Appendix D: Usability Veracity Attestation

Henry Schein Medical Systems
MicroMD EMR 13.5

Kristen Heffernan
General Manager
330-531-7035

Henry Schein Medical Systems attests that the usability standard/process and usability report submitted for the certification of MicroMD EMR 13.5 is accurate and complete per the requirements of the ONC criterion 170.315(g)(3).

Kristen Heffernan
General Manager
5/22/17

Appendix C: User-Centered Design Process Template

Henry Schein Medical Systems
MicroMD EMR 13.5

Kristen Heffernan
General Manager
330-531-7035

For public release:
Henry Schein Medical Systems used the following usability design industry standard / process in developing and designing their health IT module, MicroMD EMR 13.5: Industry Standard NISTIR 7741.

Kristen Heffernan
General Manager
5/22/17

EHR Usability Test Report of MicroMD 13.5

EHR Usability Test Report of MicroMD 13.5

Report based on ISO/IEC 25062:2006 Common Industry Format for Usability Test Reports

MicroMD 13.5

Date of Usability Test: January 30, 2017 – April 19, 2017
Date of Report: 5/1/17
Report Prepared By: Henry Schein Medical Systems

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EXECUTIVE SUMMARY

A usability test of MicroMD, 13.5, Ambulatory EHR was conducted between January and April in Boardman, Ohio by Henry Schein Medical Systems. The purpose of this test was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). During the usability test, 11 intended users matching the target demographic criteria served as participants and used the EHRUT in simulated, but representative tasks. This study collected performance data on 12 tasks typically conducted on an EHR:

1. Prescribing of a patient medication
2. Adding of a laboratory order
3. Adding of a radiology order
4. Drug-Drug and Drug-Allergy Interaction checking
5. Adding and editing of patient demographics
6. Adding and editing a patient's problem list
7. Adding a long term medication to a patient chart
8. Adding and editing a patient's medication allergies
9. Adding an applying a Clinical Decision Support rule
10. Adding an implantable device to a patient's chart
11. Reconciling a patient's clinical information discretely
12. Prescribing an electronic prescription

During the 30 minute one-on-one usability test, each participant was greeted by the administrator and asked to review and sign an informed consent/release form (included in Appendix 3); they were instructed that they could withdraw at any time. Participants both had and did not have prior experience with the EHR.[4] The administrator introduced the test, and instructed participants to complete a series of

tasks (given one at a time) using the EHRUT. During the testing, the administrator timed the test and, along with the data logger(s) recorded user performance data on paper and electronically. The administrator did not give the participant assistance in how to complete the task. Participants were given instruction sheets to educate and a brief introduction to the task to familiarize themselves with the task and windows.

Participant screens, head shots and audio were recorded for subsequent analysis. The following types of data were collected for each participant:

- Number of tasks successfully completed within the allotted time without assistance
- Time to complete the tasks
- Number and types of errors
- Path deviations
- Participant's verbalizations
- Participant's satisfaction ratings of the system

All participant data was de-identified – no correspondence could be made from the identity of the participant to the data collected. Following the conclusion of the testing, participants were asked to complete a post-test questionnaire and were

compensated for their time. Various recommended metrics, in accordance with the examples set forth in the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, were used to evaluate the usability of the EHRUT. Following is a summary of the performance and rating data collected on the EHRUT.

CPOE – Medications (170.315 (a)(1)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Adding a medication to a patient' chart	11	91	2/4	25.25	.2/.4	20%	4.625

CPOE – Laboratory 170.315 (a)(2)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
2. Adding a lab order for a patient	10	20	9/5	29.96	.6/.8	0	4.75

CPOE – Diagnostic Imaging 170.315 (a)(3)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Adding a diagnostic order for a patient	10	90	2/2	25.62	.7/1	0	4.5

Drug-drug, Drug-allergy Interaction Checks 170.315 (a)(4)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Adding a new medication to trigger interactions	10	89	2/2	9.95	.4/.6	0	4.625

Demographics 170.315 (a)(5)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Adding a new patient into the system	10	44	1/3	16.34	.5/.3	0	5
2. Editing an existing patient's demographics	10	88	1/2	36.69	0/	0	5

Problem List 170.315 (a)(6)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Adding a new patient problem to the chart	10	60	1/2	25.31	.6/.6	0	4.5
2. Editing an existing problem list item	10	100	0/1	8.81	0/.3	0	4.625

Medication List 170.315 (a)(7)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Adding a LTM into the patient's chart	10	80	6/4	20.70	1.2/2	0	4.375

Medication Allergy List 170.315 (a)(8)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Add a new drug allergy to a patient's chart	10	90	0/2	8.66	0/.2	0	4.625
2. Editing an existing allergy	10	100	0/1	2.12	0/.1	0	4.5

Clinical Decision Support 170.315 (a)(9)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Setting up a new rule to trigger on demographic information	10	70	0/4	33.26	0/.4	0	4
2. Opening a chart to review the rule just setup	10	90	0/2	14.81	0/.1	10	4

Implantable Devices 170.315 (a)(14)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Adding an implantable device to a chart	10	90	0/2	61.18	0/.2	0	3.625

Clinical Information Reconciliation and Incorporation 170.315 (b)(2)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Reconciling a CDA into a allergies, medications and problem list	10	100	7/4	42.34	.9/.7	0	3.714

Electronic Prescribing 170.315 (b)(3)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
1. Add a new prescription for a patient and process electronically to a pharmacy	10	80	0/2	62.97	0/.2	20	4.625

The results from the System Usability Scale scored the subjective satisfaction with the system based on performance with these tasks to be: 92% satisfaction rate.

