

**Gaming Laboratories International, LLC  
dba SLI Compliance**

**ONC-ACB 2018 Surveillance  
Plan**

Revision: 1.1

Document ID: ACB-Surv-Plan-18

Issued: Mar 13, 2018



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### Document History

Rev.	Date	Change
1.0	January 4, 2018	Initial Version
1.1	March 13, 2018	2.2.3: Clarified approach to random surveillance



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## 1 Introduction

This Plan describes the annual surveillance approach that SLI Compliance (SLI) will follow, as an Authorized Certification Body, for 2018. SLI is committed to conducting surveillance in an impartial and transparent manner; complying with the requirements of relevant federal regulations (specified in 45 CFR Part 170); and adhering to the requirements of ISO 17065:2012. SLI's surveillance approach is directed by the program requirements and guidance of the Office of the National Coordinator for Health Information Technology (ONC).

## 2 Surveillance Approach

SLI conducts both proactive and reactive surveillance based on the requirements of ISO 17065 as well as ONC guidance.

Proactive surveillance includes two main areas. First, SLI may execute surveillance of a sample of SLI certified health IT products each year, based on the ONC's stated guidelines and priorities. Second, SLI will conduct regular surveillance to review the use of ONC and SLI certification marks, developer disclosures, and developer complaint resolution processes.

SLI conducts reactive surveillance to follow up on complaints regarding certified products. SLI will also perform surveillance in response to three or more requests for inherited certifications for a given health IT product.

SLI shall conduct surveillance of a minimum of 2% of currently certified products for which SLI is responsible each year. If reactive surveillance in response to complaints and issues does not add up to 2% of these products by the end of Q3, SLI will select enough products to ensure surveillance of 2% using the selection method identified below.

### 2.1 In-the-field Surveillance

One condition of product certification in the ONC program is ongoing surveillance. Some of these surveillance activities take place at the location where the technology is employed by end users. SLI may use in-the-field testing and observation in proactive surveillance and also as needed when looking into complaints regarding a certified product. For complaints, SLI will first examine evidence collected by other means and determine whether more information is needed, requiring in-the-field surveillance.



### 2.1.1 Planning and Conducting In-the-field Surveillance

When planning surveillance in the field, SLI will first identify the certification requirements to review. (Specific approaches to proactive surveillance and complaint investigations are detailed below.) SLI will test in the field using procedures based on the test scripts, methods and recording techniques used by SLI's ONC-ATL. The first option in many cases is to conduct the testing remotely; on-site testing will be conducted if SLI determines a need for additional information that can't be obtained remotely.

In-the-field surveillance requires that SLI engage and work with developers and end-users to analyze and determine the causes of issues. From the developer viewpoint, open communication with the ACB in specified areas is an important part of the service agreement for continuing certification and contributes to the integrity of the certification program. Developers of certified products are required by the program to provide certain information back to the ACB, including complaints relevant to the certification criteria, disclosures and product changes. This also includes responses to requests for information or surveillance that fall within the program's specifications.

In preparation for in-the-field observation and testing, SLI will contact the developer and end user to communicate what issues or requirements are slated for observation, the timeframe, and other details. SLI will allow sufficient time for the location to prepare and to allocate resource time. When both the end user and the developer are involved, SLI aims to encourage and facilitate a respectful, collaborative process. When a complainant is an end user who wants to remain anonymous, SLI will respect confidentiality in the investigation of the complaint.

In addition to in-the-field testing, SLI will also gather additional information. Some example sources that SLI may use are:

- Complaint processes, logs and records of resolution
- Review of previous test records and developer attestations
- User surveys or other feedback
- Observation and analysis of the product in a controlled environment
- Evaluation of the product at additional sites
- Other relevant information provided by the developer

### 2.1.2 Observation Records and Nonconformities

SLI will retain records of all relevant observations and test outcomes, which will include all identified nonconformities.



NOTE: During the course of surveillance, SLI may observe protected health information (PHI). This information will be kept strictly confidential and not included reports such as the regular surveillance reports to the ONC or in the corrective action notifications submitted to the CHPL.

If any nonconformities are discovered, SLI will work with the developer (and the resources at the implementation site as appropriate) to identify the root cause. The Corrective Action section details this process.

