

Preventive Lung Cancer Screening Memorandum of Understanding

I. Introduction

Quality Insights, Inc. (“Quality Insights”), under an agreement with the Delaware Department of Health & Social Services Division of Public Health (“DPH”), is creating a preventive lung cancer screening (PLCS) electronic health record (EHR) report to assist DPH in future, state-wide, quality improvement efforts.

Quality Insights will work with physician practices to determine their current workflow and EHR capabilities to meet the reporting requirements as defined by the U.S. Preventive Services Task Force’s screening recommendations. A gap analysis will be performed and action items to minimize the gaps will be identified. To view the screening recommendations visit:

<https://www.uspreventiveservicestaskforce.org/Page/Document/UpdateSummaryFinal/lung-cancer-screening>.

Quality Insights will work with physician practices to address the gap analysis action items. A preventive lung cancer screening report will be created and executed for baseline data (1/1/2017-12/31/2017).

II. Purpose

The purpose of this Memorandum of Understanding (“MOU”), effective _____ (the “Effective Date”), is to specify the terms and conditions under which Quality Insights and _____ (“Provider Organization”) will work together to complete the following:

- Quality Insights will conduct a preventive lung cancer screening workflow assessment (includes office workflow and EHR system workflow – including EHR screenshots of dropdown selection options related to smoking status, CT Scan order options, other fields as applicable to report parameters)
- Provider Organization will approve final version of workflow assessment
- Quality Insights will produce the final workflow gap analysis and will review findings with Provider Organization
- Quality Insights will address findings in gap analysis for PLCS report requirements and office workflow/EHR data capture capabilities with Provider Organization
- Resolutions may involve vendor engagement, acquiring vendor quotes if system modifications are required for reporting, and consideration of practice workflow modifications
- Using current state EHR system functionality (i.e., no vendor system modifications that result in additional charges), Quality Insights will work with Provider Organization to create the Preventive Lung Cancer Screening EHR Report to the best of the system’s capabilities
- Quality Insights will execute a baseline annual report (Jan 1, 2017 – December 31, 2017)
- Quality Insights will document additional system needs, vendor costs, and resources

required to create the ideal state PLCS report.

- Once PLCS reports are complete and approved, Quality Insights will utilize the report to send patient reminder postcards. A workflow for patient and practice action to the reminder postcard campaign will be needed. The reports will be audited prior to mailing the postcards.

III. Provider Organization Responsibilities

In order to fully explore the possibility of a PLCS EHR report, Provider Organization is expected to:

- Designate an individual to act as the primary contact for Quality Insights.
- Participate in the workflow assessment meeting and contribute to action items to close identified gaps in current office and system workflows.
- Assist Quality Insights in obtaining pertinent EHR screen shots.
- Assist with identified action items by submitting necessary vendor support tickets.
- Assist with report set up in EHR for baseline report.
- Execute baseline report (1/1/2017-12/31/2017).
- Contribute at least 3 hours of physician or nurse practitioner time and 7 hours of support time (e.g., administration, information technology) to be eligible for the stipend in accordance with Section IV.
- Engage in developing a patient action plan for the patient reminder postcard campaign.

IV. Provider Organization Benefits

If PLCS reporting is possible, Provider Organization will be an industry leader for PLCS quality improvement efforts.

Actively participating health care practices in the project will receive a \$1,000 stipend upon submission of documentation that the Provider Organization has contributed ten (10) hours of time to the project. Three of those hours must be physician or nurse practitioner time. Once hours are met, and deliverables achieved, the stipend will be paid. Quality Insights will issue an IRS Form 1099, if applicable.

Provide organization could increase the percentage of eligible patients receiving preventive lung cancer screening.

V. Privacy and Security

To ensure the privacy and security of Protected Health Information (“PHI”) Quality Insights may have access to in the performance of its services for Provider Organization and in compliance with the Health Insurance Portability and Accountability Act, as amended (“HIPAA”), and other applicable laws and regulations governing the confidentiality of patient information, a HIPAA Business Associate Addendum (“BAA”) is attached as Exhibit A and made part of this MOU.