In addition to the performance data, the following qualitative observations were made:

- Major findings
    - No major findings were noted on the participants facial expressions or verbal responses to any of the tasks presented
- Areas for improvement
    - There were two areas detected during the study that need to be reviewed for some workflow changes and usability considerations. These areas were adding demographic information and adding a patient's chronic problem(s).

[1] See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149). Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.

INTRODUCTION

The EHRUT(s) tested for this study was MicroMD EMR 13.5 Designed to present medical information to healthcare

providers in an ambulatory setting across multiple disciplines (Family Medicine, Internal Medicine, Pediatrics, etc.) the EHRUT consists of

ambulatory based EHR system that helps practices and health centers eliminate unnecessary paper, improve clinical productivity by allowing for the capturing and reporting of discrete medical information. The usability testing attempted to represent realistic exercises and conditions.

The purpose of this study was to test and validate the usability of the current user interface, and provide evidence of usability in the EHR Under Test (EHRUT). . To this end, measures of effectiveness,
efficiency and user satisfaction, such as Task Success %, Task Success Standard Deviation %, Path Deviations, Task Time Mean, Task Time Standard Deviation, Task Time Deviation Steps, Error % and Task Rating were captured during the usability testing.

METHOD

PARTICIPANTS

A total of 11 participants were tested on the EHRUT(s). Participants in

the test were provider and healthcare users that are involved in the day to day collection and entering of medical data across multiple specialties. Also those that are exposed to reviewing and accessing part of the medical chart. Participants were recruited

by MicroMD and were compensated for their time. In addition, participants had no direct connection to the development of or organization producing the EHRUT(s). Participants were not from the testing or supplier organization. Participants were given the opportunity to have the same orientation and level of training as the actual end users would have received.

For the test purposes, end-user characteristics were identified and translated into

a recruitment screener used to solicit potential

participants; an example of a screener is provided in Appendix [1].

Recruited participants had a mix of backgrounds and demographic characteristics conforming to the recruitment screener. The following is a table of participants by characteristics, including demographics, professional experience, computing experience and user needs for assistive technology. Participant names were replaced with Participant IDs so that an individual's data cannot be tied back to individual identities.

	Part ID	Gender	Age	Education	Occupation/ role	Professional Experience	Computer Experience	Product Experience	Assistive Technology Needs
1	1	Female	40-49	Some College	Medical Assist.	13 years	13 years	6 months	No
2	2	Female	50-59	Bachelor's Degree	Systems Administ.	20 years	20 years	17 years	No
3	3	Female	40-49	Bachelor's Degree	Practice Administ.	35 years	35 years	7 years	No
4	4	Female	50-59	High School Grad	Phys Serv. Mgr./EMR Super User	25 years	25 years	4 years	No
5	5	Male	30-39	Bachelor's Degree	IT	7 years	15 years	7 years	No
6	6	Female	50-59	Bachelor's Degree	Consultant/Billing	33 years	35 years	27 years	No
7	7	Female	20-29	Some College	Front Desk	4 years	15 years	None	No
8	8	Female	60-69	High School Grad	Front Desk	20 years	20 years	None	No
9	9	Female	50-59	High School Grad	Biller	16 years	16 years	None	No
10	10	Male	60-69	Doctorate Degree/D.O	Physician	34 years	34 years	11 years	No
11	11	Female	30-39	Bachelor's Degree	Medical Assist.	9 years	20+ years	7 years	No

11 participants (matching the demographics in the section on Participants) were recruited and 11 participated in the usability

test. 0 participants failed to show for the study.

Participants were scheduled for 30 min sessions with

Several days in between each session for debrief by the administrator(s) and data logger(s), and to reset systems to proper test conditions. A spreadsheet was used to keep track of the participant schedule, and included each participant's demographic characteristics as provided by the recruiting firm.

STUDY DESIGN

Overall, the objective of this test was to uncover areas where the application performed well – that is, effectively, efficiently, and with satisfaction – and areas where the application failed to meet the needs of the participants. The data from this test may serve as a baseline for future tests with an updated version of the same EHR and/or comparison with other EHRs provided the same tasks are used. In short, this testing serves as both a means to record or benchmark current usability, but also to identify areas where improvements must be made.

During the usability test, participants interacted with 1 EHR(s). Each participant used the system in the same location, and was provided with the same instructions. The system was evaluated for effectiveness, efficiency and satisfaction as defined by measures collected and analyzed for each participant:

X Number of tasks successfully completed within the allotted time without assistance
XTime to complete the tasks XNumber and types of errors XPath deviations
XParticipant's verbalizations (comments)
XParticipant's satisfaction ratings of the system

Additional information about the various measures can be found in Section 3.9 on Usability Metrics.

