month anniversary of the expiry of the Intervention Period will also be transferred by the Provider to the incoming provider unless those individuals will achieve Milestone 1 on the next submission of the Data Output Specification to the Commissioner following the 2 month anniversary.

The Provider is responsible for complying with relevant Data Protection Legislation and the duty of confidentiality throughout the transfer process.

The 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 Provider is required to attend joint planning meetings with the incoming provider throughout the Transition Period to support operational delivery. The Provider will continue to provide data to the local health system and will provide an operational point of contact until all Service Users being provided with the Service have either completed participation in the Service or have been discharged.

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 will attend monthly meetings (whether in person or remotely) 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 will 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 will attend monthly meetings (as a minimum; whether in person or remotely) with local lead partner organisations, in whose areas the Services are delivered, to review progress and address any specific local issues relating to the delivery of the Services. These may include the rate of referrals to the Services, uptake rates, issues with the referral process or service delivery, and equity of access, uptake, retention and outcomes (particularly in relation to inequity by ethnicity and socioeconomic deprivation), and any other matters as either the Provider or the relevant local partner organisations considers relevant to the Services. Appropriate analysis and reporting of performance relating to the programme in the local health system should be made available, with particular focus on exploring and addressing inequalities. The Provider will 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 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.

The Provider must ensure that a process is in place to obtain Service User feedback, such as through use of the Family and Friends Test and a system is in place for how that feedback is considered and actioned.

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:

- The Provider will deliver the Service in accordance with all relevant clinical guidelines and other guidance and publications published nationally, in particular:
 - NICE NG 28 Type 2 Diabetes in Adults: Management (2022)
 - NICE NG 7 Preventing excess weight gain
 - 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 44 Physical activity: brief advice in primary care (2012)
 - NICE PH 41 Physical activity: walking and cycling (2013)
 - NICE CG 43 Obesity: Guidance on the prevention of overweight and obesity in adults and children (2006 and updated 2015)
 - 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)
 - Eatwell Guide (2016)
 - NICE NG 183 Behaviour change: digital and mobile health interventions (2020)

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 2 THE SERVICES

A. Service Specifications

Appendix 1

Tender Response Document



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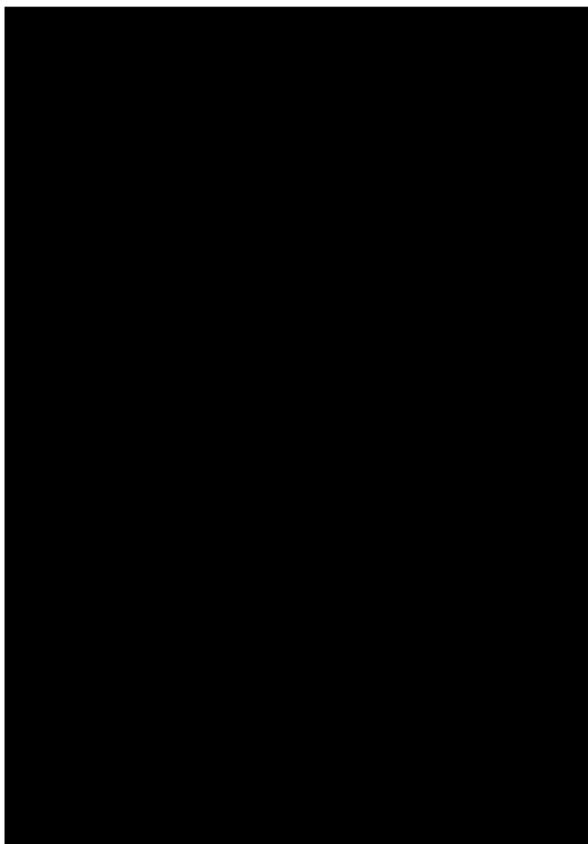
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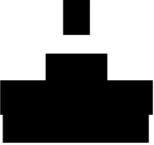
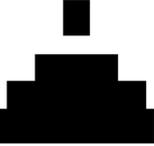
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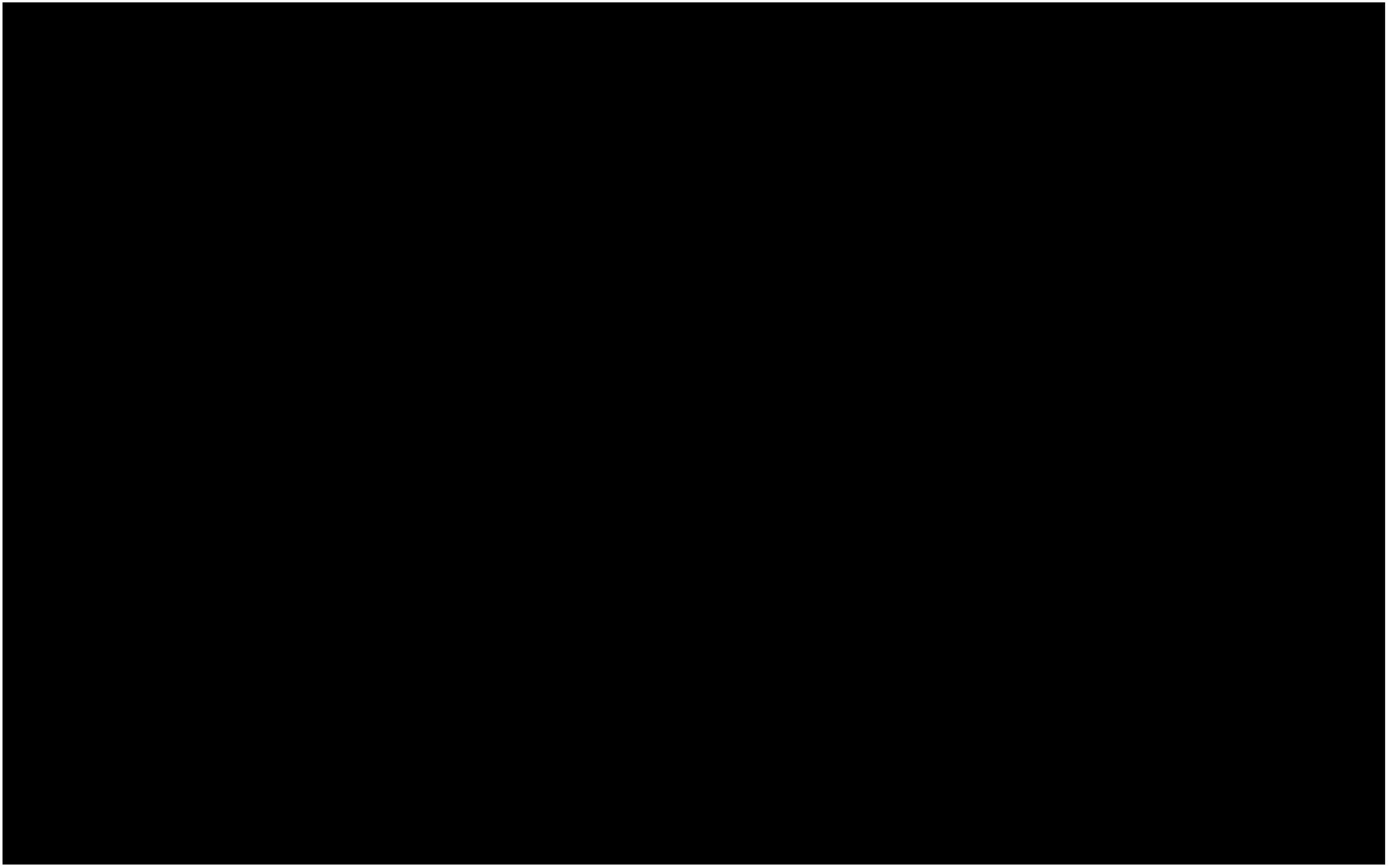
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SCHEDULE 2 – THE SERVICES

A. Service Specifications

Appendix 2

Local Service Requirements

NHS Type 2 Diabetes Path to Remission Programme (T2DR)*

ICB / ICS Prospectus

North East London Integrated Care Board

* formerly the NHS Low Calorie Diet Programme – LCD, and may be referred to as such within this document.

All clarification questions should be raised formally through the clarification process on Atamis.

Providers should not contact ICSs directly with queries in relation to the content of these prospectuses.

1.0 ICB/ ICS information	
1.1 ICB / ICS full name	North East London Integrated Care Board
1.2 Governance arrangements	<p>NEL Low Calorie Diet (LCD) Working Group, established in November 2020, has clinical, commissioner, Public Health, and provider representatives.</p> <p>The decisions about the management and implementation of the intervention will continue being held within this Working Group which reports directly into the NEL ICB Diabetes Clinical Network, formerly the NEL Diabetes Partnership Group. The NEL ICB Diabetes Clinical Network will continue to have central oversight over the programme going forward. A Terms of Reference, created in November 2020, will be reviewed and updated, as required.</p> <p>Function of the NEL ICB LCD Working Group:</p> <ul style="list-style-type: none"> • Support the provider in the roll out and delivery of the programme across NEL • Gain support and agreement from senior management and governing bodies for the programme transition, mobilisation, roll-out and on-going governance • Meet bimonthly with ad hoc meetings as required to review monitoring data and performance, and resolve any issues, linking with the available NHSE support. The frequency of these meeting is to be reviewed as the programme progresses. • Share best practice and learning within the group, to maximise the achievement of the programme across the partnership. • Review, monitor and manage referral volumes • Actively participate in regional and national learning and development events hosted by NHSE to ensure that the views and interests of the partnership are appropriately represented. <p>Function of the NEL ICB Diabetes Clinical Network:</p> <ul style="list-style-type: none"> • Point of escalation of risks, issues raised within the Working Group

	<ul style="list-style-type: none"> • Facilitate information sharing across all the partner organisations • Central monitoring of progress against implementation plans and deliverables <p>Group members will also report to internal groups/boards/bodies within their respective Places, as per their internal governance requirements and gain support and agreement from senior management and governing bodies.</p>
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<h2>2.0 ICB / ICS Partnership Geography</h2>	
<h3>2.1 Geographical spread</h3>	<p>The partnership covers 7 London boroughs and the City & Hackney in North East London. The 3+1 inner London boroughs (Newham, Tower Hamlets, and City & Hackney) are small in area but high population density. Waltham Forest is larger in area with a higher population density in the south. The 3 Boroughs that make up Barking Havering and Redbridge (BHR) are all larger areas with lower population density. The map below demonstrates the location of the partnership and constituent Boroughs within the London region</p>



- **City & Hackney:** 39 practices all belong to the City and Hackney GP Confederation. They are organised into 8 Primary Care Networks.
- **Barking & Dagenham:** 34 GP practices which are organised in to 6 Primary Care Networks (PCN).
- **Havering:** 42 GP practices are organised in to 4 Primary Care Networks (PCN). With each network ranging between 30,000 – 110,000.
- **Redbridge:** 42 GP practices are organised in 5 Primary Care Networks (PCN).
- **Tower Hamlets:** Has 4 geographical localities. The 36 GP practices are clustered in 8 primary care networks.

	<ul style="list-style-type: none"> • Newham: 48 GP practices which work in 9 geographical Networks (approximately aligned with community neighbourhoods) with between 30,000 – 50,000 population each. They all belong to the GP federation NHC • Waltham Forest: 40 practices; has 3 geographical localities and 7 primary care networks, with between 34,000 – 55,000 populations per network.
<p>2.2 Urban/Rural</p>	<p>The 3 inner London boroughs are densely populated urban areas with the City of London being primarily a business centre, with a small resident population. Hackney & Newham are densely populated urban areas.</p> <ul style="list-style-type: none"> • Barking and Dagenham and Redbridge: comprise mainly of urban areas, though one third of Redbridge is made up of open space, which includes green belt land; Havering, whilst mainly suburban, has large areas of protected open space, particularly areas on its outskirts. • WF: comprises built-up urban districts in the south with inner-city characteristics, and more affluent residential development in the north with a variety of open spaces which together cover a fifth of the borough

<p>2.3 Transport links and car usage</p>	<p>Transport links</p> <ul style="list-style-type: none"> • Barking Havering Redbridge (BHR): served by Transport for London routes, which also extends to most of Havering. Major roads leading from and to the boroughs are the A12, A13, A127, the North circular, M11 and the M25. • Hackney (H): is well served by public transport – especially over ground and bus services. Hackney has low levels of car ownership. It has infrastructure to support walking and cycling. • Newham (N): Transport infrastructure is limited with much of the borough served only by bus. Some areas especially of high deprivation are isolated by transport lack or road barriers especially in Little Ilford and Plaistow. • Tower Hamlets (TH): with 31 public transport stations and 46 bus routes, it has excellent connectivity to Central London and the rest of the country. It has the 4th lowest level of car ownership amongst the London Boroughs. • Waltham Forest (WF): is making significant investment in improving cycle and active travel infrastructure to promote more walking, cycling and public transport use and to discourage reliance on private motor transport.
<p>2.4 Any challenges with digital access – e.g. specific areas lacking broadband availability</p>	<p>London has 100% broadband penetration to each residential area. NEL code areas offer speeds up to 11MB non-fibre broadband and 67MB fibre broadband. In areas where a higher proportion of housing is privately rented, access to fixed broadband within the home may be highly variable.</p> <p>Internet Access (based on Local Needs Assessments data)</p> <ul style="list-style-type: none"> • BHR: Over four fifths (86%) of the population have internet access at home. • Hackney: There are areas in Hackney Wick which do not have access to decent internet connectivity. Only around 12% of premises in Hackney have access to full fibre (or FTTP) internet connections.

- Tower Hamlets: 87% of adults have access to internet. Borough residents in social housing are less likely to have internet access.
- Newham: More than nine in ten Newham households (91%) have access to the internet, either inside or outside the home. Broadband connection is the most common way of accessing the internet (84%)
- Waltham Forest: All homes within Waltham Forest are within reach of fast fibre enabled exchanges, with around 95% capable of being connected. However, data suggests that 10% of the population of the Borough do not have direct access to broadband primarily due to cost.

We have found that we have greater engagement with online systems for booking appointments but limited responses to questionnaires, this may be reflective of limitations around digital literacy and/or language barriers.

Data from ONS Internet Users, 2020: Published 6th April 2021:

RECENT AND LAPSED INTERNET USERS AND INTERNET NON-USERS, BY LOW LEVEL GEOGRAPHICAL LOCATION, UK, 2019 TO 2020					
NUTS Code	Persons aged 16 years and over	Used in the last 3 months		Used over 3 months ago/Never used	
		2019	2020	2019	2020
	UK - %	90.8	92.1	9.1	7.8
	London%	93.0	94.9	6.8	4.9
UKI	Hackney and Newham	95.4	93.1	4.3	6.5
UKI41	Tower Hamlets	86.8	91.3	13.2	8.7
UKI42	Barking & Dagenham and Havering	91.0	92.0	9.0	8.0
UKI52	Redbridge and Waltham Forest	88.4	97.2	11.6	2.8

Snapshot from [Digital Exclusion Risk Index Tool v1.5](#).

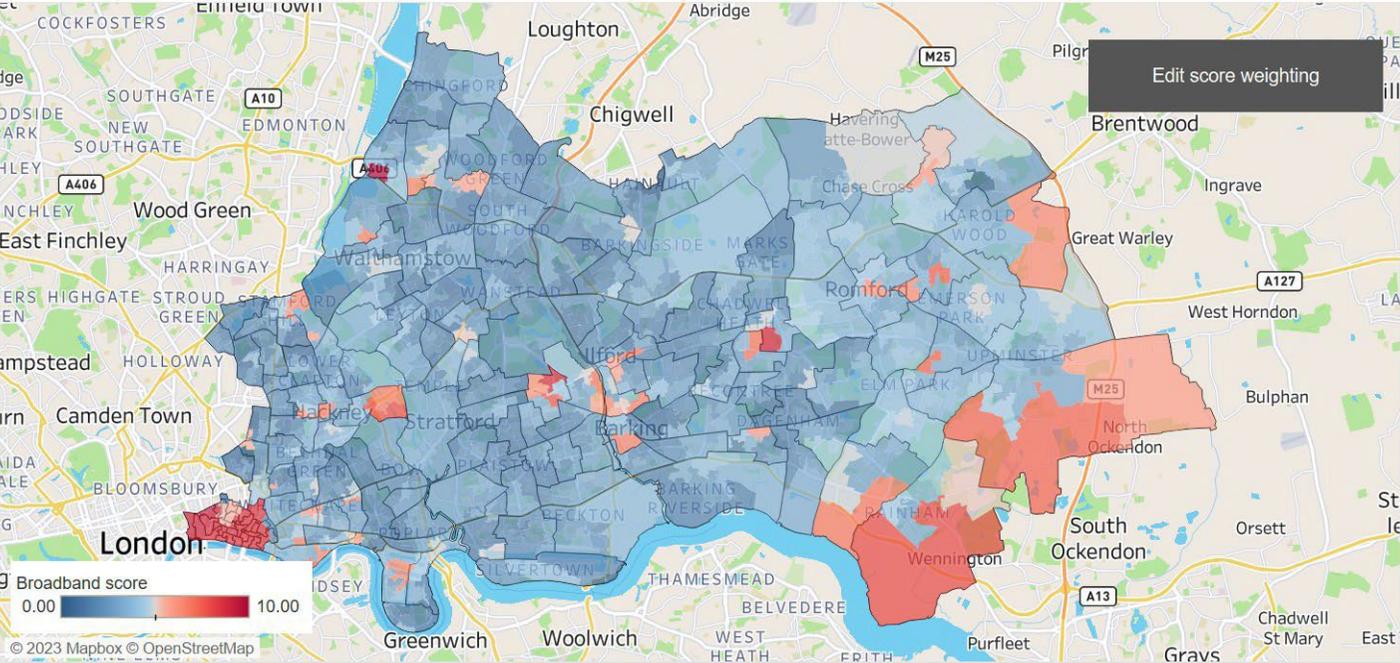
Digital Exclusion Risk Index Broadband Score

Choose a local authority / local authorities:
Multiple values

Choose a score calculation base:
Local Authority

E01004398: Waltham Forest 009A
Higham Hill

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Produced by:



Home page

3.0 ICS Partnership Demographics

3.1 State the total population numbers in each age group, by gender and Place Level

Please segment according to the locally available data.

Area	Age	Male	Female
Barking & Dagenham	18 - 44	40,397	42,073
	45 - 64	20,692	21,722
	65+	8,469	11,324
City & Hackney	18 - 44	72,187	71,590
	45 - 64	26,567	27,061
	65+	10,029	11,847
Havering	18 - 44	42,459	44,804
	45 - 64	30,937	32,717
	65+	19,818	26,423
Newham	18 - 44	95248	75601
	45 - 64	33358	32617
	65+	11494	13923

	Redbridge	18 - 44	61,087	59,520	
		45 - 64	32,562	33,613	
		65+	16,556	20,192	
	Tower Hamlets	18 - 44	92,104	82,918	
		45 - 64	28,394	23,385	
		65+	9,115	10,816	
	Waltham Forest	18 - 44	61,301	57,393	
		45 - 64	30,133	31,082	
		65+	12,888	15,907	
	Source: ONS 2017 mid-year estimates by CCG				
<p>3.2 Set out the most prevalent non-English speaking languages across the ICB / ICS footprint, including a list of the top 5 non-English speaking languages</p>	<p>The population covered by NEL ICB is highly diverse, with over 120 languages spoken across the patch. It may be difficult for patients to engage and commit to a programme if they are relying on translations from a family member, carer or friend. As such there will be interest in providers offering coaches who speak non-English languages.</p> <p>Please find below information regarding the top spoken languages across NEL, other than English.</p>				
	<p>Tower Hamlets, Newham and Waltham Forest</p>		<p>Barking & Dagenham, Havering and Redbridge</p>		<p>City & Hackney</p>
	<p>French Spanish</p>		<p>Romanian Albanian</p>		<p>Turkish Spanish</p>

	<table border="1" data-bbox="609 252 2016 391"> <tr> <td data-bbox="609 252 1077 391">Bengali Urdu Romanian Polish</td> <td data-bbox="1077 252 1547 391">Bengali Portuguese Polish</td> <td data-bbox="1547 252 2016 391">Portuguese French Yiddish</td> </tr> </table> <p data-bbox="609 459 1973 627">In addition, Somali, Lithuanian, Chinese are commonly spoken across the patch. Please note that the Somali, Sylheti and Chatgaya communities generally use word of mouth communication rather than the written word. This should be kept in mind when considering the format of the programme, and how messages can be best communicated. We also would like to highlight the need for the provider to support people living with Type 2 diabetes who are deaf through the provision of BSL interpreting services.</p>	Bengali Urdu Romanian Polish	Bengali Portuguese Polish	Portuguese French Yiddish													
Bengali Urdu Romanian Polish	Bengali Portuguese Polish	Portuguese French Yiddish															
<p data-bbox="212 738 573 991">3.3 Set out the main ethnicities, cultural needs and/or other population groups present within the ICB / ICS partnership that may require the intervention to be tailored</p>	<table border="1" data-bbox="609 802 1563 1118"> <thead> <tr> <th data-bbox="609 802 1086 871">Ethnicity</th> <th data-bbox="1086 802 1563 871">% of current diabetes list size at NEL</th> </tr> </thead> <tbody> <tr> <td data-bbox="609 871 1086 906">White</td> <td data-bbox="1086 871 1563 906">16.63%</td> </tr> <tr> <td data-bbox="609 906 1086 941">South Asian</td> <td data-bbox="1086 906 1563 941">58.16%</td> </tr> <tr> <td data-bbox="609 941 1086 976">Black</td> <td data-bbox="1086 941 1563 976">18.75%</td> </tr> <tr> <td data-bbox="609 976 1086 1011">Mixed</td> <td data-bbox="1086 976 1563 1011">1.36%</td> </tr> <tr> <td data-bbox="609 1011 1086 1046">Other</td> <td data-bbox="1086 1011 1563 1046">4.31%</td> </tr> <tr> <td data-bbox="609 1046 1086 1082">Ethnicity not recorded</td> <td data-bbox="1086 1046 1563 1082">0.48%</td> </tr> <tr> <td data-bbox="609 1082 1086 1118">Ethnicity not stated</td> <td data-bbox="1086 1082 1563 1118">0.30%</td> </tr> </tbody> </table> <p data-bbox="609 1118 1279 1139">Source: NEL Diabetes Dashboard November 2022, based on CEG data</p> <p data-bbox="609 1238 2002 1305">The North East London population is ethnically diverse, and comprises some of the most highly diverse local authorities in England. The extent and nature of ethnic diversity varies significantly between the 7</p>	Ethnicity	% of current diabetes list size at NEL	White	16.63%	South Asian	58.16%	Black	18.75%	Mixed	1.36%	Other	4.31%	Ethnicity not recorded	0.48%	Ethnicity not stated	0.30%
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	<p>boroughs.</p> <p>It is essential that the provider tailor the programme in such a way as to be culturally sensitive and appropriate for local communities e.g. offering male or female only groups, culturally sensitive diet replacement options, and considerations around how the programme can be effectively delivered to communities who may have limited understanding of written or spoken English.</p> <p>There will be interest in proposals that demonstrate how the needs of our local population can be effectively met, in such a way as to maximise engagement and retention in the programme. This may include the use of local community or faith venues.</p>
<p>3.4 Describe any population segments in your area with poorer health outcomes (i.e. those subject to the greatest inequalities) and outline how you would work with the provider to improve outcomes in these groups.</p>	<p>Wave 1 LCD was open to all NEL residents living with type 2 diabetes who met the eligibility criteria for the programme. It is essential that the provider be able to tailor the programme in such a way as to be culturally sensitive and appropriate for local communities. Proposals are welcomed from providers that clearly demonstrate how the programme may be adapted for the local population across the IMD quintiles, in such a way as to maximise engagement and retention in the programme.</p> <p>There are areas of significant deprivation across the footprint, as outlined below. During Wave 1 LCD we have had uptake of the programme across the IMD Quintiles, with the greatest uptake in the least deprived quintiles.</p> <ul style="list-style-type: none"> • Barking & Dagenham is the most deprived borough according to IMD 2019 rankings and has the highest percentage (52%) of diabetes patients residing in quintile 1 (most deprived). • City & Hackney (Hackney is the second most deprived borough according to IMD 2019 rankings) has the second highest percentage (50%) of diabetes patients residing in quintile 1 (most deprived). • Redbridge (173) and Havering (180) are in the less deprived half of local authority areas and have the highest percentages of patients in the least deprived quintiles. <p>Source: Discovery in-house data, Financial Year 22/23.</p>

<p>3.5 Type 2 diabetes prevalence</p>	<table border="1" data-bbox="607 414 1832 817"> <tr> <td></td> <td></td> </tr> <tr> <td>Barking & Dagenham</td> <td>15, 381</td> </tr> <tr> <td>Havering</td> <td>17, 002</td> </tr> <tr> <td>Redbridge</td> <td>21, 812</td> </tr> <tr> <td>City & Hackney</td> <td>15, 509</td> </tr> <tr> <td>Tower Hamlets</td> <td>20, 720</td> </tr> <tr> <td>Waltham Forest</td> <td>14, 587</td> </tr> <tr> <td>Newham</td> <td>31, 307</td> </tr> </table> <p data-bbox="607 916 1285 940">Source: NEL Diabetes Dashboard November 2022, based on CEG* data</p> <p data-bbox="607 971 1675 995">Primary Care, Wolfson Institute of Population Health, and Barts and The London School of Medicine and Dentistry.</p> <p data-bbox="607 1027 2007 1107">We support GP practices across North East London with data-driven tools and resources. We also analyse big datasets to reveal insights and inequalities in population health. We publish our findings in academic research papers and practical guidance and empower local health teams to act on the evidence.</p>			Barking & Dagenham	15, 381	Havering	17, 002	Redbridge	21, 812	City & Hackney	15, 509	Tower Hamlets	20, 720	Waltham Forest	14, 587	Newham	31, 307
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<p>3.6 Numbers identified as potentially eligible for the NHS LCD programme</p>	<table border="1" data-bbox="607 1227 2018 1331"> <tr> <td></td> <td></td> </tr> <tr> <td>Barking & Dagenham</td> <td>1,019</td> </tr> </table>			Barking & Dagenham	1,019												
Barking & Dagenham	1,019																

<p>Please detail your approach in estimating this – e.g. use of system-level searches and which criteria were used</p>	<table border="1"> <tr> <td>Havering</td> <td>848</td> </tr> <tr> <td>Redbridge</td> <td>1,433</td> </tr> <tr> <td>City & Hackney</td> <td>687</td> </tr> <tr> <td>Tower Hamlets</td> <td>1,702</td> </tr> <tr> <td>Waltham Forest</td> <td>670</td> </tr> <tr> <td>Newham</td> <td>2,925</td> </tr> <tr> <td>Total for all practices on CEG Dashboard* These figures are based on local data taken directly from general practice systems with the LCD criteria applied</td> <td>9,284</td> </tr> <tr> <td>Total 11 practices not on CEG Dashboard. This is an estimate based on average eligible population per practice.</td> <td>396</td> </tr> <tr> <td>Final Total</td> <td>9680</td> </tr> </table>	Havering	848	Redbridge	1,433	City & Hackney	687	Tower Hamlets	1,702	Waltham Forest	670	Newham	2,925	Total for all practices on CEG Dashboard* These figures are based on local data taken directly from general practice systems with the LCD criteria applied	9,284	Total 11 practices not on CEG Dashboard. This is an estimate based on average eligible population per practice.	396	Final Total	9680
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<p>Source: NEL Diabetes Dashboard November 2022, based on CEG data</p>																			
<p>3.7 Existing local provision of locally commissioned Total Diet Replacement (TDR), other Low Calorie Diet (LCD) / type 2 diabetes remission programmes</p>	<p>Currently, there are no locally commissioned TDR, other Low-Calorie diet or type 2 diabetes remission programmes.</p> <p>The national programme has been delivered in NEL since 2020, there will be a transition from this pilot programme delivery to framework delivery in 2023.</p>																		

4.0. Intervention allocation and monthly profiling

4.1 Intervention allocation to the ICB / ICS for the 2 year contract.

Allocation means the number of places used on the NHS LCD (people who commenced TDR / programme starts).

4.2 Monthly referral profiling based on an uptake rate of 65%.

Planned referral trajectory:

Referrals Year 1												
June 2023	July	Aug	Sept	Oct	Nov	Dec	Jan 2024	Feb	March	April	May	Total
18	23	23	31	38	31	23	31	43	43	40	40	385

Referrals Year 2												
June 2024	July	Aug	Sept	Oct	Nov	Dec	Jan 2025	Feb	March	April	May	Total
38	34	34	31	38	31	25	31	31	31	31	31	385

<p>4.3 How will the ICS/ ICB plan to manage referral flow to align with profile while taking into account provider capacity and delivery considerations – i.e. what actions you will take to adjust referral activity, as may be indicated, during the contract?</p> <p>If you need to increase referral activity, how would this be accomplished?</p> <p>Describe any incentive schemes you may have planned.</p>	<ul style="list-style-type: none"> • Referrals will be carefully monitored to provider capacity and the Working Group and LCD Project Lead will closely work with the provider and PCNs to identify issues that could be causing low or poor referrals • Referral profiles will be reflective of seasonality and population reflective of learning from other programmes, for example, lower referrals are typically seen during summer and during Ramadan. • We will draw on learning from Wave 1 NHS LCD Pilot to tailor the invitation, communication to GPs and other healthcare professionals and patients to optimise uptake and salience. <p>High Level Transition plan including:</p> <ul style="list-style-type: none"> • Agree approach to managing referrals down towards contract end with current NHS LCD provider • Agree approach to ensuring there is little or no waiting list to be transferred over to the new contract • Intentions for a joint working forum with current and incoming provider • Timely communication and engagement activities with Primary Care regarding contract end, transition period management and any relevant updates regarding new NHS LCD proforma and the referral pathways. <p>Managing referrals and waiting lists down</p> <ul style="list-style-type: none"> • A communication plan will be put together to ensure that identified practices are reached and informed of new approach. • Waiting lists will continue to be monitored alongside referrals. Mitigation plans will be put into place • Referral numbers will be carefully monitored to provider capacity and the Working Group and LCD Project Lead will closely work with the provider to identify issues that could be causing referral blockage or waiting lists • The partnership is working with the present provider regarding capacity and adapting as required • A communications plan with patients, will be co-produced with the provider as required; adhering to data protection regulations (e.g. informing re-new provider, new website, etc.) • Meetings will be set up between the current provider and the new provider for handover
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5.0. Planned mobilisation and transition

5.1 Outline the details of how the ICB / ICS will work with existing and/ or new NHS LCD providers to ensure successful mobilisation/ seamless transition of services.