In addition to nonconformities related to technical capabilities, another type of issue may result from business or implementation practices of the health IT developer that negatively affect functioning of the certified product in the field. Such an issue, when substantiated, is considered to be a nonconformity against certification requirements. Another category of nonconformity is the non-disclosure of material information about limitations or attestation provided with regard to additional types of costs associated with a certified health IT product. For more information, see the SLI Certification Guide section “Suspension, Withdrawal, or Revocation of Certification”.

## 2.2 Proactive Surveillance

As part of the certification program, SLI will conduct surveillance of at least 2% of certified products for which SLI is responsible (above and beyond routine surveillance as described below). If reactive surveillance based on known issues and complaints does not cover 2% of such products, SLI will select one or more additional products for proactive surveillance. (The selection method is described below.) For each selected product, SLI shall perform surveillance of each capability (where applicable) prioritized by the ONC.

SLI will assess:

- Health IT’s conformity to the prioritized certification criteria described in the ONC’s “Prioritized Elements of Surveillance,” plus any other criteria to which the product is certified, at SLI’s discretion.
- The adequacy of developers’ user complaint processes.
- Developers’ compliance with the mandatory disclosure requirements of 45 CFR § 170.523(k)(1).\*
- Appropriate use of the ONC and SLI Certification Marks.\*

SLI endeavors to conduct routine proactive surveillance on each actively certified product annually, within each 12-month period after certification, covering the areas marked with “\*” above. This routine surveillance involves monitoring websites related to the certified health IT and may also include review of other publicly available materials. Additionally,



for follow-up purposes, SLI may request information from certified product developers regarding certified products.

### **2.2.1 Sampling and Selection**

Where needed to ensure non-routine proactive surveillance of 2% of certified products, SLI shall select from the products to which SLI's ONC-ACB has issued a certification (i.e., all active certifications). SLI will implement weighting techniques that account for the number of users of certified products and risks identified during the testing process. These risks include the risk that a product may fail to meet certification requirements in the field due to difficulty of completing the testing or lack of readiness (e.g., multiple re-tests needed).

SLI shall exclude from this surveillance any product for which non-routine proactive surveillance was conducted within the last 12 months.

Prior to randomly selecting products for proactive surveillance, SLI will assign weights to certified products based on how many users have adopted certified products from each of SLI's vendor customers and how many retests were needed. This increases the probability that the certified products selected for surveillance will include products with larger numbers of users and/or higher risks of failure to meet the test criteria in the field. SLI will check HealthIT.gov or a comparable source to determine the number of providers using each vendor's certified products. Based on the numbers of users, SLI will enter products and weights into a random number generator to determine the products selected.

For each selected product, SLI will again use the random number generator to randomly choose a site where the product is in use. SLI will inform the developer, contact the selected location and attempt to schedule surveillance at that location.

### **2.2.2 Prioritized Capabilities and Other Prioritized Elements**

When SLI selects a product for randomized surveillance, the evaluation of the product in the field shall include the assessment of any capabilities that are (1) within the scope of the certification criteria to which the technology is certified and (2) associated with any certification criterion prioritized by the ONC. 45 CFR §170.556(c)(1). SLI shall include all applicable elements from the prioritized capabilities listed in the ONC's 2016 guidance. (No additional guidance was published by the ONC for 2018.) Any other certified areas may be assessed at the discretion of the SLI assessor.

Prioritized criteria are listed in Appendix A.

SLI shall address each of the additional ONC prioritized elements. These include assessments of developers' disclosures, assessment of potential nonconformities related



to implementation or business practices, adequacy of developers' user complaint processes, and appropriate use of the ONC Certification Mark.

Surveillance of prioritized capabilities and elements may include further assessment by SLI's ACB or additional evaluation by an ONC-ATL. As needed, SLI may request additional information, such as sample data outputs and live demonstrations of the product in the field. SLI may request additional information from the developer, including documentation to substantiate that previously certified functionality has not been compromised.

### **2.2.3 Exclusion and Exhaustion**

When a certified product has been selected for randomized surveillance, SLI shall make a good faith effort to conduct remote and/or in-the-field surveillance of the selected product at the first randomly-selected location. If, after making this good faith effort, SLI cannot complete the surveillance at the selected location for reasons beyond our control, SLI may exclude such location and substitute another location that meets the random selection requirements described above. Similarly, if SLI exhausts all available locations for a particular certified product, we may exclude that product.