TASKS

A number of tasks were constructed that would be realistic and representative of the kinds of activities a user might do with this EHR, including:

1. Prescribing of a patient medication
2. Adding of a laboratory order
3. Adding of a radiology order
4. Drug-Drug and Drug-Allergy Interaction checking
5. Adding and editing of patient demographics
6. Adding and editing a patient's problem list
7. Adding a long term medication to a patient chart
8. Adding and editing a patient's medication allergies
9. Adding an applying a Clinical Decision Support rule

10. Adding an implantable device to a patient's chart
11. Reconciling a patient's clinical information discretely
12. Prescribing an electronic prescription

Tasks were selected based on their frequency of use, criticality of function, and those that may be most troublesome for users.[6] Tasks should always be constructed in light of the study objectives.

PROCEDURE

Upon arrival, participants were greeted; their identity was verified and matched with a name on the participant schedule. Participants were then assigned a participant ID.[7] Each participant reviewed and signed an informed consent and release form (See Appendix 3). A representative from the test team witnessed the participant's signature.

To ensure that the test ran smoothly, two staff members participated in this test, the usability administrator and the data logger. The usability testing staff conducting the test was experienced usability practitioners with <1 year usability experience,8+ years utilizing the system and bachelor degrees of the test administrator(s) and data logger(s)].

The administrator moderated the session including administering instructions and tasks. The administrator also monitored task times, obtained post-task rating data, and took notes on participant comments. A second person served as the data logger and took notes on task success, path deviations, number and type of errors, and comments.

Participants were instructed to perform the tasks (see specific instructions below):

- As quickly as possible making as few errors and deviations as possible.

[6] Constructing appropriate tasks is of critical importance to the validity of a usability test. These are the actual functions, but most tasks contain larger and more fleshed out context that aligns with the sample data sets available in the tested EHR. Please consult usability references for guidance on how to construct appropriate tasks.

[7] All participant data must be de-identified and kept confidential.

- Without assistance; administrators were allowed to give immaterial guidance and clarification on tasks, but not instructions on use.
- Without using a think aloud technique.

For each task, the participants were given a written copy of the task. Task timing began once the administrator finished reading the question. The task time was stopped once the participant indicated they had successfully completed the task. Scoring is discussed below in Section 3.9.

Following the session, the administrator gave the participant the post-test questionnaire (e.g., the System Usability Scale, see Appendix 5), compensated them for their time, and thanked each individual for their participation.

Participants' demographic information, task success rate, time on task, errors, deviations, verbal responses, and post-test questionnaire were recorded into a spreadsheet.

Participants were thanked for their time and compensated. Participants signed a receipt and acknowledgement form (See Appendix 6) indicating that they had received the compensation.

TEST LOCATION

The test facility included a waiting area and a quiet testing room with a table, computer for the participant, and recording computer for the administrator. To ensure that the environment was comfortable for users, noise levels were kept to a minimum with the ambient temperature within a normal range. All of the safety instruction and evacuation procedures were valid, in place, and visible to the participants.

TEST ENVIRONMENT

The EHRUT would be typically be used in a healthcare office or facility.

In this instance, the testing was conducted at Henry Schein Medical Systems Boardman location for testing, the computer used was an Intel Core i7 running Windows 7.

The participants used a mouse and keyboard when interacting with the EHRUT.

The MicroMD EMR 13.5 used a 16" monitor set at 1280x1024 resolution. The application was set up by Henry Schein Medical Systems according to the vendor's documentation describing the system set-up and preparation. The application itself was running on a SQL Server using a demo database on a LAN connection. Technically, the system performance (i.e., response time) was representative to what actual users would experience in a field implementation. Additionally, participants were instructed not to change any of the default system settings (such as control of font size).

TEST FORMS AND TOOLS

During the usability test, various documents and instruments were used, including:

1. Informed Consent
2. Moderator's Guide
3. Post-test Questionnaire
4. Incentive Receipt and Acknowledgment Form

Examples of these documents can be found in Appendices 3-6 respectively. The Moderator's Guide was devised so as to be able to capture required data.

The participant's interaction with the EHRUT was captured and recorded digitally with screen capture software running on the test machine. A Camtasia session and GoToMeeting session captured and recorded each participant's facial expressions synced with the screen capture, and verbal comments as well. [8] The test session were electronically stored locally where the data logger could review to ensure accurate notes.

PARTICIPANT INSTRUCTIONS

The administrator reads the following instructions aloud to the each participant (also see the full moderator's guide in Appendix 4):

Thank you for participating in this study. Your input is very important. Our session today will last about 30 minutes. During that time you will use an instance of an electronic health record. I will ask you to complete a few tasks using this system and answer some questions. You should complete the tasks as quickly as possible making as few errors as possible. Please try to complete the tasks on your own following the instructions very closely. Please note that we are not testing you we are testing the system, therefore if you have difficulty all this means is that something needs to be improved in the system. I will be here in case you need specific help, but I am not able to instruct you or provide help in how to use the application.

Overall, we are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. I did not have any involvement in its creation, so please be honest with your opinions. All of the information

[8] There are a variety of tools that record screens and transmit those recordings across a local area network for remote observations.

that you provide will be kept confidential and your name will not be associated with your comments at any time. Should you feel it necessary you are able to withdraw at any time during the testing.

Following the procedural instructions, participants were shown the HER and were given a few minutes explanation for those that weren't familiar with our EMR. Once this task was complete, the administrator gave the following instructions:

For each task, I will read the description to you and say "Begin." At that point, please perform the task and say "Done" once you believe you have successfully completed the task. I would like to request that you not *talk aloud or verbalize while you are doing the tasks.* [9] *I will ask you your impressions about the task once you are done.*

Participants were then given 12 tasks to complete. Tasks are listed in the moderator's guide in Appendix [B4].