VI. Term and Termination

This MOU shall be effective from the Effective Date through June 30, 2018, and shall, subject to funding availability, automatically renew for successive one (1) year terms, unless or until terminated in accordance with the following:

- By either party, without cause, by giving thirty (30) days written notice;
- By Quality Insights, upon immediate written notice if funding from the State of Delaware Division of Public Health is terminated or suspended;
- By Quality Insights, upon ten (10) days' written notice in the event that, upon review and evaluation by Quality Insights, Quality Insights has determined that there is not adequate funding available from the State of Delaware Division of Public Health to continue providing services in accordance with this MOU.
- Any stipend for which Provider Organization has qualified prior to termination by either party will be paid by Quality Insights.

VII. Entire Agreement

This MOU, including referenced exhibits, represents all terms and conditions agreed upon by the parties. No other understandings or representations, oral or otherwise, regarding the subject matter of this MOU shall be deemed to exist or to bind any of the parties hereto.

VIII. Amendment

This MOU may be altered, amended, or waived only by a written amendment executed by both parties.

IX. Assignment

Neither party may assign, convey, sell or otherwise transfer this MOU or any rights or duties hereunder without the prior written consent of the other party. Provided, however, that Quality Insights may assign or transfer the Agreement to a successor organization as a result of a merger, acquisition or name change without Provider Organization's consent.

X. Conformance

If any provision of this MOU violates any statute or rule of law of the State of Delaware, it is considered modified to conform to that statute or rule of law.

XI. Relationship of the Parties

The parties to this MOU are independent contractors. This MOU may not be construed to establish a relationship of partnership, joint venture, agency or employment. Neither party shall have the authority to bind the other party.

THIS MEMORANDUM OF UNDERSTANDING is executed as of the date first written above by the persons signing below who warrant that they have the authority to execute this Memorandum of Understanding.

QUALITY INSIGHTS, INC.

PROVIDER ORGANIZATION

By: Patricia B. Ruddick

By: _____

Printed Name: Patricia B. Ruddick

Printed Name: _____

Title: Director of HIT Services

Title: _____

Address: 3001 Chesterfield Avenue
Charleston, WV 25304

Address: _____

HIPAA Business Associate Addendum – Exhibit A

This business associate addendum (“Addendum”) is made by and between Quality Insights (“Business Associate”) and the health care provider organization (“Provider Organization”) identified in the Memorandum of Understanding to which this Addendum is attached (the “MOU”). Provider Organization and Business Associate are each a “Party” and together are the “Parties.” This Addendum is incorporated into and made part of the MOU.

WHEREAS, Provider Organization possesses Protected Health Information (hereinafter defined) that is subject to the privacy and security provisions of the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), the Health Information Technology for Economic and Clinical Health Act, as incorporated in the American Recovery and Reinvestment Act of 2009 (the “HITECH Act”), and the implementing regulations for those Acts (45 C.F.R. Parts 160-164), including any amendments to those regulations (collectively, the “HIPAA Requirements”); and

WHEREAS, Provider Organization wishes to receive certain services involving the Use or Disclosure of Protected Health Information to identify certain at-risk patients for the purposes of improving health care outcomes and lowering health care costs; and

WHEREAS, Business Associate maintains the personnel and expertise to provide certain services as Provider Organization desires; and

WHEREAS, Business Associate acknowledges that providing such services involves the Use or Disclosure of Protected Health Information such that Business Associate is subject to certain provisions of the HIPAA Requirements; and

WHEREAS, the HIPAA Requirements require that Provider Organization receive satisfactory assurances that Business Associate will comply with certain obligations with respect to Protected Health Information received in the course of providing services to or on behalf of Provider Organization;

NOW THEREFORE, in consideration of the mutual promises and covenants contained herein, and for other good and valuable consideration, the Parties agree as follows:

(1) **Definitions.**

(A) **Terms Not Defined.** Capitalized terms not defined in this section will have the meaning established in 45 C.F.R. §§ 160.103, 164.103, 164.304, 164.402, and 164.501.

(B) **Terms Defined in Preamble.** The terms “Addendum,” “Business Associate,” “HIPAA,” “HIPAA Requirements,” “HITECH Act,” “Party,” and “Provider Organization” each have the meaning established in the preamble to this Addendum.

(C) **Protected Health Information.**

(i) *Protected Health Information* has the meaning established in 45 C.F.R. § 160.103, limited to the protected health information that Business Associate creates for or receives on behalf of Provider Organization.

(ii) *Electronic Protected Health Information* has the meaning established in 45 C.F.R. § 160.103, limited to the electronic protected health information that Business Associate creates for or receives on behalf of Provider Organization.