Please outline how you will support the provider to identify secure resources and venues.

Primary care communications and engagement

We will draw on learning from Wave 1 NHS LCD Pilot to tailor the invitation, communication to GPs and other healthcare professionals and patients to optimise uptake and salience.

The programme places would be available to all NEL PCNs. We would introduce the LCD programme (eligibility criteria, the anticipated referral process and proforma) at various healthcare professional forums; e.g. Practice Nurse, GP, Practice Manager, Clinical Directors for PCNs. We would offer training to all Practices, develop crib sheets for staff to help deliver a consistent message regarding the LCD intervention. PCNs would receive a regular referral and uptake summary to help sustain the referral rate and to identify any discrepancies that may indicate a training need for a particular PCN.

We will undertake focussed communications and training with PCNs. PCN mobilisation and implementation learning will be shared via NEL LCD Working Group.

A communication plan will be implemented ensuring that Primary Care is informed of changes, through messages, newsletters, bulletins, appropriated forums, etc. The plan will also ensure provider website details and printed materials are widely available and promoted within primary care. The Working Group will monitor and review the plan, as needed.

	<p>Resources and venues Place based leads have developed a venue list for NHS DPP which can be shared with the provider, as required.</p>
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<p>6.0 Delivery plans</p>	
<p>6.1 Communications, engagement and training</p>	<ul style="list-style-type: none"> • Existing communication material includes a monthly LCD newsletter to PCNs, weekly reporting at practice level. • We would introduce the LCD programme (eligibility criteria, the anticipated referral process and proforma) at various healthcare professional forums; e.g. Practice Nurse, GP, Practice Manager, Clinical Directors for PCNs. • All relevant information will be included on the LCD webpage on the NEL ICB GP Portal and regular bulletins will be circulated to PCNs. • All relevant information will be disseminated via the LCD Working Group and NEL Diabetes Clinical Network, place based meetings and PCN meetings. • Support would be sought from the NEL Communications and Engagement team to support primary care and public engagement, as deemed appropriate.
<p>6.2 Primary care data systems used across the ICB / ICS</p>	

6.0 Delivery plans

CCG	Data systems (e.g. SystemOne, EMIS)	How well integrated is this with other systems?
BHR	EMIS web, Vision, System 1 and Microtest.	Full integration between GP practices and CEG Integrated with Microsoft word; Can take referrals automatically
City & Hackney	EMIS	Full integration between GP practices and CEG Integrated with Microsoft word; Can take referrals automatically
Newham	All GP practices use EMIS web	Full integration between GP practices and CEG. Integrated with Microsoft word; Can take referrals automatically
Tower Hamlets	EMIS Web	Full integration between GP practices and CEG Integrated with Microsoft word; Can take referrals automatically
Waltham Forest	EMIS web, SystemOne	Integrated with Microsoft word; Can take referrals automatically

7.0 Additional Information

7.1 Other specific factors which a provider would need to consider in order to develop a service in this area (if not covered elsewhere in the prospectus)

There will be interest in proposals that demonstrate the following:

- Patient facing delivery which is flexible, appealing, salient, accessible, close to the location of the patients and timed to fit around work and non-negotiable life events.
- Patient facing delivery which is inclusive of and tailored for those living with learning disability and/or severe mental illness (SMI). For example, offering easy read communication and programme adaptations suited to this population.
- Patient facing model which offers a menu of options, including cultural adaptations around diet, which is reflective of the diversity within our patient population.
- Delivery approach which considers the pressured context within primary care and takes into consideration how wider primary care roles or provider roles (e.g. engagement officers) can support identifying, coaching eligible patients before the referral is made.

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Appendix 3

Provider IPR

- Details of our delivery model
- Staff names
- Pricing

SCHEDULE 2 – THE SERVICES

Ai. Service Specifications – Enhanced Health in Care Homes

Not Applicable

SCHEDULE 2 – THE SERVICES

Aii. Service Specifications – Primary and Community Mental Health Services

Not Applicable

SCHEDULE 2 – THE SERVICES

B. Indicative Activity Plan

Not Applicable

SCHEDULE 2 – THE SERVICES

C. Activity Planning Assumptions

Not Applicable

SCHEDULE 2 – THE SERVICES

D. Essential Services (NHS Trusts only)

Not Applicable

SCHEDULE 2 – THE SERVICES

E. Essential Services Continuity Plan (NHS Trusts only)

Not Applicable

SCHEDULE 2 – THE SERVICES

F. Clinical Networks

Not Applicable

SCHEDULE 2 – THE SERVICES

G. Other Local Agreements, Policies and Procedures

Not applicable

SCHEDULE 2 – THE SERVICES

H. Transition Arrangements

Transition Arrangements are set out in the Transition section of the Service Specification at section 3.11

SCHEDULE 2 – THE SERVICES

I. Exit Arrangements

Exit arrangements are set out in the Transition section of the Service Specification at section 3.11

SCHEDULE 2 – THE SERVICES

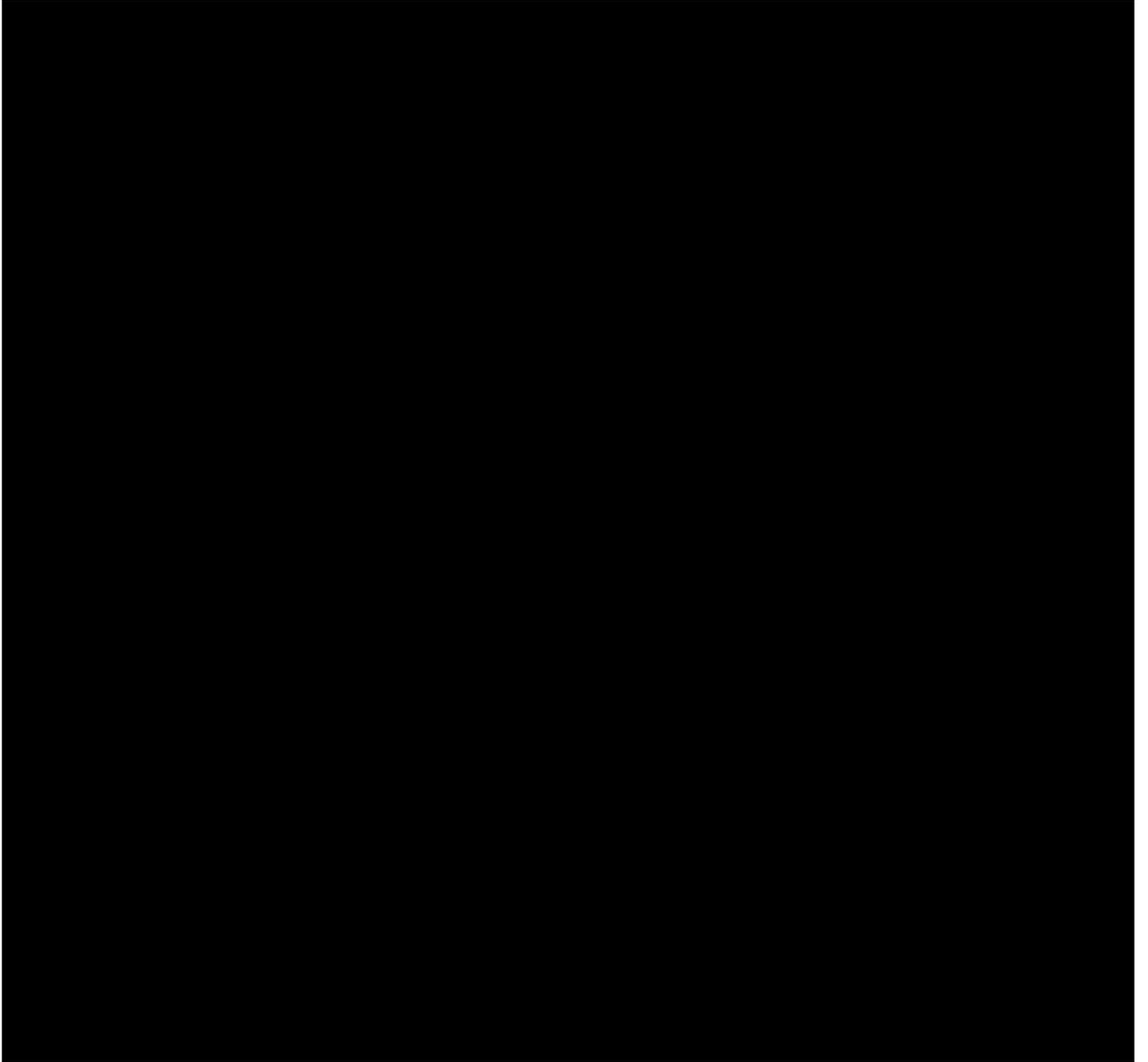
J. Transfer of and Discharge from Care Protocols

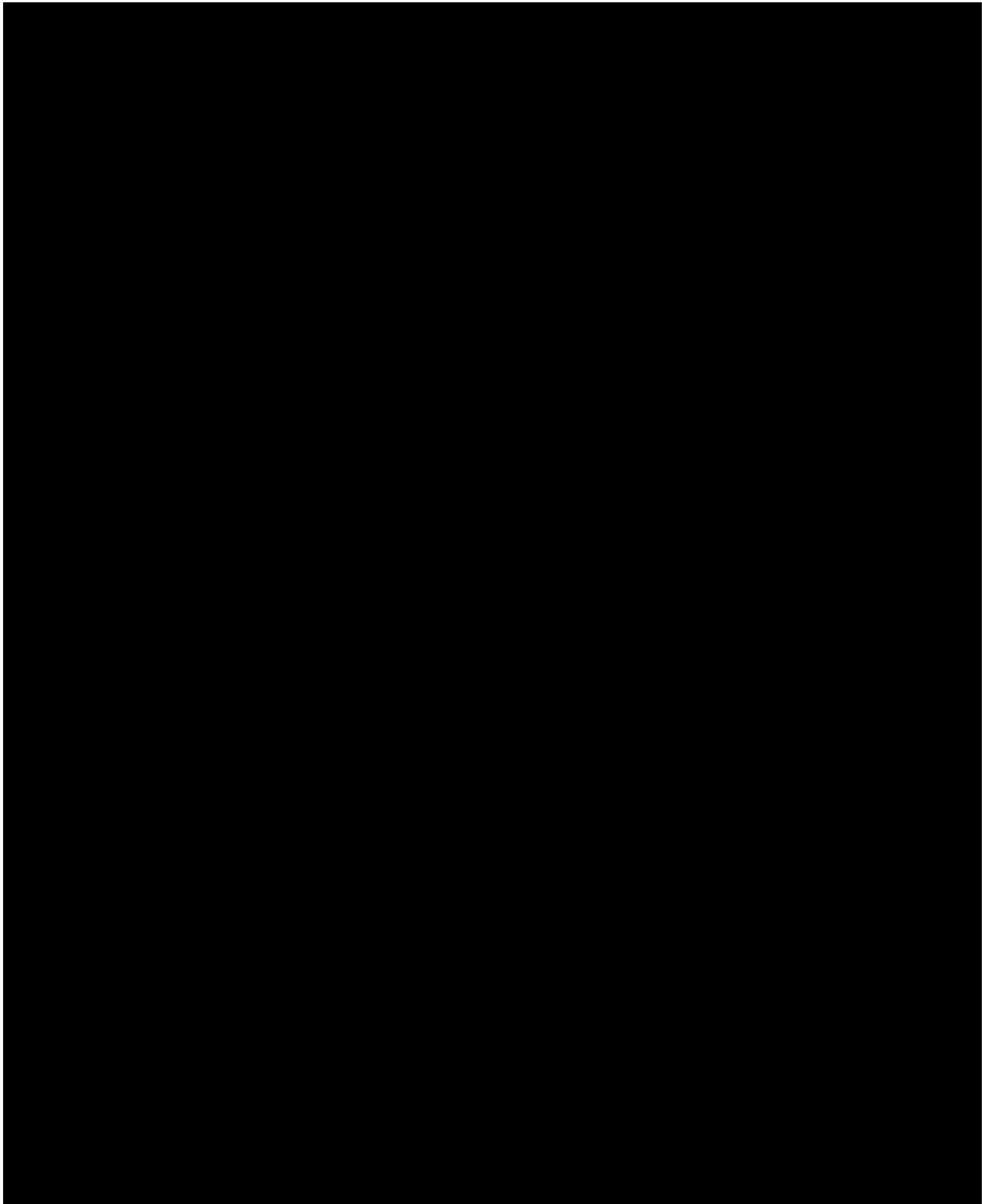
Not Applicable

SCHEDULE 2 – THE SERVICES

K. Safeguarding Policies and Mental Capacity Act Policies

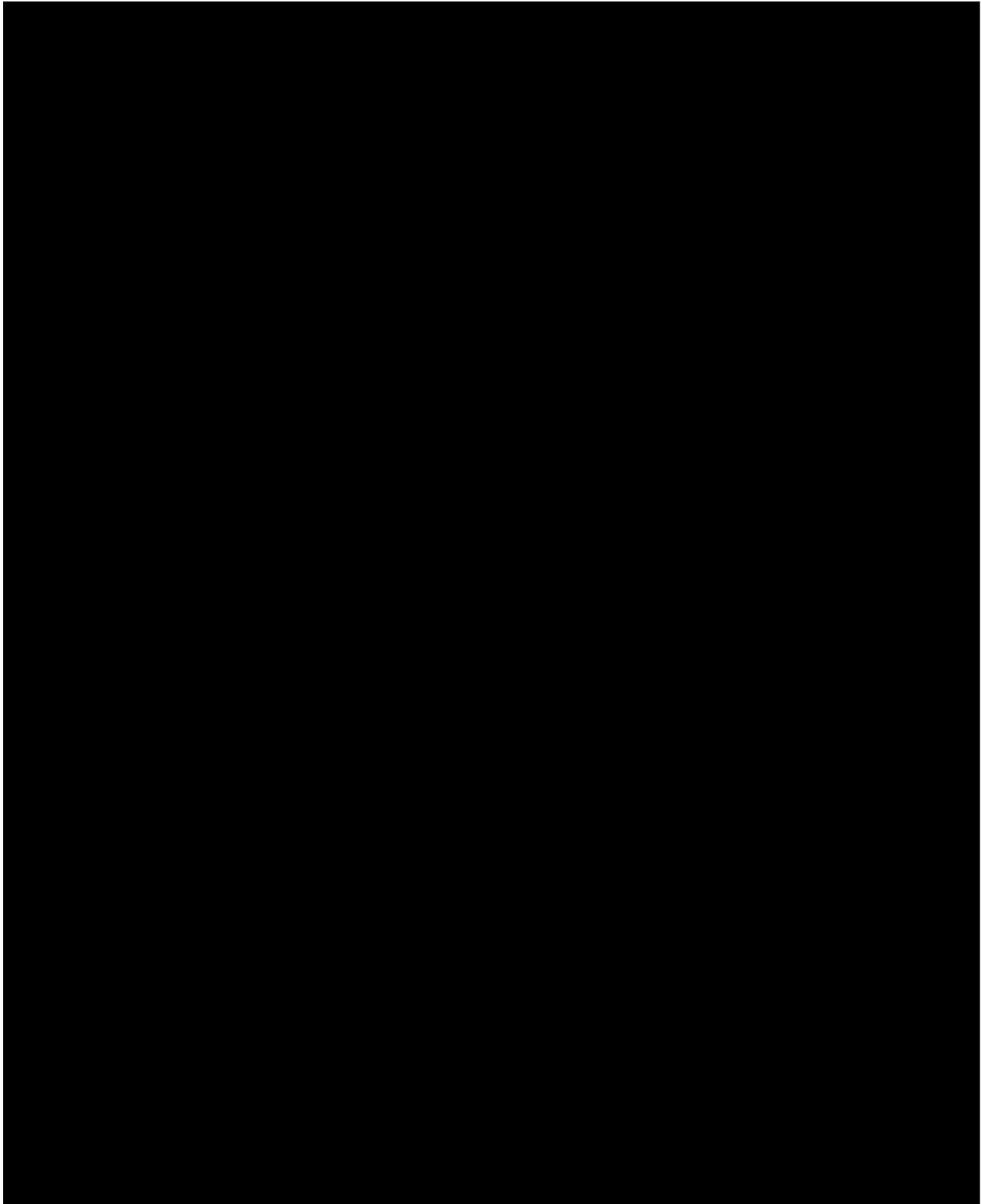
- Mental Capacity Act Policy
- Safeguarding Policy