USABILITY METRICS

According to the *NIST Guide to the Processes Approach for Improving the Usability of Electronic Health Records*, EHRs should support a process that provides a high level of usability for all users. The goal is for users to interact with the system effectively, efficiently, and with an acceptable level of satisfaction. To this end, metrics for effectiveness, efficiency and user satisfaction were captured during the usability testing.

The goals of the test were to assess:

1. Effectiveness MicroMD EMR 13.5 by measuring participant success rates and errors
2. Efficiency of MicroMD EMR 13.5 by measuring the average task time and path deviations
3. Satisfaction with MicroMD EMR 13.5 by measuring ease of use ratings

[9] Participants should not use a think-aloud protocol during the testing. Excessive verbalization or attempts to converse with the moderator during task performance should be strongly discouraged. Participants will naturally provide commentary, but they should do so, ideally, after the testing. Some verbal commentary may be acceptable between tasks, but again should be minimized by the moderator.

DATA SCORING

The following table (Table [x]) details how tasks were scored, errors evaluated, and the time data analyzed.[10]

Measures	Rationale and Scoring
Effectiveness: Task Success	A task was counted as a "Success" if the participant was able to achieve the correct outcome, without assistance, within the time allotted on a per task basis. The total number of successes were calculated for each task and then divided by the total number of times that task was attempted. The results are provided as a percentage. Task times were recorded for successes. Observed task times divided by the optimal time for each task is a measure of optimal efficiency. Optimal task performance time, as benchmarked by expert performance under realistic conditions, is recorded when constructing tasks. Target task times used for task times in the Moderator's Guide must be operationally defined by taking multiple measures of optimal performance and multiplying by some factor [e.g., 1.25] that allows some time buffer because the participants are presumably not trained to expert performance. Thus, if expert, optimal performance on a task was [x] seconds then allotted task time performance was [x * 1.25] seconds. This ratio should be aggregated across tasks and reported with mean and variance scores.
Effectiveness: Task Failures	If the participant abandoned the task, did not reach the correct answer or performed it incorrectly, or reached the end of the allotted time before successful completion, the task was counted as an "Failures." No task times were taken for errors. The total number of errors was calculated for each task and then divided by the total number of times that task was attempted. Not all deviations would be counted as errors.[11] This should also be expressed as the mean number of failed tasks per participant. On a qualitative level, an enumeration of errors and error types should be collected.
Efficiency: Task Deviations	The participant's path (i.e., steps) through the application was recorded. Deviations occur if the participant, for example, went to a wrong screen, clicked on an incorrect menu item, followed an incorrect link, or interacted incorrectly with an on-screen control. This path was compared to the optimal path. The number of steps in the observed path is divided by the number of optimal steps to provide a ratio of path deviation.

[10] An excellent resource is Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman. Also see www.measuringusability.com

[11] Errors have to be operationally defined by the test team prior to testing.

	It is strongly recommended that task deviations be reported. Optimal paths (i.e., procedural steps) should be recorded when constructing tasks.
Efficiency: Task Time	Each task was timed from when the administrator said "Begin" until the participant said, "Done." If he or she failed to say "Done," the time was stopped when the participant stopped performing the task. Only task times for tasks that were successfully completed were included in the average task time analysis. Average time per task was calculated for each task. Variance measures (standard deviation and standard error) were also calculated.
Satisfaction: Task Rating	Participant's subjective impression of the ease of use of the application was measured by administering both a simple post-task question as well as a post-session questionnaire. After each task, the participant was asked to rate "Overall, this task was:" on a scale of 1 (Very Difficult) to 5 (Very Easy). These data are averaged across participants. [12] Common convention is that average ratings for systems judged easy to use should be 3.3 or above. To measure participants' confidence in and likeability of the [EHRUT] overall, the testing team administered the System Usability Scale (SUS) post-test questionnaire. Questions included, "I think I would like to use this system frequently," "I thought the system was easy to use," and "I would imagine that most people would learn to use this system very quickly." See full System Usability Score questionnaire in Appendix 5.[13]

Table [x]. Details of how observed data were scored.

RESULTS

DATA ANALYSIS AND REPORTING

The results of the usability test were calculated according to the methods specified in the Usability Metrics section above. Participants who failed to follow session and task instructions had their data excluded from the

Analyses.

[12] See Tedesco and Tullis (2006) for a comparison of post-task ratings for usability tests. Tedesco, D. & Tullis, T. (2006) A comparison of methods for eliciting post-task subjective ratings in usability testing. *Usability Professionals association Conference*, June 12 – 16, Broomfield, CO.

[13] The SUS survey yields a single number that represents a composite measure of the overall perceived usability of the system. SUS scores have a range of 0 to 100 and the score is a relative benchmark that is used against other iterations of the system.

The usability testing results for the EHRUT are detailed below (see Table [x])[14]. The results should be seen in light of the objectives and goals outlined in Section

3.2 Study Design. The data should yield actionable results that, if corrected, yield material, positive impact on user performance.

