Intervention Risk Management Summary

November 1, 2024

Contents

315 Deaderick Street, Suite 2300 Nashville, TN 37238 qualifacts.com

I. Disclosure Attestation

Disclaimer: Qualifacts Systems LLC ("Qualifacts") Certified Electronic Health Record Technologies are compliant with the ASTP/ONC Certification Criteria for Health IT § 170.315(b)(11) and have been certified by an ONC-ACB in accordance with the applicable certification criteria adopted by the Secretary of Health and Human Services. This certification does not represent an endorsement by the U.S. Department of Health and Human Services.

This Intervention Risk Management (IRM) Summary is provided to ensure transparency regarding the Predictive Decision Support Interventions available to Qualifacts EHR customers utilizing CareLogic, Credible, and InSync EMR/PM software. This summary is posted publicly at https://www.qualifacts.com/onc-certification-and-costs/ and on the ONC Certified HealthIT Product List (CHPL).

Qualifacts agrees to review and update the Intervention Risk Management Summary annually as required by §170.315(b)(11) and notify the respective ONC-ACBs of any and all future changes to IRM practices. Furthermore, Qualifacts understands and agrees that the ASTP/ONC Health IT Certification Program Final Rule statement gives ONC-ACBs the sole responsibility for ensuring compliance and determining appropriate consequences if EHR Technology developers fail to divulge accurate transparency and disclose information.

Qualifacts, in addition, understands and agrees to provide our respective ONC-ACBs copies of or access to any and all websites, marketing materials, communication statements, and other assertions made by Qualifacts regarding the ASTP/ONC certification status of our certified products in a reasonable time to ensure the transparency and accuracy of the information disclosed.

Authorized Representative Name:	Hope Winkowski, Vice President of Product Compliance
Authorized Representative Email:	hope.winkowski@qualifacts.com
Authorized Representative Phone:	301-652-9500 X0428
Date of Attestation:	November 4, 2024
Authorized Representative Signature:	Hope Winkowski M.Ed, NCC, OHCC

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II. EHR Software General Information:

Developer Name:	Qualifacts Systems, LLC
Product Name:	**CareLogic**
Version Number:	Enterprise S3
Certified Health IT Product List (CHPL) ID:	15.04.04.3124.Care.S3.00.1.181220
ONC-Authorized Certification Body:	Drummond Group
Certification Date:	December 20, 2018

Developer Name:	Qualifacts Systems, LLC
Product Name:	**Credible Behavioral Health**
Version Number:	Version 11
Certified Health IT Product List (CHPL) ID:	15.04.04.3124.Cred.11.01.1.221230
ONC-Authorized Certification Body:	Drummond Group
Certification Date:	December 30, 2022

Developer Name:	Qualifacts Systems, LLC
Product Name:	**InSync EMR/PM**
Version Number:	Version 10
Certified Health IT Product List (CHPL) ID:	15.02.05.3124.INSY.01.03.1.220314
ONC-Authorized Certification Body:	SLI Compliance
Certification Date:	March, 14, 2022

III. Artificial Intelligence Acceptable Use Commitment

At Qualifacts, we are committed to harnessing the power of Artificial Intelligence (AI) to enhance healthcare outcomes and improve patient care.

Qualifacts maintains internal policies and procedures regarding the development, deployment, implementation, and maintenance of AI technologies in accordance with applicable ISO standards and requirements established by the Assistant Secretary of Technology Policy and Office of the National Coordinator (ASTP/ONC).

Customer data is handled and maintained in accordance with the customer's Business Associate Agreement (BAA) and Master Services Agreement (MSA) with Qualifacts.

The use of AI tools can help to build efficiencies in day-to-day operations. As the technology continues to develop rapidly and the Behavioral Health and Healthcare Industries advance the use of AI in their business operations, Qualifacts is dedicated in providing our customers AI products that augment the clinician's workflow for improved efficiency and aid the clinician in providing high quality care.

IV. Predictive Decision Support Intervention

The Assistant Secretary of Technology Policy and Office of the National Coordinator (ASTP/ONC) defines predictive decision support interventions as technology that uses algorithms or models to support decision-making using various techniques including machine learning, algebraic equations, natural language processing among others.