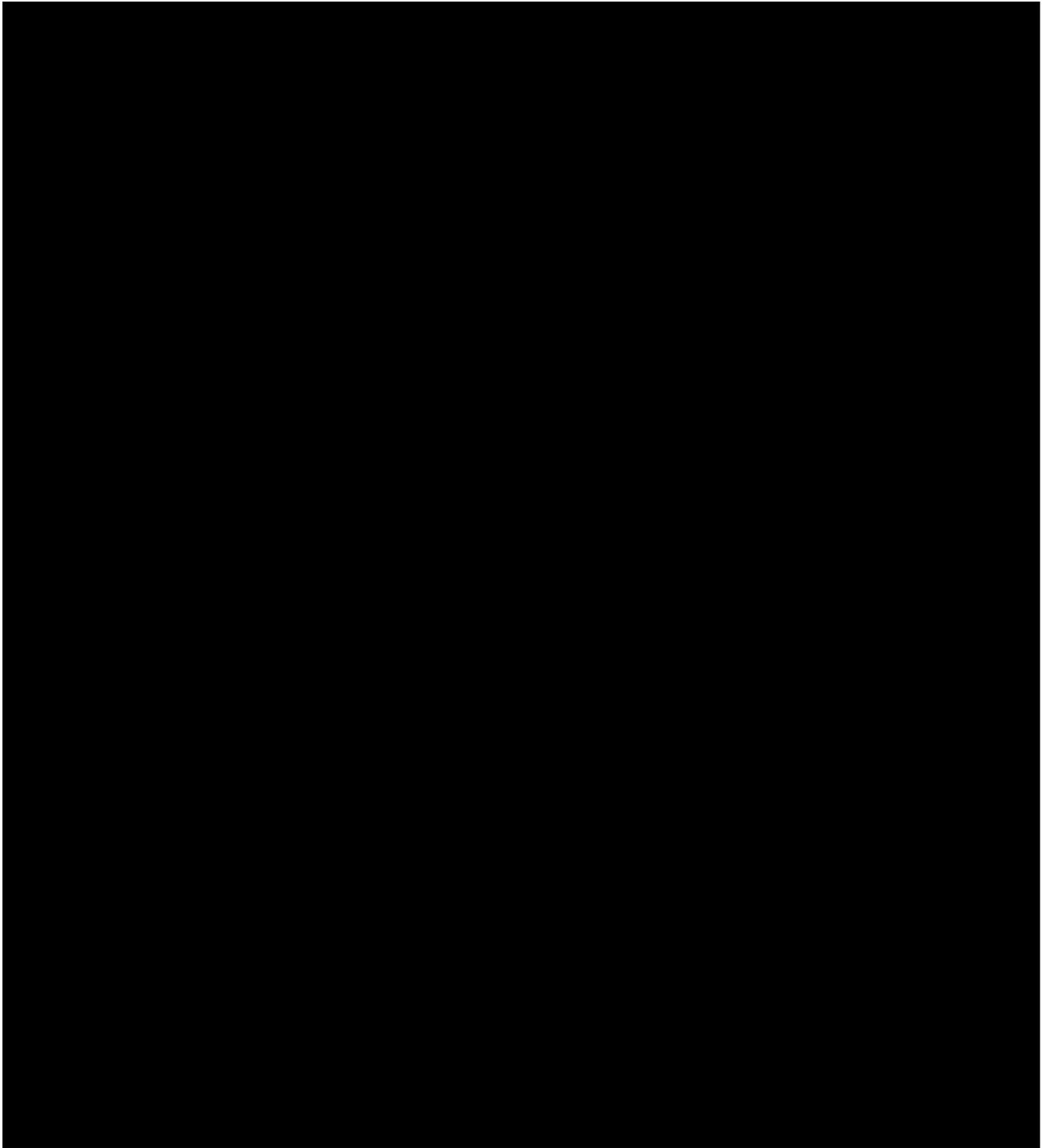


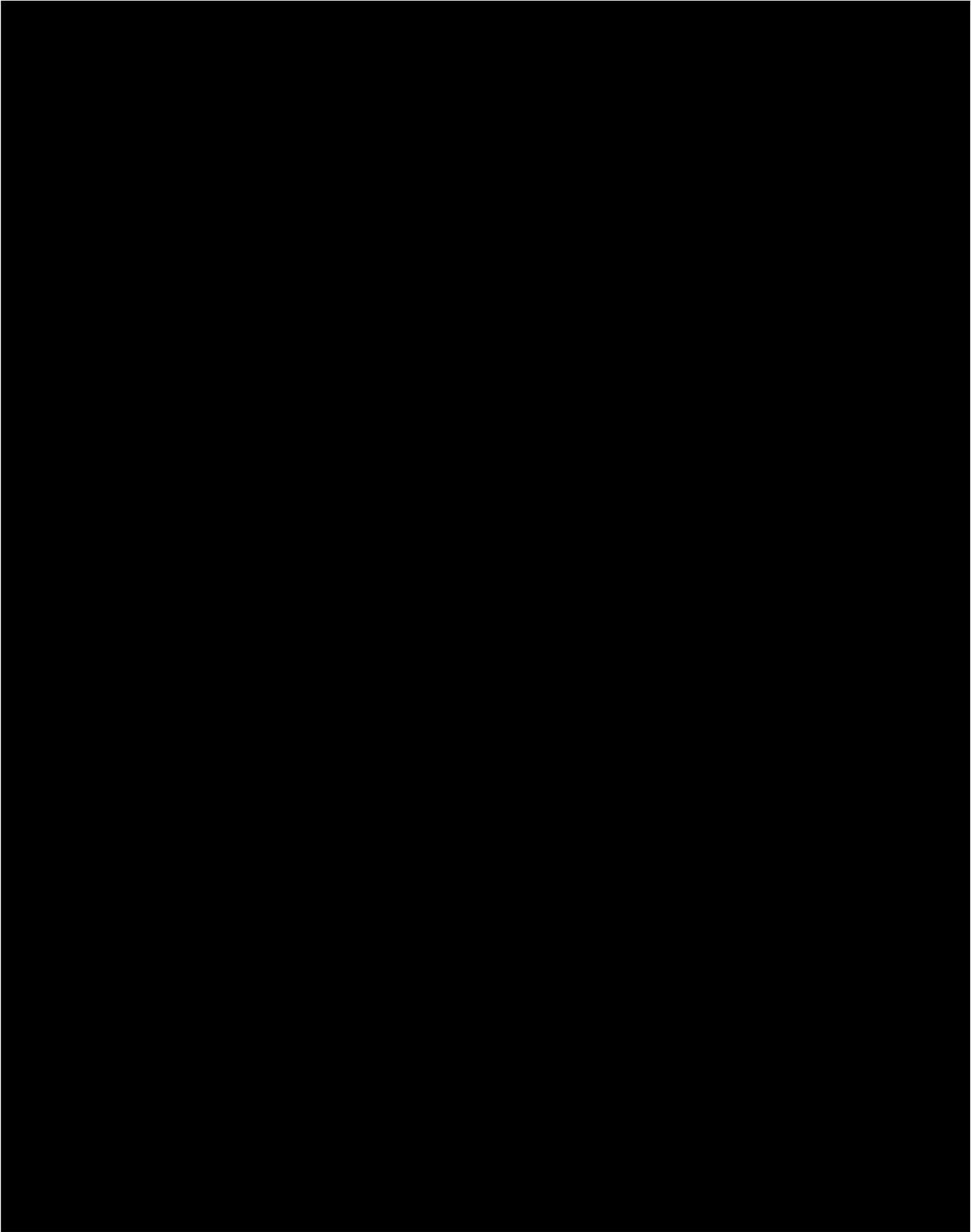


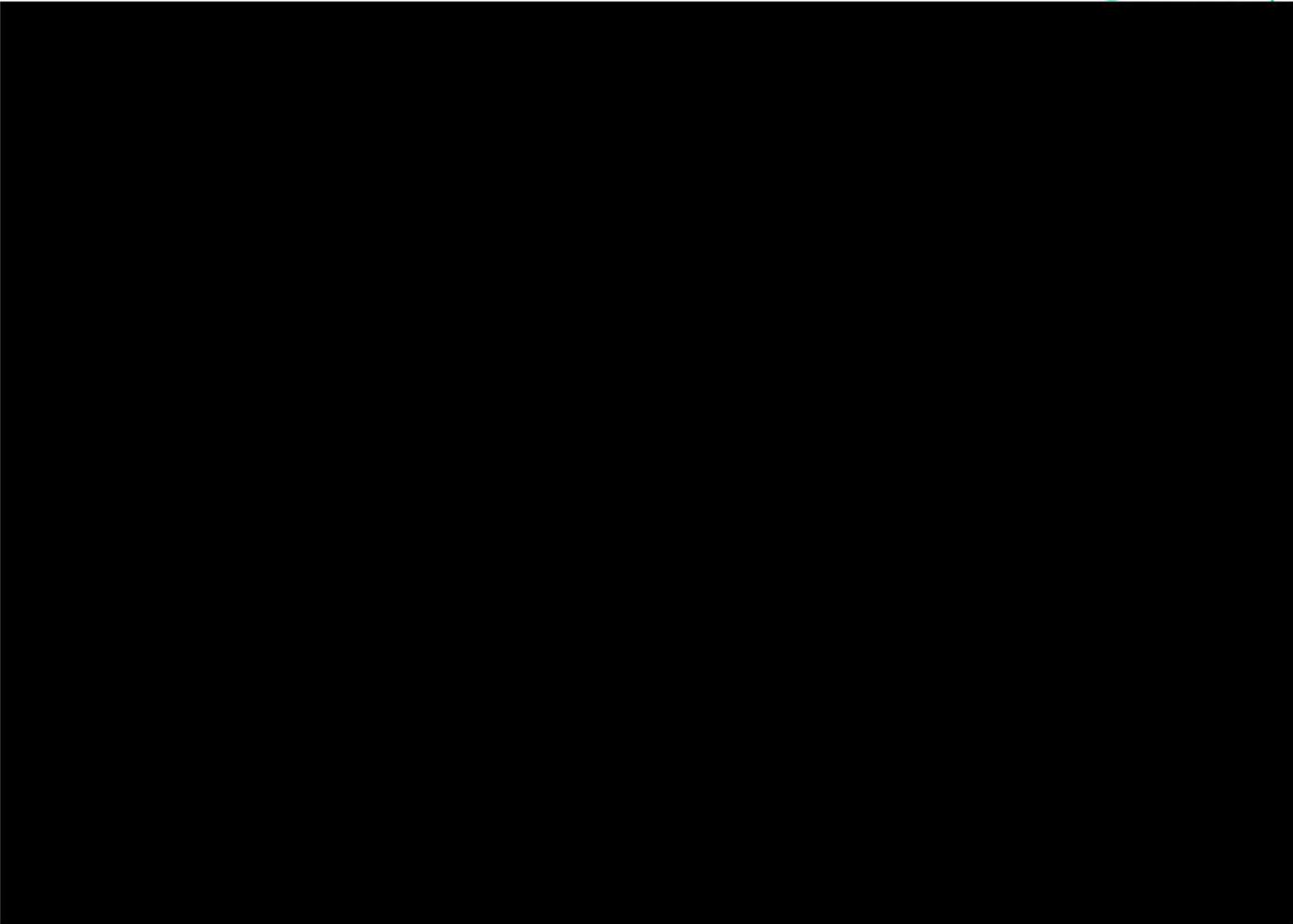


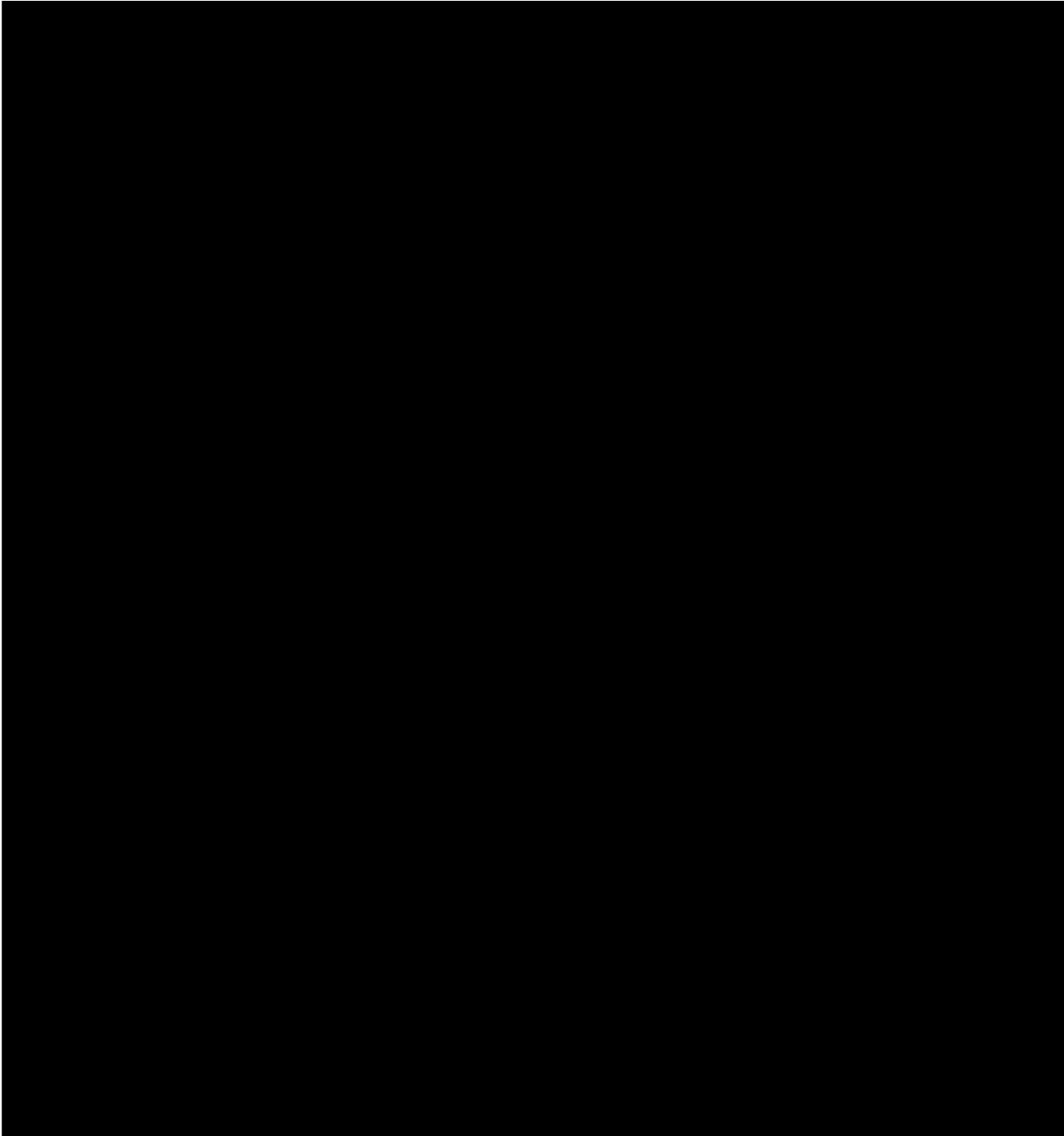
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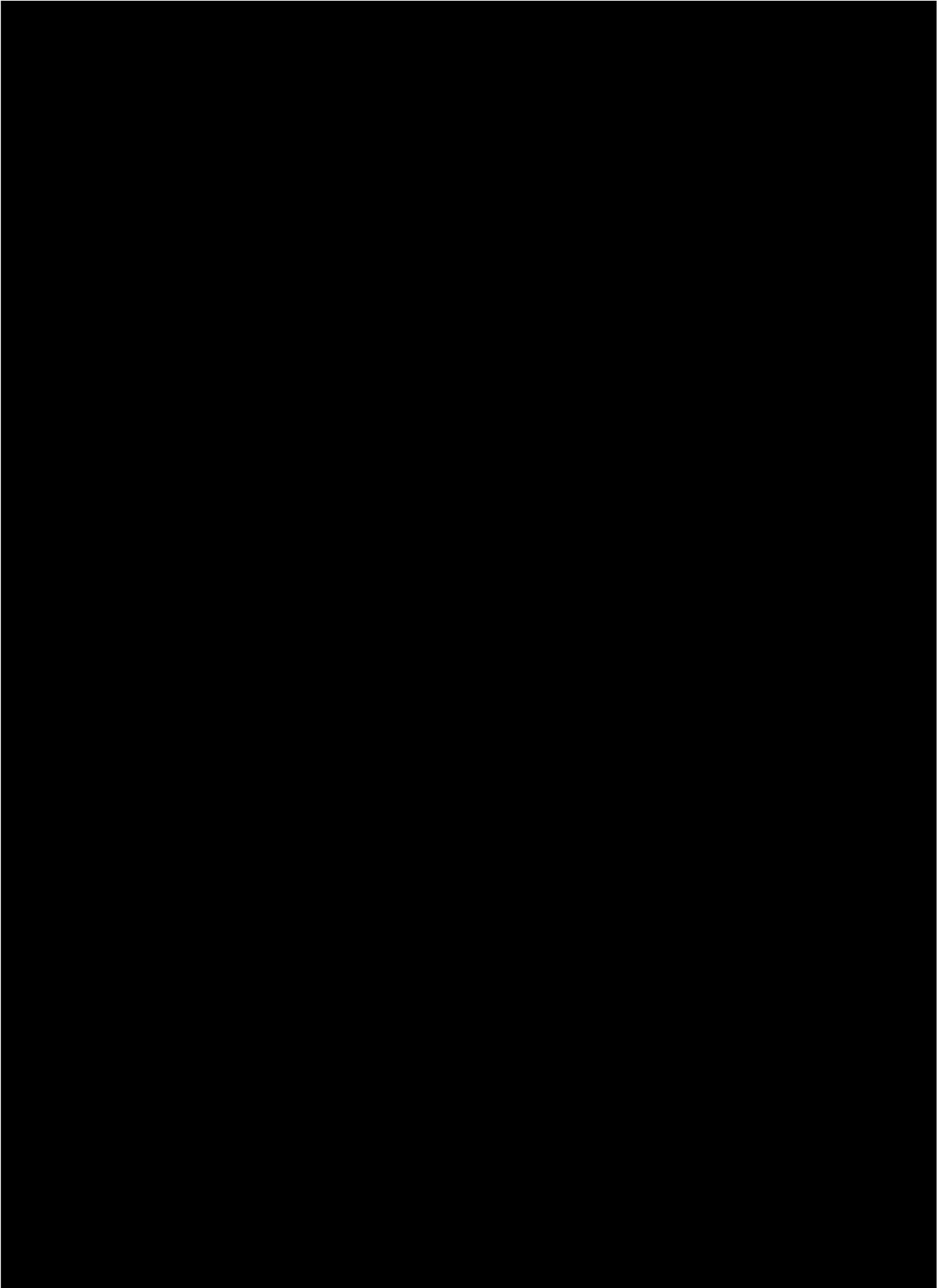