CPOE – Medications (170.315 (a)(1)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
3. Adding a medication to a patient' chart	11	91	2/4	25.25	.2/.4	20%	4.625

CPOE – Laboratory 170.315 (a)(2)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
4. Adding a lab order for a patient	10	20	9/5	29.96	.6/.8	0	4.75

CPOE – Diagnostic Imaging 170.315 (a)(3)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
2. Adding a diagnostic order for a patient	10	90	2/2	25.62	.7/1	0	4.5

Drug-drug, Drug-allergy Interaction	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**	**Errors**	**Task Ratings** 5=Easy

Checks 170.315 (a)(4)	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
2. Adding a new medication to trigger interactions	10	89	2/2	9.95	.4/.6	0	4.625

Demographics 170.315 (a)(5)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
3. Adding a new patient into the system	10	44	1/3	16.34	.5/.3	0	5
4. Editing an existing patient's demographics	10	88	1/2	36.69	0/	0	5

Problem List 170.315 (a)(6)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
3. Adding a new patient problem to the chart	10	60	1/2	25.31	.6/.6	0	4.5
4. Editing an existing problem list item	10	100	0/1	8.81	0/.3	0	4.625

Medication List 170.315 (a)(7)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
2. Adding a LTM into the patient's chart	10	80	6/4	20.70	1.2/2	0	4.375

Medication Allergy List 170.315 (a)(8)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**	**Errors**	**Task Ratings** 5=Easy

	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
3. Add a new drug allergy to a patient's chart	10	90	0/2	8.66	0/.2	0	4.625
4. Editing an existing allergy	10	100	0/1	2.12	0/.1	0	4.5

Clinical Decision Support 170.315 (a)(9)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
3. Setting up a new rule to trigger on demographic information	10	70	0/4	33.26	0/.4	0	4
4. Opening a chart to review the rule just setup	10	90	0/2	14.81	0/.1	10	4

Implantable Devices 170.315 (a)(14)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
3. Adding an implantable device to a chart	10	90	0/2	61.18	0/.2	0	3.625

Clinical Information Reconciliation and Incorporation 170.315 (b)(2)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
2. Reconciling a CDA into a allergies, medications and problem list	10	100	7/4	42.34	.9/.7	0	3.714

Electronic Prescribing 170.315 (b)(3)	***N***	**Task Suc-cess**	**Path Deviation**	**Task Time**		**Errors**	**Task Ratings** 5=Easy
	#	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Deviations (Observed / Optimal)	Mean (SD)	Mean (SD)
2. Add a new prescription for a patient and process electronically to a pharmacy	10	80	0/2	62.97	0/.2	20	4.625

The results from the SUS (System Usability Scale) scored the subjective satisfaction with the system based on performance with these tasks to be: Mainly above average. There was one category that was considered average and one that was considered to be below average. Broadly interpreted, scores under 60 represent systems with poor usability; scores over 80 would be considered above average.[15]

[14] Note that this table is an example. You will need to adapt it to report the actual data collected.
[15] See Tullis, T. & Albert, W. (2008). Measuring the User Experience. Burlington, MA: Morgan Kaufman (p. 149).

DISCUSSION OF THE FINDINGS

EFFECTIVENESS

Overall based on the data the system is effective workflow wise. There are a couple areas such as demographics and adding a long term medication that have an opportunity for some workflow improvements for a better more effective user experience.

EFFICIENCY

Overall the task times were in line with the optimal and expected time that were calculated prior to testing. The task times that were documented as being over the allotted time were in line with the categories listed above under effectiveness.

SATISFACTION

Overall both usability study participants that had used our system and hadn't used our system seemed to be satisfied with the workflow and usability of the MicroMD EMR software.

MAJOR FINDINGS

There were no major findings discovered.

AREAS FOR IMPROVEMENT

A couple of areas were noticed while observing the participants that seem to be a consistent area where they seem to spend some unnecessary time. Specifically when adding demographics and long term medications to the chart. We will be reviewing these areas to propose some potential workflow changes and run it by our client advisory board for approval.

APPENDICES

The following appendices include supplemental data for this usability test report. Following is a list of the appendices provided:

1: Recruiting Screener Form

2: Participant demographics

3: Non-Disclosure Agreement (NDA) and Informed Consent Form

4: Moderator's Guide

5: System Usability Scale Questionnaire

6: Incentive receipt and acknowledgment form

Appendix 1: RECRUITING SCREENER FORM

Recruiting Screener Form

Hello, my name is_____, calling from *Henry Schein MicroMD*. We are recruiting individuals to participate in a usability study for an electronic health record. We would like to ask you a few questions to see if you qualify and if would like to participate. This should only take a few minutes of your time. This is strictly for research purposes. If you are interested and qualify for the study, you will be paid to participate. Can I ask you a few questions?

