NHS East Kent Clinical Commissioning Groups

Wet Age-Related Macular Degeneration Service

Memorandum of Information

Commercial in Confidence

Version: Final

Reference No: P2014-013

Date Issued: 04 March 2015

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1 Executive summary

1.1 Purpose of this Document

1. This Memorandum of Information (MOI) describes the procurement (the Procurement) of a Wet Age-Related Macular Degeneration Service(WAMD or the Service) by NHS East Kent Clinical Commissioning Groups (the Commissioner) consisting of NHS Ashford Clinical Commissioning Group, NHS Canterbury and Coastal Clinical Commissioning Group, NHS South Kent Coast Clinical Commissioning Group and NHS Thanet Clinical Commissioning Group. NHS Canterbury and Coastal Clinical Commissioning Group is acting as the Lead Commissioner and will be the contract holder on behalf of all members of the Commissioner.

2. The Commissioner is supported and advised in the Procurement by NHS South East CSU (the CSU) and its procurement partner NHS Commercial Solutions (NHSCS).

3. The MOI gives details of:

   - the Procurement and its objectives
   - the Commissioner's service requirements
   - the Procurement process
   - the Procurement commercial framework, and
   - the Procurement governance and administration requirements.

4. The purpose of this MOI is to provide potential Bidders with sufficient information on the Procurement to enable them:

   - To make an informed decision about whether they wish to participate, and
   - To submit an Expression of Interest (EOI).

1.2 Organisation of this document

5. This MOI is organised into the following sections:

Section	***Purpose***
Section 1 - Purpose, structure and next steps for Bidders	Detailing the purpose and organisation of the MOI and the next steps for Bidders.
Section 2 - Introduction and overview	Detailing the background and objectives to the Procurement, the scope of services to be procured, the bidder pool

Section	*Purpose*
	and the factors critical to the success of the Procurement.
Section 3 - Procurement process overview	Detailing the steps involved in the Procurement.
Section 4 - Commercial framework	Detailing the key commercial terms and other legal and contractual arrangements for the Procurement.
Section 5 - Governance and administration	Detailing key governance and administration requirements of the Procurement.

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6. Further important information is contained in the PQQ and its annexes, including:

- A glossary of terms used in the MOI
- The outline timetable for the procurement
- The draft specification of service
- The contract to be signed by the Commissioner and the Provider

1.3 Next Steps for Bidders

7. Bidders wishing to participate in the Procurement must submit a Pre-Qualification Questionnaire (PQQ) response in the manner detailed in section 3.3.3 Expression of Interest.

8. The PQQ response must arrive before:

9. 12:00 noon on Friday 27 March 2015

10. Failure to return a completed PQQ by the deadline above will normally result in the disqualification of the Bidder from participating in this procurement.

2 Introduction and Overview

2.1 Commissioner

11. The service is being commissioned by NHS East Kent Clinical Commissioning Groups consisting of NHS Ashford Clinical Commissioning Group, NHS Canterbury and Coastal Clinical Commissioning Group, NHS South Kent Coast Clinical Commissioning Group and NHS Thanet Clinical Commissioning Group.

12. Further details on the Commissioner can be found on its web sites at:

- www.ashfordccg.nhs.uk
- www.canterburycoastalccg.nhs.uk
- www.southkentcoastccg.nhs.uk
- www.thanetccg.nhs.uk

2.2 Background and context

13. Currently all treatment and monitoring of Wet Age-related Macular Degeneration (WAMD) and Myopic Degeneration with CNV (Myopia CNV) is delivered by acute services, however it has been demonstrated that there is now potential to safely repatriate these patients back to receive treatment and monitoring in primary/community care through appropriate commissioning. This will allow already overburdened acute services to concentrate on treating the other more complex indications for intravitreal therapy such as macular oedema due to diabetes or retinal vein occlusion as well providing a more cost-effective service closer to home for patients.

14. At present, all patients experiencing symptoms or signs of these two macular conditions are required to attend an acute service site for assessment and initiation of a loading dose of 3 intravitreal injections each one month apart. Subsequently every 4-5 weeks they must re-attend for monitoring and decision as to whether they require further injections. If an injection is deemed necessary they must attend the acute site for this – if not they continue to re-attend the acute site every 4-5 weeks for further monitoring indefinitely.