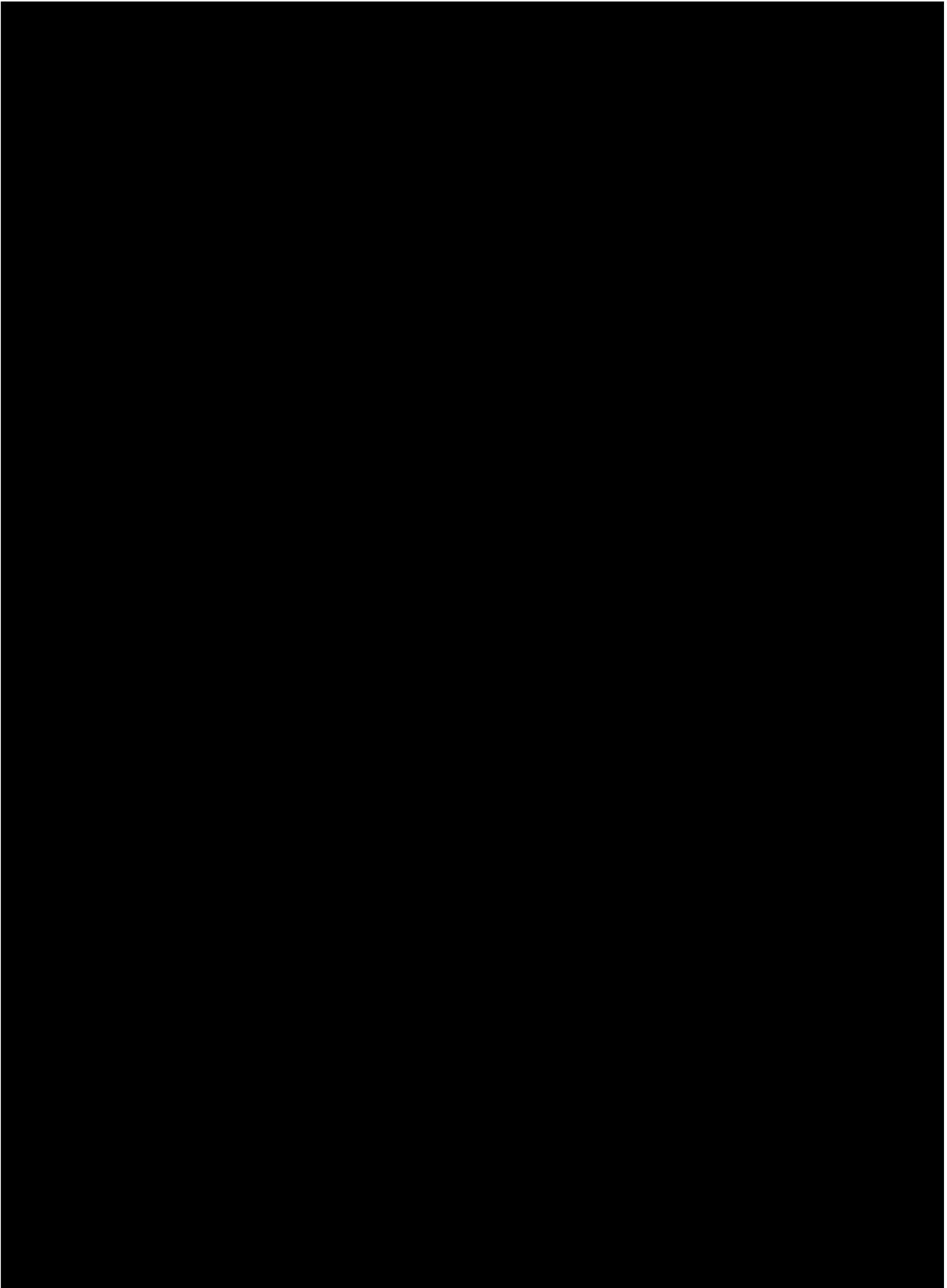


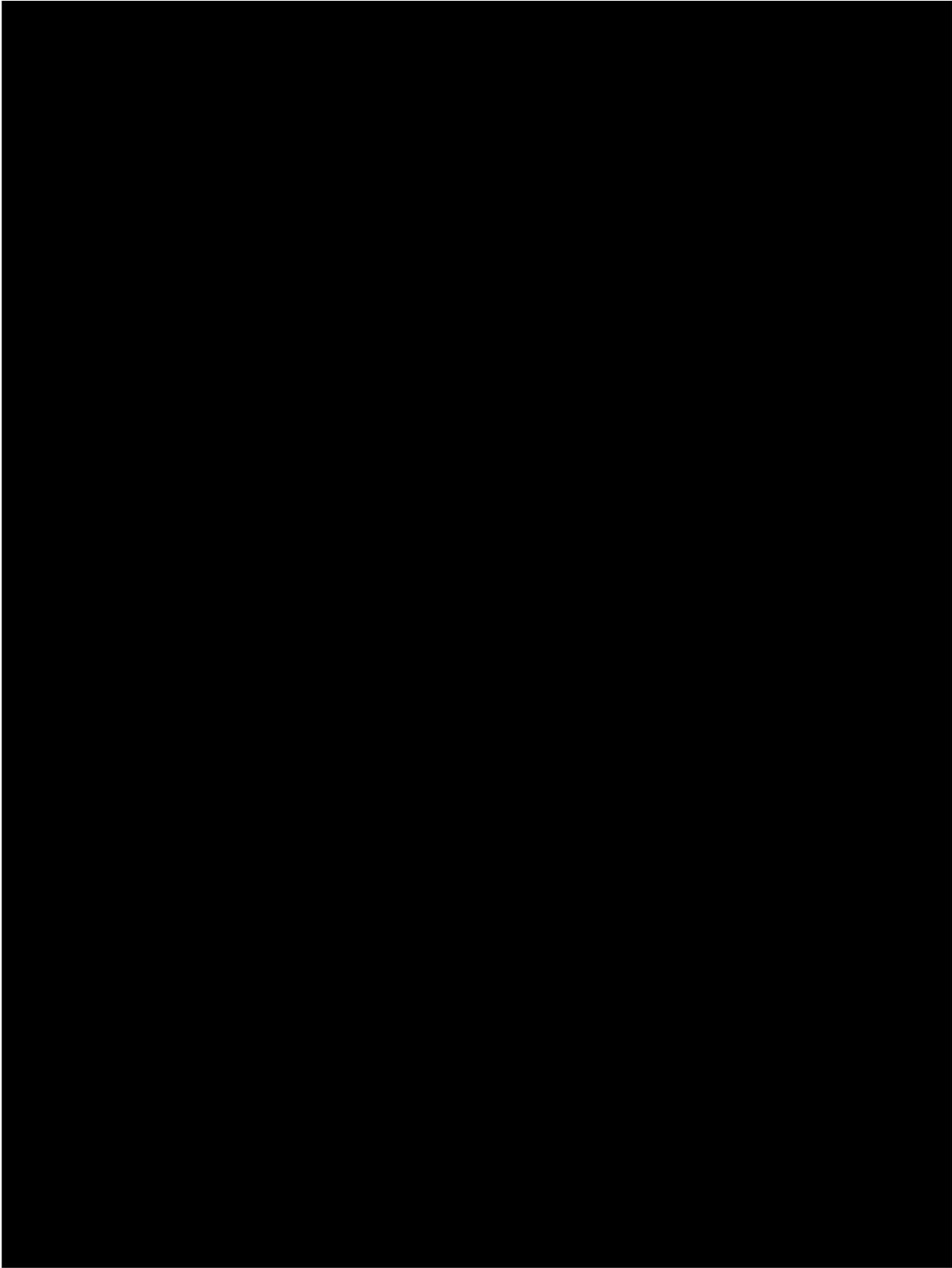


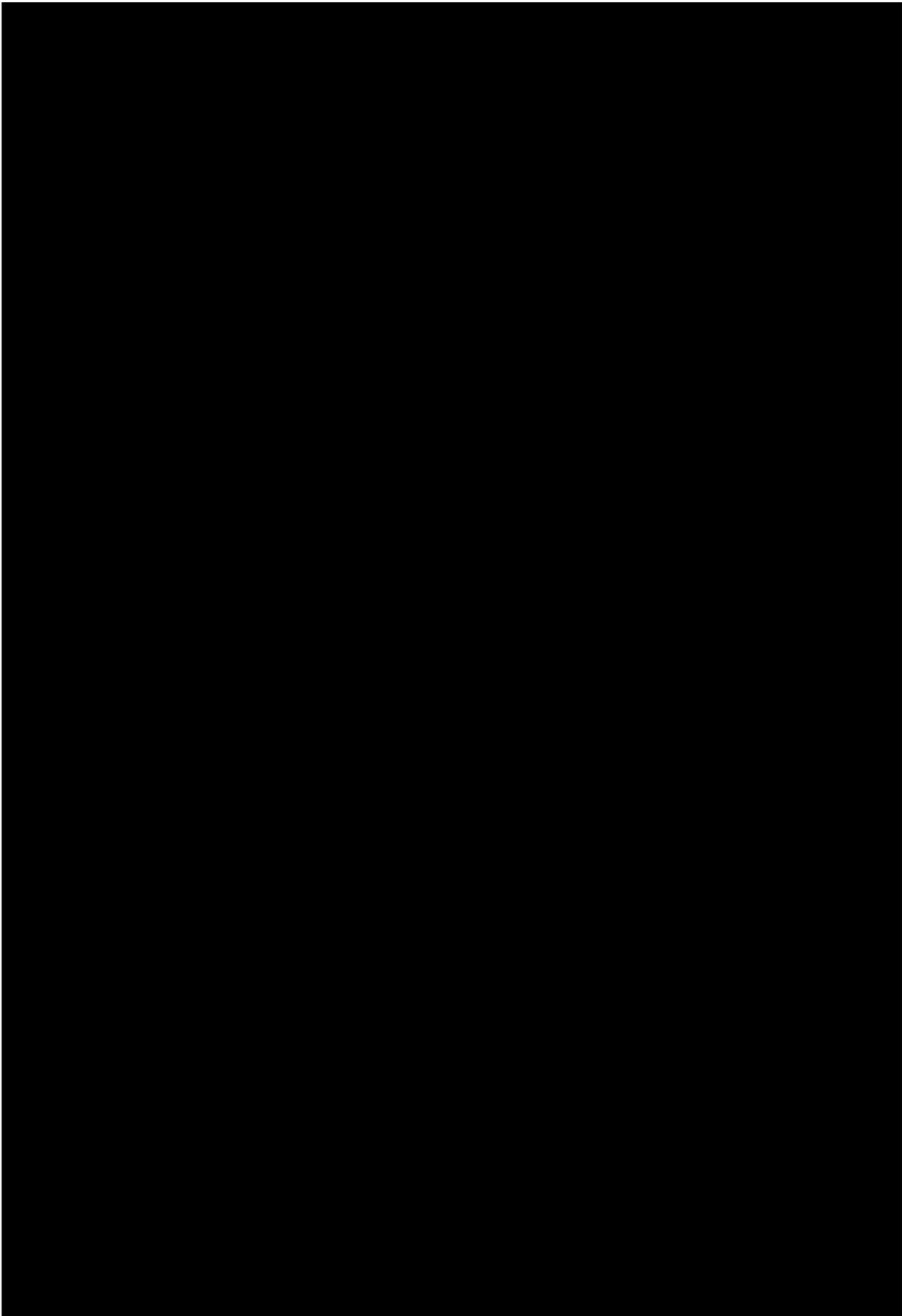


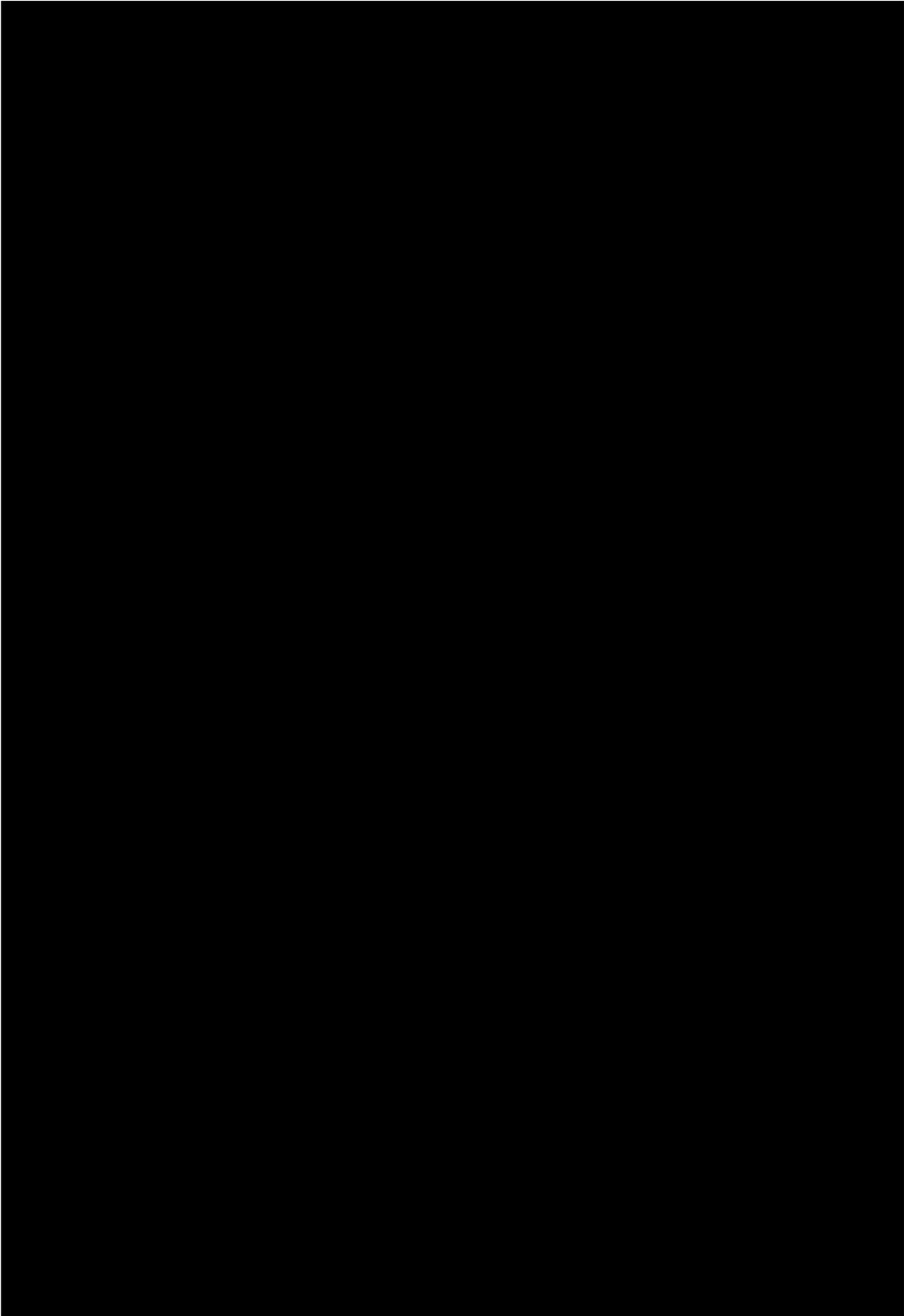


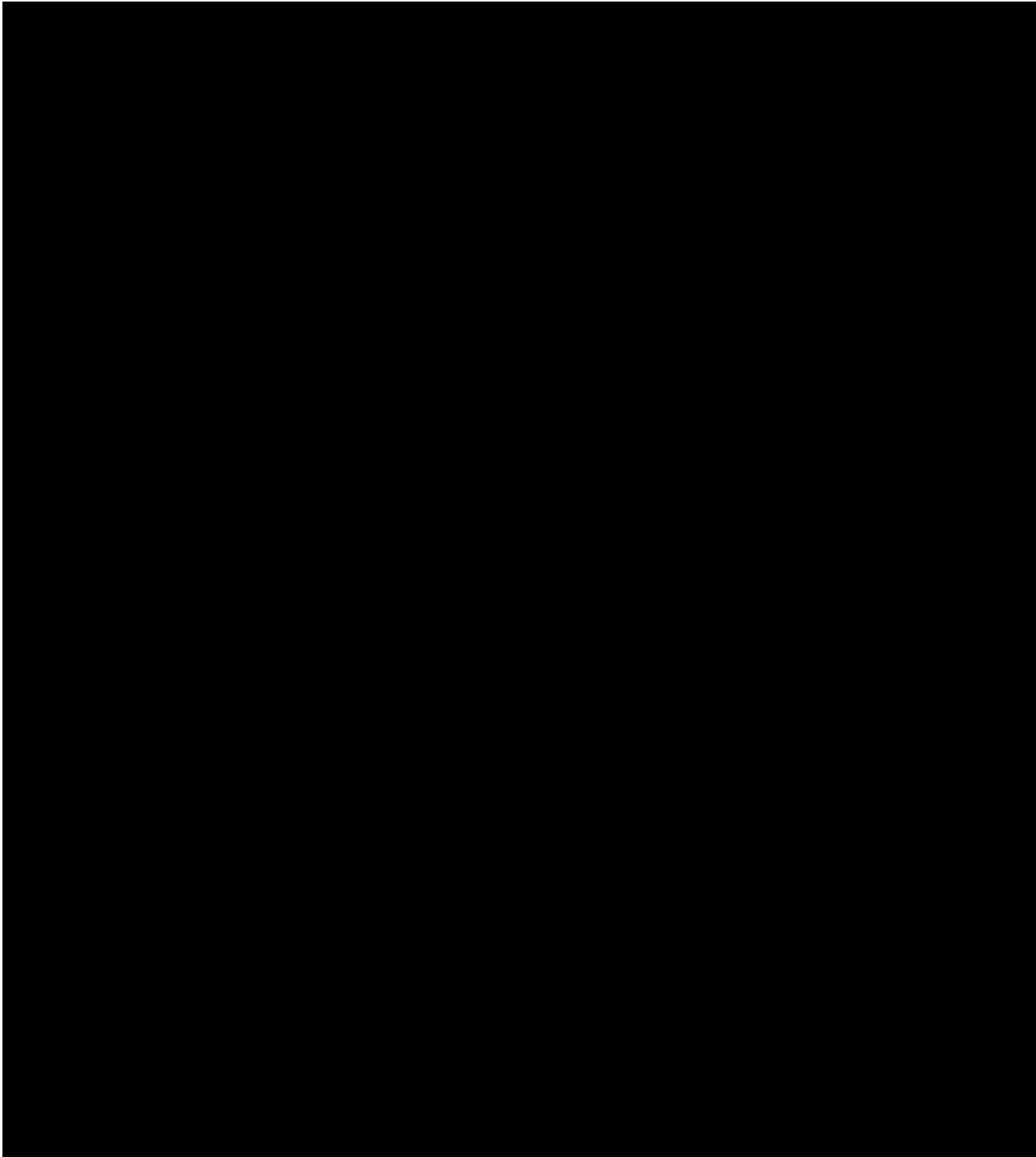


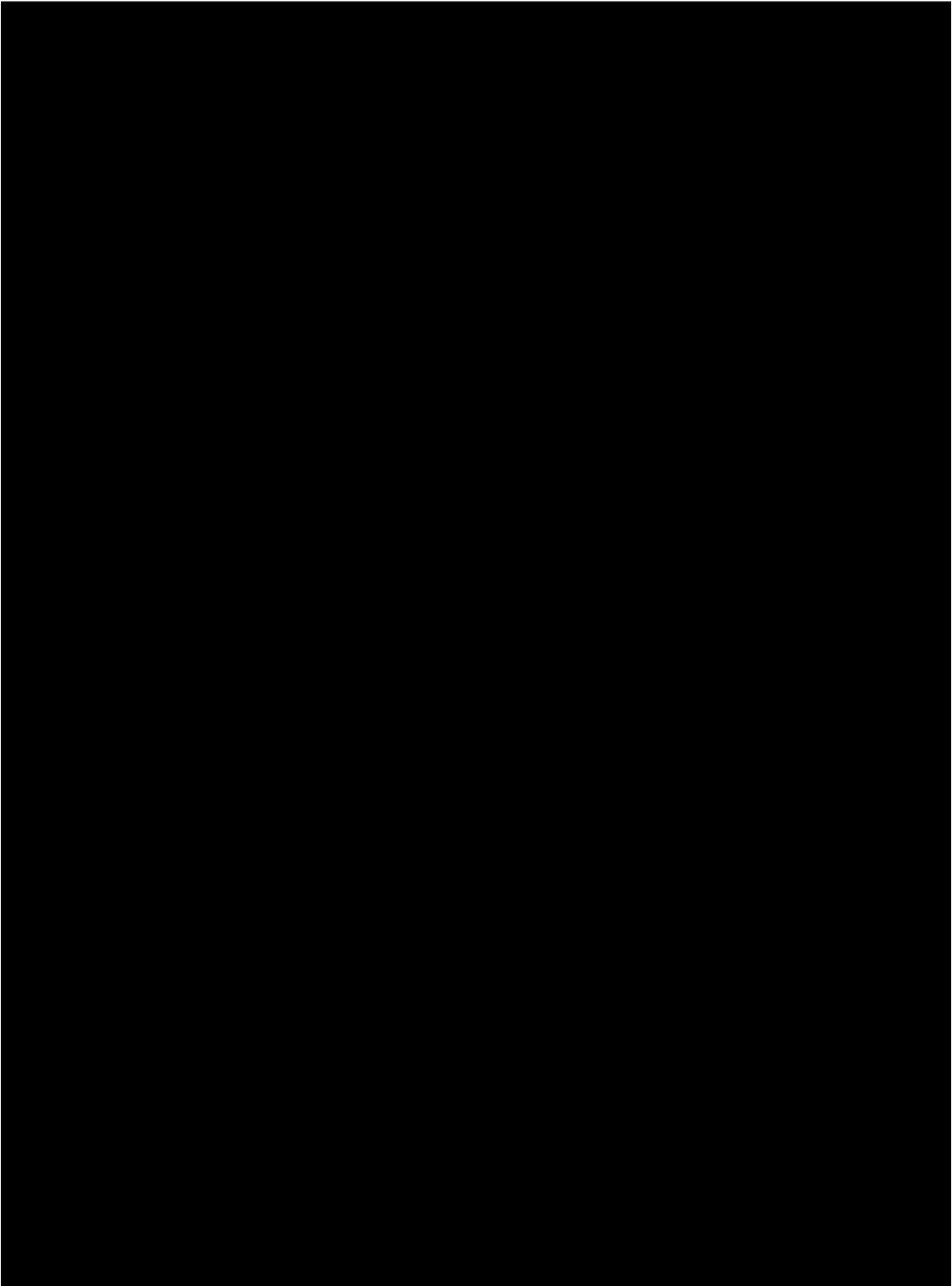


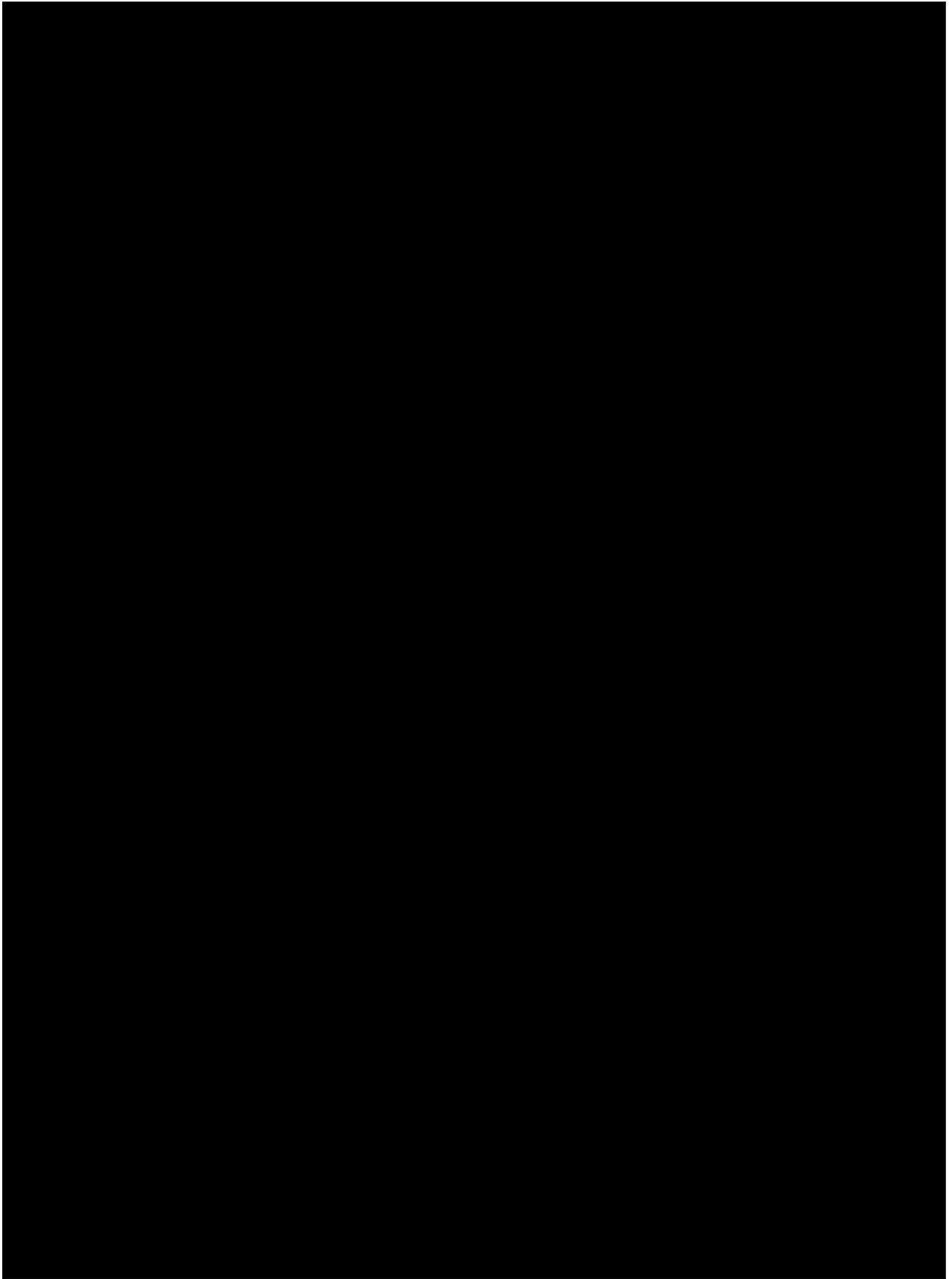


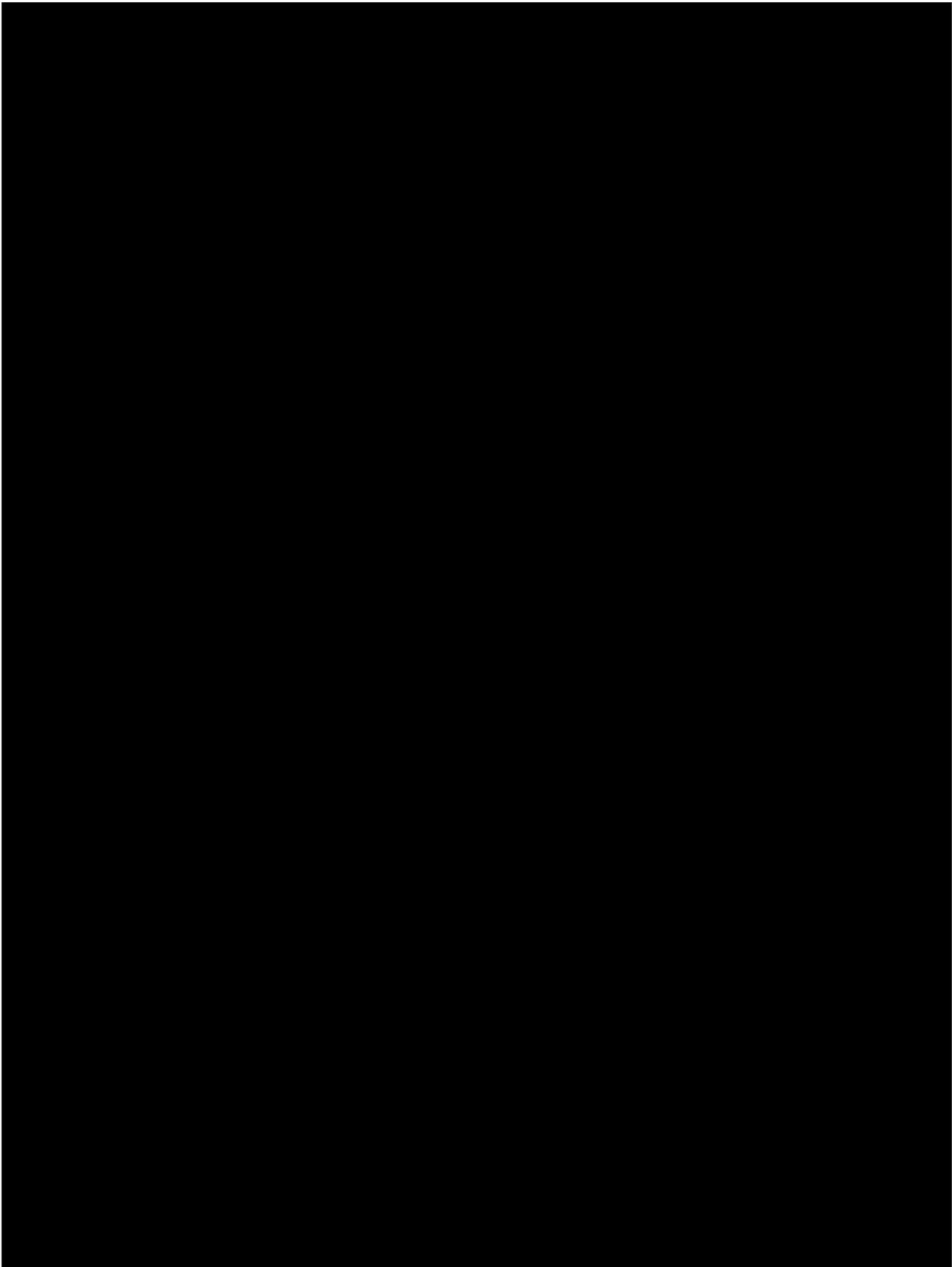


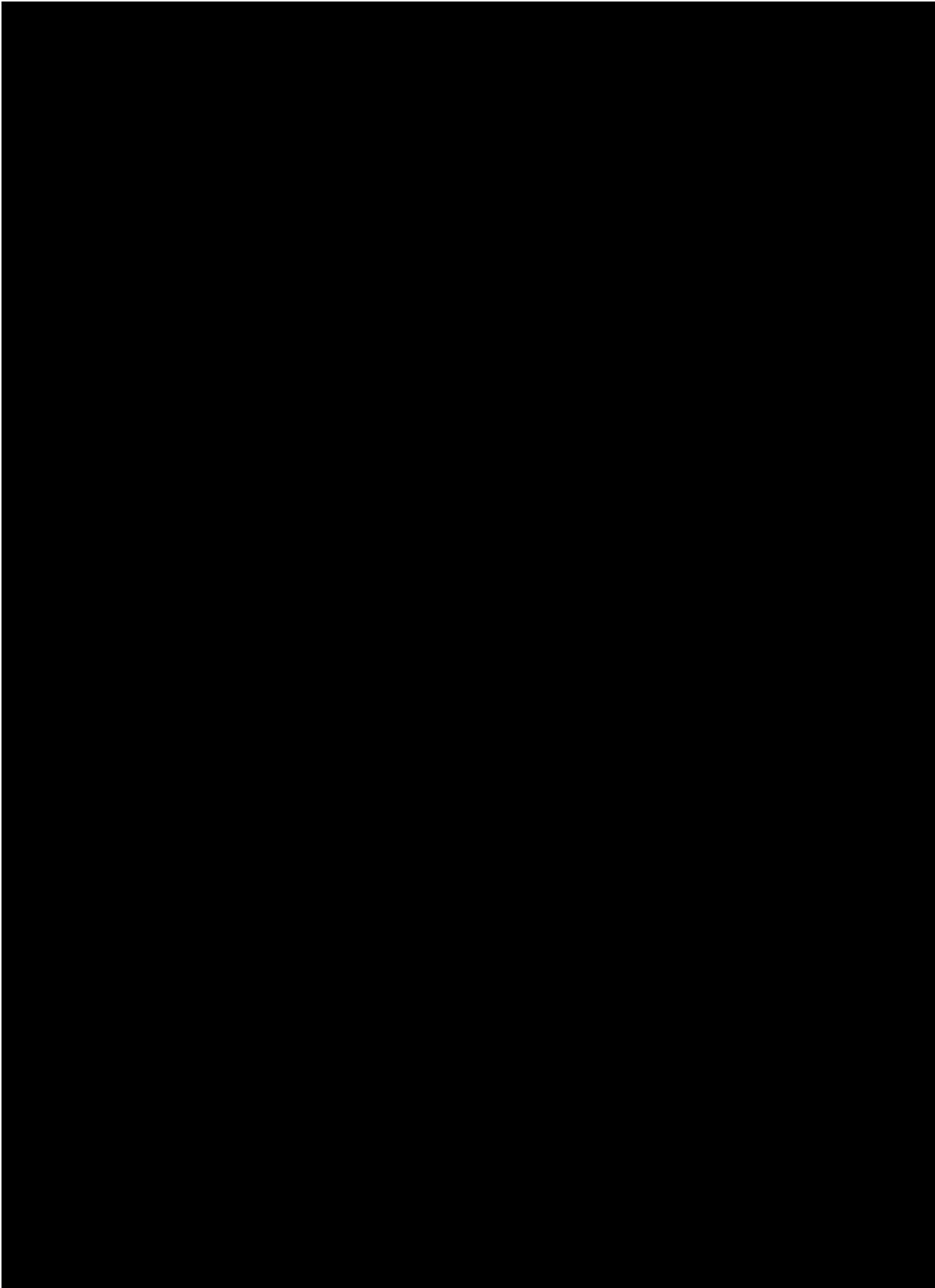


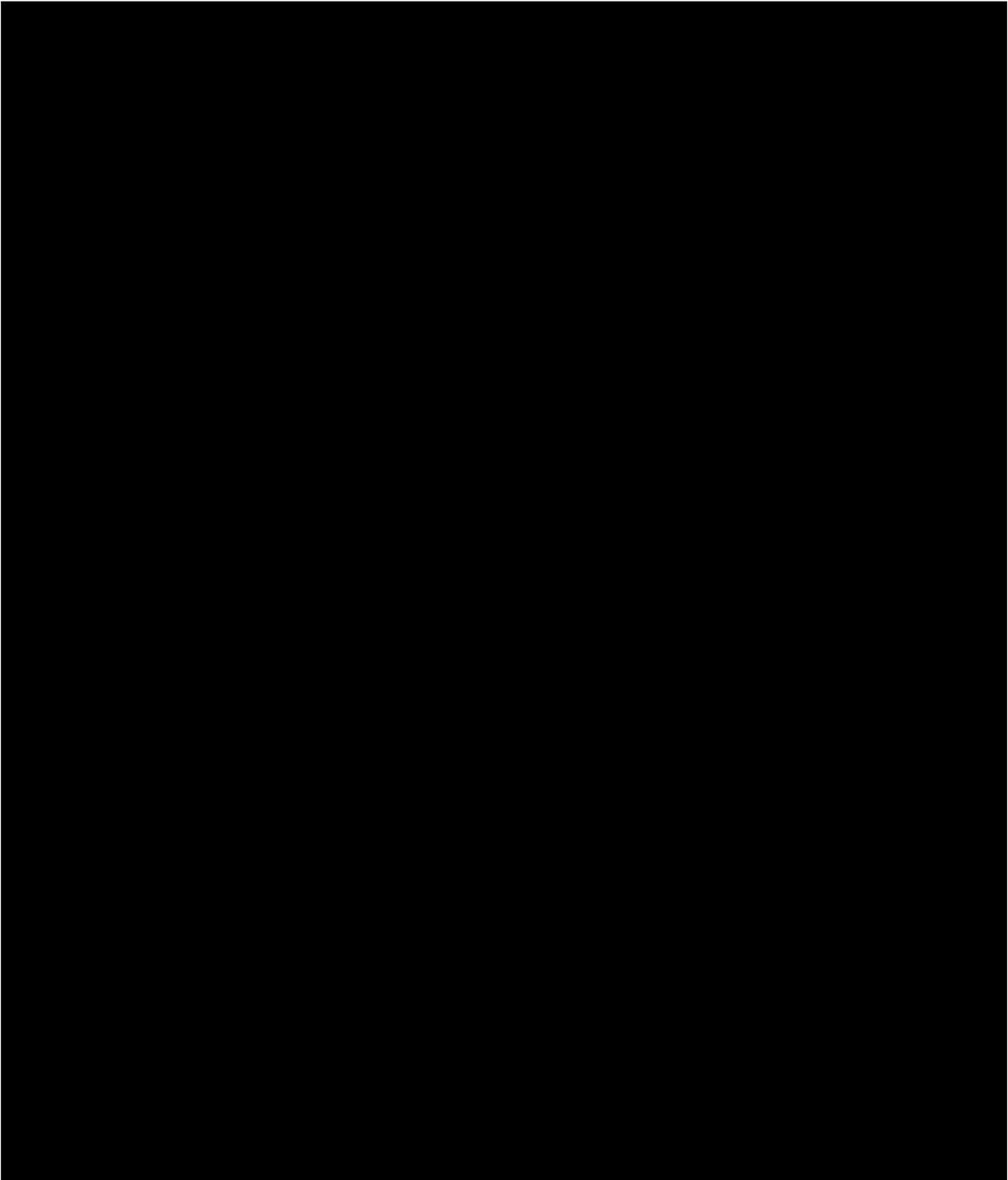


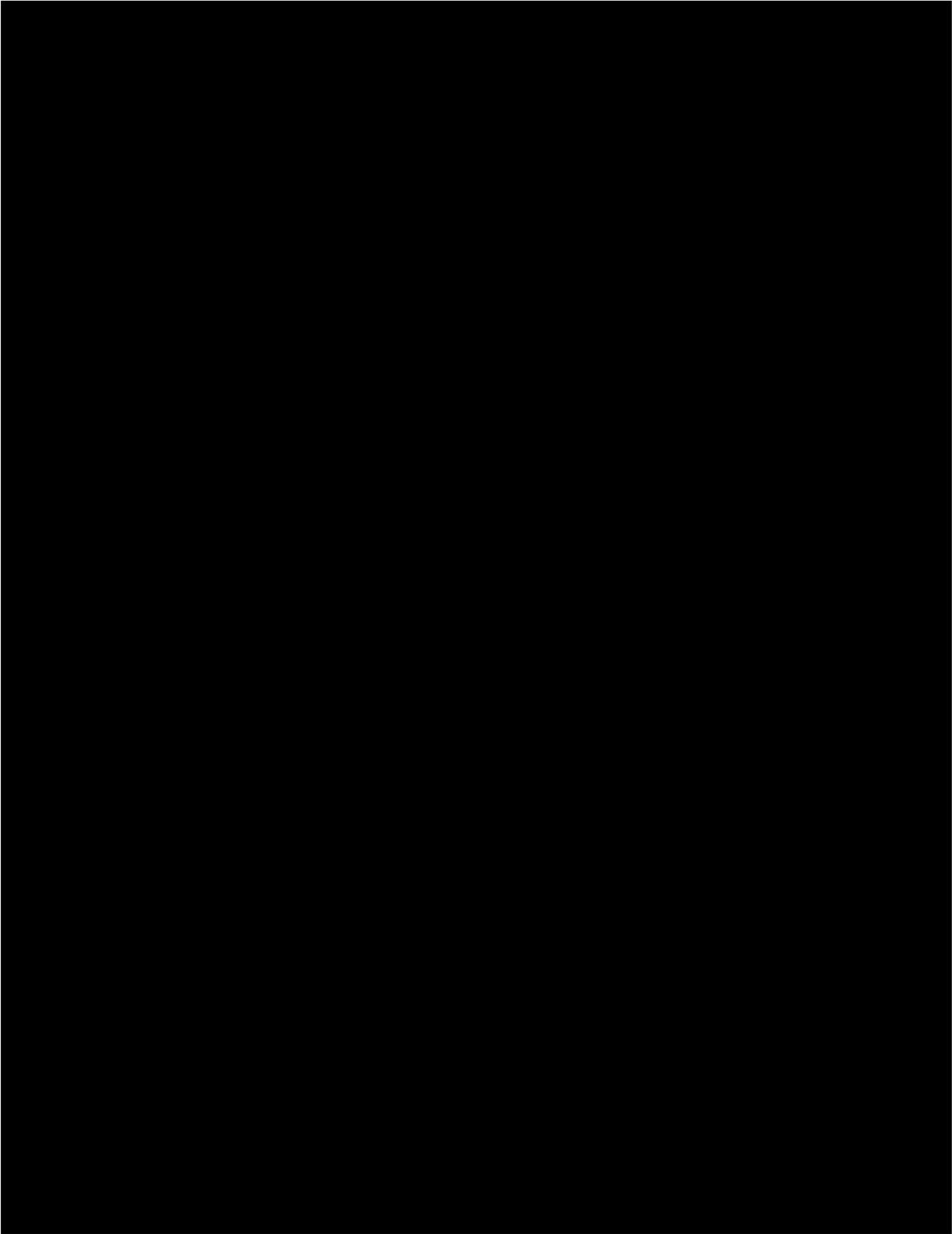


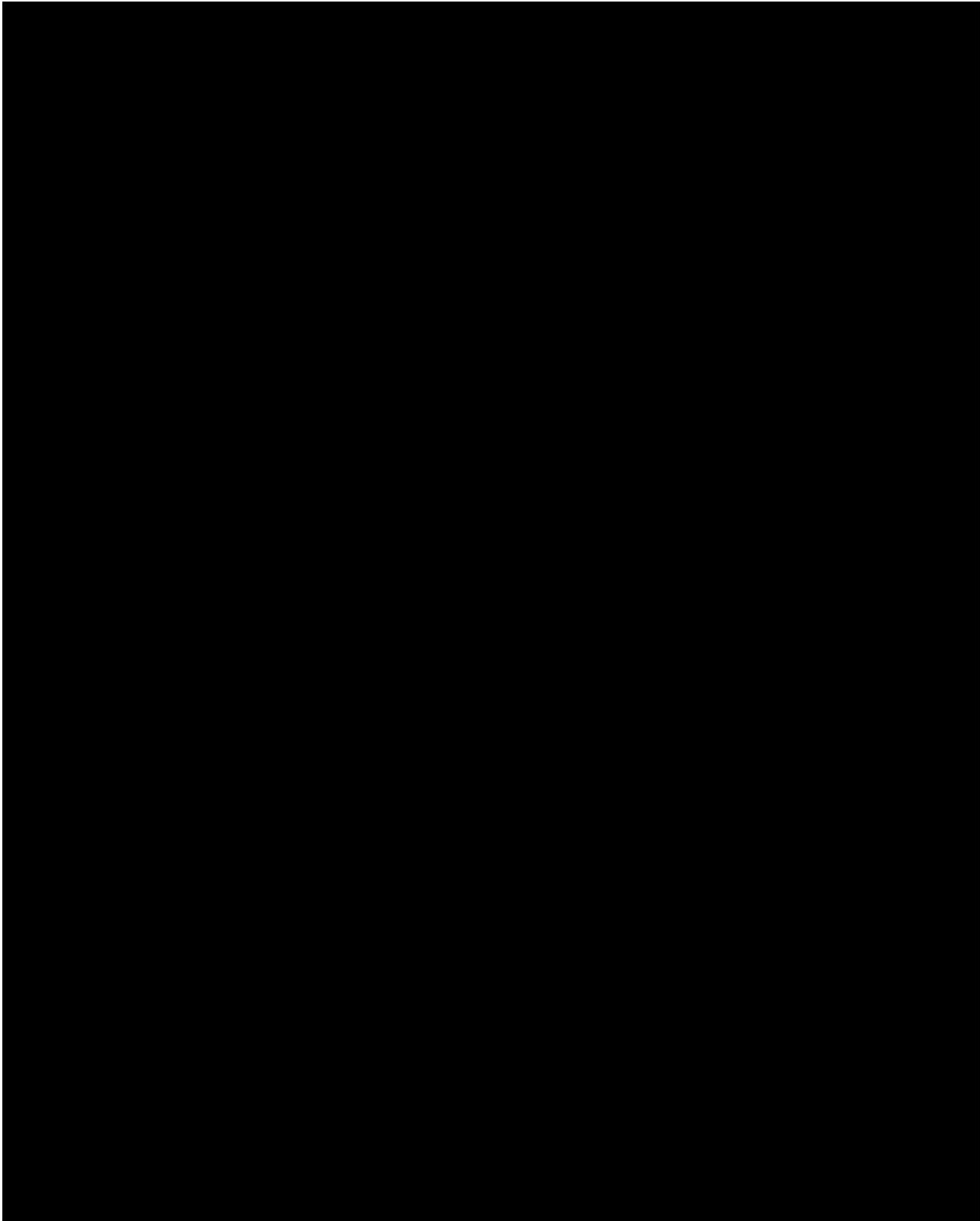


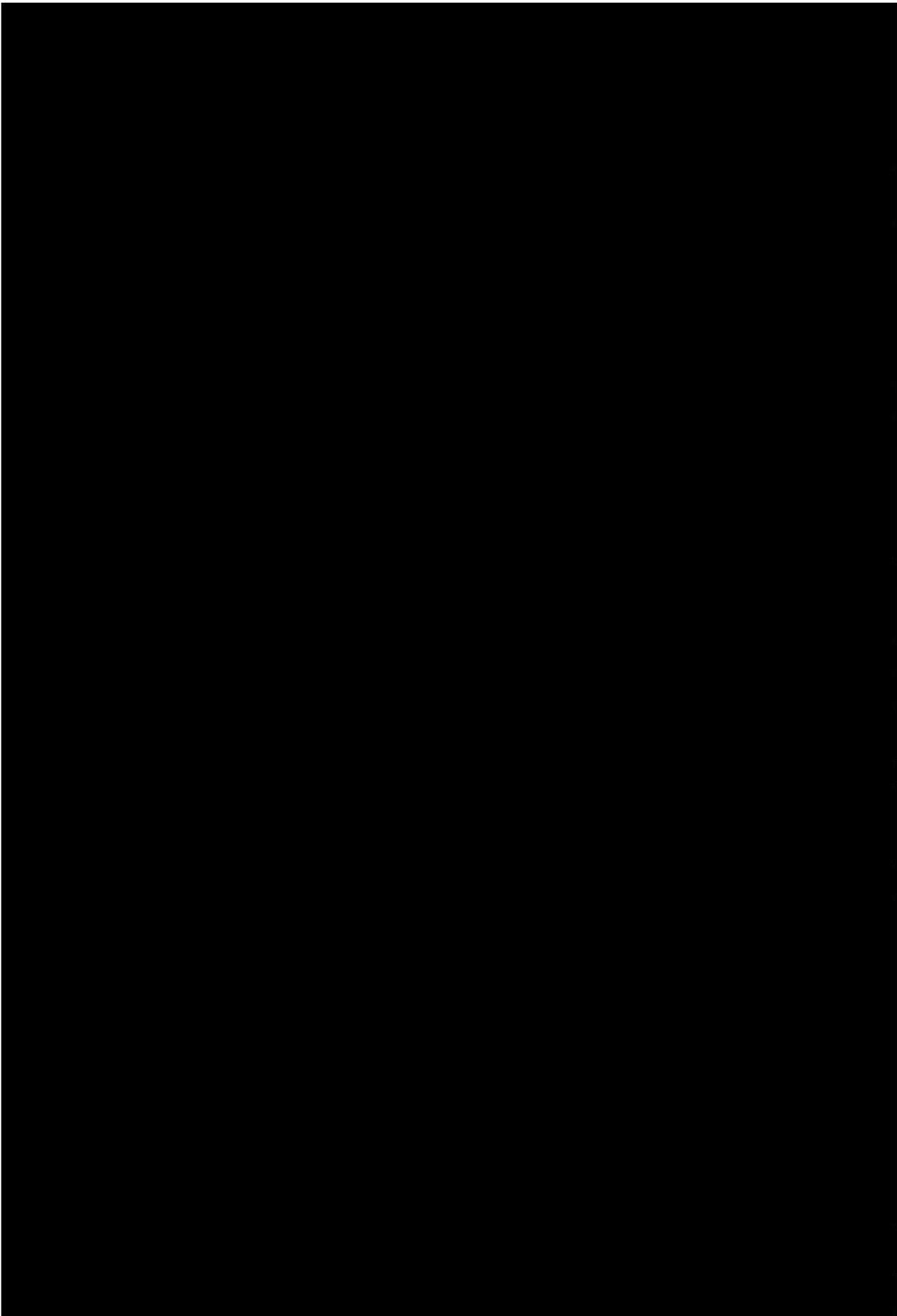












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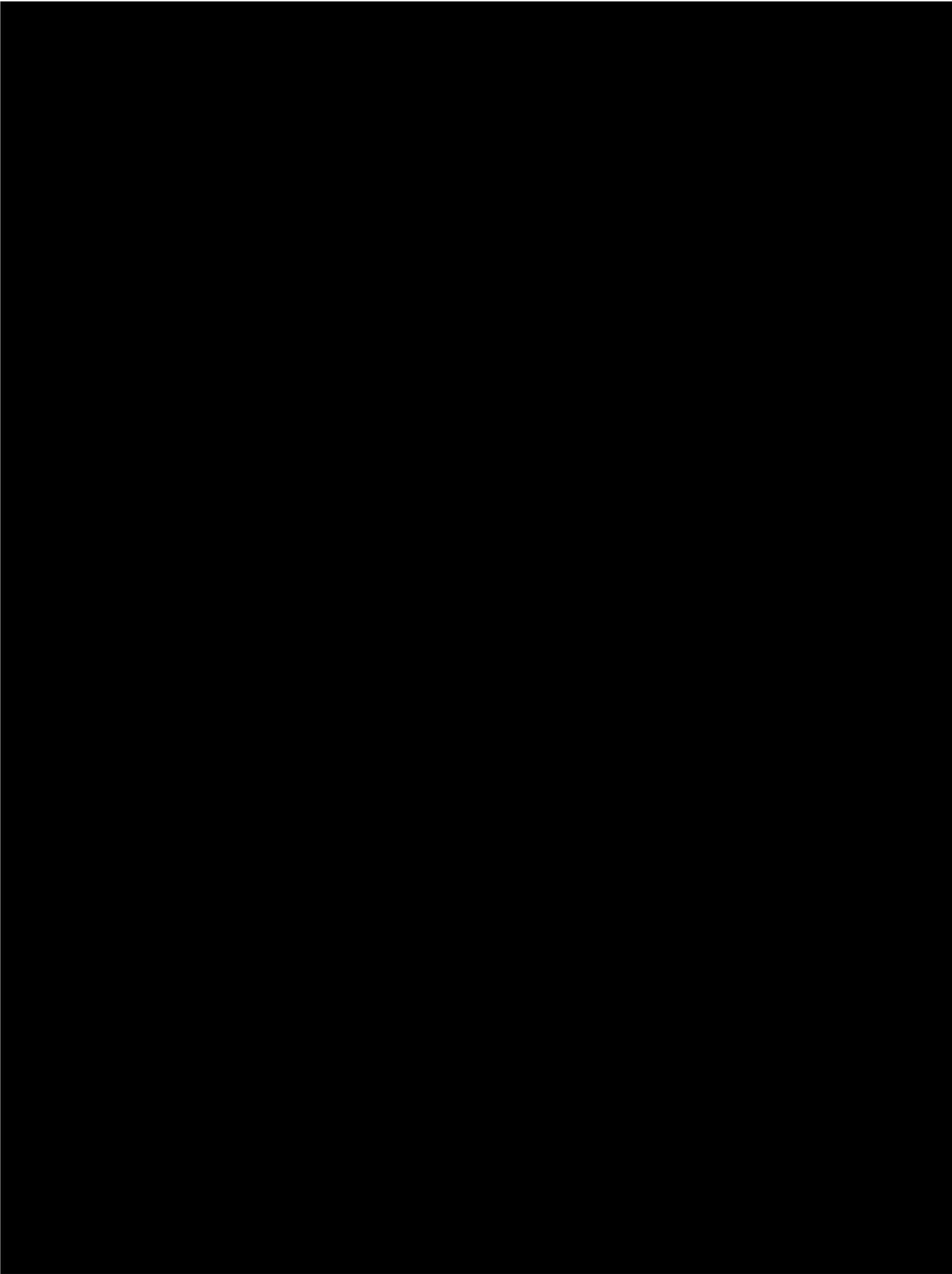
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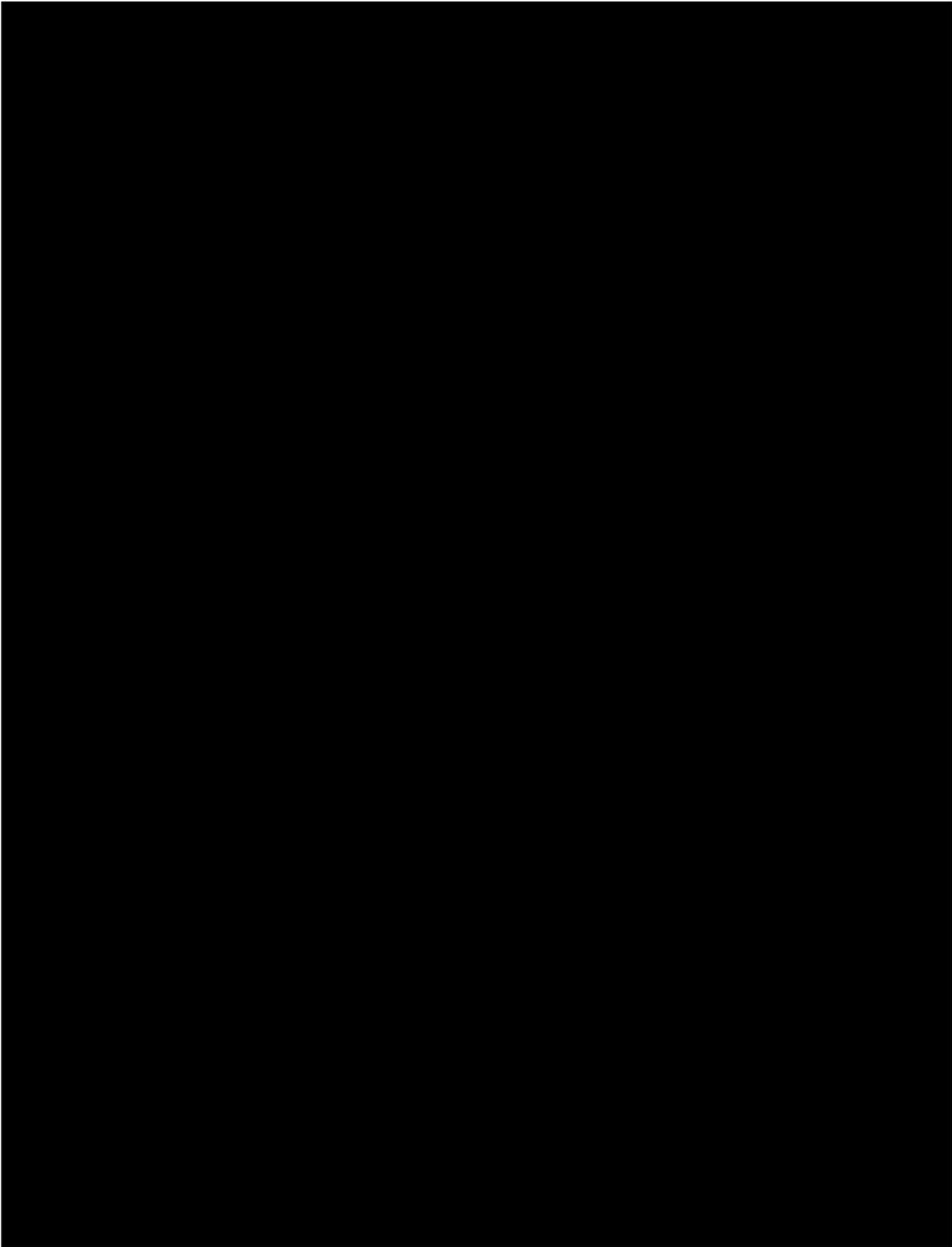
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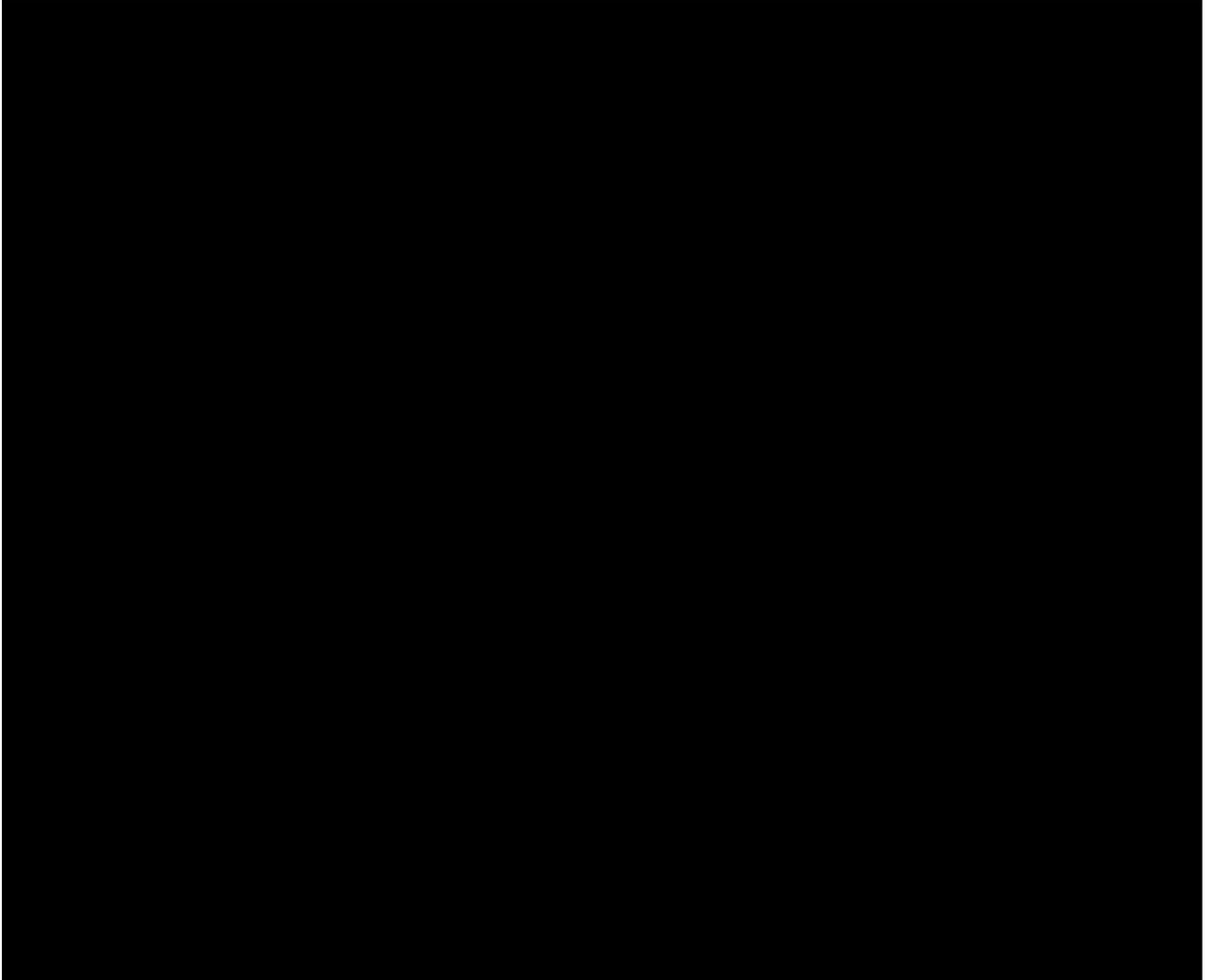
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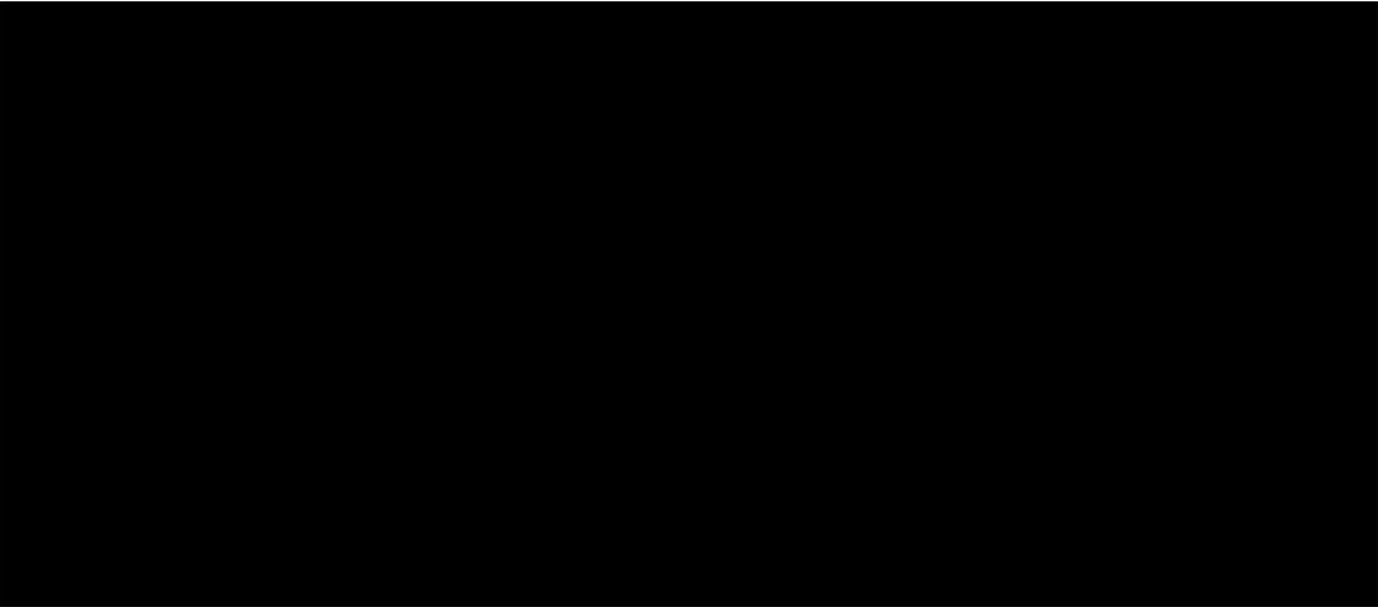
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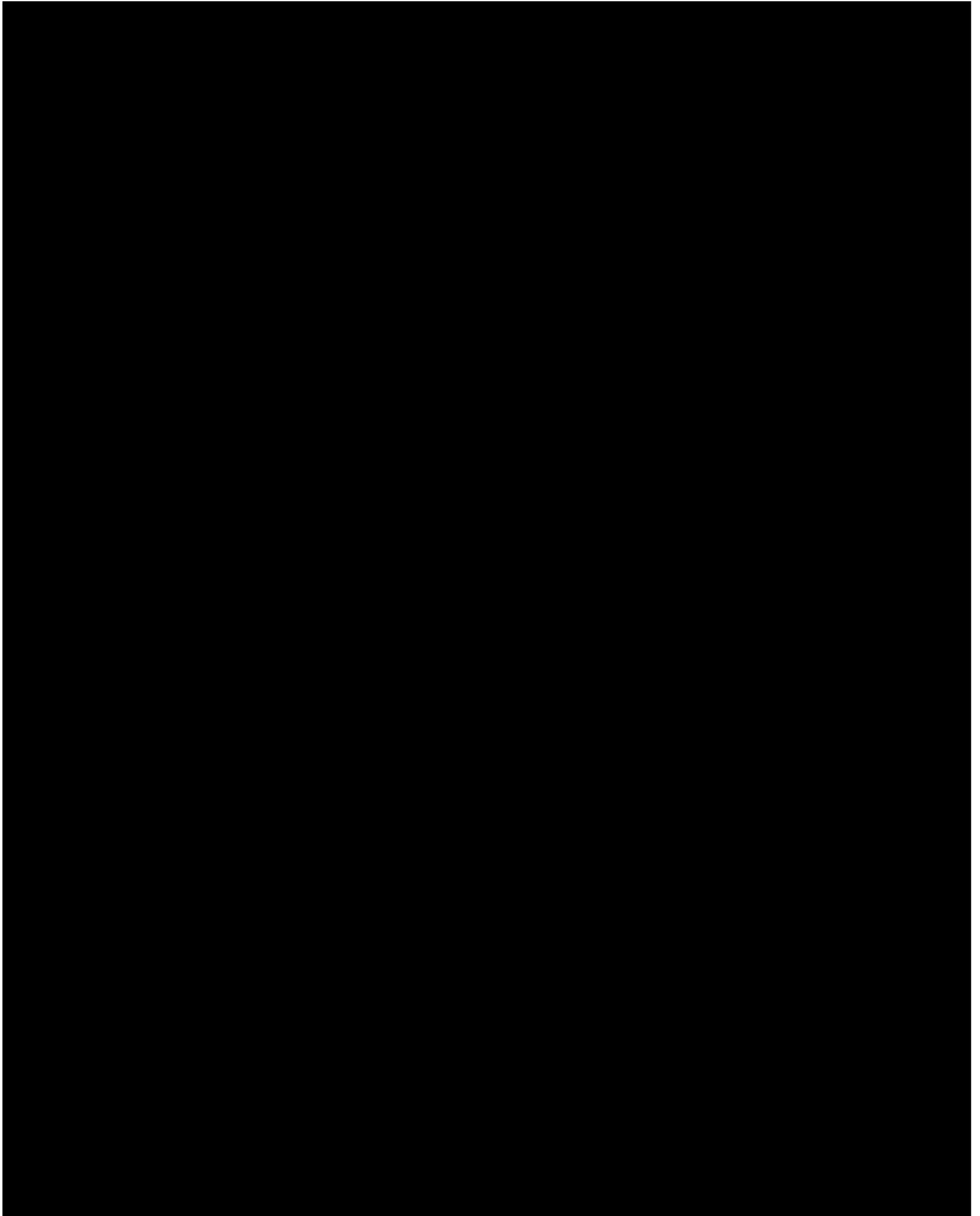