Customize this by dropping or adding questions so that it reflects your EHR's primary audience

1. Which of the following best describes your age? [23 to 39; 40 to 59; 60 - to 74; 75 and older] [Recruit Mix]
2. Do you require any assistive technologies to use a computer? [if so, please describe]

Professional Demographics *Customize this to reflect your EHR's primary audience*

3. What is your current position and title? (Must be healthcare provider)
   - ☐ RN: Specialty _____
   - ☐ Physician: Specialty_____
   - ☐ Resident: Specialty _____
   - ☐ Administrative Staff
   - ☐ Other [Terminate]

4. How long have you held this position?
5. Describe your work location (or affiliation) and environment? (Recruit according to the intended users of the application) [e.g., private practice, health system, government clinic, etc.]
6. Which of the following describes your highest level of education? [e.g., high school graduate/GED, some college, college graduate (RN, BSN), postgraduate (MD/PhD), other (explain)]

Computer Expertise *Customize this to reflect what you know about your EHR's audience*

7. Besides reading email, what professional activities do you do on the computer? [e.g., access EHR, research; reading news; shopping/banking; digital pictures; programming/word processing, etc.] [If no computer use at all, Terminate]
8. About how many hours per week do you spend on the computer? [Recruit according to the demographics of the intended users, e.g., 0 to 10, 11 to 25, 26+ hours per week]
9. What computer platform do you usually use? [e.g., Mac, Windows, etc.]
10. What Internet browser(s) do you usually use? [e.g., Firefox, IE, AOL, etc.]
11. In the last month, how often have you used an electronic health record? How many years have you used an electronic health record?
12. How many EHRs do you use or are you familiar with?

Contact Information *If the person matches your qualifications, ask*

Those are all the questions I have for you. Your background matches the people we're looking for. For your participation, you will be paid [$XX]

Would you be able to participate on [date, time]? [If so collect contact information]

Before your session starts, we will ask you to sign a release form allowing us to videotape your session. The videotape will only be used internally for further study if needed. Will you consent to be videotaped?

This study will take place at our main headquarters in Boardman,Ohio. I will confirm your appointment a couple of days before your session and provide you with directions to our office

Appendix 2: PARTICIPANT DEMOGRAPHICS

Demographic Sheet – MicroMD Usability Study

1. Name: _____
2. Credentials (if applicable): _____
3. Gender: _____
4. Age:
    a. 0-9
    b. 10-19
    c. 20-29
    d. 30-39
    e. 40-49
    f. 50-59
    g. 60-69
    h. 70-79
    i. 80-89
    j. 90-99
    k. 100+
5. Highest Level of Education
    a. High School graduate/GED
    b. Some College
    c. College Graduate
    d. Postgraduate
    e. Other _____

6. Occupation: _____
7. Specialty of Practice: _____
8. Professional Experience: _____
9. How many years of experience to you have using computers for personal or professional activities? : _____
10. How many years of experience do you have using MicroMD? : _____

Is there any assistive technology needed to utilize a software

As an appendix to the report, the full participant breakdown (de-identified) should be included.

Appendix 3: NON-DISCLOSURE AGREEMENT AND INFORMED CONSENT FORM

Non-Disclosure Agreement

THIS AGREEMENT is entered into as of _____ between _____ and the testing organization Henry Schein MicroMD located at 760 Boardman-Canfield Rd, Boardman, Ohio 44512.

The participant acknowledges his or her voluntary participation in today's usability study may bring the Participant into possession of Confidential Information. The term "Confidential Information" means all technical and commercial information of a proprietary or confidential nature which is disclosed by Henry Schein MicroMD, or otherwise acquired by the Participant, in the course of today's study.

By way of illustration, but not limitation, Confidential Information includes trade secrets, processes, formulae, data, know-how, products, designs, drawings, computer aided design files, and other computer files, computer software, ideas, improvements, inventions, training methods and materials, marketing techniques, plans, strategies, budgets, financial information, or forecasts.

Any information the Participant acquires relating to this product during this study is confidential and proprietary to Henry Schein MicroMD and is being disclosed solely for the purpose of the Participant's participation in today's usability study. By signing this form the Participant acknowledges that s/he will receive monetary compensation for feedback and will not disclose this confidential information obtained today to anyone else or any other organizations.

Participant's printed name:

_____

Signature: _____ **Date:** _____

Informed Consent

Henry Schein MicroMD would like to thank you for participating in this study. The purpose of this study is to evaluate an electronic health records systems. If you decide to participate, you will be asked to perform several tasks and give your feedback. They study will last approximately 60 minutes. At the conclusion of the test, you will be compensated for your time.

Agreement

I understand and agree that as a voluntary participant in the present study conducted *by Henry Schein MicroMD* I am free to withdraw consent or discontinue participation at any time. I understand and agree to participate in the study conducted and recorded by *Henry Schein MicroMD*.

I understand and consent to the use for research purposes and for auditing purposes if required by the meaningful use certifying body, the recordings obtained during the usability study. My name will not be released to any other source or be made public. I relinquish any rights to the recording and understand that the recording may be copied and used by Henry Schein MicroMD without further permission.

I understand and agree that the purpose of this study is to make software applications more useful and usable in the future.

I understand and agree that the data collected form this study may be shared outside of *Henry Schein* MicroMD and *Henry Schein MicroMD's* clients. I understand and agree that data confidentiality is assured, because only de-identified data – ie. Participant identification numbers not names – will be used in analysis and reporting of the results.

I agree to immediately raise any concerns or areas of discomfort with the study administrator. I understand that I can leave at any time.

Please check one of the following:

□ YES, I have read the above statement and agree to be a participant.

□□NO, I choose not to participate in this study.