In the case of exhaustion, the ONC has clarified that the excluded certified product will be counted towards the minimum number of products an ONC-ACB is required to surveil during the calendar year surveillance period. However, SLI must carefully and accurately document our efforts to complete surveillance for each product and at each location. Any information regarding the selection and exhaustion of locations will be reported in regular surveillance reports to the ONC.

### **2.2.4 Developer Customer Lists**

SLI shall obtain and integrate health IT developers' customer lists into its randomized sampling and other aspects of proactive and reactive surveillance. Obtaining this information is part of the certification process for new customers and is required for the product update process. SLI will also request customer lists at least once per year, in conjunction with one of the quarterly requests for complaint information. Additionally, before initiating any in-the-field surveillance activities, SLI will request a customer list from the selected health IT developer.

Access to accurate customer and user lists is essential to an ONC-ACB's ability to contact users for in-the-field surveillance and to conduct surveys and other activities necessary to obtain and synthesize information about the performance of certified health IT. Therefore, if a health IT developer refuses to provide this information to SLI, SLI may regard the refusal as a refusal to participate in surveillance under the ONC Health IT



Certification Program and institute appropriate procedures, consistent with SLI's accreditation to ISO 17065, to suspend or terminate the health IT certification per 80 FR 62601, 62716.

## 2.3 Reactive Surveillance

SLI will initiate surveillance of a certified product whenever it becomes aware of information that would cause a reasonable person to question the health IT's continued conformity to the requirements of its certification. Reactive surveillance occurs mainly in response to complaints from end user customers or any other entities regarding certified health IT product(s), and also where there are repeated inheritance requests (products with 3 or more inherited certified status requests). Reactive surveillance may include in-the-field surveillance as needed.

When SLI becomes aware of a complaint that may be related to the certification criteria applicable to a health IT product, SLI will look into the complaint to determine whether the matter is in scope for the product's certification. If the complaint appears to be in scope, SLI will gather additional information and evaluate the issue.

SLI may obtain and analyze information, including but not limited to the following:

- Complaints and other information about certified health IT submitted directly to SLI or to the ONC by customers or users of certified health IT, by the ONC, or by another entity.
- Health IT developers' complaint logs, service tickets, and documentation concerning the analysis and resolution of complaints or issues reported to the developer.
- Developers' public and private disclosures regarding certified health IT capabilities.
- Information from publicly available sources (e.g., a developer's website or user forums).
- Repeated inherited certified status requests (3 or more for a single product).
- Other relevant facts and circumstances of which SLI is aware – in particular, information relevant to areas prioritized by the ONC as listed in Appendix A.

SLI will conduct a thorough investigation of the issue. This will include examining all data relevant to the complaint and may also include interviewing developer personnel. SLI shall always review health IT developers' disclosures when performing reactive surveillance and will also examine developers' complaint logs and responses to complaints relevant to the issue. To establish whether the product remains conformant, SLI will consider all information obtained including factors contributing to the issue and the scope of the



impact, as well as the response from the developer and all other data collected. In-the-field surveillance may be employed if other methods to gather data are not sufficient.

All reactive surveillance will be documented in regular surveillance reports provided to the ONC. If SLI determines any issue to be a non-conformity, the corrective action process as described in this plan will be followed.

### 3 Transparency and Disclosure Requirements

As part of proactive and reactive surveillance, SLI will obtain information to ensure developer compliance with mandatory disclosure requirements. Surveillance is carried out by monitoring developer websites and may include reviews of other publicly available materials as needed for follow-up purposes. SLI reviews each developer's website and assesses whether the information shown corresponds to the information in the developer's attestation made for product certification.

SLI may begin reviewing websites for certified products 60 days after certification is posted on the ONC CHPL. SLI performs web surveillance on an ongoing basis and will check each actively certified developer's website at least once per year. The following items will be monitored:

- ONC Certified Mark (if used – use is not required but if the mark is used, the usage must conform to ONC requirements)
- ONC disclaimer and certification information
- Disclosure of costs and limitations

SLI will communicate any apparent issues with the above information to the developer per our Corrective Action Procedure. SLI will provide the developer an opportunity to correct any nonconformities. Please see the SLI Certification Guide section "Suspension, Withdrawal, or Revocation of Certification" for more information.