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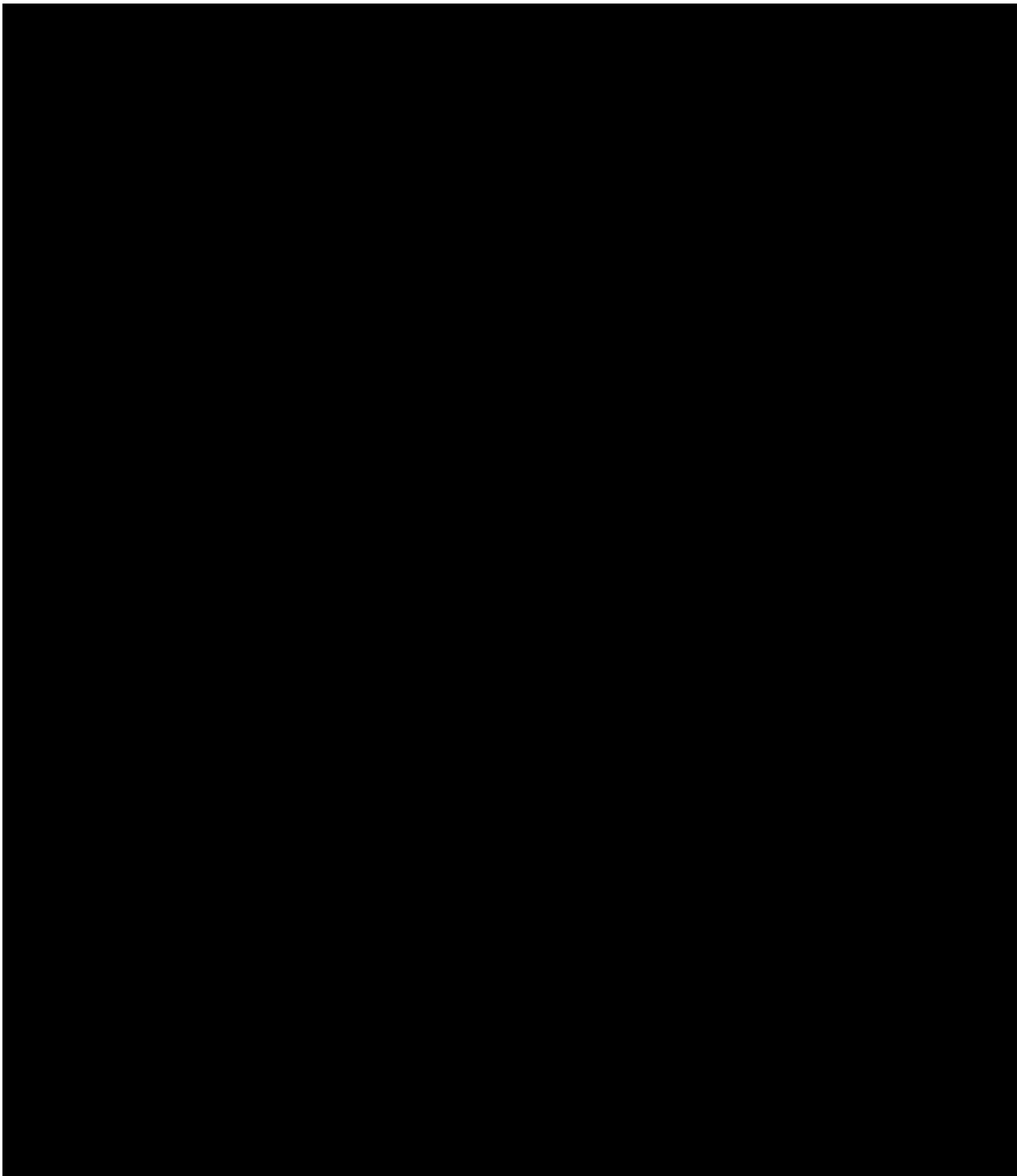
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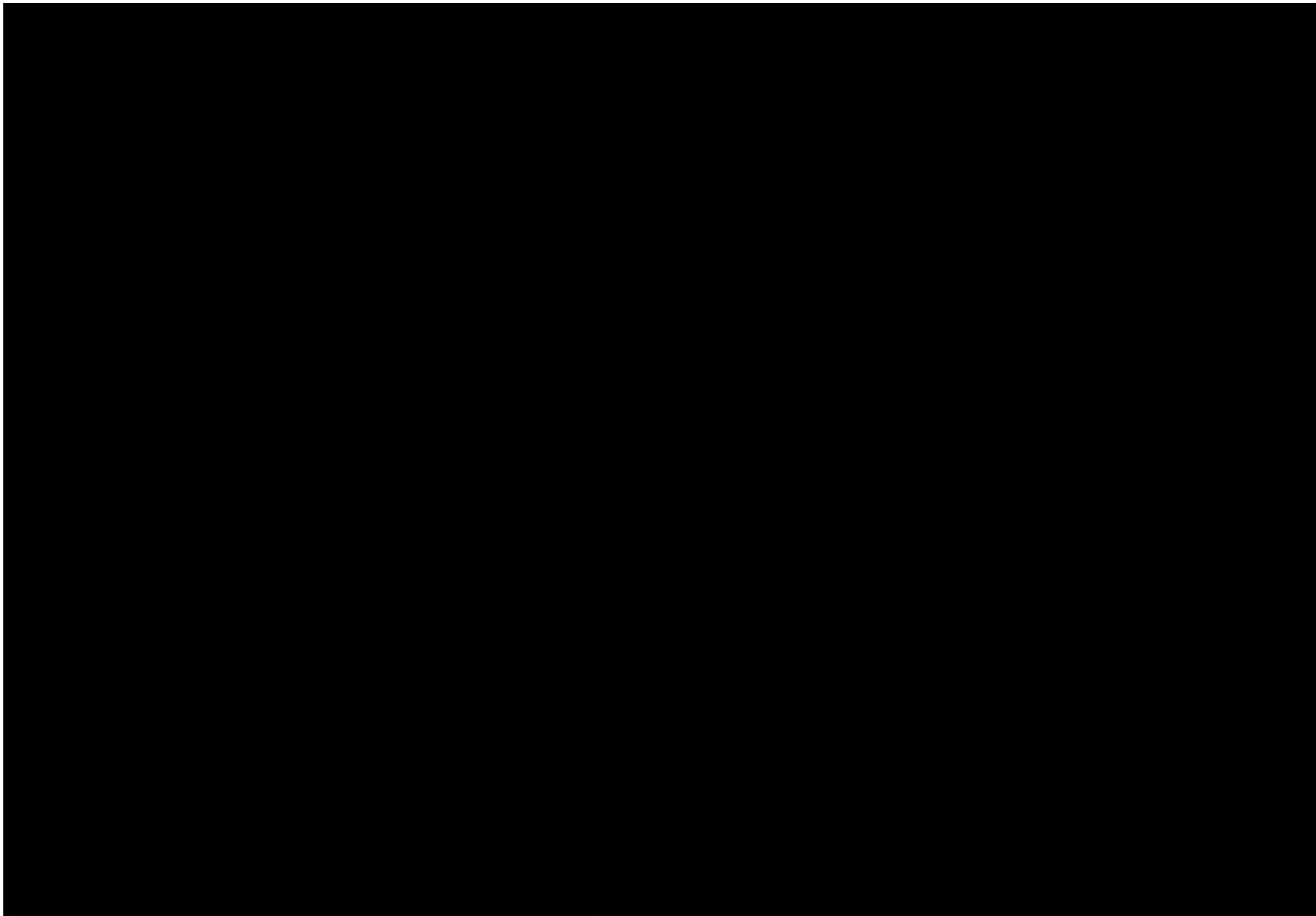
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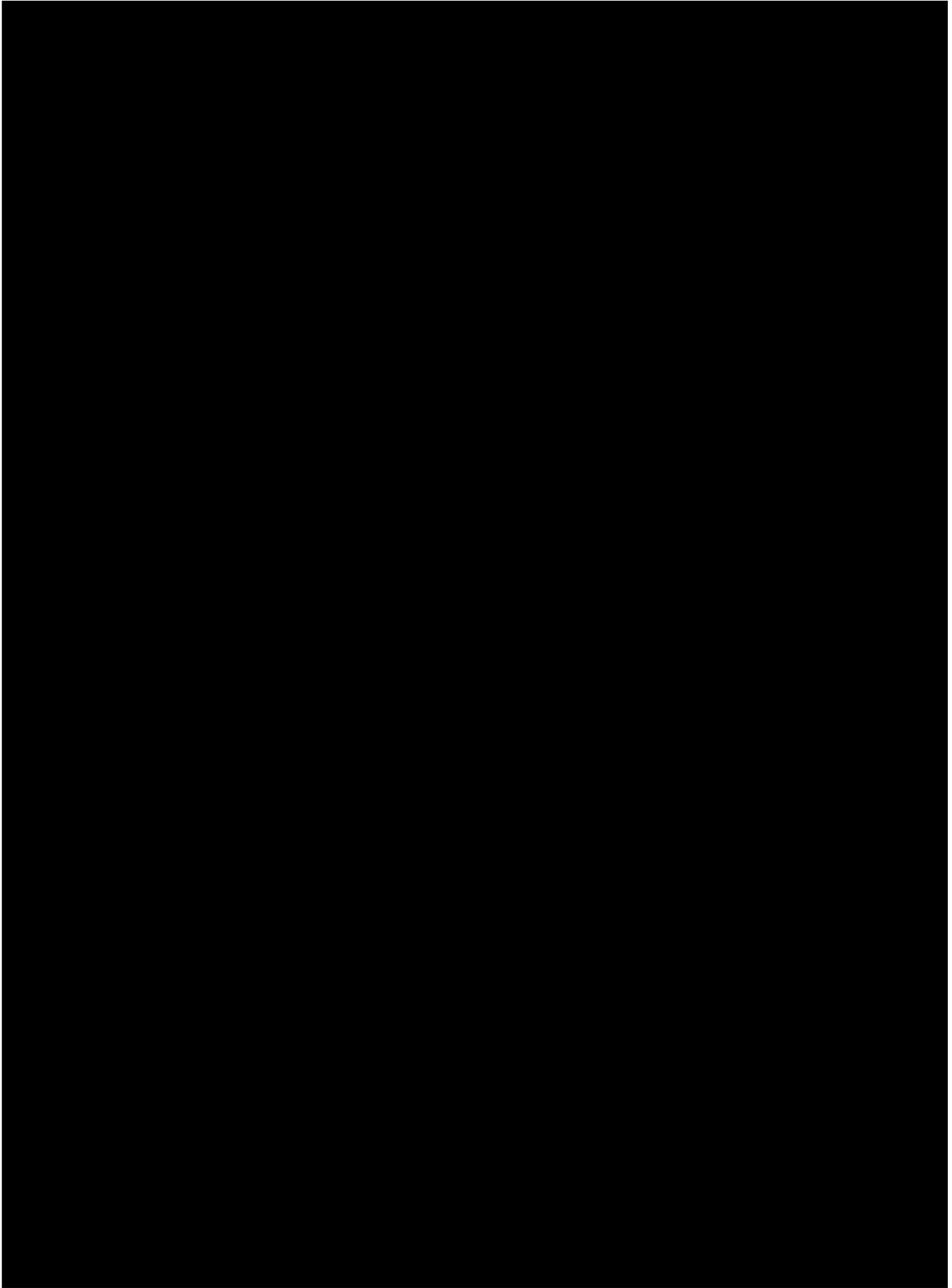




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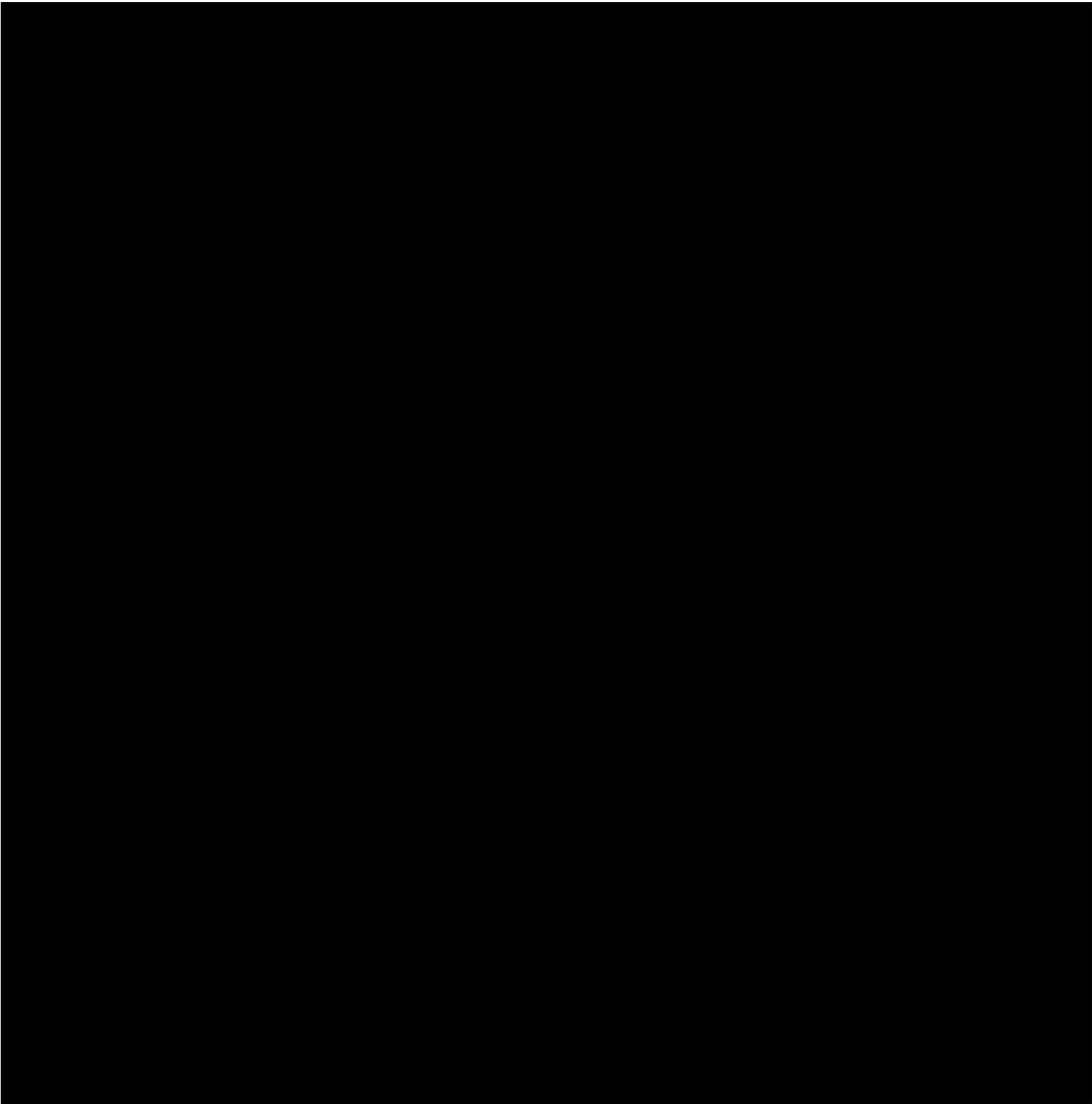
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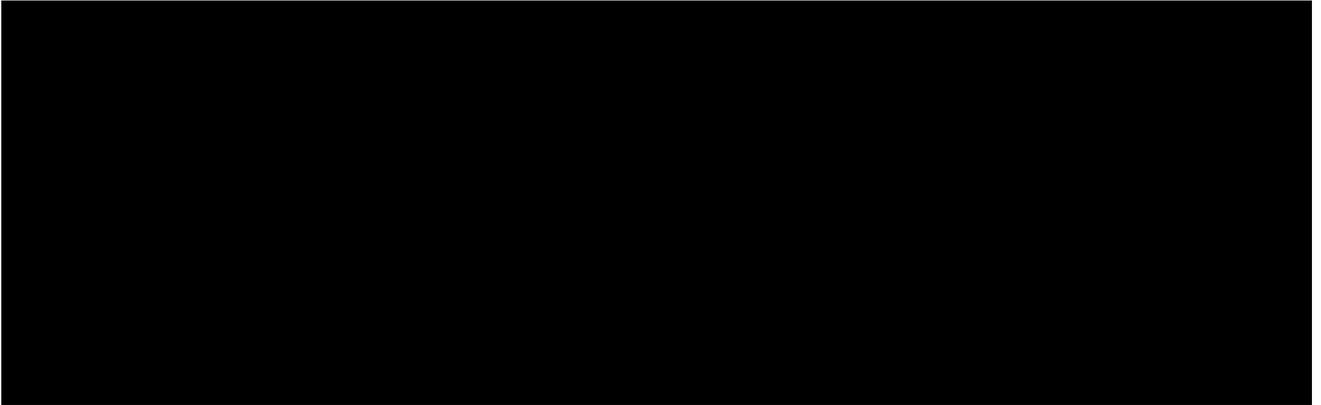
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SCHEDULE 2 – THE SERVICES

L. Provisions Applicable to Primary Medical Services

Requirements relating to tailoring the Services to the characteristics of the local population are contained in the Service Specification

SCHEDULE 2 – THE SERVICES

M. Development Plan for Personalised Care

Not Applicable

SCHEDULE 2 – THE SERVICES

N. Health Inequalities Action Plan

Requirements relating to tailoring the Services to the characteristics of the local population are contained in the Service Specification

SCHEDULE 3 – PAYMENT

A. Aligned Payment and Incentive Rules

Not Applicable.