Signature: _____ **Date:** _____

Appendix 4: EXAMPLE MODERATOR'S GUIDE

EHRUT Usability Test

Prior to testing
- Confirm schedule with Participants
- Ensure EHRUT lab environment is running properly
- Ensure lab and data recording equipment is running properly

Prior to each participant:
- Reset application
- Start session recordings with *tool*

Prior to each task:
- Reset application to starting point for next task

After each participant:
- End session recordings with *tool*

After all testing
- Back up all video and data files

Orientation

Thank you for participating in this study. Our session today will last ***30*** **minutes**. During that time you will take a look at an electronic health record system.

I will ask you to complete a few tasks using this system and answer some questions. We are interested in how easy (or how difficult) this system is to use, what in it would be useful to you, and how we could improve it. You will be asked to complete these tasks on your own trying to do them as quickly as possible with the fewest possible errors or deviations.

The product you will be using today is *MicroMD EMR.* Some of the data may not make sense as it is placeholder data.

We are recording the audio and screenshots of our session today. All of the information that you provide will be kept confidential and your name will not be associated with your comments at any time.

Do you have any questions or concerns?

Take the participant to the starting point for the task.

Task: CPOE Medication Order **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A → Screen B → Drop Down B[1] → "OK" Button → Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: CPOE Laboratory Order **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B*[1] → *"OK" Button* → *Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: CPOE Diagnostic Imaging Order **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A → Screen B → Drop Down B[1] → "OK" Button → Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Drug-drug, Drug-allergy Interaction Checking **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B*[1] → *"OK" Button* → *Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Demographics **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B*[1] → *"OK" Button* → *Screen X…*

- ☐ Correct
- ☐ Minor Deviations: Describe below
- ☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

- ☐ Yes
- ☐ No

Task was:

- ☐ Easily completed
- ☐ Completed with difficulty or help: Describe below
- ☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Problem List **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B[1]* → *"OK" Button* → *Screen X…*

- ☐ Correct
- ☐ Minor Deviations: Describe below
- ☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

- ☐ Yes
- ☐ No

Task was:

- ☐ Easily completed
- ☐ Completed with difficulty or help: Describe below
- ☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Medication List **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B*[1] → *"OK" Button* → *Screen X…*

- ☐ Correct
- ☐ Minor Deviations: Describe below
- ☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

- ☐ Yes
- ☐ No

Task was:

- ☐ Easily completed
- ☐ Completed with difficulty or help: Describe below
- ☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Medication Allergy List **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A → Screen B → Drop Down B[1] → "OK" Button → Screen X…*

- ☐ Correct
- ☐ Minor Deviations: Describe below
- ☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

- ☐ Yes
- ☐ No

Task was:

- ☐ Easily completed
- ☐ Completed with difficulty or help: Describe below
- ☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Clinical Decision Support **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B*[1] → *"OK" Button* → *Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Implantable Device List **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B*[1] → *"OK" Button* → *Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Clinical Information Reconciliation and Incorporation **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A → Screen B → Drop Down B[1] → "OK" Button → Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Task: Electronic Prescribing **Participant #: _____**

Take the participant to the starting point for the task.

Task Start Time: _____am/pm

Number of Steps Taken: _____

Number of Deviations: _____

Optimal Path: *Screen A* → *Screen B* → *Drop Down B*[1] → *"OK" Button* → *Screen X…*

☐ Correct
☐ Minor Deviations: Describe below
☐ Major Deviations: Describe below

Comments:

Number of Errors: _____

Success:

Participant was able to complete the task successfully:

☐ Yes
☐ No

Task was:

☐ Easily completed
☐ Completed with difficulty or help: Describe below
☐ Not completed

Comments:

Task End Time: _____am/pm

Total Task Time: _____ seconds

Appendix 5: SYSTEM USABILITY SCALE QUESTIONNAIRE

*In 1996, Brooke published a "*low-cost usability scale that can be used for global assessments of systems usability*" known as the System Usability Scale or SUS.*[16] *Lewis and Sauro (2009) and others have elaborated on the SUS over the years. Computation of the SUS score can be found in Brooke's paper, in at* http://www.usabilitynet.org/trump/documents/Suschapt.doc *or in Tullis and Albert (2008).*

	Strongly disagree				Strongly agree
1. I think that I would like to use this system frequently	1	2	3	4	5
2. I found the system unnecessarily complex	1	2	3	4	5
3. I thought the system was easy to use	1	2	3	4	5
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5
5. I found the various functions in this system were well integrated	1	2	3	4	5
6. I thought there was too much inconsistency in this system	1	2	3	4	5
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5
8. I found the system very cumbersome to use	1	2	3	4	5
9. I felt very confident using the system	1	2	3	4	5
10. I needed to learn a lot of things before I could get going with this system					

[16] Brooke, J.: SUS: A "quick and dirty" usability scale. In: Jordan, P. W., Thomas, B.,

Weerdmeester, B. A., McClelland (eds.) *Usability Evaluation in Industry* pp. 189--194. Taylor & Francis, London, UK (1996). SUS is copyrighted to Digital Equipment Corporation, 1986.