#### 3.1 Surveillance of Developers' Disclosures

The developer of a certified health IT product is required to disclose (or link to a disclosure) in plain language—on its website and in all marketing materials, communications statements, and other assertions related to its certified health IT—a detailed description of all known material information concerning limitations and additional types of costs that a person may encounter or incur to implement or use certified health IT capabilities, whether to meet meaningful use objectives and measures or to achieve any other use within the scope of the health IT's certification. Such



information is required if the failure to disclose it could substantially interfere with the ability of a user or prospective user to implement or use certified health IT for any use within the scope of the product's certification. Certain kinds of limitations and additional types of costs, if known, must be disclosed. These include but are not limited to:

- Additional types of costs or fees (whether fixed, recurring, transaction-based, or otherwise) imposed by a developer (or any third-party from whom the developer purchases, licenses, or obtains any technology, products, or services in connection with its certified health IT) to purchase, license, implement, maintain, upgrade, use, or otherwise enable and support the use of capabilities to which health IT is certified; or in connection with any data generated in the course of using any capability to which health IT is certified.
- Limitations, whether by contract or otherwise, on the use of any capability to which technology is certified for any purpose within the scope of the technology's certification; or in connection with any data generated in the course of using any capability to which health IT is certified.
- Limitations, including but not limited to technical or practical limitations of technology or its capabilities, that could prevent or impair the successful implementation, configuration, customization, maintenance, support, or use of any capabilities to which technology is certified; or that could prevent or limit the use, exchange, or portability of any data generated in the course of using any capability to which technology is certified.

ONC Notes: Developers are not required to disclose information of which they are not and could not reasonably be aware, nor to account for every conceivable type of cost or implementation hurdle that a customer may encounter. "Developers are required, however, to describe **with particularity** the nature, magnitude, and extent of the limitations or types of costs." 80 FR 62601, 62722 (emphasis in original). A developer's disclosure must contain sufficient information and detail from which a reasonable person under the circumstances would, without special effort, be able to reasonably identify the specific limitations he or she may encounter and reasonably understand the potential costs that may be incurred when implementing and using capabilities for any purpose within the scope of the health IT's certification.

### 3.2 Attestation

SLI includes the transparency attestation detailed in Appendix B as part of new certification applications and in the update process for previously certified products.



In addition to ensuring that the developer has made the proper attestation, SLI shall include the developer's attestations in the information submitted to the ONC for inclusion in the CHPL.

## 4 Corrective Action Procedures

The ONC has clarified that a corrective action plan (CAP) is required any time an ACB finds that a product or a developer is non-compliant with any certification criterion or any other requirement of certification, including the transparency and disclosure requirements.

When SLI determines that a certified health IT product or developer does not conform to the requirements of the relevant certification, SLI shall notify the developer of these findings and require the developer to submit a proposed CAP for the applicable certification criterion/criteria or other certification requirement. This CAP must include:

- A description of the identified non-conformities or deficiencies;
- An assessment of how widespread or isolated the identified non-conformities or deficiencies may be across all of the developer's customers and users of the certified product;
- How the developer will address the identified non-conformities or deficiencies, both at the locations under which surveillance occurred and for all other potentially affected customers and users;
- How the developer will ensure that all affected and potentially affected customers and users are alerted to the identified non-conformities or deficiencies, including a detailed description of how the developer will assess the scope and impact of the problem, including identifying all potentially affected customers; how the developer will promptly ensure that all potentially affected customers are notified of the problem and plan for resolution; how and when the developer will resolve issues for individual affected customers; and how the developer will ensure that all issues are in fact resolved.
- The timeframe under which corrective action will be completed.
- Any additional elements specified by the ONC or that the ONC-ACB deems appropriate, consistent with its accreditation. (These are based on the specific finding and guidance will be provided if this requirement is applicable.)



- A requirement that the developer attest to having completed all elements of the corrective action plan.

SLI will notify a developer when one or more deficiencies are found, along with providing a template and a timeframe for providing a CAP to SLI. The timeframe is typically 30 days, but SLI reserves the right to adjust this timeframe based on the type of issue and the urgency of resolving it.

If the CAP is not returned in the appropriate timeframe, SLI will take necessary actions as required by the ONC Surveillance Guidance to suspend or terminate the health IT's certification.

SLI will submit corrective action information to ONC for inclusion on the Certified Health IT Product List (CHPL). This information will be updated weekly.