SCHEDULE 3 – PAYMENT

B. Locally Agreed Adjustments to NHS Payment Scheme Unit Prices

Not Applicable

SCHEDULE 3 – PAYMENT

C. Local Prices

1. The Commissioner will pay the Provider for the Services in accordance with this Schedule 3C.
2. Notwithstanding General Condition 1.2, the Parties expressly agree that Service Condition 36 shall only apply to and be incorporated into this Contract as follows:

Sub-Conditions of Service Condition 36 which are incorporated into this Contract	Sub-Conditions of Service Condition 36 which are excluded from this Contract
36.2	36.1
36.6	36.3 – 36.5
36.29	36.7 - 36.28 (inclusive)
36.33	36.30 – 36.32 (inclusive)
36.34	36.35

Definitions

3. In this Schedule 3C the following definitions are used:

“Achieved”	means a Milestone and/or the Outcomes (as relevant) that have been achieved by the Provider in accordance with the Achievement Criteria and “Achieve” and “Achievement” shall be construed accordingly;
“Achievement Criteria”	means the Digital Achievement Criteria and the Face-to-Face Achievement Criteria;
“Data Output Specification”	means the data output specification to be submitted by the Provider to the Commissioner in accordance with Schedule 6A;
“Digital Achievement Criteria”	means the criteria which must be met by the Provider in relation to a Service User being provided with the Digital Delivery Model in order to Achieve a Milestone as set out in column 3 of Table 2 of this Part 1 of this Schedule 3C;
“Digital Delivery Model Price”	means the maximum price per Service User (set out in Table 1 of this Part 1 of this Schedule 3C) for the provision of the Service via the Digital Delivery Model payable to the Provider when all Milestones have been Achieved;
“Face-to-Face Achievement Criteria”	means the criteria which must be met by the Provider in relation to a Service User being provided with the Face-to-Face Delivery Model in order to Achieve a Milestone as set out in column 2 of Table 2 of this Part 1 of this Schedule 3C;

“Face to-Face Delivery Model Price”	means the maximum price per Service User (set out in Table 1 of this Part 1 of this Schedule 3C) for the provision of the Service via the Face-to-Face Delivery Model payable to the Provider when all Milestones have been Achieved;
“Final Episode of Engagement”	has the meaning set out in section 3.2.16 of Schedule 2A (Service Specification);
“Final Session”	has the meaning set out in section 3.2.16 of Schedule 2A (Service Specification)
“Individual Assessment”	means the individual assessment following acceptance by a Service User of an invitation to participate in the Service at which a Service User is assessed in accordance with section 3.2.5 of Schedule 2A (Service Specification);
“Intervention Cap”	has the meaning set out in section 3.10 of Schedule 2A (Service Specification);
“Intervention Period”	has the meaning set out in section 3.10 of Schedule 2A (Service Specification);
“Milestone”	means a milestone in the provision of the Service for which payment is made as set out in Tables 1 and 2 of this Part 1 of this Schedule 3C;
"Milestone Engagement Methods"	means the following engagement methods: <ul style="list-style-type: none"> • conversation with a health coach (via telephone or a voice over internet protocol system); or • exchange of messages with a health coach (with a minimum of six messages exchanged).
"Milestone 2 Period"	means the period beginning on the Start Date and ending 12 weeks after the Start Date;
"Milestone 3 Period"	means the period beginning immediately after the end of the Milestone 2 Period and ending 52 weeks after the Start Date;
“Minimum Episodes of Engagement”	means the minimum number of episodes of engagement with a Service User to be provided in accordance with section 3.2.6 of Schedule 2A (Service Specification);
“Minimum Sessions”	means the minimum number of sessions with a Service User to be provided in accordance with section 3.2.6 of Schedule 2A (Service Specification);
"Outcomes"	means the Outcomes Achievement Criteria;
"Outcomes Achievement Criteria"	means the criteria which must be met by the Provider in relation to a Service User as set out in paragraph 7 of Part 1 of this Schedule 3C;
"Service"	means the service described in Schedule 2A (Service Specification);

"Service Prices"	means the Face-to-Face Delivery Model Price and the Digital Delivery Model Price;
"Start Date"	means the Monday of the week in which the Service User starts the, or participates in their, first session of, or episode of engagement within, the TDR Phase following the Individual Assessment in accordance with section 3.2.5 of Schedule 2A (Service Specification).

General Principles of Payment

4. The Provider will be paid for the Service it provides under Schedule 2A (Service Specification) subject to the Milestones and Outcomes being Achieved in accordance with Part 1 of this Schedule 3C.
5. Payments payable to the Provider under Part 1 of this Schedule 3C will be paid in accordance with Part 2 of this Schedule 3C.

Part 1 – Payment Calculation – Service Price

1. Subject to paragraphs 2 and 3 of this Part 1:
 - 1.1. the Face-to-Face Delivery Model Price will be paid by the Commissioner for each Service User being provided with the Service via the Face-to-Face Delivery Model; and
 - 1.2. the Digital Delivery Model Price will be paid by the Commissioner for each Service User being provided with the Service via the Digital Delivery Model,

in staged payments depending upon Milestones Achieved by the Provider for each Service User and the Outcomes Payment will be paid by the Commissioner for each Service User which satisfies the Outcomes. The Provider will be paid monthly in arrears in respect of the staged payments for Milestones Achieved and the Outcomes Payment in accordance with Part 2 of this Schedule 3C.
2. The Provider will not be paid for any Service provided to additional Service Users who are invited to participate in the Service after the Intervention Cap has been reached. For the avoidance of doubt, once the Intervention Cap is reached, the Commissioner will continue to pay the Provider for the Service provided to existing Service Users subject to the Milestones being Achieved.
3. The Provider will not be paid for any Service provided to additional Service Users who are invited to participate in the Service after the Intervention Period has elapsed. For the avoidance of doubt, once the Intervention Period has elapsed, the Commissioner will continue to pay the Provider for the Service provided to existing Service Users who were invited to participate in the Service before the Intervention Period elapsed subject to the Milestones being Achieved.
4. The Provider will provide the Data Output Specification in accordance with Schedule 6A (Reporting Requirements) to enable the Commissioner to verify invoices submitted by the Provider to the Commissioner in accordance with Part 2 of this Schedule 3C.
5. Table 1 below shows:
 - 5.1. the Service Prices;
 - 5.2. the percentage of the Service Price payable on Achievement of each Milestone for each Service User; and
 - 5.3. the percentage of the Service Price payable on Achievement of the Outcomes for each Service User.

Table 1

Face-to-Face Delivery Model Price	██████		
Digital Delivery Model Price	██████		
Milestone	1	2	3
% of relevant Service Price payable on Achievement of Milestone	30%	30%	30%
Outcomes Payment - % of relevant Service Price payable on Achievement of Outcomes	10%		

6. Table 2 below shows the Achievement Criteria at each Milestone for the Service provided via the Face-to-Face Delivery Model and the Digital Delivery Model, to be Achieved by the Provider for each Service User (as applicable).

Table 2 – Milestones for Digital Delivery Model

Milestone	Face-to-Face Achievement Criteria	Digital Achievement Criteria
Milestone 1	<p>All of the following criteria have been fulfilled:</p> <ul style="list-style-type: none"> (1) the Individual Assessment has been provided to the Service User by the Provider; (2) the Provider has in writing from the referrer confirmation of the specific medication changes which are required (or that no medication changes are required) and the Provider has ensured that prior to the first day of the TDR Phase, the Service User understands the medication changes to take 	<p>All of the following criteria have been fulfilled:</p> <ul style="list-style-type: none"> (1) the Service User has registered for the Service or created a digital account (as relevant); (2) the Individual Assessment has been provided to the Service User by the Provider; (3) the Provider has in writing from the referrer confirmation of the specific medication changes which are required (or that no medication changes are required) and the Provider has ensured that prior to the first day of the TDR Phase, the Service User understands the medication changes to take place (or that no medication changes are required);

⁵ Successful bidder’s Face-to-Face Delivery Model Price to be inserted here prior to contract award.

⁶ Successful bidder’s Digital Delivery Model Price to be inserted here prior to contract award.

	<p>place (or that no medication changes are required);</p> <p>(3) the the Service User has started the TDR Phase and the first of the Minimum Sessions has been provided to the Service User by the Provider;</p> <p>(4) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(5) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>	<p>(4) the Service User has started the TDR Phase and the first of the Minimum Episodes of Engagement using at least one of the Milestone Engagement Methods has been provided to the Service User by the Provider;</p> <p>(5) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User has been taken in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(6) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>
Milestone 2	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 2 Period has elapsed;</p> <p>(2) the Service User has attended at least six of the eight Minimum Sessions within the Milestone 2 Period;</p> <p>(3) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken for each session attended by the Service User in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(4) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 2 Period has elapsed;</p> <p>(2) there is a time stamped record that the Service User has logged into the Service within the Milestone 2 Period;</p> <p>(3) the Service User has participated in at least eight of the Minimum Episodes of Engagement using at least one of the Milestone Engagement Methods within the Milestone 2 Period;</p> <p>(4) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken, for each of the Minimum Episodes of Engagement that the Service User has participated in in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(5) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>
Milestone 3	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 3 Period has elapsed;</p>	<p>All of the following criteria have been fulfilled:</p> <p>(1) the Milestone 3 Period has elapsed;</p>

	<p>(2) the Service User has attended at least seven of the twelve Minimum Sessions within the Milestone 3 Period and one of those Minimum Sessions was the Final Session;</p> <p>(3) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken for each session attended by the Service User in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(4) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>	<p>(2) there is a time stamped record that the Service User has logged into the Service within the Milestone 3 Period;</p> <p>(3) the Service User has participated in at least seven of the Minimum Episodes of Engagement using at least one of the Milestone Engagement Methods within the Milestone 3 Period and one of those Minimum Episodes of Engagement was the Final Episode of Engagement;</p> <p>(4) valid weight and blood glucose measurements (and blood pressure measurements if applicable) for the Service User have been taken, for each of the Minimum Episodes of Engagement that the Service User has participated in, in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and</p> <p>(5) the Data Output Specification has been submitted by the Provider to the Commissioner in accordance with Schedule 6A in relation to the Service User.</p>
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7. To Achieve the Outcomes for each Service User:

- 7.1. all of the Service User's weight measurements at 0, 3, 6 and 12 months must have been taken in accordance with section 3.2.17 of Schedule 2A (Service Specification) and reported in accordance with Schedule 6A; and
- 7.2. the recorded weight of the Service User at the Final Session or the Final Episode of Engagement (as relevant) must indicate a weight loss of at least 10% of the weight recorded at Milestone 1.

8. The Commissioner shall determine whether or not the Provider has Achieved a Milestone or the Outcomes in accordance with the reports submitted by the Provider in accordance with Schedule 6A (Reporting Requirements) (including the Data Output Specifications submitted).

9. For the avoidance of doubt, the Provider will not be entitled to any increase to the Service Price during the Contract Term to account for inflation, indexation or any other factor which may increase the Provider's costs of delivering the Service.

10. The Commissioner may deduct from any payments due to the Provider under this Part 1 of Schedule 3C any sums that the Commissioner is entitled to withhold or retain in accordance with Part 2 of Schedule 4 (Local Quality Requirements). If the Commissioner exercises its right to make such deductions, the Commissioner may deduct such sum from the amount payable under the applicable invoice issued by the Provider. If the amount due under the applicable invoice has been paid before the applicable deduction has been applied, the Commissioner may require the Provider to repay such amount that it would have been entitled to deduct or the Commissioner may deduct such amount from any subsequent invoice. Any sums that are withheld by the Commissioner that are subsequently to be paid to the Provider in accordance with Part 2 of Schedule 4 (Local Quality Requirements) shall be included in the next invoice issued by the Provider in accordance with Part 2 of this Schedule 3C.

Part 2 – Invoicing Process

1. The Commissioner uses an online service provided by Tradeshift Network Ltd of 55 Baker Street London W1U 7EU found online at www.tradeshift.com (“Tradeshift”) as its online platform for receiving invoices. The Provider will create an online account with Tradeshift from the Effective Date for the purpose of submitting electronic invoices to the Commissioner in accordance with this Part 2 of this Schedule 3C.
2. The Provider will utilise one of the integration options provided by Tradeshift in order to deliver electronic invoices to the Commissioner.
3. The Provider shall:
 - 3.1. comply with the technical requirements of Tradeshift including any changes to such requirements that may be required by Tradeshift from time to time; and
 - 3.2. ensure that all electronic invoices are received by the Commissioner in accordance with the timescales set out in this Part 2 of Schedule 3C.
4. The Provider shall be responsible for its relationship with Tradeshift at all times.
5. Prior to uploading invoices to Tradeshift, the Provider will submit an electronic invoice to the Commissioner in accordance with paragraphs 1-4 of this Part 2 within 10 Operational Days after the end of the month in which a Milestone and/or the Outcomes have been Achieved for a Service User setting out the payment due to the Provider.
6. Following submission of an invoice in accordance with paragraphs 1-5 of this Part 2, the Commissioner will consider and verify the invoice as against the Data Output Specifications provided by the Provider in accordance with Schedule 6A for the relevant month within 20 days of receipt of the invoice.
7. If the Commissioner is unable to verify an invoice in accordance with paragraph 6, the Commissioner will request that the Provider submits a revised electronic invoice in accordance with paragraph 1 above. Paragraph 6 above shall then apply in respect of the Commissioner’s verification of the revised invoice.
8. The final invoice will be verified by agreement between the Commissioner (including any representative acting on behalf of the Commissioner) and the Provider, and if the parties do not verify the invoice paragraph 6 above shall apply.
9. Subject to paragraph 10 of Part 2 of this Schedule 3C, the Commissioner will pay the Provider any sums due under an invoice no later than 30 days from the date on which the Commissioner determines that the invoice is valid and undisputed in accordance with paragraph 6.
10. The Parties agree that paragraph 10 of Part 1 of this Schedule 3C shall apply in relation to breaches of thresholds of the Local Quality Requirements as set out in Schedule 4 (Local Quality Requirements).
11. Where any Party disputes any sum to be paid by it then a payment equal to the sum not in dispute shall be paid and the dispute as to the sum that remains unpaid shall be determined in accordance with General Condition 14. Provided that the sum has been disputed in good faith, Interest due on any sums in dispute shall not accrue until the date falling 5 Operational Days after resolution of the dispute between the Parties.
12. For the avoidance of doubt, Service Condition 36.47 (Set Off) shall apply.
13. The Provider will maintain complete and accurate records of, and supporting documentation for, all amounts which may be chargeable to the Commissioner pursuant to this Contract. Such records shall be retained for inspection by the Commissioner for 6 years from the end of the Contract Year to which the records relate.

SCHEDULE 3 – PAYMENT

D. Expected Annual Contract Values

Not Applicable

SCHEDULE 3 – PAYMENT

E. Timing and Amounts of Payments in First and/or Final Contract Year

Not Applicable

SCHEDULE 3 – PAYMENT

F. CQUIN

<p>Not Applicable</p>

SCHEDULE 4 – LOCAL QUALITY REQUIREMENTS

Part 1

NHS Standard Contract 2023/24

Quality Requirement	Method of Measurement and Thresholds	Consequence of Breach	Period over which the Requirement is to be achieved
<p>KPI 1 Component: Data Quality</p> <p>The Provider shall comply with the reporting requirements set out in the Data Output Specification detailed in Annex 2 of Schedule 6A. This includes the monthly reporting of particulars related to Service Users' attendance on the programme. This is to be done to the level of detail, format and quality prescribed in the "Data Output Specifications" document and the "Data Format Specification" document. These are set out in Annexes 2 and 3, respectively, of Schedule 6A and are together referred to, in this Schedule 4C, as the "Data Specifications".</p>	<p>KPI 1a: The proportion of Service User data records at referral that are recorded in line with the Data Specifications.</p> <ul style="list-style-type: none"> • 100% - "Target" • Between 95% and 99.9% "Mid Threshold" • <95% - "Lower Threshold" 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
	<p>KPI 1b: The proportion of Service Users' data records at Individual Assessment that are recorded in line with the 'Outcome' fields in the Data Specifications.</p> <ul style="list-style-type: none"> • 100% - "Target" • Between 95% and 99.9% "Mid Threshold" • <95% - "Lower Threshold" 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
	<p>KPI 1c: The proportion of Service Users' data records at Individual Assessment that are recorded in line with the 'Demographic' fields in the Data Specifications.</p> <ul style="list-style-type: none"> • 100% - "Target" • Between 95% - and 99.9% "Mid Threshold" • <95% - "Lower Threshold" 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
	<p>KPI 1d: The proportion of Service Users' data records at Individual Assessment that are recorded in line with the 'Administration' fields in the Data Specifications.</p> <ul style="list-style-type: none"> • 100% - "Target" • Between 95% -and 99.9% "Mid Threshold" • <95% - "Lower Threshold" 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>

NHS Standard Contract 2023/24

	<p>KPI 1e: The proportion of Service Users' weight fields that are recorded in line with the Data Specifications.</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% -and 99.9% “Mid Threshold” • <95% - “Lower Threshold” <p>For Service Users on the Face-to-Face Delivery Model weight measurements are recorded for each session. For Service Users on the Digital Delivery Model, weight measurement requirements are set out in Schedule 3C.</p>	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
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NHS Standard Contract 2023/24

<p>KPI 2 Component: Eligibility</p>	<p>KPI 2: The proportion of Service Users starting the first episode of engagement of the TDR Phase that meet the eligibility criteria at referral as defined in Schedule 2A (Service Specification)</p> <ul style="list-style-type: none"> • 100% - “Target” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
<p>KPI 3 Component: Uptake The Provider will be required to report on the KPIs requirements listed under this component allowing sufficient time for Service Users to have attended the specified number of sessions. Provider performance against KPI 3 and KPI 4 will be reviewed as part of the Quarterly Contract Review Meetings.</p>	<p>KPI 3a: The proportion of eligible Service Users who have attended the Individual Assessment (where 3 months has elapsed since the date of referral).</p> <ul style="list-style-type: none"> • ≥85% - “Target” • Between 75% - 84.9% - “Mid Threshold” • <75% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 3b: The proportion of eligible Service Users who have commenced TDR through either the Face-to-Face Delivery Model or the Digital Delivery Model and have attended the first TDR session or participated in the first episode of engagement (where 3 months has elapsed since the date of referral).</p> <ul style="list-style-type: none"> • ≥80% - “Target” • Between 70% - 79.9% - “Mid Threshold” • <70% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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<p>KPI 4 Component: Efficacy</p>	<p>KPI 4a: The percentage of Service Users on the Face-to-Face Delivery Model for whom:</p> <ul style="list-style-type: none"> • sufficient time has elapsed to have been on the programme for 3 months, <p>who have lost 10% of their baseline weight by the time the Service User passes the 3-month mark on the programme.</p> <ul style="list-style-type: none"> • ≥55% have lost 10% of weight compared with the baseline weight recorded- “Target” • Between 50% - 54.9% have lost 10% of weight compared with the baseline weight recorded - “Mid Threshold” • <49.9% have lost 10% of weight compared with the baseline weight recorded- “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 4b: The percentage of Service Users on the Digital Delivery Model for whom:</p> <ul style="list-style-type: none"> • sufficient time has elapsed to have been on the programme for 3 months, <p>who have lost 10% of their baseline weight by the time the Service User passes the 3-month mark on the programme.</p> <ul style="list-style-type: none"> • ≥55% have lost 10% of weight compared with the baseline weight recorded- “Target” • Between 50% - 54.9% have lost 10% of weight compared with the baseline weight recorded - “Mid Threshold” • <49.9% have lost 10% of weight compared with the baseline weight recorded- “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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	<p>KPI 4c: The percentage of Service Users on the Face-to-Face Delivery Model for whom:</p> <ul style="list-style-type: none"> • sufficient time has elapsed to have been on the programme for 12 months, <p>who have lost 10% of their baseline weight by the time the Service User passes the 12-month mark on the programme.</p> <ul style="list-style-type: none"> • ≥45% have lost 10% of weight compared with the baseline weight recorded- “Target” • Between 40% - 44.9% have lost 10% of weight compared with the baseline weight recorded - “Mid Threshold” • <39.9% have lost 10% of weight compared with the baseline weight recorded- “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 4d: The percentage of Service Users on the Digital Delivery Model for whom:</p> <ul style="list-style-type: none"> • sufficient time has elapsed to have been on the programme for 12 months, <p>who have lost 10% of their baseline weight by the time the Service User passes the 12 month mark on the programme.</p> <ul style="list-style-type: none"> • ≥45% have lost 10% of weight compared with the baseline weight recorded- “Target” • Between 40% - 44.9% have lost 10% of weight compared with the baseline weight recorded - “Mid Threshold” • <39.9% have lost 10% of weight compared with the baseline weight recorded- “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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<p>KPI 5 Component: Milestone 2 Retention</p>	<p>KPI 5a: For Service Users:</p> <ul style="list-style-type: none"> • who have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 1; and • for whom sufficient time has elapsed for the Face-to-Face Achievement Criteria that relate to Milestone 2 to have been fulfilled, <p>to have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 2.</p> <ul style="list-style-type: none"> • ≥90% - “Target” • Between 80% - 89.9% - “Mid Threshold” • <80% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 5b: For Service Users:</p> <ul style="list-style-type: none"> • who have fulfilled the Digital Achievement Criteria that relate to Milestone 1; and • for whom sufficient time has elapsed for the Digital Achievement Criteria that relate to Milestone 2 to have been fulfilled, <p>to have fulfilled the Digital Achievement Criteria that relate to Milestone 2.</p> <ul style="list-style-type: none"> • ≥90% - “Target” • Between 80% - 89.9% - “Mid Threshold” • <80% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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<p>KPI 6 Component: Milestone 3 Retention</p>	<p>KPI 6a: For Service Users:</p> <ul style="list-style-type: none"> • who have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 1; and • for whom sufficient time has elapsed for the Face-to-Face Achievement Criteria that relate to Milestone 3 to have been fulfilled, <p>to have fulfilled the Face-to-Face Achievement Criteria that relate to Milestone 3.</p> <ul style="list-style-type: none"> • $\geq 60\%$ - “Target” • Between 50% - 59.9% - “Mid Threshold” • $< 50\%$ - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 6b: For Service Users:</p> <ul style="list-style-type: none"> • who have fulfilled the Digital Achievement Criteria that relate to Milestone 1; and • for whom sufficient time has elapsed for the Digital Achievement Criteria that relate to Milestone 3 to have been fulfilled, <p>to have fulfilled the Digital Achievement Criteria that relate to Milestone 3.</p> <ul style="list-style-type: none"> • $\geq 60\%$ - “Target” • Between 50% - 59.9% - “Mid Threshold” • $< 50\%$ - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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<p>KPI 7 Demographic referral</p> <p>Component: Data at</p>	<p>KPI 7a: Eligible referrals have a valid data entry, and are not recorded as “not stated” (i.e. [999]) for the following fields:</p> <ul style="list-style-type: none"> • Sex • Ethnicity • 95% - “Target” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
	<p>KPI 7b: Eligible referrals have a valid data entry i.e. an actual weight or height and not a “not stated” or “unknown” entry for the following fields:</p> <ul style="list-style-type: none"> • Height • Weight • Blood Glucose • Blood Pressure (where applicable) • 100% - “Target” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>
<p>KPI 8 Discharge</p> <p>Component:</p>	<p>KPI 8: That notification of discharge is communicated to the Service User’s GP and the Service User within 10 Operational Days once the discharge criteria has been met.</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Monthly</p>

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<p>KPI 9: Equality of access commencing the programme</p>	<p>KPI 9a: For individuals from Black, Asian and other ethnic groups referred to the Face-to-Face Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of ethnicity:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” <p>KPI 9b: For individuals from Black, Asian and other ethnic groups referred to the Digital Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of ethnicity:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 9c: For individuals from the most deprived quintile referred to the Face-to-Face Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of deprivation:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” <p>KPI 9d: For individuals from the most deprived quintile referred to the Digital Delivery Model the uptake proportions (Milestone 1) are in line with the proportions commencing the service regardless of deprivation:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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<p>KPI 10: Equality of retention on the TDR phase</p>	<p>KPI 10a: For individuals from Black, Asian and other ethnic groups referred to the Face-to-Face Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of ethnicity:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” <p>KPI 10b: For individuals from Black, Asian and other ethnic groups referred to the Digital Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of ethnicity:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 10c: For individuals from the most deprived quintile referred to the Face-to-Face Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of deprivation:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” <p>KPI 10d: For individuals from the most deprived quintile referred to the Digital Delivery Model the retention proportions at Milestone 2 are in line with the proportions retained to Milestone 2 regardless of deprivation:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

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<p>KPI 11: Equality of retention to end of programme</p>	<p>KPI 11a: For individuals from Black, Asian and other ethnic groups referred to the Face-to-Face Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of ethnicity:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” <p>KPI 11b: For individuals from Black, Asian and other ethnic groups referred to the Digital Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of ethnicity:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>
	<p>KPI 11c: For individuals from the most deprived quintile referred to the Face-to-Face Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of deprivation:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” <p>KPI 11d: For individuals from the most deprived quintile referred to the Digital Delivery Model the retention proportions at Milestone 3 are in line with the proportions retained to Milestone 3 regardless of deprivation:</p> <ul style="list-style-type: none"> • 100% - “Target” • Between 95% - 99.9% - “Mid Threshold” • <95% - “Lower Threshold” 	<p>As set out in Part 2 of this Schedule 4 <i>(Local Quality Requirements)</i></p>	<p>Quarterly</p>

Part 2

1. In Part 2 of this Schedule 4 (*Local Quality Requirements*) the following definitions are used:

- “KPIs”** means the KPIs set out in the table in Part 1 of this Schedule 4 (*Local Quality Requirements*), which are also known as the Local Quality Requirements;
- “KPI Periods”** means the periods within which the Provider’s performance against each KPI is to be measured, as set out in in the column headed “Period over which the Requirement is to be achieved” in the table in Part 1 of this Schedule 4 (*Local Quality Requirements*);
- “Lower Threshold”** means the Lower Threshold applicable to a KPI, as set out in Part 1 of this Schedule 4 (*Local Quality Requirements*) and, to avoid doubt, is considered a threshold for the purpose of Service Condition 3.1.2;
- “Mid Threshold”** means the Mid Threshold applicable to a KPI, as set out in Part 1 of this Schedule 4 (*Local Quality Requirements*) and, to avoid doubt, is considered a threshold for the purpose of Service Condition 3.1.2;
- “Target”** means the Target applicable to each of the KPIs, as set out in Part 1 of this Schedule 4 (*Local Quality Requirements*) and, to avoid doubt, the Targets are considered thresholds for the purpose of Service Condition 3.1.2; and

2. If the Provider fails to meet or exceed the Lower Threshold applicable to any of the KPIs for the relevant KPI Period, the Commissioner reserves the right, by notice to the Provider to require that the Provider submits, within 10 Operational Days of the notice, a remedial action plan to the Commissioner that sets out the actions that the Provider will take prior to the end of the next KPI Period applicable to the relevant KPI to remedy the failure to meet or exceed the target in relation to that KPI.
3. If the Provider exceeds the Lower Threshold applicable to any of the KPIs but fails to meet or exceed the Target applicable to that KPI for the relevant KPI Period, the Commissioner reserves the right, by notice to the Provider:
- 3.1. to issue a Contract Performance Notice to the Provider in accordance with GC 9.4 (Contract Management): or
 - 3.2. to require that the Provider submits, within 10 Operational Days of the notice, a remedial action plan to the Commissioner that sets out the actions that the Provider will take prior to the end of the next KPI Period applicable to the relevant KPI to remedy the failure to meet or exceed the Target in relation to that KPI.

4. Where the Provider does not provide a remedial action plan to the Commissioner within the relevant timescale in accordance with paragraphs 2 and/or 3.2 of Part 2 of this Schedule 4 (*Local Quality Requirements*), the Commissioner may, by notice to the Provider, immediately and permanently retain up to 1% of the Actual Monthly Value applicable to the relevant KPI Period, where the relevant KPI Period is monthly, or up to 1% of the Actual Quarterly Value applicable to the relevant KPI Period, where the relevant KPI Period is Quarterly.
5. Where the Provider has provided a remedial action plan to the Commissioner within the relevant timescale in accordance with paragraphs 2 and 3.2 of Part 2 of this Schedule 4 (*Local Quality Requirements*), then if the Provider:
 - 5.1. fails to meet or exceed the Target applicable to that KPI for the next KPI Period applicable to that KPI, the Commissioner may, by notice to the Provider, immediately and permanently retain up to 1% of the Actual Monthly Value applicable to the relevant KPI Period, where the relevant KPI Period is monthly, or up to 1% of the Actual Quarterly Value applicable to the relevant KPI Period, where the relevant KPI Period is Quarterly, and issue a Contract Performance Notice to the Provider; or
 - 5.2. meets or exceeds the Target applicable to that KPI for the next KPI Period applicable to that KPI, the Commissioner will confirm that the remedial action plan has been achieved.
6. For the avoidance of doubt, nothing in paragraphs 4 or 5 of Part 2 of this Schedule 4 (*Local Quality Requirements*) will prevent the Commissioner from retaining any further sums in relation to the next (or any subsequent) KPI Period for the relevant KPI in accordance with paragraphs 2 or 3 of Part 2 of this Schedule 4 (*Local Quality Requirements*), subject to paragraph 7 of Part 2 of this Schedule 4 (*Local Quality Requirements*).
7. The Commissioner will not retain more than 10% of the Actual Monthly Value applicable to any individual month pursuant to Part 2 of this Schedule 4 (*Local Quality Requirements*).
8. Without prejudice to any other rights or remedies that may be available to the Commissioner under Part 2 of this Schedule 4 (*Local Quality Requirements*), if for any KPI Period the Provider fails to meet or exceed any Target in relation to any KPI that does not have a Mid Threshold figure and a Lower Threshold figure), the Commissioner will be entitled to issue a Contract Performance Notice to the Provider in accordance with GC9.4 (*Contract Management*).
9. The parties acknowledge and agree that for the purposes of GC17.10.4 the Provider will be deemed to be in persistent or repetitive breach of the Quality Requirements if, in the Commissioner's reasonable opinion, the Provider has repeatedly failed to meet or exceed the Targets applicable to any of the KPIs in such a manner as to reasonably justify the Commissioner's opinion that the Provider's conduct is inconsistent with it having the intention or ability to meet or exceed the relevant requirements over a reasonable period of the remaining Contract Term.

