SLI Compliance, a Division of Gaming Laboratories International, LLC

ONC-ACB 2026 Surveillance Plan

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Document History

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1.0	09/25/2025	Initial Version
1.1	01/06/2026	Updated per ASTP comments

Contents

1 Introduction

This plan describes the annual surveillance approach that SLI Compliance (SLI) will follow, as an Authorized Certification Body, for 2026. 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/IEC 17065:2012. SLI's surveillance approach is directed by the program requirements and guidance of the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (hereafter ONC).

To submit information to SLI about any SLI Certified product, please email us at ACB@slicompliance.com, or go to http://www.slicompliance.com/services/testing-certification-health/sli-acb-certified-products-feedback-and-complaints/. The web link allows for anonymous or non-anonymous reporting of information/complaints. SLI will follow up on information received and will further investigate relevant information regarding any SLI Certified product's conformity to the applicable requirements.

Developers of ONC Certified Health IT are required to adhere to program requirements to maintain certification. One key element is cooperation with the ACB to support ONC program activities, including but not limited to inquiries relevant to the certified criteria, requirements and conditions/maintenance of certification; surveillance; requests for customer lists, complaint logs and supporting documentation; and corrective actions. Likewise, SLI's approach is to treat developers fairly and impartially, conduct activities in a transparent manner and respond to developers' inquiries.

1.1 References

This document incorporates by reference the following ONC guidance documents:

- ONC HEALTH IT CERTIFICATION PROGRAM Program Policy Resource #18–03: Surveillance Resource (10/5/2018)

- ONC HEALTH IT CERTIFICATION PROGRAM Program Policy Resource #18–01: Post-certification Assessment of Program Requirements (10/5/2018)

- ONC HEALTH IT CERTIFICATION PROGRAM Program Policy Resource #18–02: Disclosure of Material Information (10/5/2018)

- Applicability of Inherited Certified Status and Gap Certification Program Guidance #16-01-A (updated 8/13/2025)

This document also references the current version of SLI's Certification Program Manual, available on http://www.slicompliance.com/services/testing-certification-health.

2 Surveillance Approach

SLI Compliance conducts reactive surveillance based on the requirements of ISO/IEC 17065 and ONC guidance. SLI may execute proactive (random) surveillance as described below, and also conducts routine oversight activities.

Routine oversight by the ONC-ACB includes reviews of developer websites. SLI performs regular reviews of developers' use of the ONC and SLI certification marks, developer disclosures, and Program requirements around websites and communications. Other routine checks include tracking to ensure developers meet specific Conditions and Maintenance of Certification requirements within the timeframes specified in the relevant regulation (including bi-annual attestations and Real World Test Plans/Reports), and tracking to ensure developers complete required updates to their certified products. SLI Compliance evaluates nonconformities discovered by developers during Real World Testing and initiates reactive surveillance where warranted.

Additionally, SLI may execute surveillance of a random sample of SLI certified health IT products each year, based on the ONC's stated guidelines and priorities. When the ONC exercises enforcement discretion around random surveillance and when random surveillance is not currently required in the regulation, SLI will only conduct such surveillance if SLI management deems it necessary.

SLI conducts reactive surveillance to follow up on complaints and suspected nonconformities applicable to SLI certified products. SLI will also perform surveillance in response to every fourth request for inherited certifications for a given health IT product.

Surveillance activities are reportable to the associated listing on the Certified Health IT Product List (CHPL) even when no nonconformities are identified, whereas routine oversight activities that do not constitute surveillance are not reportable.

Prior to initiating surveillance, SLI will consult the relevant regulations and resources, including 45 CFR 170.556 (https://www.ecfr.gov/cgi-bin/text-idx?SID=429be73364bbb51d21cd984f70c60a0f&mc=true&node=se45.1.170_1556&rgn=div8), any other relevant criteria in 45 CFR section 170, and the current ONC guidance (https://www.healthit.gov/topic/certification-ehrs/onc-health-it-certification-program-guidance).