2.3 Aims of the service

15. The aims of commissioning the Service are:

- To respond to what WAMD service users in East Kent have identified as key issues now and in the future
- To ensure that the needs of WAMD service users are integral to current and future delivery of Ophthalmology services in East Kent

- To ensure that the local delivery of WAMD services follows national legislative, policy and good practice guidelines
- To respond to increasing local demand for WAMD services

2.4 Drivers for change

16. An aging population coupled with new treatments and treatment regimes are resulting in:

- Increased waiting times in clinic
- Large numbers of patients per clinic
- Pressured timelines between injections
- Risk of delays

2.5 Objectives of this Procurement

17. The new pathway is expected to follow a community-based two-tier system with providers designated as Tier 1 or 2 dependent level of involvement in the pathway. Potential providers may provide Tier 1 or Tier 2 only or both. Both Tier 1 and Tier 2 services are expected to be a one stop clinic process.

18. The role of each Tier is as follows:

Tier 1 New Patients - Patient assessment and treatment initiation

Tier 2 Follow-up Patients - Monitoring and treatment continuation

The details of each Tier can be found in the service specification.

19. The Commissioner aims to deliver the following outcomes for WAMD service users:

- Reduction in waiting times
- Local service delivery
- Increased choice and control
- Dignity and safety
- Person centred, and needs led approach
- Effective communication
- Independence and quality of life improved

- Service users and carers enabled to shape service delivery.
- An integrated approach ensuring best use of resources

2.6 Scope and structure of this Procurement

2.6.1 Procurement Scope

20. The Procurement covers the provision of a Wet Age-Related Macular Degeneration Service as described in the draft specification included in the PQQ.

2.6.2 Structure

21. This Procurement is structured as multiple lots on the basis of locality. The Commissioner intends to appoint a single Provider for each lot. The Provider for each Lot must have a service delivery capability within the locality covered by that Lot, but may treat patients from all localities covered by the Service.

22. There is no restriction on the number of Lots a bidder may bid for. The Provider for each Lot will be selected without reference to the Bids for any other Lot.

2.7 Bidder Pool

23. The Commissioner wishes to receive responses to the Pre-Qualification Questionnaire (PQQ) from suitably qualified and experienced providers (including NHS organisations, social enterprises, third sector organisations and other providers) with the necessary capacity and capability (or a demonstrable ability to provide the necessary capacity and capability) to provide the range of services in the specification in a safe and effective manner and to meet the critical success factors (CSFs) described below.

24. Bidders may bid in partnership with other organisations such that the Service Supplier may be different to the Bidder.

2.8 Critical Success Factors

25. The Commissioner requires the Provider to meet the following Critical Success Factors (CSFs) throughout the life of the Contract:

- **Quality** – Patient centred services delivered in a safe, friendly and effective manner with by appropriately trained and qualified staff operating to clinical best practices.

- **Access** – The services must be easily accessible by the patient within the Commissioner's area and patients will be given a choice of provider and will be able to change provider.

- **Flexible and Responsive** – The service must be flexible and respond to changing needs

- **Communication and Performance Information** – High-quality communication with commissioners to discuss flexible and innovative approaches. Good quality and regular information must be provided on activity, finance and quality of service provision

- **Value for Money** – The service must provide value for money. This must be demonstrated through the contract performance management system, throughout the life of the contract, and

- **Integration** – Seamless working between the provider and other organisations to provide a joined up approach to improving patient care, and wellbeing.

3 Procurement process overview

26. The Procurement approach, timescale and operational processes are summarised below.

3.1 Procurement approach

27. To ensure operation in a fair and controlled manner, the Commissioner conducts procurements using a web-based system – sometimes referred to as an eSourcing portal. The Commissioner will use this system to make available to providers all documents used during the procurements, and for all communications with participants in the procurements. Providers will also use this system to make their submissions to the Commissioner.

28. Registration and use of the eSourcing portal system is free of charge and places providers under no obligation to participate. It takes approximately 10 minutes to complete registration, which can then be used for any procurement conducted through the system.

29. Once registered, providers may use the system to express their interest in any procurement, and thereafter they will be notified automatically of events throughout the procurement process. Providers can use the system to access the documents for procurements in which they have expressed an interest.