(2) **Permitted Uses and Disclosures.** Business Associate may not Use or Disclose Protected Health Information except as permitted or required by this Addendum. Subject to section (3), Business Associate may Use or Disclose Protected Health Information as follows:

(A) **On Provider Organization's Behalf.** Business Associate may Use and Disclose Protected Health Information to perform the functions and activities for which it is responsible and to perform other functions and activities as directed by Provider Organization.

(B) **For the Benefit of Third Parties.** Business Associate may Use and Disclose Protected Health Information for the Treatment and Payment activities of a Health Care Provider and the Payment activities of another Covered Entity. Business Associate may Use and Disclose Protected Health Information for another Covered Entity's Health Care Operations, provided that Provider Organization would be permitted to Use or Disclose the information under 45 C.F.R. § 164.506(c).

(C) **As Required By Law.** Business Associate may Use or Disclose Protected Health Information as Required By Law.

(D) **Business Associate's Proper Management and Administration.**

(i) *Use of Protected Health Information.* Business Associate may Use Protected Health Information as necessary for Business Associate's proper management and administration or to carry out Business Associate's legal responsibilities.

(ii) *Disclosure of Protected Health Information.* Business Associate may Disclose Protected Health Information as necessary for Business Associate's proper management and administration or to carry out Business Associate's legal responsibilities, provided that (I) Business Associate obtains reasonable written assurances from the person to whom the information will be Disclosed that the information will be held confidentially and Used or further Disclosed only as Required By Law or for the purpose for which the information is Disclosed and (II) the person will notify Business Associate (who will promptly notify Provider Organization) of any confidentiality breach related to the Protected Health Information of which the person becomes aware.

(E) **Data Aggregation.** Business Associate may Use and Disclose Protected Health Information to perform Data Aggregation related to Provider Organization's Health Care Operations.

(F) **De-identified Data.** Business Associate may de-identify Protected Health Information, provided that such de-identification is conducted in accordance with the requirements of 45 C.F.R. § 164.514(b) including any documentation requirements, and may use or disclose such de-identified data in aggregated form (de-identified, aggregated data) in support of the services identified in the MOU and for reporting to the State of Delaware

Division of Public Health. De-identified data does not constitute Protected Health Information and is not subject to the terms of this Addendum.

(3) **Restrictions on Uses and Disclosures.**

- (A) **Compliance with Privacy Rule.** Notwithstanding sections (2)(A)-(C), Business Associate shall not Use or Disclose Protected Health Information in a manner that would violate the Privacy Rule or the HITECH Act if Provider Organization made the Use or Disclosure, except as permitted by sections 2(D) - (F) above.
- (B) **Minimum Necessary.** Business Associate shall, in the performance of its functions and activities on Provider Organization's behalf, make reasonable efforts to Use, to Disclose, or to request of a Covered Entity only the minimum necessary amount of Protected Health Information to accomplish the intended purpose of the Use, the Disclosure, or the request when Provider Organization would be required to do so by 45 C.F.R. § 164.502(b).
- (C) **Subcontractors.** Business Associate may not Disclose to a Subcontractor or otherwise allow a Subcontractor to access Protected Health Information until the Subcontractor agrees in writing to the same restrictions and conditions that apply to Business Associate with respect to Protected Health Information, including but not limited to compliance with the HIPAA Security Rule (45 C.F.R. Part 164, Subpart C).

(4) **Information Safeguards; Breach of Safeguards**

(A) **Information Safeguards.**

- (i) *Privacy.* Business Associate shall use reasonable and appropriate safeguards to prevent the Use or Disclosure of Protected Health Information other than as permitted or required by this Addendum.
- (ii) *Security.* Business Associate shall comply with the requirements of the HIPAA Security Rule (45 C.F.R. Part 164, Subpart C).

- (B) **Breach of Unsecured Protected Health Information.** Business Associate shall report, following discovery and without unreasonable delay, any "Breach" of "Unsecured Protected Health Information," as these terms are defined in 45 C.F.R. § 164.402. Business Associate shall make an initial report to Provider Organization not more than five (5) days after Business Associate learns of the Breach. Business Associate shall cooperate with Provider Organization in investigating the Breach and in meeting Provider Organization's obligations under the HITECH Act and any other security breach notification law.