V. Criteria | §170.315(b)(11)

Qualifacts' PDSI Offering: In July 2024, Qualifacts announced the launch of Qualifacts iQ, a scribe technology for use with a Qualifacts' EHR software solution, utilizing large language models to transcribe session content into summarized documentation suggestions, allowing clinical staff more efficiency in building their clinical documentation. This add-on feature is available, at an additional cost, to clinical staff who are customers of Qualifacts' suite of electronic health records, CareLogic, Credible, and/or InSync, and provide telehealth individual therapy services. Additional use cases, such as ambient in-office scribing, are anticipated in early 2025.

VI. Intervention Risk Management Practices

A. Model Card: Qualifacts iQ

1. Details and output of the intervention

(*i*) **Name and contact information for the intervention developer**

Qualifacts Systems, LLC
315 Deaderick St.
Nashville, TN 37238, USA
Phone: 301-652-9500
Web: http://www.qualifacts.com

(*ii*) **Funding source of the technical implementation for the intervention(s) development**

Qualifacts Systems, LLC

(*iii*) **Description of value that the intervention produces as an output**

Qualifacts iQ converts and summarizes transcripts of client sessions into formatted therapy notes (e.g. DAP, SOAP, BIRP, Progress styles). Clinicians can copy and paste the note into the supported EHR, then make additional edits as needed to finalize documentation. Qualifacts iQ reduces the burden of creating documentation, allowing staff to focus on serving clients.

(*iv*) **Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output.**

Qualifacts iQ transcribes and summarizes the therapy session, providing recommended text summaries to use as a basis for clinical documentation.

2. Purpose of the intervention

(*i*) **Intended use of the intervention**

Automated clinical documentation and summarization of client session transcripts.

(*ii*) **Intended patient population(s) for the intervention's use**

Adults, adolescents, and children using spoken English to communicate during clinical sessions.

(*iii*) **Intended user(s)**

Clinical staff (i.e. therapists, case managers, psychologists, psychologists) communicating using spoken English with clients during individual therapy sessions.

(*iv*) **Intended decision-making role for which the intervention was designed to be used/for (***e.g.,* **informs, augments, replaces clinical management)**

Augments the clinician documentation process by providing auto-generated summarization of the session to which a clinician may choose to incorporate into the clinical documentation.

3. Cautioned out-of-scope use of the intervention:

(*i*) **Description of tasks, situations, or populations where a user is cautioned against applying the intervention**

Qualifacts iQ is not intended to diagnose, treat, cure, or prevent any disease, nor is it a substitute for clinical judgment. Languages other than English may result in incomplete transcript summarization.

(*ii*) **Known risks, inappropriate settings, inappropriate uses, or known limitations.**

Qualifacts iQ is unable to process non-verbal communication (such as gestures and facial expressions) or sign language. Qualifacts iQ relies upon audio recordings and should be used in private, one-on-one settings. Public settings, settings with significant ambient noise and/or more than two participants may create incomplete transcriptions which in turn may hinder the summarization.

4. Intervention development details and input features:

(*i*) **Exclusion and inclusion criteria that influenced the training data set**

Qualifacts iQ will only train on data from customers using Qualifacts iQ. The general Qualifacts customer base includes agencies across the United States, located in rural, suburban, and urban communities, and serving a diverse population. Customers self-select to use Qualifacts iQ and separately opt-in to allow training on their data.

(*ii*) **Use of variables in paragraphs (b)(11)(iv)(A)(*5*) through (*13*) of this section as input features**

To date no customer data has been used to train the model due to the recent launch of the product. In 2025, output data will be utilized to train the model and exclusion are provided below:

Race: Not included in training data
Ethnicity: Not included in training data
Language: Not included in training data

Sexual Orientation: Not included in training data
Gender Identity: Not included in training data
Sex: Not included in training data
Date of Birth (age): Not included in training data
Social Determinants of Health: Not included in training data
Health Status Assessments: Not included in training data

(*iii*) **Description of demographic representativeness according to variables in paragraphs (b)(11)(iv)(A)(*5*) through (*13*) of this section, including, at a minimum, those used as input features in the intervention**

Race: Not included in training data
Ethnicity: Not included in training data
Language: Not included in training data
Sexual Orientation: Not included in training data
Gender Identity: Not included in training data
Sex: Not included in training data
Date of Birth (age): Not included in training data
Social Determinants of Health: Not included in training data
Health Status Assessments: Not included in training data

(*iv*) **Description of relevance of training data to intended deployed setting**

Qualifacts iQ is only sold to behavioral health agencies, and any training data used is derived from those behavioral health agencies that opt in. To date no customer data has been used to train the model due to the recent launch of the product. In 2025 the customer data will be used to fine tune the model.