30. The eSourcing portal is provided by BravoSolution. Providers who encounter problems registering on the system should contact the BravoSolution help desk by email at help@bravosolution.co.uk or call UK by telephone on UK number 0800 368 4850. The help desk is available Monday to Friday from 8.00 am to 6.00 pm UK time.

31. A provider who wishes to participate in a procurement but who has not already registered with the eSourcing portal, must register as follows

    a. Browse to the eSourcing Portal: https://commercialsolutions.bravosolution.co.uk

    b. Click the link ‘Register here’

    c. Enter the correct business and user details

    d. Note the username chosen and click ‘Save’ when complete

    e. The provider will shortly receive an email with your unique password (please keep this secure).

32. Providers who require any further assistance on the eSourcing portal should use the online help, or contact the BravoSolution help desk as above.

3.2 Procurement timeline

33. The timeline for the Procurement is set out in the PQQ. It should be noted that the dates are expected dates at the time of issuing this MOI and may be subject to change.

34. Further details on the timeline for the Invitation to Tender (ITT) stage will be detailed in the documents issued for that stage.

3.3 Advert and MOI

3.3.1 Advert

35. An advertisement has been published on Contracts Finder (CF) describing, in general terms, the services being procured by the Commissioner, with the aim of encouraging responses from a range of organisations.

3.3.2 Memorandum of Information

36. This MOI is published on the eSourcing portal.

37. This MOI should provide Bidders with sufficient information on the Procurement and the Service to enable them to make an informed decision about whether they wish to register their interest in the Procurement.

38. Bidders must register their interest by submitting an EOI in accordance with the requirements of paragraph 3.3.3.

39. Providers who require any further assistance on the eSourcing portal should use the online help, or contact the BravoSolution help desk as above.

3.3.3 Expression of Interest

40. To express an interest in this procurement, a provider must:

    a. Browse to the eSourcing portal:

    b. https:// commercialsolutions.bravosolution.co.uk

    c. Login using their username/password

    d. Click the link ‘Open Access PQQs’ (these are Pre-Qualification Questionnaires open to any registered provider)

    e. Click the link for specific procurement PQQ to access the content.

    This project is identified on the Bravo portal by the title:

    NHS East Kent Wet AMD Service

f. Click the button ‘Express Interest’ in the box ‘Actions’ on the left-hand side of the page. This will move the PQQ into the ‘My PQQs’ page.

g. Click on the PQQ code, and access any attachments by clicking the link ‘Settings and Buyer Attachments’ in the box ‘Actions’

h. Choose to ‘Reply’ or ‘Reject’ (please give a reason if rejecting)

i. Optionally use the ‘Messages’ function to communicate with the Commissioner and seek any clarification

j. Note the deadline for completion, then follow the instructions onscreen and in the PQQ documents to complete the PQQ and submit it.

41. Providers who require any further assistance on the eSourcing portal should use the online help, or contact the BravoSolution help desk as above.

3.4 Pre-Qualification Questionnaire

42. The PQQ provides detailed information on the PQQ process, guidance on how to complete the PQQ and a series of questions for Bidders to answer.

43. The PQQ will be made available through the eSourcing portal to all Bidders. Bidders for the Scheme must respond to the PQQ before the deadline stated in the PQQ. The Commissioner reserves the right not to consider any PQQ submission received after that deadline.

44. A clarification process will operate during the PQQ stage to resolve questions from bidders – this process is explained in the PQQ documentation.

45. The PQQ is designed to evaluate the eligibility, capability, and capacity of Bidders to provide the services which are the subject of this Procurement.

46. The PQQ evaluation will include a short-listing process and Bidders will be told whether or not they have been short-listed.

47. Further details of the PQQ process and evaluation will be set out in the PQQ.

3.5 Bidder Information Event

48. The Commissioner does not intend to hold a bidder information event, but will operate a clarification process throughout the period of the PQQ to provide an accessible and responsive web-enabled process to answer questions from Bidders.

3.6 Invitation to Tender

49. Bidders invited to proceed to the next stage of the Procurement will be given access to the ITT.

The ITT will detail:

- the process for the next stages of the procurement
- the requirements of the services to be provided – including implementation timescales
- the information required from Bidders, and
- the timescales for submission of bids.

50. A clarification process will operate during the ITT stage to resolve questions from Bidders – this process will be explained in the ITT documentation.

51. The Commissioner will evaluate Bids in accordance with the process described in the ITT, which will include the evaluation criteria and their relative weighting.