- (C) **Privacy Obligation Breach.** With respect to any incident not subject to reporting under § 4(B) of this Addendum, Business Associate shall report to Provider Organization any Use or Disclosure of Protected Health Information not permitted by this Addendum or in writing by Provider Organization. Business Associate shall make the report to Provider Organization not more than five (5) days after Business Associate learns of such non-permitted Use or Disclosure.

(D) **Security Incidents.** With respect to any incident not subject to reporting under § 4(B) or § 4(C) of this Addendum, Business Associate shall report to Provider Organization any successful (a) unauthorized Access, Use, Disclosure, modification, or destruction of Provider Organization’s Electronic Protected Health Information or (b) unauthorized interference with system operations in Business Associate’s Information System, of which Business Associate becomes aware. Business Associate shall make the report to Provider Organization not more than five (5) days after Business Associate learns of such incident. Business Associate shall, upon Provider Organization’s request, report to Provider Organization any attempted, but unsuccessful (a) unauthorized Access, Use, Disclosure, modification, or destruction of Provider Organization’s Electronic Protected Health Information or (b) unauthorized interference with system operations in Business Associate’s Information Systems, of which Business Associate becomes aware.

(5) **Privacy Right Compliance**

(A) **Access.** Within fifteen (15) days of receiving a notification from Provider Organization of an individual’s request for access to records in a Designated Record Set, Business Associate shall furnish Provider Organization any Protected Health Information that Business Associate maintains in a Designated Record Set pertaining to the individual so that Provider Organization may comply with the individual’s access rights, pursuant to 45 C.F.R. § 164.524.

(B) **Amendment.** Within fifteen (15) days of receiving notification from Provider Organization of an individual’s request to amend records in a Designated Record Set, Business Associate shall amend the records that Business Associate maintains in a Designated Record Set so that Provider Organization may comply with the individual’s amendment rights, pursuant to 45 C.F.R. § 164.526.

(C) **Disclosure Accounting.**

(i) *Tracking Disclosures.* Business Associate shall collect for each Disclosure of Protected Health Information for which Provider Organization may be required to account pursuant to 45 C.F.R. § 164.528 all information that 45 C.F.R. § 164.528 requires for Provider Organization’s accounting.

(ii) *Accounting for Disclosures.* Within fifteen (15) days of becoming aware of a Disclosure for which Provider Organization may be required to account under 45 C.F.R. § 164.528, Business Associate shall furnish Provider Organization all information that 45 C.F.R. § 164.528 requires for an accounting so that Provider Organization may comply with an individual’s Disclosure accounting rights.

(D) **Electronic Health Records.** With respect to Protected Health Information Business Associate Uses or maintains in an “Electronic Health Record” (as defined in the HITECH Act, § 13400(5) (42 U.S.C. § 17921(5))), Business Associate shall:

(i) Make information an individual requests pursuant to his/her access rights under 45 C.F.R. § 164.524 available in electronic format, in the manner and when required by the HITECH Act and the HIPAA Requirements;

- (ii) Account for Disclosures for Treatment, Payment, and Health Care Operations in the manner and when required by the HITECH Act and the HIPAA Requirements;
- (iii) Provide directly to an individual who requests an accounting of Disclosures pursuant to 45 C.F.R. § 164.528 the required information in the manner and when required by the HITECH Act and the HIPAA Requirements.

(E) **Restriction Agreements and Confidential Communications.** Business Associate shall Use and Disclose Protected Health Information in compliance with (i) any restriction request to which Provider Organization agrees pursuant to 45 C.F.R. § 164.522(a) and (ii) any confidential communications request that Provider accommodates pursuant to 45 C.F.R. § 164.522(b).

(6) **Other Requirements.**

(A) **Inspection of Books and Records.** Business Associate shall make its internal practices, books, and records relating to the Use and Disclosure of Protected Health Information available to the U.S. Department of Health and Human Services for purposes of determining Provider Organization's compliance with 45 C.F.R. Part 164, Subpart E.

(B) **Transactions Rule Compliance.** Business Associate shall use the standard format required by 45 C.F.R. Part 162 (the "HIPAA Transactions Rule") when using electronic media to conduct on Provider's behalf any transaction that is subject to the HIPAA Transactions Rule.

(C) **Mitigation.** Business Associate shall mitigate, to the extent practicable, any harmful effect that is known to Business Associate of a Use or Disclosure of Protected Health Information made in violation of this Addendum.