SCHEDULE 5 – GOVERNANCE

A. Documents Relied On

Not applicable

SCHEDULE 5 - GOVERNANCE

B. Provider's Material Sub-Contracts

Sub-Contractor [Name] [Registered Office] [Company number]	Service Description	Start date/expiry date	Processing Personal Data – Yes/No	If the Sub-Contractor is processing Personal Data, state whether the Sub-Contractor is a Data Processor OR a Data Controller OR a joint Data Controller
[DN: To be populated prior to Contract award as appropriate]				

SCHEDULE 5 - GOVERNANCE

C. Commissioner Roles and Responsibilities

Not Applicable

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A. Reporting Requirements

	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
National Requirements Reported Centrally				
1. As specified in the Schedule of Approved Collections published at https://digital.nhs.uk/isce/publication/nhs-standard-contract-approved-collections where mandated for and as applicable to the Provider and the Services	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance	All
1a. Without prejudice to 1 above, daily submissions of timely Emergency Care Data Sets, in accordance with DAPB0092-2062 and with detailed requirements published at https://digital.nhs.uk/data-and-information/data-collections-and-data-sets/data-sets/emergency-care-data-set-ecds/ecds-latest-update	As set out in relevant Guidance	As set out in relevant Guidance	Daily	A+E, U
2. Patient Reported Outcome Measures (PROMS) https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms	As set out in relevant Guidance	As set out in relevant Guidance	As set out in relevant Guidance	All
National Requirements Reported Locally				
1a. Activity and Finance Report	Monthly	In the format specified in the relevant Information Standards Notice (DCB2050)	[For local agreement]	A, MH
1b. Activity and Finance Report	Monthly	[For local agreement]	[For local agreement]	All except A, MH
2. Service Quality Performance Report, detailing performance against National Quality Requirements, Local Quality Requirements and the duty of candour, including, without limitation: <ol style="list-style-type: none"> a. details of any thresholds that have been breached and breaches in respect of the duty of candour that have occurred; b. details of all requirements satisfied; 	Monthly	[For local agreement]	Within 15 Operational Days of the end of the month to which it relates	All All

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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
c. details of, and reasons for, any failure to meet requirements				All
3. Where CQUIN applies, CQUIN Performance Report and details of progress towards satisfying any CQUIN Indicators, including details of all CQUIN Indicators satisfied or not satisfied	[For local agreement]	[For local agreement]	[For local agreement]	All
4. Complaints monitoring report, setting out numbers of complaints received and including analysis of key themes in content of complaints	[For local agreement]	[For local agreement]	[For local agreement]	All
5. Report against performance of Service Development and Improvement Plan (SDIP)	In accordance with relevant SDIP	In accordance with relevant SDIP	In accordance with relevant SDIP	All
6. Summary report setting out relevant information on Patient Safety Incidents and the progress of and outcomes from Patient Safety Investigations, as agreed with the Co-ordinating Commissioner	Monthly	[For local agreement]	[For local agreement]	All
7. Data Quality Improvement Plan: report of progress against milestones	In accordance with relevant DQIP	In accordance with relevant DQIP	In accordance with relevant DQIP	All
8. Report on outcome of reviews and evaluations in relation to Staff numbers and skill mix in accordance with GC5.2 (Staff)	Annually (or more frequently if and as required by the Co-ordinating Commissioner from time to time)	[For local agreement]	[For local agreement]	All
9. Report on its performance against the National Workforce Race Equality Standard and action plan setting out the steps the Provider will take to improve performance	Annually	[For local agreement]	By 31 October in each Contract Year; submission to Co-ordinating Commissioner	All
10. (If the Provider is an NHS Trust or an NHS Foundation Trust) report on its performance against the National Workforce Disability Equality Standard and action plan setting out the steps the Provider will take to improve performance	Annually	[For local agreement]	By 31 October in each Contract Year; submission to Co-ordinating Commissioner	All
11. Where the Services include Specialised Services and/or other services directly commissioned by NHS England (or commissioned by an ICB, where NHS England has delegated the function of commissioning those services), specific reports as set out at https://www.england.nhs.uk/nhs-standard-	As set out at https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/	As set out at https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/	As set out at https://www.england.nhs.uk/nhs-standard-contract/dc-reporting/	All

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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
contract/dc-reporting/ (where not otherwise required to be submitted as a national requirement reported centrally or locally)				
12. Report on progress against Green Plan in accordance with SC18.2 (NHS Trust/FT only)	Annually	[For local agreement]	[For local agreement]	All
Local Requirements Reported Locally				
13. Data Output Specification	Data to be collected on an ongoing basis in line with the timing set out in the "Data Format Specification" document in Annex 3 of this Schedule 6A.	The format of the report is as set out in the "Data Output Specifications" document in Annex 2 of this Schedule 6A. The data must be inputted into the report format above in accordance with the codes set out in the "Data Format Specification" document in Annex 3 of this Schedule 6A.	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided within 10 Operational Days of the end of the month to which it relates.	
14. Waiting Times Report	Monthly	Reporting template as provided by the Commissioner or the Commissioner Representative – this will include as a minimum: <ul style="list-style-type: none"> Numbers waiting for course starts (by month of receipt of referral) Reasons for wait 	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided within 10 Operational Days of the end of the month to which it relates.	

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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
		and and/or non-attendance to date		
15. Capacity Planning Report	Monthly	Reporting template as provided by the Commissioner or the Commissioner Representative – this will include as a minimum: <ul style="list-style-type: none"> • Expected referrals per month • Number of Service Users waiting for course starts • Planned number of courses 	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided within 10 Operational Days of the end of the month to which it relates.	
16. Service User Surveys Report	Quarterly	Reporting template as provided by Commissioner or the Commissioner Representative	To be submitted electronically to the Contract management provider as appointed and advised by the Commissioner using the templates provided in advance of the Quarterly Review meeting and within 10 Operational Days of the beginning of the month in which that review meeting falls	
17. Operational & Service Delivery Reports – for local contract areas	Monthly	Reporting template as provided by the Commissioner Representative – this will include, as a minimum:	To be submitted electronically to the lead local health economy representative as detailed in a notification by the Commissioner to	

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	Reporting Period	Format of Report	Timing and Method for delivery of Report	Service category
		<ul style="list-style-type: none"> • Number of referrals received (accepted & rejected) • Number of attendees at first session (group face to face only)Number of courses course starts booked in next 3 months • Number of individuals declining the Service • Waiting times for course starts 	the Provider	

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A Reporting Requirements

Annex 1 – Service Quality Performance Report

The Parties acknowledge that the headings and tables below are the tab headings and the tables set out in the Service Quality Performance Report spreadsheet provided to the Provider.

Submission details

Service Quality Performance Report			
Submitted by (name, title & organisation):		Signed off by (name, title & organisation):	
Submitted by (e-mail address):		Signed off by (email address):	
Full Name of Organisation responsible for Submission:		Date Submitted:	

Duty of Candour Report

Duty of Candour Report	
This section must be reported:	Monthly
Period covered by report:	Jan-00
Have any breaches of the National Quality Requirement relating to the Duty of Candour occurred?	
If relevant, provide details of the breach:	
If relevant, provide details of and reasons for any failure to meet the requirement in relation to the Duty of Candour:	
If relevant, provide details of consequence actions taken/required:	

Never Events Report

Never Events Report	
This section must be reported:	Monthly
Period covered by report:	Jan-00
Have any Never Events occurred?	
If relevant, provide details of action taken consequent to the Never Event and complain with the Never Event Policy framework:	
If relevant, provide details of the Never Event:	
If relevant, provide details and reasons for any failure to meet the requirement in relation to Never Events:	

Adverse Events Report

Adverse Events Report	
This section must be reported:	Monthly
Period covered by report:	Jan-00
How many Adverse Events have occurred?	0
For each Adverse Event provide a summary of the adverse event and details of actions taken consequent to the incident:	

Complaints Report

Complaints Report	
This section must be reported:	Monthly
Period covered by report:	Jan-00
How many complaints have been received?	
For each complaint, provide a summary of the complaint and details of actions taken consequent to the complaint:	
Provide an analysis of key themes from the complaints:	

Incidents Report

Incidents Report	
This section must be reported:	Monthly
Period covered by report:	Jan-00
How many incidents requiring reporting have occurred?	0
For each Incident provide a summary of the incident and details of actions taken consequent to the incident:	

National Workforce Race Equality Standard Report

National Workforce Race Equality Standard Report	
This section must be reported:	Annually
Period covered by report:	Jan-00
Provide details of compliance with the National Workforce Race Equality Standard:	

Equality and Health Inequality Impact Assessment

Equality & Health Inequality Impact Assessment	
This section must be reported:	annually
Period covered by report:	
Provide details of Equality & Health Inequality Impact Assessment:	

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Area	Actions	Timescales	Link to Equality Objectives	Associated Monitoring	Update
Leadership and Strategy					
Access and Inclusion (for those with protected characteristics)					
Service Delivery					
Recruitment and Workforce Diversity					

TDR Product and Equipment Suppliers

TDR Product and Equipment Suppliers

This section must be reported: **Annually**

Period covered by report:

Provide details of Total Diet Replacement product and equipment suppliers

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

A Reporting Requirements

Annex 3 – Data Format Specification

The Parties acknowledge that the headings and wording/tables below are the tab headings and the wording/tables set out in the Data Format Specification spreadsheet provided to the Provider.

Low Calorie Diet Minimum Data Set Guidance

Low Calorie Diet Minimum Data Set Guidance

- The minimum data set for the Low Calorie Diet pilot programme consists of 3 files; Referrals, Contacts and Health Incidents
- A separate Finance file is also required for invoicing purposes
- Referrals contains all the participant and pathway data. Records are updated throughout the pathway, up to discharge
- Contacts contains 1 row for every planned session or engagement in line with the minimum episodes of engagement as defined in the spec. For example, a SU that completes the programme without a rescue package will have a minimum of 20 rows (regardless of delivery method) by the end of the programme
- If a providers planned standard pathway includes more than the minimum number of sessions as set out in the spec, these should all be submitted in the minimum data set. Please provide standard pathway details to the email address below
- For SU's on a face to face delivery method, anything outside the delivery of sessions (or catch up sessions) should not be submitted including follow up calls or digital engagements
- If a participant takes part in a rescue package, additional rows should be added to document each weekly session that is booked to take place during the rescue package.
- For digital contracts the number of engagements that take place within the timeframe should be included on the appropriate row. All Digital engagements will fall into a digital session engagement period
- See Digital Engagement Periods tab for example of digital session engagement periods
- Health Incidents contains details of side effects and adverse events reported by participants
- Submissions include all data from the commencement of the programme to the end of the most recent month. For example in September 2021 data from 1 September 20 to 31 August 21 is submitted
- There are 2 submissions each month; version 1 is due by 5pm on working day 10, version 2 is due by 5pm on working day 20
- Submissions are made via the Digital Landing Portal (DLP). For more information and to get set up on the DLP please visit <https://digital.nhs.uk/services/data-landing-portal>
- The DLP recipient organisation is DSCRO South (South Collaborative)
- Please send any queries to scwcsu.lcdpilot@nhs.net and scwcsu.healthieryou@nhs.net

Key

The following colours have been used to highlight changes made to the previous version of the MDS

- Field or entry no longer used. We are unable to delete fields due to historic data so entries to retired fields should be null. Retired entries (codes) should not be used
- Change to existing field or entry (code) or expansion of existing guidance
- New field or entry (code)

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MDS Referrals

Unique Field	Field name	Format	Codes	Data Values	Time of data	Additional information
	Administrative data					
R001	Date_of_Referral	DATEYYYY-			Point of referral	The date the referral is received by provider
R088	Source_of_Referral	an6 (6 char)	1 2	Referral from GP Transfer		Transfer to be used when transferring from one contract to another, whether within a provider or to a different provider
R002	Unique_Referral_ID	an12 (as example)				Unique id within provider
R003	Organisation_code_of_referrer	an6 (6 char)				The code of the referring organisation. In most cases this is a NHS organisation code. If the referral is from a private organisation without a national code then providers should develop a unique code for each organisation. For transfers, the organisation code of the transferring provider should be entered here
R004	Registered_practice_code	an6 (6 char)				The code of the participant's GP practice
R005	Organisation_code_of_LCD_provider	an8				Code allocated to provider of LCD by NHS Digital https://digital.nhs.uk/services/organisation-data-service
R006	NHS_Number	nnnnnnnn				NHS number is mandatory.
R007	Date_of_referral_HbA1c_reading	DATEYYYY-MM-DD				HbA1c reading provided at referral. All referrals should have a referral HbA1c reading within 12 months prior to referral to the LCD Programme. It is expected that submitted HbA1c reading will be 87 mmol/mol or lower (although obviously not all of these would be considered eligible for the service). Values outside of this range may not be used in analysis. If there is any concern that HbA1c may have changed since last measured, such that repeat testing may indicate that the individual would not be eligible for the LCD programme at present, HbA1c should be rechecked before referral is considered.
R008	Referral_HbA1c_reading	int				
R009	Height	numeric	n.nn	[In metres]		The height of the person in metres. It is expected that most heights submitted will fall within the range 1m - 2.5m. Values outside of this range may not be used in analysis.
R010	Date_of_referral_weight_measurement	DATEYYYY-MM-DD		DATE		Referral weight must be taken within 12 months prior to referral date to be eligible. Self-measured weight is acceptable for referral. If this cannot be obtained, a clinic-measured value within the last 12 months may be used, provided there is no concern that weight may have reduced since last measured such that the individual would not be eligible for the LCD programme at present
R011	Referral_weight_measurement	numeric	nnn.nn	[Kilograms]		
R147	On_Hold_Eligibility_Check	an1	Y	Yes		To be used when eligibility information is missing or needs to be checked. Once eligibility information is complete, field can be null
R150	Date_Eligibility_Complete	DATEYYYY-				The date eligibility information is complete
R012	Family_Name	an68				Name, address and email and telephone should only be submitted if the participant agrees to be contacted for evaluation purposes.
R013	Given_Name	an68				
R014	Address_Line_1	an68				5 lines available but only 3 required. However email or telephone can be collected instead of postal address if preferred.
R015	Address_Line_2	an68				
R016	Address_Line_3	an68				
R017	Address_Line_4	an68				
R018	Postcode	an8				Postcode is mandatory for all participants.
			ZZ99	No fixed abode		

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R018	Email	en63			
R020	Telephone	en10			
R021	Date_of_Birth	DATE YYYY-			The date of birth of the participant.
R022	Is_Service_User_on_Learning_Disability_Register	en1	Y Yes N No X Not known		Whether the participant has been recorded on the learning disability register at their general practice. The register is produced by the practice from diagnostic information and therefore participants may not know that they are on the register. This information should only be collected from referrers / General Practices and not from the participant.
R023	Is_Service_User_on_SMI_Register	en1	Y Yes N No X Not known		Whether the participant has been recorded on the Serious Mental Illness register at their general practice. The register is produced by the practice from diagnostic information and therefore participants may not know that they are on the register. This information should only be collected from referrers / General Practices and not from the participant.
R024	Sex	en1	1 Male 2 Female 3 Indeterminate Z Not Stated (Person asked but declined to provide a response) X Not known / not recorded		The participant's sex. Indeterminate means "unable to be classified as either male or female" - this may also be known as intersex
R025	Ethnicity	en2	White A White British or white Mixed British B White Irish C Any other white background Mixed D White and Black Caribbean E White and Black African F White and Asian G Any other mixed background Asian or Asian British H Indian J Pakistani K Bangladeshi L Any other Asian background Black or Black British M Caribbean N African P Any other black background Other Ethnic Groups R Chinese S Any other ethnic group Z Not Stated 99 Not Known		The ethnicity of the participant, as specified by the participant. "Not Stated" should be used where the participant has been given the opportunity to state their ethnic category but chose not to. "Not known" should only be used when the participant has not been asked. This is required to assess eligibility with regards to BMI range.
R026	Date_diagnosed_with_Type_2_Diabetes	DATE YYYY-			Individual must have been diagnosed within the last 5 years prior to referral date to be eligible for programme
R027	Medication_discussed	en1	Y Yes N No X Not known		Participant should have discussed medication changes with their GP, if confirmed mark as "Yes" If no such discussion has taken place, mark as "No" and defer the start date. This is required for the Individual Assessment. Not known should be used as a temporary default entry until relevant information is captured.
R028	Confirmation_of_Medication_eligibility	en1	Y Yes N No - participant discharged X Not known		Confirmation that the participant has agreed with the referrer, as part of their medication review, that they will cease taking sulphonylureas / meglitinides / SGLT2 inhibitors prior to commencement of TDR. Not known should be used as a temporary default entry until relevant information is captured.
R029	Taking_diabetes_medication	en1	Y Yes N No X Not known		Whether the participant is taking diabetes medication on referral. This is required to know what the HbA1c eligible range is
R030	Taking_blood_pressure_lowering_meds	en1	Y Yes N No X Not known		Whether the participant is taking blood pressure lowering medication on referral. If so, a blood pressure check must be done regularly whilst on the programme. Not known should be used as a temporary default entry until relevant information is captured.
R089	Refers_Blood_Pressure_Systolic_and_Diastolic	us(wh)71		Example: 120/80	If date has not been provided, entry can be null
R090	Date_of_Refers_Blood_Pressure_Measurement	DATE YYYY-			This is only required for those who are on blood pressure lowering medication.
R032	Metformin	en1	Y/N		Metformin
R033	Sulphonylureas	en1	Y/N		Gliclazide, Glibenclamide, Glinetipride Must NOT be taken during TDR phase - risk of hypoglycaemia
R034	Meglitinides	en1	Y/N		Repaglinide, Nateglinide Must NOT be taken during TDR phase - risk of hypoglycaemia
R035	Pioglitazone	en1	Y/N		Pioglitazone
R036	PP4_inhibitors_(glitins)	en1	Y/N		Liraglutin, Albiglutin, Sitagliptin, Saxagliptin, Victoza, Victoza
R037	SGLT2_inhibitors_(flozins)	en1	Y/N		Dapagliflozin, Canagliflozin, Empagliflozin, Ertugliflozin Must NOT be taken during TDR phase - risk of ketoacidosis
R038	GLP1_analogues_(tides)	en1	Y/N		Ertugliflozin, Dulaglutide, Liraglutide, Lixisenatide, Semaglutide
R033	Acarbose	en1	Y/N		Acarbose
Assessment of Health Inequalities					
R040	Date_of_initial_contact_attempt	DATE YYYY-MM-DD			Before IA and after referral
R041	Method_of_initial_contact_attempt	in1/en1	1 Letter 2 Telephone 3 Text 4 E-mail 5 In person		The communication method by which a participant is contacted to attend an Individual Assessment.
R042	Date_of_initial_contact_attempt2	DATE YYYY-			In the event of no response, make an attempt to contact the participant at least another 2 times, using at least 2 different methods of contact
R043	Method_of_contact_attempt2/Method_of_contact_attempt2	in1/en1	1 Letter 2 Telephone 3 Text 4 E-mail		The communication method by which a participant is contacted to attend an Individual Assessment.

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R044	Date_of_initial_contact_attempt_3	DATEYYYY-	5	In person			
R045	Method_of_contact_attempt_3	int/an/1	1	Letter			In the event of no response, make an attempt to contact the participant at least another 2 times, using at least 2 different methods of contact. This is the communication method by which a participant is contacted to attend an Individual Assessment.
			2	Telephone			
			3	Text			
			4	E-mail			
			5	In person			
R046	Date_of_Acceptance_to_take_part_in_programme	DATEYYYY-MM-DD					Once a person has agreed to participate in the programme this should be populated with the date that they accept. If person does not accept, has yet to accept or is never able to be contacted this will remain blank, and if appropriate the participant should be discharged with a date of discharge and reason for discharge completed. If the person declines the IA this should remain blank and the reason for decline
R047	Reason_for_declining	int/an/1	1	No reason given			The reason given by the person for declining to attend an Individual Assessment. Please refer to the Service Specification and any other guidelines from NHS England regarding the eligibility criteria. Date of acceptance should remain blank if a person declined the service. If a participant withdraws after this stage the decline reason should remain blank, and the most appropriate discharge reason used (see below for further details)
			2	Unable to commit time			
			3	Inconvenient time			
			4	Inconvenient location			
			5	Not motivated at this time			
			6	Other			
R048	Religion	an/1	A	Bahai	IA – provider to collect		A participant's religious or other belief system affiliation. Where the participant has been asked but they are unsure "Other" should be used. "Not known" should only be used when the participant has not been asked. Religion is a protected characteristic so is collected for equality and monitoring equity of access purposes.
			B	Buddhist			
			C	Christian			
			D	Hindu			
			E	Jain			
			F	Jewish			
			G	Muslim			
			H	Pagan			
			I	Sikh			
			J	Zoroastrian			
			K	Other			
			L	None			
			M	Declines to Disclose			
			N	Patient Religion Unknown			
R049	Does_the_Service_User_have_a_disability	an/1	1	Yes			Whether the participant has a disability. This can be where they have been diagnosed as disabled, or they consider themselves to be disabled.
			2	No			
			3	Not Stated (Person asked but declined to provide a response)			
			4	Not known			
R050	Behaviour_and_Emotional	an/1	Y/N	Behaviour and Emotional			The participant's disabilities. This should only be completed if the participant has said "Yes" to "Does the participant have a disability?" Each of these fields must be completed with either a "Y" for "Yes", or a "N" for "No". The participant can say "Yes" to more than one disability.
R051	Hearing	an/1	Y/N	Hearing			
R052	Manual_Dexterity	an/1	Y/N	Manual Dexterity			
R053	Memory_or_ability_to_concentrate_learn_or_understand_(Learning_Disability)	an/1	Y/N	Memory or ability to concentrate, learn or understand (Learning Disability)			
R054	Mobility_and_Gross_Motor	an/1	Y/N	Mobility and Gross Motor			
R055	Perception_of_Physical_Danger	an/1	Y/N	Perception of Physical Danger			
R056	Personal_Self_Care_and_Continence	an/1	Y/N	Personal, Self-Care and Continence			
R057	Progressive_Conditions_and_Physical_Health_(such_as_HIV_cancer_multiple_sclerosis_fits_etc)	an/1	Y/N	Progressive Conditions and Physical Health (such as HIV, cancer, multiple sclerosis, fits etc.)			
R058	Sight	an/1	Y/N	Sight			
R059	Speech	an/1	Y/N	Speech			
R060	Other	an/1	Y/N	Other			
R061	Is_Service_User_a_smoker	an/1	1	Smoker			Current smoker: Adults who smoke cigarettes now adays. Ex-smoker: Adults who used to smoke cigarettes regularly but no longer do so. http://content.digital.nhs.uk/catalogue/PUB17526/stat-smok-eng-2015-rep.pdf
			2	Ex-smoker			
			3	Non-smoker			
			Z	Not Stated (Person asked but declined to provide a response)			
			X	Not known			
R062	Is_the_Service_User_happy_to_receive_the_service_in_English	an/1	Y	Yes			
			N	No			
R063	Preferred_language	int	1	English			What language would the participant have preferred the programme to be delivered in?
			2	Arabic			
			3	Bengali			
			4	British Sign Language			
			5	Chinese			
			6	Farsi			
			7	Gujarati			
			8	Hindi			
			9	Kurdish			
			10	Lithuanian			
			11	Nepali			
			12	Pakistani			
			13	Polish			
			14	Punjabi			
			15	Slovak			
			16	Somali			
			17	Tamil			
			18	Turkish			
			19	Urdu			
			20	Other			

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R064	Preferred_language_Other	freetext (50)			If Preferred Language is Other - 20 then please specify the additional language here. This should only be used where the preferred language is not one of the 19 already listed.
R065	Delivered_language	int	1 English 2 Arabic 3 Bengali 4 British Sign Language 5 Chinese 6 Farsi 7 Gujarati 8 Hindi 9 Kurdish 10 Lithuanian 11 Nepali 12 Pakistani 13 Polish 14 Punjabi 15 Slovak 16 Somali 17 Tamil 18 Turkish 19 Urdu 20 Other		What language was the programme delivered in?
R066	Delivered_language_Other	freetext (50)			If Delivered Language is Other - 20 then please specify the additional language here. This should only be used where the delivered language is not one of the 19 already listed.
R067	Consent_for_future_contact_for_evaluation	an1	Y Yes N No (blank) Not Recorded		The person agrees to be contacted in the future to take part in the evaluation of LCD.
R068	Confirmation_of_eligibility	an1	Y Yes N No X Not known		Confirm that the participant remains eligible for LCD TDR. Please refer to the Service Specification and any other guidelines from NHS England regarding the eligibility criteria. Not known should be used as a temporary default entry until relevant information is captured.
R091	Date_of_Confirmation_of_Eligibility	DATEYYYY-MM-DD			The date the participant's eligibility was confirmed. If SU choice means there's a gap between IA and TDR start, the date the SU's eligibility was re-confirmed prior to TDR start should be provided. If multiple dates apply, the latest should be provided.
R093	Date_of_Individual_Assessment_Attendance	DATEYYYY-MM-DD			The date the participant attended/participated in the Individual Assessment. If a planned IA was not attended, enter the actual date of attendance once it has been attended.
R092	Delivery_Method_of_Individual_Assessment		1 1:1 in person 2 Remote		The method of delivery for the individual assessment applies to Framework 1 face to face delivery only Not applicable to wave 1 and 2 contracts and should be NULL.
R093	Delivery_Method_Choice		1 1:1 in person 2 Digital		The choice of delivery method selected by the participant Not applicable to wave 1 and 2 contracts and should be NULL.
R070	SU_agrees_attend_diabetes_review_appts_at_GP_practice_whether_remission_is_achiev	an1	Y N		
R071	SU_notify_GP_practice_of_any_unexpected_or_concerning_symptoms_which_are_urgent	an1	Y N		
R072	SU_will_notify_GP_practice_if_they_disengage_or_drop_out_before_the_end_of_the_inte	an1	Y N		
R073	Service_user_has_no_known_allergies_to_the_ingredients_of_the_issued_TDR_products	an1	Y N		Yes - the participant does not have any known allergies to TDR product ingredients No - the participant does have known allergies to TDR product ingredients
R074	Date_of_Individual_Assessment_booking_attempt_1_following_non-attendance	DATEYYYY-MM-DD		If needing to rebook IA	In the event of non-attendance, make an attempt to re-book at least 3 times, using at least 2 different methods of contact.
R075	Method_of_contact_attempt_1_following_non-attendance	an1/int	1 Letter 2 Telephone 3 Text 4 E-mail 5 In person		This is the communication method by which an participant is contacted to re-book the session.
R076	Date_of_Individual_Assessment_booking_attempt_2_following_non-attendance	DATEYYYY-MM-DD			In the event of non-attendance, make an attempt to re-book at least 3 times, using at least 2 different methods of contact.
R077	Method_of_contact_attempt_2_following_non-attendance	an1/int	1 Letter		This is the communication method by which an participant is contacted to re-book the session.