Lewis, J R & Sauro, J. (2009) "The Factor Structure Of The System Usability Scale." in *Proceedings of the Human Computer Interaction International Conference (HCII 2009), San Diego CA, USA*

Appendix 6: INCENTIVE RECEIPT AND ACKNOWLEDGMENT FORM

Acknowledgement of Receipt

I hereby acknowledge receipt of *$*_____ for my participation in a research study run by *Test Company.*

Printed Name:_____

Address:_____

_____

Signature:_____Date: _____

Usability Researcher:_____

Signature of Usability Researcher: _____

Date:_____

Witness: _____

Witness Signature:_____

Date:_____

Drummond group

Appendix A: Attestation Template for Approach #1

Privacy and Security Certification Documentation

Kristen Heffernan
General Manager
330-531-7035
MicroMD 13.5

MicroMD only needs to be tested once per each applicable privacy and security criteria as the privacy and security capabilities apply to the full scope of capabilities included in the requested testing and certification, except for the following:

- Any health IT system presented for certification to § 170.315(e)(1) must be separately tested to § 170.315(d)(9) [Per the ONC Final Rule].
- Any health IT system presented for certification to § 170.315(e)(2) must be separately tested to § 170.315(d)(9) [Per the ONC Final Rule].
- 170.315 (g)(7) – Application Access – Patient Selection
- 170.315 (g)(8) – Application Access – Data Category Request
- 170.315 (g)(9) – Application Access – All Data Request

I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.

Kristen Heffernan, General Manager
1/20/17

Drummond group

Appendix C: Auditable Events (d.2) Attestation Template

Privacy and Security Certification Documentation

Kristen Heffernan
General Manager
330-531-7035

Henry Schein Medical Systems attests to the validity of the information below to satisfy the documentation requirements for testing and certification of the ONC 2015 Edition criteria: *170.315(d)(2).*

1. **Does the health IT module audit logging capability monitor each of the required actions for all instances of electronic health information utilized by the health IT module in accordance with the specified standard ASTM E2147-01?**
   [IN170.315(d)(2)(i)(A)]

   Yes. *Yes, the system captures the appropriate actions except Copy. The system does not support a copy function therefore would not be part of the auditing.*

2. **If applicable, and if the health IT module allows it be disabled, is the default state for audit log and audit log status recording enabled by default?**
   [IN170.315 (d)(2)(i)(B) and (ii)]

   Yes. *An administrative person that has access to the DB directly could disable the audit log through SQL. You would have to login as the SA account to get to this part of the DB. It cannot be disabled through the application. By default the audit log is always enabled. By doing this we only disable the data auditing not the action auditing so for example if disabled we will still know that a user accessed a patients chart but we might not know that they changed the street address of a patient.*

3. **If applicable, and if the health IT module allows it to be disabled, is the encryption of electronic health information on end-user devices enabled by default?**
   [IN170.315(d)(2)(i)(C) and (ii)]

   Yes. *Encryption cannot be turned off.*

Drummond group

4. **Describe the method(s) through which the audit log protects the following from being changed, overwritten, or deleted by the health IT module.**
[IN170.315(d)(2)(iv)]

Recording of actions related to electronic health information: SHA-2
Recording of audit log status: SHA-2
Recording of encryption status: SHA-2

5. **Describe the method(s) through which the health IT module is capable of detecting whether the audit log(s) have been altered. Note: This type of alteration would be from outside the health IT module (e.g., hacking, manual tampering, and other software besides the health IT module).**
[IN170.315(d)(2)(v)]

The system scans the audit log once a week (for audit data and audit actions) and runs a hash comparison of the data compared to the hash when it was created. If there is a discrepancy an internal message is sent to anyone designated as an administrator stating that the audit log has potentially been tampered with. SQL Server authentication by the use of SQL Server logins is used for accessing the database. General users are not granted database administration access.

I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.

Kristen Heffernan, General Manager
1/20/17

Drummond group

Appendix D: Auditing Actions (d.7) Attestation Template

Privacy and Security Certification Documentation

Kristen Heffernan
General Manager
330-531-7035

Henry Schein Medical System attests to the validity of the information below to satisfy the documentation requirements for testing and certification of the ONC 2015 Edition criteria: *170.315(d)(7).*

All data is stored in SQL Server on a centralized server and not on an end user device.

I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.

Kristen Heffernan, General Manager
1/20/17

Kristen Heffernan
General Manager
330-531-7035

Henry Schein Medical Systems attests that in accord with ONC criteria §170.315(g)(4), the following Quality Management System was used in the development, testing, implementation, and maintenance for the criteria in which certification is being sought as outlined below:

When completing this attestation, select the applicable option (either "a" or "b") for these two sections:

Identify Standard:

b) Modified/mapped Federal or SDO standard QMS was used. We use a combination of ISO 1207, IEEE 730, and ISO 14764
For ISO 14764 we have a process in place for Monthly Maintenance builds. We call it HSMS-DEV-022. Additional documentation provided
For IEEE 730 we have a process in place for our testing. Additional documentation provided (test scripts upon request)
For ISO 1207 we have a process for our software development life cycle and use Projectmanager.com to track our process and assignments.

Identify if standard declared above is applicable to:

a) Used a single QMS was used for all criteria in which certification is being sought, please specify. This included our quality assurance department following the above criteria for their alpha and regression testing.

I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.

Kristen Heffernan, General Manager
1/3/17

Accessibility-Centered Design (170.315.g.5)

Kristen Heffernan
General Manager
330-531-7035

Henry Schein Medical Systems does not use any health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of capabilities of each module in the 2015 Edition Certification.

I hereby attest that all above statements are true, as an authorized signing authority on behalf of my organization.

Kristen Heffernan
5/8/17