(D) **Delegation.** To the extent that Provider Organization delegates to Business Associate any obligation imposed on Provider Organization by the Privacy Rule (45 C.F.R. Part 164, Subpart E), Business Associate shall comply with the requirements of the Privacy Rule that apply to Provider Organization in the performance of such delegated obligation.

(7) **Termination of Addendum.**

(A) **Termination for Material Breach.** Provider Organization may terminate this Addendum upon Business Associate's material breach of this Addendum. To exercise its termination right, Provider Organization shall provide Business Associate written notice of the breach, which will include a description of the breach and establish a reasonable cure period, as determined by Provider Organization. At the end of the cure period, Provider Organization may provide Business Associate notice of termination, which will be effective immediately or at such later date specified by Provider Organization, unless Business Associate has cured the breach.

(B) **Return or Destruction.** Upon termination, expiration, or other conclusion of this Addendum or the MOU for any reason, with respect to Protected Health Information that Business Associate and its Subcontractors maintain or control, including any copy, compilation, or other documentation (whether in electronic or other form) that (1) is

derived from Protected Health Information and (2) has not been de-identified in accordance with 45 C.F.R. § 164.514(b) ("Provider Organization's PHI"):

- (i) *Return or Destroy Information if Feasible.* Business Associate shall return or, at Business Associate's discretion, destroy all of Provider Organization's PHI that Business Associate does not retain pursuant to section (7)(B)(ii). Business Associate shall complete the return or destruction of Provider Organization's PHI as promptly as possible, but in any event within thirty (30) days.
- (ii) *Retain Information if Return or Destruction Not Feasible.* Business Associate shall document the nature of any of Provider Organization's PHI that Business Associate believes cannot feasibly be returned or destroyed and the reason that return or destruction is not feasible. Business Associate (or its Subcontractor) may retain such information, subject to section (7)(C).

- (C) **Continuing Privacy and Security Obligations.** After termination, expiration, or other conclusion of this Addendum for any reason, Business Associate shall (i) extend all protections of this Addendum to any of Provider Organization's PHI that Business Associate, its Subcontractors retain and (ii) limit further Uses and Disclosures of the information to those purposes that make return or destruction infeasible for as long as Business Associate maintains the Protected Health Information.

(8) **General Provisions.**

- (A) **Amendment to Addendum.** By furnishing Provider Organization notice of an amendment to the Addendum at least thirty (30) days prior to the amendment's effective date, Business Associate may amend the Addendum to reflect changes to Business Associate's policies for complying with or changes to the HIPAA Requirements or other laws affecting information privacy, security, or transmission. Provider Organization may reject the terms of the amendment by providing written notice of rejection to Business Associate within thirty (30) days of receiving the amendment. If Provider Organization fails to provide such notice, Provider Organization will be deemed to have agreed to the amendment and the amendment will be binding on Provider Organization without signature or other action by Provider Organization.

If Provider Organization rejects the amendment, the Parties shall in good faith attempt to negotiate an amendment that is mutually acceptable. If the Parties cannot reach agreement and Business Associate determines that it cannot remain in compliance with HIPAA Requirements without an amendment, then Business Associate may terminate this Addendum and the MOU by providing written notice to Provider Organization at least thirty (30) days prior to the effective date of termination.

- (B) **Conflicts.** The Parties agree that any ambiguity or conflicts in this Addendum will be resolved in a manner that permits the Parties to comply with the HIPAA Requirements.
- (C) **Indemnification.** Each Party will indemnify and hold the other Party and its respective officers, agents, directors, trustees and employees harmless from any and all losses, claims, liabilities, damages, costs and expenses, including reasonable attorney's fees, resulting from claims by third parties of negligent and/or willful misconduct or violation

of any law caused by or arising from the indemnifying Party's acts or omissions related to performance of its duties under this Addendum.

- (D) **Limitation of liability.** In no event shall either Party be liable for any indirect, incidental, consequential, punitive or special damages, including but not limited to lost revenues, profits or savings, even if a Party has been advised of the possibility of such damages.
- (E) **Notice.** Any notice required or authorized under this Addendum shall be in writing and shall be delivered by personal delivery, commercial courier, or U.S. mail (postage prepaid). Notice shall be effective upon receipt. If delivered by mail, such notice shall be deemed received three (3) days after mailing. Notice shall be directed to the person, and at the address, identified on the signature page of the MOU.