5. Process used to ensure fairness in the development of the intervention

(*i*) **Description of the approach the intervention developer has taken to ensure that the intervention's output is fair**

All LLM prompts used within Qualifacts iQ are designed to ensure the output is focused on the objective summarization of a session transcript. Prompts are designed to avoid outputting judgmental statements, use of pronouns, suggestions for analysis or diagnosis, or offering clinical decisions.

(*ii*) **Description of approaches to manage, reduce, or eliminate bias**

The developer has worked extensively on the prompts to manage, reduce, or eliminate bias in the output. A sample size of outputs are reviewed along with the session transcript, but a team of clinical staff who analyze and provide feedback on biases noticed which would then be corrected by prompts.

6. External validation process

(*i*) **Description of the data source, clinical setting, or environment where an intervention's validity and fairness has been assessed, other than the source of training and testing data**

Qualifacts has an in-house team of clinical subject matter experts that analyzes a sample of outputs for each documentation format type and provide feedback regarding the validity of the clinical documentation or any concerns regarding fairness. Additionally, Qualifacts engaged with a third-party vendor to analyze and evaluate multiple large language models to determine the most appropriate, valid, and fair tool to utilize as the foundation of the offering.

(*ii*) **Party that conducted the external testing**
External testing from entities beyond Qualifacts and Alpha & Beta customers of the iQ product has not been conducted in 2024. External review of the product is anticipated in 2025. The privately hosted large language model utilized in the development of Qualifacts iQ undergoes additional testing. Please find the LLM system card: https://cdn.openai.com/papers/gpt-4-system-card.pdf

(*iii*) **Description of demographic representativeness of external data according to variables in paragraph (b)(11)(iv)(A)(*5*)-(*13*) including, at a minimum, those used as input features in the intervention**

Input features include transcripts of individual behavioral health telehealth appointments. To date while the input of transcripts are utilized to then generate behavioral health therapy note suggestions, it merits note that no data from the transcripts have been utilized to date train the model. Model training is anticipated in 2025. The details below relate to the demographic representativeness of the external data for the approximately 500 sessions captured during the Alpha release of Qualifacts iQ.

Race: Not entered as input
Ethnicity: Not entered as input
Language: spoken English
Sexual Orientation: Not entered as input
Gender Identity: Not entered as input
Sex: male and female
Date of Birth (age): 13-70 years of age
Social Determinants of Health: economic stability, education, social supports, neighborhood safety, access to healthcare, transportation, disability status, child welfare involvement, legal involvement, family structure
Health Status Assessments: No assessments were entered into the transcript input data.

(*iv*) **Description of external validation process**
Clinicians reviewed the transcript and output of clinical documentation suggestions to determine the validity, fairness, and appropriateness of the suggested clinical documentation. Clinicians reported feedback to developers who then made updates to the AI system by prompting the model to address the feedback, such as 'do not use pronouns' in the clinical documentation, but rather refer to the client and therapist as 'the client' and 'the clinician' etc.

7. Quantitative measures of performance

(*i*) **Validity of intervention in test data derived from the same source as the initial training data**
Human review of over 500 sessions by clinical subject matter experts were conducted. To date training data has not been utilized to train the model. The training of the model is anticipated in 2025. To date 7 corrective prompts were made to the model based on the feedback from clinicians to improve outputs. Qualifacts iQ is currently demonstrating a 99% validity rate.

(*ii*) **Fairness of intervention in test data derived from the same source as the initial training data**
Qualifacts iQ provides only text summarizations and does not suggest clinical interventions or infer treatment or diagnoses. The use of pronouns was removed from the output, referring to all patients as 'the client'. To date, no corrective prompts have been warranted to address fairness.

(*iii*) **Validity of intervention in data external to or from a different source than the initial training data**
Human review of over 500 sessions by clinical subject matter experts were conducted. To date training data has not been utilized to train the model. The training of the model is anticipated in 2025. To date 7 prompts were made to the model based on the feedback from clinicians to improve outputs.