52. A clarification process will operate during the evaluation to resolve questions from the Commissioner to enable the evaluation to be completed – this process will be explained in the ITT documentation. The Commissioner may invite one or more Bidders to clarify their bids by face-to-face presentation.

3.7 Contract Award

53. Based on the outcome of the evaluation, recommendations will be made to the Commissioner's Board for the Board to consider. Following approval by the Board, the Commissioner and the recommended Bidder(s) may enter into the contract.

3.8 Service Commencement

54. Following contract award and in accordance with the Provider's mobilisation plan, the Commissioner and the Provider will work together towards service commencement at the contractually agreed date.

55. The date for service commencement is 1 September 2015.

56. Commercial Framework

57. Bidders' attention is drawn to the following commercial information.

3.9 Contract

58. The contract to be entered into by the Commissioners and the selected Provider(s) for the Procurement will be the NHS Standard Contract.

59. The standard contract will be adapted as necessary to reflect the requirements of the Service.

60. The Contract will be separate to and independent of any existing contract currently in place between the Commissioners and the Provider(s).

3.10 Contract Duration

61. The Contract will be for a term of three years plus potential to extend by 1 year, and with an option to extend by one further year subject to agreement by the Commissioner and the Provider.

3.11 Payment Mechanism

62. The contract price must cover all aspects of the Service, including service delivery, administration, support and infrastructure. The Commissioner will not make any other payment to Providers in respect of the Service.

63. Payment to the Provider will be on a cost per contact. There will be no minimum income guarantee ("collar") and no maximum income limit ("cap"). Further details of the payment mechanism for the scheme will be set out in the ITT.

64. Payments will be subject to achievement of a range of Key Performance Indicators (KPIs). Failure to reach the KPIs may be subject to financial penalties.

3.12 Quality and Performance Monitoring

65. The Provider will be required to provide a range of regular reports on service quality and performance. Monitoring of quality and performance will be ongoing, and based on a range of Key Performance Indicators.

66. Further information about the quality and performance monitoring framework and the reporting requirements will be detailed in the ITT.

3.13 Clinical / service information

67. The Commissioner is looking for providers with the necessary capacity and capability (or a demonstrable ability to provide the necessary capacity and capability) to deliver high quality, patient-centred and VfM service to meet mobility needs of patients, delivered in a safe and effective manner.

68. Providers must demonstrate the capability to work in accordance with local and national policies regarding safe guarding children and vulnerable adults (POVA).

3.14 Workforce

3.14.1 Policies and Strategies

69. Bidders will be required to provide evidence that all proposed workforce policies, strategies, processes and practices comply with all relevant employment legislation and guidance applicable in the UK.

70. At PQQ stage, Bidders will be required to provide summary information on each of the following, with full copies of policies and other documentation being required at a later stage:

- recruitment, health and safety and other relevant policies including those on environmental protection
- procedures for ensuring compliance that all clinical staff, including doctors, nurses and allied health professionals, are registered with the relevant UK professional and regulatory bodies
- policy for ensuring clinical staff meet the CPD requirements of their professional and regulatory bodies
- staff handbook setting out terms and conditions of employment for staff

71. Further details of the staff resourcing and workforce policy requirements will be included in the ITT.

3.14.2 Staff Transfers (TUPE and pensions)

72. TUPE does not apply to this procurement.

3.15 Premises, Facilities Management and Equipment

3.15.1 Premises

73. The Provider must provide suitable premises to deliver the service. These premises must be within the boundaries of the Commissioner's area, and must be accessible in compliance with Equality Act 2010.

74. The Provider will be expected to fund all costs related to the premises, including rent, rates, utility costs, capital work, maintenance and insurance costs.

75. Bidder provided premises will be subject to acceptance by the Commissioner.

76. Further details this aspect of the scheme will be set out in the ITT.

3.15.2 Facilities Management Services

77. The Provider will be expected to and provide facilities management (FM) services for premises.

78. The Commissioner will not provide (nor arrange the provision of) FM services for premises.

79. The costs of FM services are included in the pricing.

3.15.3 Equipment

80. The Provider will be responsible for the provision, maintenance and cost of equipment required to deliver the Services.

81. The Commissioner will not provide (nor arrange the provision of) equipment required to deliver the Service.

82. The costs of equipment are included in the pricing.

3.16 IM&T

83. The Services must be supported by Information Management and Technology (IM&T) Systems to process and store patient information in a safe and secure way in accordance with the standards outlined below.