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				2 Telephone		
				3 Text		
				4 E-mail		
				5 In person		
R078	Date_of_Individual_Assessment_booking_attempt_3_following_non-attendance	DATEYYYY-MM-DD				In the event of non-attendance, make an attempt to re-book at least 3 times, using at least 2 different methods of contact.
R079	Method_of_contact_attempt_3_following_non-attendance	an1int		1 Letter		This is the communication method by which an participant is contacted to re-book the session.
				2 Telephone		
				3 Text		
				4 E-mail		
				5 In person		
R149	On_Hold_Waiting	an1	Y	Yes		To be used when a participant is waiting for a particular group or delivery method (eg. a particular language or in person to resume). Waiting times as per the service specification apply.
R080	Planned_date_of_commencement_of_TDR	DATEYYYY-MM-DD			Starting the programme	The date that the participant and provider planned for the participant to begin TDR.
R081	Actual_date_of_commencement_of_TDR	DATEYYYY-MM-DD				The date that the participant commenced TDR as confirmed by the provider. It may be the same as the planned date, or different if the SU did not begin on the planned day after all.
R094	Baseline_Weight	numeric	nnn.nn	[Kilograms]		The weight captured at the first session/engagement within the TDR phase. If this doesn't fall on the TDR start date then the weight captured closest to this date (within 7 days either side) should be provided.
R140	Actual_date_of_commencement_of_FR	DATEYYYY-MM-DD			During the	The date that the participant commenced FR as confirmed by the provider
R141	Actual_date_of_commencement_of_WM	DATEYYYY-MM-DD				The date that the participant commenced WM as confirmed by the provider
R142	Rescue_Package_Start_Date	DATEYYYY-MM-DD				If a participant is eligible for a rescue package and accepts the offer, the date the rescue package is started
R143	Rescue_Package_End_Date	DATEYYYY-MM-DD				If a participant is eligible for a rescue package and accepts the offer, the date the rescue package ends. The maximum duration for a rescue package is 28 days.
R095	Pause_Start_Date	DATEYYYY-MM-DD				Please see service specification for further details relating to a pause
R096	Pause_End_Date	DATEYYYY-MM-DD				Please see service specification for further details relating to a pause
R082	Date_of_Digital_Registration	DATEYYYY-MM-DD			Progressing through the Digital	The date that the digital participant registers on the digital platform. This will be blank for one to one and group contracts. This is required for digital MS1 payment.
R083	Date_of_TimeStamped_Log_In_MS2	DATEYYYY-MM-DD				The date at which the participant logs in to the digital platform in the MS2 period. This will be blank for one to one and group contracts. This is required for digital MS2 payment.
R084	Date_of_TimeStamped_Log_In_MS3	DATEYYYY-MM-DD				The date at which the participant logs in to the digital platform in the MS3 period. This will be blank for one to one and group contracts. This is required for digital MS3 payment.
R097	GP_notified_of_referral_receipt	an1	Y	GP notification sent		
			N	GP notification not sent		
R098	Date_GP_notified_of_referral_receipt	DATEYYYY-MM-DD		[Date]		
R099	GP_notified_of_IA_Completion	an1	Y	GP notification sent		
			N	GP notification not sent		
R100	Date_GP_notified_of_IA_Completion	DATEYYYY-MM-DD		[Date]		
R101	GP_notified_of_TDR_Start	an1	Y	GP notification sent		
			N	GP notification not sent		
R102	Date_GP_notified_of_TDR_Start	DATEYYYY-MM-DD		[Date]		
R103	GP_notified_of_TDR_End	an1	Y	GP notification sent		
			N	GP notification not sent		
R104	Date_GP_notified_of_TDR_End	DATEYYYY-MM-DD		[Date]		
R105	GP_notified_of_pause	an1	Y	GP notification sent		

R106	Date_GP_notified_of_pause	DATEYYYY-MM-DD	N	GP notification not sent		
				[Date]		
R107	GP_notified_of_programme_completion	an1	Y	GP notification sent		
			N	GP notification not sent		
R108	Date_GP_notified_of_programme_completion	DATEYYYY-MM-DD		[Date]		
R087	GP_notified_of_discharge	an1	Y	GP notified of completion status and outcomes		
			N	GP not notified of completion status and outcomes		
R109	Date_GP_notified_of_discharge	DATEYYYY-MM-DD		[Date]		The date notification of discharge was sent to GP
R085	Date_of_discharge	DATEYYYY-MM-DD		[Date]	At discharge	The date the participant was discharged
R086	Reason_For_Discharge	int/an2		1 Participant completed the programme		A reason for discharge should be selected for anyone discharged, whether they have started the programme or not. Please choose the most appropriate reason from the list. 'Other' should be used as a last resort only when the preceding options are not applicable.
				2 Incomplete - participant taking incompatible medication		1 - finishes the programme (1 year). If final session is missed reason 8 should be used
				3 Incomplete - participant did not respond within 1 month of referral		2 - usually identified before IA but would be known at IA at the latest
				4 Incomplete - participant declined service prior to starting		3 - only applicable before date_of_acceptance
				5 Incomplete - participant accepted IA invitation but has not attended within 2 months of contact		4 - only applicable before IA attended (Reason_for_Decline also required)
				6 Incomplete - participant not eligible on contact		5 - only applicable before IA attended
						6 - usually identified before IA but would be known at IA at the latest. Please provide reason for ineligibility in additional fields provided
				12 Incomplete - missing information meaning eligibility cannot be confirmed		12 - only applicable before IA attended
				13 Incomplete - missing other required information (not eligibility related)		13 - only applicable before IA attended

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		7	Incomplete - participant has not attended first intervention session within 6 months of referral OR after 3 suitable offers		7 - only applicable after IA and before first session has been attended
		8	Incomplete - participant disengaged during programme		8 - only applicable after TDR start date
		14	Incomplete - participant unable to comply		14 - only applicable after TDR start date
		9	Incomplete - participant became pregnant		9 - applicable at any time in the pathway
		10	Incomplete - adverse event		10 - only applicable after TDR start date
		15	Incomplete - participant did not want to continue with chosen delivery method		15 - only applicable to framework 1 and after TDR start date
		16	Incomplete - participant unable to restart following pause		16 - only applicable following a pause, pause start date should also be present (please see service spec for more details on pauses)
		17	Transferred to other provider / contract		17 - to be used when transferring from one contract to another, whether within a provider or to a different provider
		11	Incomplete - other		11 - only to be used as a last resort if any of the above list do not cover the reason, applicable at any time in the pathway
					If a SU is discharged as ineligible (Reason_For_Discharge = 6) please provide reason(s) for ineligibility. More than 1 can be provided for each SU, if applicable. These should only be used where the data has been provided and it confirms the SU is ineligible, not if data is missing meaning eligibility cannot be confirmed.
R110	Ineligible_Age		Y / Null		Age outside permitted range
R111	Ineligible_Date_of_Diagnosis		Y / Null		Date of diagnosis outside permitted range
R112	Ineligible_BMI		Y / Null		BMI outside permitted range
R113	Ineligible_HbA1c		Y / Null		Date or reading outside permitted range
R114	Ineligible_Diabetes_Review_Attendance		Y / Null		Service user has not attended last diabetes review
R115	Ineligible_Insulin		Y / Null		Service user is currently taking insulin
R116	Ineligible_Pregnant_Breastfeeding		Y / Null		Service user is currently pregnant, planning to become pregnant within next 6 months or currently breastfeeding
R117	Ineligible_Comorbidty		Y / Null		Service user has at least 1 of the comorbidities listed in the service specification
R118	Ineligible_Bariatric_Surgery		Y / Null		Service user has had bariatric surgery
R119	Ineligible_Understanding_or_Meet_Demands		Y / Null		Service user is unable to understand or meet the demands of the programme
R120	Ineligible_Medication_Changes_in_Writing		Y / Null		Service user does not have medication changes provided in writing
R121	Ineligible_ReReferral		Y / Null		Service user has previously been referred to the programme and started TDR
R122	Ineligible_Other		Y / Null		Service user is ineligible for a reason not listed above

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MDS Contacts

All Contracts - Enter 1 row for every planned session or engagement in line with the minimum episodes of engagement as defined in the spec. See Guidance tab for further information						
Unique Field ID	Field name	Format	Code	Data Values	Time of Data Collection	Additional Information
C088	Unique_Referral_ID	an12 (as example)			For every core session/engagement	The same unique referral id as used for the participant in the Referral dataset.
C089	Organisation_code_of_LCD_provider	an8				The LCD provider code.
C090	Phase_of_intervention	an35	TDR	TDR		The provider should indicate what stage of the programme the participant is in for every session/engagement. Where a participant is in Weight Maintenance but has been given a rescue package at the last session/engagement, the provider should select WMRP to indicate that the participant is using a rescue package.
			FR	Food Reintroduction		
			WM	Weight Maintenance		
			WMRP	Weight Maintenance - Rescue Package		If the phase of the programme deviates from the plan, the phase provided should reflect the phase the
C091	Date_of_Session_or_Engagement	DATEYYYY-MM-DD		[Date]		The date of the booked session / the date the digital engagement occurs. For digital, the date should be provided of the engagement with a health coach ('Conversation With Health Coach' or 'Exchange of Messages With Health Coach'). If more than 1 has taken place within the engagement period, please provided the latest
C001	Session_or_Engagement_Number	int/an2				Sessions should be numbered 1-20. Sessions that take during a rescue package should have the phase_of_intervention coded as WMRP and the session prefixed with R. Rescue package sessions start at 1 (eg. R1, R2, etc). Where a core sessions/engagement takes place during a rescue package and the weekly rescue package session is incorporated into this, the core session number should take precedence and the phase coded as WMRP. For Digital anything that takes place before engagement period 1 is session 0, anything that takes place after week 54 is session 100.
C092	Attendance	int/an1	1	Attended		For digital, if an engagement with a coach (Conversation with Health Coach or Mentor or Exchange of messages with a health coach or mentor) has not taken place in the digital engagement period, the attendance should be 2 - did not attend
			2	Did not attend		
			3	Cancelled (by provider)		
C093	Facilitator_Qualification	int/an2	11	Nutritionist		The primary qualification (as relevant to the programme) of the facilitator.
			12	Health Professional (Nurse)		For digital engagements, if more than 1 engagement has taken place within the engagement period with different facilitators, please submit the qualification that appears first in the list provided.
			13	Health Professional (Health Trainer)		If a session or engagement was not attended, the facilitator qualification of the planned session should be provided.
			14	Health Professional (Dietician)		Option 10 is no longer a valid entry.
			15	Health Professional (Physiotherapist)		
			16	Health Practitioner (Practitioner Psychologist)		
			17	Physical Activity Professional		

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			18	Other (paid)	
			19	Other (volunteer)	
			10	None (digital engagements)- no longer used	
C094	Type_of_Contact	int/an1	1	In person group	This should be completed for every contact. For wave 1 and wave 2 contracts, this should usually match the delivery method assigned at contract level. Alternative delivery mechanisms may be used to support delivery and participant engagement eg. a planned 1:1 session on group delivery as part of the pathway For framework 1 contracts, this should match the delivery method selected by the SU for that session (or catch up session) (option 2, 5 or 6 for 1:1 or option 7 for digital). In person relates to physical face to face; remote telephone is traditional phone calls; remote web is video calls (teams, zoom etc.)
			2	In person 121	
			3	Remote (telephone) group	
			4	Remote (web) group	
			5	Remote (telephone) 121	
			6	Remote (Web) 121	
			7	Digital	
C095	Length_of_Contact	int		[In minutes]	Digital is any interactive content (eg. watch a video or take a quiz) Length in minutes of session. Only required for face to face delivery (remote group, in person group, remote 1:1, in person 1:1)
C096	Type_Of_Engagement_NLU	int/an2	1	Conversation with Health Coach or Mentor	No longer used
			2	Participation in an online group Conversation	
			3	Exchange of messages with a health coach or mentor (min message limit applies)	
			4	Accessing education materials via digital platform	
			5	Personalised Goal setting or Action Plan agreed	
			6	Watch a Video or Complete A Quiz	
			7	Use of tracking technology with associated data logged	
			8	Recording of achievement against set goals	
			9	Method A	
			10	Method B	
C002	Engagement_Conversation_With_Health_Coach_Number	int			Only required to be completed for digital participants. Count of all engagements during engagement period
C003	Engagement_Conversation_With_Health_Coach_Length	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C004	Engagement_Exchange_of_Messages_With_Health_Coach_Number	int			Only required to be completed for digital participants. Count of all engagements during engagement period. Minimum message limit for exchange of messages with health coach or mentor is 3 each way within 24 hour period.
C005	Engagement_Exchange_of_Messages_With_Health_Coach_Length	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C006	Engagement_Participation_in_Online_Group_Number	int			Only required to be completed for digital participants. Count of all engagements during engagement period
C007	Engagement_Participation_in_Online_Group_Length	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C008	Engagement_Access_Education_Materials_Number	int			Only required to be completed for digital participants. Count of all engagements during engagement period
C009	Engagement_Access_Education_Materials_Length	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C010	Engagement_Goal_Setting_or_Action_Plan_Number	int			Only required to be completed for digital participants. Count of all engagements during engagement period
C011	Engagement_Goal_Setting_or_Action_Plan_Length	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C012	Engagement_Video_or_Quiz_Number	int			Only required to be completed for digital participants. Count of all engagements during engagement period
C013	Engagement_Video_or_Quiz_Length	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C014	Engagement_Tracking_Technology_Data_Length	int			Only required to be completed for digital participants. Count of all engagements during engagement period
C015	Engagement_Tracking_Technology_Data_Number	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C016	Engagement_Goal_Recording_Number	int			Only required to be completed for digital participants. Count of all engagements during engagement period
C017	Engagement_Goal_Recording_Length	int		[In minutes]	Only required to be completed for digital participants. Cumulative length of all engagements during engagement period
C144	TDR_Consumption	an1	1	Full TDR	Captures TDR product consumption Only applicable during TDR, FR and WMRP phases or following a Rescue Package (if required to record wean off products) If more than 1 applies since the last session please select the one that applies for majority of days between the sessions Full TDR - TDR has been consumed as defined in the service specification Partial TDR - anything less than full adherence to the guidance defined in the spec either due to the participant being in the food reintroduction phase or for another reason in the list provided. If selecting option 3, the number of full days TDR has been missed can be entered in the next question (#99) Please see service specification relating to the contract area regarding partial rescue packages
			2	Partial TDR - FR/WMRP	
			3	Partial TDR - participant unable to fully comply	
			4	Partial TDR - adverse event	
			6	No TDR - FR	
			5	No TDR - adverse event	No TDR due to completing weaning off products before the end of FR phase
C097	Number_of_days_on_TDR_since_last_contact_or_session(any_days_where_TDR_used_at_all)_NLU	int			field no longer used (NLU) entry should be null
C098	Number_of_meals_that_replaced_TDR_per_day(on_average)since_last_contact_or_session_NLU	int			field no longer used (NLU) entry should be null
C099	Number_of_days_of_TDR_missed_since_last_contact_or_session	int			This should be completed for every contact in TDR, FR and WMRP If a participant was planned to take TDR products but missed an entire day, enter the number of days missed here. If they are in FR and were not planned to take any products 0 should be entered
C115	Fibre_supplements_provided_for_use_until_next_planned_session_NLU	an1	Y	Fibre supplement has been provided to participant	No longer used
			N	Fibre supplement has not been provided to participant	
C116	Previously_supplied_fibre_supplements_consumed	an1	Y	Service user confirms fibre supplement has been used (entry no longer used)	Y - is no longer an acceptable response to this question and should not be used.
			F	Full	Full - The full recommended amount of fibre has been consumed (7g per day (usually issued in 2 x 3.5g portions

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			P	Partial		of lspaghula Husk/Psyllium Husk/Hyboga()) during the TDR Phase).
C104	Weight	nnn.nn	N	None	(Kilograms)	Partial - Fibra has been consumed but less than the recommended amount
						The weight of the patient in kilograms. Essential data collection points are articulated in the specification document. If there is a delay in obtaining weight prior to submission 599 can be entered as a temporary measure until actual weight can be obtained. Once correct weight obtained it should be added for next submission
C105	Type_of_weight_measura	an1	O	Objective		For digital, if more than 1 weight has been captured in the engagement period please provide the latest. If more
			S	Self-reported		Whether the weight of the participant has been measured by the provider, or by the participant themselves and self-reported.
C106	Date_of_Weight_Measurment	DATE YYYY-MM-DD				The date of the weight measurement
C109	Capillary_blood_glucose_test_result	nn.nn				For digital, if more than 1 blood glucose measurement has been captured in the engagement period please provide the latest
C110	Capillary_blood_test_measurement_type	an1	O	Objective		Whether the finger prick test was done by the provider, or done by the participant and then self-reported.
			S	Self-reported		
C107	Blood_pressure_(systolic_and_diastolic)	varchar(7)			Example: 120/80	This is only required for those who are on blood pressure lowering medication.
						For digital, if more than 1 blood pressure measurement has been captured in the engagement period please provide the latest
C108	Blood_Pressure_measurement	an1	O	Objective		Whether the blood pressure of the participant was measured by the provider, or measured by the participant themselves and then self-reported.
			S	Self-reported		
C100	Rescue_package_offered_since_last_session_of_engagement	an1	N	Not applicable		This should be completed for every contact.
			A	Not offered - adverse event		Please see service specification for rescue package eligibility criteria
			Y	Offered - accepted		Rescue package is offered (where applicable) at a WM session (Phase_of_intervention). If accepted submit Y on session that it was accepted.
			D	Offered - declined		If a rescue package is offered in between core sessions/engagements, the response should be added to the next session/engagement.
			P	Offered - declined full, accepted partial		Any sessions that take place during the RP have the phase of intervention code WMRP and this question will be N.
			M	Offered and accepted but Medication review required		Each participant can only have 1 rescue package (if the eligibility criteria is met)
						Rescue package dates are entered in the referral file.
						Not applicable - no weight gain (or less than the required amount), already accepted a Rescue Package, taking incompatible medication
						Not offered - adverse event - the participant is eligible for rescue package but it is not appropriate to offer due to an adverse event that occurred during the TDR phase meaning restarting TDR products is not appropriate
						Offered - accepted - the participant has been offered a rescue package and accepted the offer
						Offered - declined - the participant has been offered a rescue package and declined the offer (please supply reason for decline in next question)
						Offered - declined full, accepted partial - the participant has been offered a rescue package and declined a full rescue package, but accepted a partial (applicable to framework 1)
						Medication review required - the participant has been offered a rescue package and accepted however they are taking (or are unsure if they are taking) sulphonylureas / meglitinides / SGLT2 inhibitors therefore a
C145	Rescue_Package_Reason_for_Decline	an1	1	Weight gain not deemed significant		The reason given by the participant for declining a Rescue Package.
			2	Will reengage with weight maintenance methods		A participant may decline a rescue package offer more than once and each decline should be captured and applied to closest session/engagement after (if it takes place outside a core session/engagement)
			3	Aversion to TDR products		Please choose the most appropriate reason from the list. 'Other' should be used as a last resort only when the preceding options are not applicable.
			4	Inconvenient time		
			5	Other		
C101	Length_of_rescue_package	int			(Number of days)	The length of time on the rescue package since last session. This should be blank if a rescue package has not been given.
C102	Type_of_rescue_package	an1	P	Partial TDR		Please see service specification relative to the contract area regarding partial rescue packages
			2	Don't know		commencement of rescue package. If the medication has been taken the participant cannot commence with the rescue package.
			3	Medication taken		If the participant doesn't know whether there has been a change in their medication confirmation must be
C113	Presence_of_any_other_diabetes_related_complications_since_last_contact	an1	Y	Participant has other diabetes related complications		The purpose of this is to allow the participant to raise any non-serious adverse events they feel are significant enough to mention. It is not necessary to provide them with a list. If they answer yes, a record should be added
			N	Participant has no other diabetes related complications		New detection of a co-morbidity
C114	Presence_of_any_other_health_complications_since_last_contact	an1	Y	Participant has other health conditions		
			N	Participant has no other health conditions		
C111	Date_of_reschedule_attempt	DATE YYYY-MM-DD			[Date]	If the participant does not attend a session, insert the date of the reschedule attempt.
C112	Method_of_contact	int/an1	1	Letter		This is the communication method by which the participant is contacted to re-book the session.
			2	Telephone		
			3	Text		
			4	E-mail		
			5	In person		

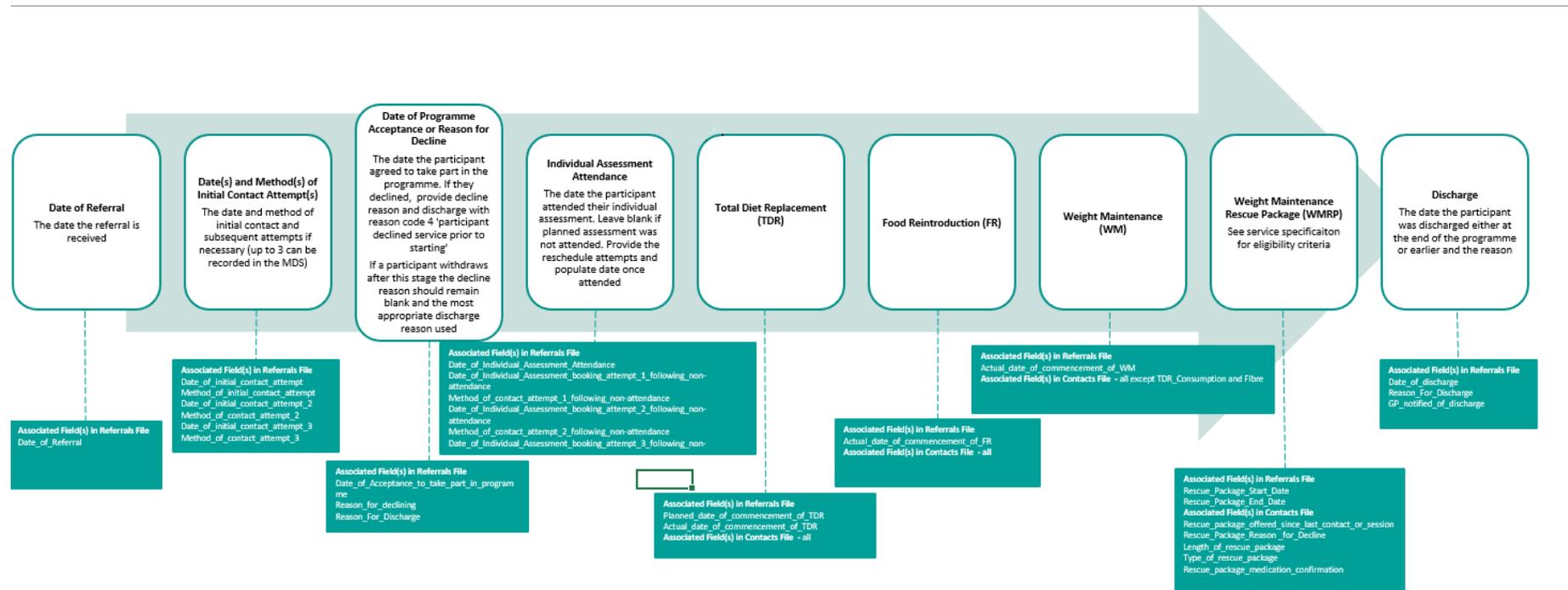
MDS Health Incidents

Each row is a single incident - if a participant has both side effect and adverse event, submit 2 records (one for each incident)						
Unique Field ID	Field name	Format	Code	Data Values	Additional information	
H117	Unique_Referral_ID	an12 (as example)				
H118	Organisation_code_of_LCD_provider	an8				
H137	Date_of_Session_or_Engagement	DATE YYYY-MM-DD			The date of the contact session at which the health incident was reported. If not at a session, the date it was reported	
H119	Type_of_Health_Incident	AN2	S	Side effect	Side effects	
			A	Adverse event	Adverse events as defined in the service spec	
H120	Date_of_health_incident	DATE YYYY-MM-DD			Date side effect or adverse event occurred	
H121	Type_of_side_effect	AN2	1	Constipation	Required entry when Type_of_Health_Incident = S	
			2	Sensitivity to cold	These should be reported when it has been significant enough for the patient to mention and suspected to be a side effect of the programme (not a pre-existing condition) or severe enough to impact their TDR consumption. 'Other' should only be used when none of the other options are suitable. Please do not combine multiple events into 'other'	
			3	Headache		
			4	Dizziness		
			5	Fatigue		
			6	Mood change		
			7	Nausea		
			8	Diarrhoea		
			9	Heartburn / indigestion		
			10	Hair loss		
			11	Blurred Vision		
			13	Other Stomach Complaints		
			14	Skin Conditions		
			15	Illness / infection		
			12	Other		
H138	Type_of_side_effect_other	free text (AlphaNumericSpecial 50)				Where the adverse event is not listed, please provide brief summary. This should only be used where complaint is not already listed. Please ensure no PID entered here
H126	Type_of_adverse_event	an2	1	Myocardial infarction (MI)	Required entry when Type_of_Health_Incident = A	
			2	Stroke	'Other' should only be used when none of the other options are suitable.	
			3	Gall stones	Please do not combine multiple events into 'other'	
			4	Pancreatitis		
			5	Cancer		
			6	Severe allergic reaction		
			8	Eating Disorder		
			9	Fall requiring admission		
			10	Infection / sepsis		including any infection needing hospital admission
			11	Severe constipation / impaction		
			12	Seizure		
			7	Other		

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H139	Type_of_adverse_event_other	free text (AlphaNumericSpecial 200)			Where the adverse event is not listed, please provide brief summary. This should only be used where complaint is not already listed. Please ensure no PID entered here
H127	Fibre_Supplement_pack_provided	AN2	Y	Yes	If additional fibre supplement has been provided in relation to side effect
			N	No	
H128	Date_fibre_Supplement_pack_provided	DATE YYYY-MM-DD			If yes, date provided
H130	Has_the_capillary_blood_glucose_flag_been_triggered	an2	Y	Yes	Please see service specification for thresholds.
			N	No	
H131	Date_capillary_blood_glucose_flag_triggered	DATE YYYY-MM-DD			If yes, date triggered
H132	Has_blood_pressure_flag_been_triggered	an2	H	Yes - high	Please see service specification for thresholds. BP reading meets high threshold for action
			L	Yes - low	BP reading meets low threshold for action
			N	No	
H133	Date_blood_pressure_flag_triggered	DATE YYYY-MM-DD			If yes, date triggered
H124	Serious_adverse_event_NLU	AN2	Y	Yes	Serious unintended health incidents / adverse events / side effects (major)
			N	No	
H125	Date_serious_adverse_event_occurred_NLU	DATE YYYY-MM-DD			If yes, date adverse event occurred
H122	Programme_deintensified	AN2	Y	Yes	Impact of adverse event required programme deintensification
			N	No	
H123	Date_programme_deintensified	DATE YYYY-MM-DD			If yes, date programme de-intensified
H146	Date_programme_reintensified	DATE YYYY-MM-DD			To be completed once de-intensification period has ended
H129	Any_alerts_discussed_with_Medical_Director	an2	Y	Yes	
			N	No	
H134	Number_of_unique_alerts_given_to_primary_care	numeric		[Number]	Alerts sent for all adverse events, all incidents of blood capillary glucose flag or blood pressure flag being triggered. Number entered relates to the alerts sent for the adverse event being reported. If none please submit 0
H135	Date_of_alert_given_to_primary_care	DATE YYYY-MM-DD		[Date]	
H136	Action(s)_taken	free text (AlphaNumericSpecial 200)			Please ensure no PID entered here

Pathway Summary



Digital Engagement Periods

Enter TDR Start Date	01-Jun-22
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Framework 1

Week 1 begins on TDR start date (Actual_date_of_commencement_of_TDR)

Session Number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Week number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Phase	TDR														
Day number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Date	01-Jun-22	02-Jun-22	03-Jun-22	04-Jun-22	05-Jun-22	06-Jun-22	07-Jun-22	08-Jun-22	09-Jun-22	10-Jun-22	11-Jun-22	12-Jun-22	13-Jun-22	14-Jun-22	15-Jun-22
Rescue Package Sessions															

Wave 1 and Wave 2

Week 1 begins the Monday of the week TDR is started

Session Number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Week number	1	1	1	1	1	1	1	2	2	2	2	2	2	2	3
Phase	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR	TDR
Day number	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Date (adjust TDR start date as required)	#####	#####	01-Jun-22	02-Jun-22	03-Jun-22	04-Jun-22	05-Jun-22	06-Jun-22	07-Jun-22	08-Jun-22	09-Jun-22	10-Jun-22	11-Jun-22	12-Jun-22	13-Jun-22
Rescue Package Sessions															

All digital engagements should be included within the relevant Session number, based on when they take place

Any digital engagements that take place before TDR start should be assigned to session '0'

Any digital engagements that take place after the end of week 54 should be assigned to session '100'

Rescue Package sessions should be numbered R1, R2, R3, R4 etc.

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14	14	14	14	14	14	14	14	14	14	14	14	14	14	15	15
25	25	25	26	26	26	26	26	26	26	26	27	27	27	27	27
WM															
173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188
20-Nov-22	21-Nov-22	22-Nov-22	23-Nov-22	24-Nov-22	25-Nov-22	26-Nov-22	27-Nov-22	28-Nov-22	29-Nov-22	30-Nov-22	01-Dec-22	02-Dec-22	03-Dec-22	04-Dec-22	05-Dec-22
R3	R3	R3	R3	R3	R4										

14	14	14	14	14	14	14	14	14	14	14	14	14	14	15	15
25	25	25	26	26	26	26	26	26	26	26	27	27	27	27	27
WM															
173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188
18-Nov-22	19-Nov-22	20-Nov-22	21-Nov-22	22-Nov-22	23-Nov-22	24-Nov-22	25-Nov-22	26-Nov-22	27-Nov-22	28-Nov-22	29-Nov-22	30-Nov-22	01-Dec-22	02-Dec-22	03-Dec-22
R3	R3	R3	R3	R3	R4										

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

B. Data Quality Improvement Plans

Data Quality Indicator	Data Quality Threshold	Method of Measurement	Milestone Date

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

C. Service Development and Improvement Plans

	Milestones	Timescales	Expected Benefit

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

D. Surveys

Type of Survey	Frequency	Method of Reporting	Method of Publication
Friends and Family Test (where required in accordance with FFT Guidance)	As required by FFT Guidance	As required by FFT Guidance	As required by FFT Guidance
National Quarterly Pulse Survey (NQPS) (if the Provider is an NHS Trust or an NHS Foundation Trust)	As required by NQPS Guidance	As required by NQPS Guidance	As required by NQPS Guidance
Staff Survey (appropriate NHS staff surveys where required by Staff Survey Guidance) - the Parties agree that the nationally used NHS staff surveys are not required to be carried out by the Provider as it is not required by the Staff Survey Guidance. Notwithstanding this, the Parties agree that the Commissioner will instruct the Provider of the matters to be covered in a Staff Survey, the frequency and method of reporting and/or publication from time to time during the Term and the Provider agrees to carry out the Staff Survey in accordance with those instructions	As required by The Commissioner	As required by The Commissioner	As required by The Commissioner

SCHEDULE 6 – CONTRACT MANAGEMENT, REPORTING AND INFORMATION REQUIREMENTS

E. Data Processing Services

Not applicable

SCHEDULE 7 – PENSIONS

Not Applicable

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

Contact: england.contractshelp@nhs.net

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