(*iv*) **Fairness of intervention in data external to or from a different source than the initial training data**
Qualifacts iQ provides only text summarizations and does not suggest clinical interventions or infer treatment or diagnoses. The use of pronouns was removed from the output, referring to all patients as 'the client'.

(*v*) **References to evaluation of use of the intervention on outcomes, including, bibliographic citations or hyperlinks to evaluations of how well the intervention reduced morbidity, mortality, length of stay, or other outcomes**
System card of LLM utilized for development: https://cdn.openai.com/papers/gpt-4-system-card.pdf

8. Ongoing maintenance of intervention implementation and use

(*i*) **Description of process and frequency by which the intervention's validity is monitored over time**
For clinical documentation usage, Qualifacts iQ tracks when a clinician uses the note suggestions and to what extent the note suggestions differ from the final note that the clinician submitted in the EHR. Time saved on documentation is also tracked.

(*ii*) **Validity of intervention in local data**
Out of 500 initial sessions, 10 items of feedback were received. The feedback was successfully resolved utilizing 7 corrective prompts for a 99% validity rate.

(*iii*) **Description of the process and frequency by which the intervention's fairness is monitored over time**
Clinician feedback is a guiding factor in measuring the perceived fairness and validity of the Qualifacts iQ note suggestions over time. QA Engineers monitor fairness, validity, and appropriateness during each development sprint. Additionally, clinical SMEs review the output for validity, fairness, and appropriateness on a quarterly basis. Quarterly review of findings by Product and Engineering teams to the AI and Data Governance Committee and recommendations for remediations executed promptly.

(*iv*) **Fairness of intervention in local data**
Not available for review. Qualifacts iQ provides only text summarizations and does not suggest clinical interventions or infer treatment or diagnoses. The use of pronouns was removed from the output, referring to all patients as 'the client' upon clinical SME feedback in order to structure the output in a manner that meets programmatic licensure requirements for clinical documentation in outpatient behavioral health. Of the initial 500 sessions reviewed, 0 items related to fairness were identified in the local data.

9. Update and continued validation or fairness assessment schedule

(*i*) **Description of process and frequency by which the intervention is updated**
Monthly review of clinical feedback as part of ongoing quality testing. Quarterly review of session output comparison to input transcripts by subject matter experts. Quarterly review of findings by Product and Engineering teams to the AI and Data Governance Committee.

(*ii*) **Description of frequency by which the intervention's performance is corrected when risks related to validity and fairness are identified**
Performance and corrections are rated on a Priority scale and incorporated into the Qualifacts Software Development Life Cycle and Standard Operating Procedures. Based on the priority assigned, a remediation timeline is identified. For example, critical items are addressed immediately, high priority items are generally corrected within 30 business days.

VII. Governance:

Qualifacts' AI and Data Governance Committee for the oversight of Data and AI Innovations reviews and approves all AI use cases for new product development and monitors existing AI technologies and partnerships to ensure ethical development. This cross-functional committee,

established in April 2024, consists of subject matter experts in the areas of clinical direct care, regulatory compliance, medical billing, patient advocacy, customer implementation, data science, quality assurance testing, and monitoring, Engineering, and Information Security, to name a few.

In alignment with the Qualifacts' Core Values of innovation, Customer-First, Action, Respect, and Enjoyment, as well as the FAVES principles established by the Assistant Secretary of Technology Policy and Office of the National Coordinator (ASTP/ONC), the following summarizes several governance activities and edicts implemented in 2024 as Qualifacts commercially launched its first Predictive Decision Support Intervention, Qualifacts iQ:

1. Development of Qualifacts Data Artificial Intelligence Acceptable Use and Development Policy
2. The design and implementation of AI technology partnerships and/or development provided for commercial use by Qualifacts will ensure human oversight remains required in clinical workflows in alignment with applicable law and other standards that are reasonable for a particular AI Tool.
3. Adopted ISO 42001- AI Management Systems and 42005 -AI System Impact Assessment. Full implementation is anticipated to span 2025.
4. Incorporation of FAVES principles into engineering processes and practices.
5. Incorporation of clinical subject matter experts' periodic review and feedback on fairness, validity, and appropriateness.
6. Development of procedures for oversight and approval of AI Use Cases for development.