84. IM&T Systems means all IM&T infrastructure, computer hardware, software, networking, training, support and maintenance necessary to support and ensure effective delivery of the Services, management of patient care and contract management.

85. The Commissioner will not provide (nor arrange the provision of) IM&T services required to deliver the Services.

86. The Provider must supply, manage and maintain any IM&T systems or services that the Provider deems necessary to deliver the Service. The Provider must gain agreement and approval from the Commissioner for all IM&T systems and services prior to their use to deliver the Service.

87. The Bidder's IM&T Systems used for the Services must comply with the following standards as appropriate:

- GP Systems of Choice (GPSoC) programme
- National Programme for Information Technology (NPfIT)
- NHS Terminology Service
- Provider must be IG Toolkit compliant

88. The costs of IM&T Systems are included in the pricing.

89. Further details on IM&T requirements for the Service will be set out in the PQQ and the ITT.

3.17 Financial Standing

90. Financial standing requirements for the Procurement will be limited at the PQQ stage to confirmation of identity, solvency, liquidity, profitability and proposed business structure, with no other financial requirements.

3.18 Performance Security

91. The Commissioners do not expect that performance security will be required from Providers for the Procurement.

3.19 Insurance

92. A comprehensive schedule of insurances that the Provider(s) will be required to obtain for the Scheme will be set out in the ITT. This will typically include public liability, corporate medical malpractice and certain property cover.

93. The insurance requirements will also require Providers to ensure that:

- the Commissioner's interests are fully protected
- members of the public utilising the services are fully protected to the extent that they have a valid claim against the Provider or the Commissioner
- the Provider maintains insurance which meets at least the minimum statutory requirements

94. Providers will be required to indemnify the Commissioner against any claims that may be made against the Commissioner arising from the provision of the services by the Provider. The Commissioner will expect the Provider(s) to offer evidence that they have sourced appropriate (and sufficient) insurance or other arrangements. For the avoidance of doubt, this will include provisions for clinical negligence insurance covering all staff and operational risk in the facilities from which the Provider's services are to be provided.

4 Governance and Administration

4.1 Procurement Costs

95. Each Bidder and Relevant Organisation will be responsible for its own costs incurred throughout each stage of the Procurement. The Commissioner will not be responsible for any costs incurred by any Bidder or Relevant Organisation or any other person for this process.

4.2 Consultation

96. The Commissioner will lead on all local stakeholder engagement issues. All Commissioner schemes are subject to ongoing patient and public consultation under the NHS Act 2006.

4.3 The Public Contract Regulations 2006

97. The services to which this procurement relates fall within Part B of Schedule 3 to the Public Contracts Regulations 2006 (“the Regulations”) as amended from time to time and Annex II B to Council Directive 2004/18/EC. Neither the inclusion of a Bidder selection stage nor the use of the term “Pre-Qualification Questionnaire" nor any other indication shall be taken to mean that the Commissioner intends to hold itself bound by any of the Regulations, save those applicable to Part B services.

4.4 Conflicts of interest

98. In order to ensure a fair and competitive procurement process, the Commissioner requires that all actual or potential conflicts of interest that a Bidder may have are identified and resolved to the satisfaction of the Commissioner.

99. Bidders must notify the Commissioner of any actual or potential conflicts of interest in their response to the PQQ. If the Bidder becomes aware of an actual or potential conflict of interest following submission of the PQQ it must immediately notify the Commissioner via the eSourcing portal. Such notifications should provide details of the actual or potential conflict of interest.

100. If, following consultation with the Bidder, such actual or potential conflict(s) are not resolved to the satisfaction of the Commissioner, then the Commissioner reserves the right to exclude at any time any Bidder from the procurement process should any actual or potential conflict(s) of interest be found by the Commissioner to confer an unfair competitive advantage on one or more Bidder(s), or otherwise to undermine a fair and competitive procurement process.

4.5 Non-collusion and Canvassing

101. Bidders must neither disclose to, nor discuss with any other Bidder (whether directly or indirectly), any aspect of any response to any of the Procurement documents.

102. Bidders must not canvass or solicit or offer any gift or consideration whatsoever as an inducement or reward to any officer or employee of, or person acting as an adviser to, either the NHS or the DH in connection with the selection of Bidders in relation to the Procurement.