SLI shall verify that developers have completed all requirements of corrective action specified in the approved corrective action plan. SLI requires developers to attest that the developer has completed all required elements of the plan, and then SLI validates that attestation. SLI will also verify that developers have notified all affected and potentially affected customers and users and will notify the developer of the outcome of the CAP process.

## **5 Submission of Corrective Action and Surveillance Information**

SLI shall submit information regularly to the ONC, as described below.

### **5.1 Submission of Corrective Action Information**

SLI will document and, at least once weekly, submit corrective action information to ONC for inclusion in the CHPL. This report will include each product that failed to conform to its certification and for which corrective action was instituted under 45 CFR § 170.556. SLI will use the CHPL product number to identify the certified products.

For each finding of nonconformity, SLI will report the specific certification requirements to which the product failed to conform. SLI is also required by the ONC to report other information about the nature, details and status of each nonconformity. Details are included in SLI's internal procedure for reporting, which includes all bulleted items from the ONC Guidance document (Program Policy Guidance #15-01A, section Submission of Corrective Action Information).



## 5.2 Submission of Surveillance Information

### 5.2.1 Surveillance Narratives and Corroborating Documentation

SLI shall report surveillance results to the ONC on a quarterly and annual basis. When submitting annual surveillance results, SLI will identify each instance of surveillance performed during CY18 and the results of that surveillance. In each case, SLI will submit a detailed narrative and corroborating documentation and evidence to support its determination, including:

- Each certified health IT product, certification criterion, and certification program requirement that was subjected to surveillance during CY18. SLI will use the CHPL product number to identify the certified products.
- The type of surveillance initiated in each case.
- The grounds for initiating surveillance and for deciding whether or not to evaluate the certified health IT in the field.
- Whether or not SLI confirmed a non-conformity.
- The substantial factors that, in SLI's assessment, caused or contributed to the apparent non-conformity (e.g., implementation problem, user error, limitations on the use of capabilities in the field, a failure to disclose known material information, etc.).
- The steps SLI took to obtain and analyze evidence and to arrive at its conclusions.

This surveillance plan describes in detail the process by which SLI will collect and submit all of the information described above, including the procedural aspects required by the ONC (Program Policy Guidance #15-01A, section Submission of Surveillance Information).

### 5.2.2 Review of Developer Complaint Processes

Once per year, developers of certified Health IT products are required to provide details of their complaint handling process for complaints relating to the scope of functionality certified in the ONC HIT Certification Program.

SLI will identify, for each health IT developer whose technology was subject to any type of (non-routine) surveillance during the applicable calendar year:

- The extent to which the developer followed its complaint process, and any observed deficiencies with its process.
- The frequency of complaints made to the developer associated with the prioritized elements in Part IV.



SLI reviews the complaint handling processes of each developer whose product is subject to surveillance to determine whether the appropriate actions were taken, along with the developer's adherence to their own complaint handling process. If any issues weren't properly addressed, SLI will follow up and will report this finding to the ONC. SLI will also evaluate the frequency of complaints made to the developer that were associated with the ONC's areas for prioritized surveillance. Issues found will trigger SLI's Corrective Action procedure.

### **5.3 Due Process and Exclusion of Certain Sensitive Information**

#### **5.3.1 Meaningful Opportunity for Input and Comment on ONC-ACB Findings**

SLI shall complete our review of all relevant facts and circumstances, including those raised by the developer in the course of SLI's surveillance, prior to making a non-conformity or other determination and prior to submitting its surveillance results and, where applicable, corrective action information to the ONC.

In addition, SLI shall provide a meaningful opportunity for the developer to explain any deficiencies prior to a final non-conformity determination. When the developer has provided an explanation of the deficiencies identified as the basis for SLI's determination, SLI shall include the developer's explanation (subject to any exclusions described below) in its submission of this information to the ONC.

#### **5.3.2 Exclusion of Certain Information from Submission of Corrective Action Information and Surveillance Results**

In submitting corrective action information and surveillance results to the ONC, SLI shall exclude any information that would identify any customer or user, any health care provider, location, or practice site that participated in or was subject to surveillance, or any person who submitted a complaint or other information to a health IT developer or ONC-ACB.