103. Bidders must not except as expressly authorized by the Commissioner contact any officer or employee or agent of the Commissioner about any aspect of the Procurement including (without limitation) for the purposes of discussing the possible transfer to the employment of the Bidder or a Relevant Organisation of such employee or officer for the purpose of the procurement or for soliciting information in connection with the Procurement

4.6 Freedom of Information

104. The Commissioner is committed to open government and meeting its legal responsibilities under the Freedom of Information Act (FOIA). Accordingly, any information created by or submitted to the Commissioner (including, but not limited to, the information contained in the PQQ and the submissions, bids and clarification answers received from Bidders) may need to be disclosed by the Commissioner in response to a request for information.

105. In making a submission or bid or corresponding with the Commissioner at any stage of the Procurement, each Bidder, and each Relevant Organisation acknowledges and accepts that the Commissioner may be obliged under the FOIA to disclose any information provided to it:

- without consulting the Bidder
- following consultation with the Bidder and having taken its views into account

106. Bidders must clearly identify any information supplied in response to the PQQ that they consider to be confidential or commercially sensitive and attach a brief statement of the reasons why such information should be so treated and for what period.

107. Where it is considered that disclosing information in response to a FOIA request could cause a risk to the procurement process or prejudice the commercial interests of any Bidder, the Commissioner may wish to withhold such information under the relevant FOIA exemption.

108. However, Bidders should be aware that the Commissioner is responsible for determining at its absolute discretion whether the information requested falls within an exemption to disclosure, or whether it must be disclosed.

109. Bidders should therefore note that the receipt by the Commissioner of any information marked “confidential” or equivalent does not mean that the Commissioner accepts any duty of confidence by virtue of that marking, and that the Commissioner has the final decision regarding

the disclosure of any such information in response to a request for information.

4.7 Disclaimer

110. The information contained in this MOI is presented in good faith and does not purport to be comprehensive or to have been independently verified.

111. Neither the Commissioner nor any of their advisers accept any responsibility or liability in relation to its accuracy or completeness or any other information which has been, or which is subsequently, made available to any Bidder, Clinical Services Supplier, financiers or any of their advisers, orally or in writing or in whatever media.

112. Interested parties and their advisers must therefore take their own steps to verify the accuracy of any information that they consider relevant. They must not, and are not entitled to, rely on any statement or representation made by the Commissioner or any of their advisers.

113. This MOI is intended only as a preliminary background explanation of the Commissioner activities and plans and is not intended to form the basis of any decision on the terms upon which the Commissioner will enter into any contractual relationship.

114. The Commissioner reserves the right to change the basis of, or the procedures (including the timetable) relating to, the Procurement, to reject any, or all, of the submissions and bids, not to invite a Bidder to proceed further, not to furnish a Bidder with additional information nor otherwise to negotiate with a Bidder in respect of the Procurement.

115. The Commissioner shall not be obliged to appoint any of the Bidders and reserves the right not to proceed with the Procurement, or any part thereof, at any time.

116. Nothing in this MOI is, nor shall be relied upon as, a promise or representation as to any decision by the Commissioner in relation to this Procurement. No person has been authorised by the Commissioner or its advisers or consultants to give any information or make any representation not contained in this MOI and, if given or made, any such information or representation shall not be relied upon as having been so authorised.

117. Nothing in this MOI or any other pre-contractual documentation shall constitute the basis of an express or implied contract that may be concluded in relation to the Procurement, nor shall such documentation or information be used in construing any such contract. Each Bidder must rely on the terms and conditions contained in any contract when, and if, finally executed, subject to such limitations and restrictions that may be specified in such contract. No such contract will contain any representation or warranty in respect of the MOI or other pre-contract documentation.

118. In this section, references to this MOI include all information contained in it and any other information (whether written, oral or in machine-readable form) or opinions made available by or on behalf of the Commissioner or any of their advisers or consultants in connection with this MOI or any other pre-contract documentation.

4.8 Copyright

119. This MOI document, including all attachments, appendices, and any subsequent correspondence or communication in writing relating to the MOI, represent the original proprietary material of the Commissioner and are subject to Copyright, and may not be reproduced, altered, or revised in any manner or form unless prior, express, written permission has been obtained from the Commissioner.