#### **5.3.3 Exclusion of Certain Information from Submission of Corrective Action Information**

With respect to the submission of corrective action information to the ONC for inclusion in the CHPL, SLI will not submit any information that is in fact legally privileged or protected from disclosure and that therefore should not be listed on a publicly available website. SLI may also implement other appropriate safeguards, as necessary, to protect information that, while not legally protected from disclosure, SLI believes should not be reported to a publicly available website.



The ONC requires ACBs to ensure that such safeguards are narrowly tailored and consistent with the goal of promoting the greatest possible degree of transparency with respect to certified health IT and the business practices of certified health IT developers, especially the disclosure of material information about limitations and types of costs associated with certified health IT. ONC-ACBs are required to accurately report the results of their surveillance and to explain in detail the facts and circumstances on which their conclusions are based.

#### **5.4 Due Date and Submission Method**

CY18 surveillance results are due to ONC quarterly in the agreed upon template. ONC will only accept electronic submissions of surveillance results via [ONC-ACB@hhs.gov](mailto:ONC-ACB@hhs.gov).

### **6 Public Accountability**

SLI Compliance acknowledges that ONC-ACBs should make their annual surveillance plans publicly available after submission to ONC and that ONC may at any time publish surveillance information to the extent permitted by law.

### **7 Appendix A: Prioritized Criteria**

#### Interoperability and Information Exchange

- 45 CFR § 170.314(b)(1) Transitions of care – receive, display and incorporate transition of care/referral summaries.
- 45 CFR § 170.314(b)(2) Transitions of care – create and transmit transition of care/referral summaries.
- 45 CFR § 170.314(b)(7) Data portability.
- 45 CFR § 170.314(b)(8) Optional – transitions of care.
- 45 CFR § 170.314(e)(1) View, download, and transmit to 3rd party.
- 45 CFR § 170.314(h)(1) Optional – Transmit - Applicability Statement for Secure Health.
- 45 CFR § 170.314(h)(2) Optional – Transmit - Applicability Statement for Secure Health Transport and XDR/XDM for Direct Messaging.



### Safety-related

- 45 CFR § 170.314(a)(2) Drug-drug, drug-allergy interaction checks.
- 45 CFR § 170.314(a)(8) Clinical decision support.
- 45 CFR § 170.314(a)(16) Inpatient setting only—electronic medication administration record.
- 45 CFR § 170.314(b)(4) Clinical information reconciliation.
- 45 CFR § 170.314(b)(9) Optional – Clinical information reconciliation and incorporation.

### Security

- 45 CFR § 170.314(d)(2) Auditable Events and Tamper-Resistance.
- 45 CFR § 170.314(d)(7) End-User Device Encryption.

### Population Management

- 45 CFR § 170.314(c)(2) Clinical quality measures – import and calculate

## **8 Appendix B: Transparency Attestation**

As a condition of certification, health IT developers must make one of the following attestations:

In the affirmative:

In support of enhanced marketplace transparency and visibility into the costs and performance of certified health IT products and services, and the business practices of health IT developers, [Developer Name] hereby attests that it will provide in a timely manner, in plain writing, and in a manner calculated to inform, any part (including all) of the information required to be disclosed under 45 CFR § 170.523(k)(1) under the following circumstances:

- To all persons who request such information.



- To all persons who request or receive a quotation, estimate, description of services, or other assertion or information from [Developer Name] in connection with any certified health IT or any capabilities thereof.
- To all customers prior to providing or entering into any agreement to provide any certified health IT or related product or service (including subsequent updates, add-ons, or additional products or services during the course of an on-going agreement).

- OR -

In the negative:

[Developer Name] hereby attests that it has been asked to make the voluntary attestation described by 45 CFR § 170.523(k)(2)(i) in support of enhanced marketplace transparency and visibility into the costs and performance of certified health IT products and services, and the business practices of health IT developers. [Developer Name] hereby declines to make such attestation at this time.

-- OR --

Self-Developer:

[Developer Name] hereby attests that it is a self-developer exempt from the disclosure requirements of 45 CFR 170.523(k)(1)(iii) and 170.523(k)(2). [Developer Name] further attests that as a self-developer it does not and will not market, sell, or license its certified Health IT Module(s).

Note that a developer's attestation under 45 CFR §170.523(k)(2) does not broaden or change the scope of the information a developer is required to disclose under 45 CFR §170.523(k)(1).

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End of Document

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