2.1   In-the-field Surveillance

One condition of product certification in the ONC Health IT Certification Program (ONC program) is ongoing surveillance. Some of these surveillance activities take place at the location where the technology is employed by end users. SLI will use in-the-field testing and observation as needed for surveillance activities. For complaints, SLI will first gather and examine evidence collected by other means and determine whether more information is needed to determine conformity, requiring in-the-field surveillance. For example, a reported problem may not occur in a controlled environment but is reported in the field, or a problem may occur intermittently but not in every instance. A high level of complexity surrounding a problem may also necessitate 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.) In addition, SLI will consider the context of the product's marketing, implementation and use. This includes the developer's targeted users, situations of use and real-world use cases.

The first choice for selecting a location is to use the location where the reported problem occurred. If this is not possible, such as for an anonymous complaint, SLI will attempt to identify a similar implementation.

Also, the first option in many cases is to conduct the testing, observation or other investigation remotely; on-site testing will be conducted if SLI determines a need for additional information that can't be obtained remotely.

SLI's in-the-field activities, conducted by the ONC-ACB, may include tests based on the test scripts, methods and recording techniques used for testing in the ONC program. SLI is required by the ONC to determine whether the use of test data would yield similar product behavior and be equally comprehensive to data used in production systems. This analysis is based on the issue identified, its complexity, and the options for use of the relevant product feature(s).

SLI recognizes that some capabilities are within the scope of the certification criteria but cannot be fully tested in a controlled environment. For reactive surveillance, SLI will identify such capabilities (relevant to the known problem or complaint) and will plan other types of observations to evaluate conformity to the requirements in production environments. It may be necessary to consult with the developer and/or end users to determine the best approaches within the workflow at the production site.

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 ONC 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 and will also work with the provider to minimize the burden of participating. 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.

When a health care provider does not cooperate with SLI's surveillance activities or frustrates those activities, SLI will document its efforts to complete in-the-field surveillance for that product and location, including a provider's failure to cooperate in good faith. SLI will provide this information in its periodic surveillance reports to the ONC.

SLI will observe and evaluate the certified capabilities, including consistency and reliability of performance, and will record detailed notes. If potential non-conformities are observed, SLI will investigate the cause(s) to determine whether and to what extent they are under the control of the developer.

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

- Developers' websites, marketing materials, and other communications
- Complaint processes, logs and records of resolution
- Review of previous test records and developer declarations
- User surveys or other feedback
- Observation and analysis of the product in a controlled environment
- Contract between the developer and user(s)
- Evaluation of the product at additional sites
- Other relevant information provided by the developer

Survey program: SLI may develop end user surveys to gather information regarding the certification criteria and other certification requirements. SLI analyzes the criteria to be

investigated and develops a series of questions that ask users in plain language about their experience using the product in the areas being evaluated. (Example: Regarding [Software name, version], does your electronic records software's audit log of user activity allow you to sort the audit log report according to each data element?). These surveys may be sent to a randomly selected set of user contacts from the most recent customer list supplied by the developer, or they may be sent to a selected set of users with a specific implementation to investigate a reported problem. After a reasonable time (about a week if the surveys are emailed), SLI will remind the recipients who did not respond to the surveys. SLI will follow up on any issues identified in the survey responses. Follow-up may include asking the respondent for additional details, expanding the survey pool, and/or initiating other surveillance activities as appropriate.

2.1.2 Observation Records and Nonconformities

SLI will retain records of all relevant observations and test outcomes, which will include all identified nonconformities. These records will also include relevant details and their sources where appropriate, SLI's activities and analysis, and dates. SLI personnel conducting reactive surveillance are encouraged to keep a log of activities, references, persons contacted, analysis and follow-up, and dates, in order to establish a timeline of events.

NOTE: During surveillance, SLI may observe protected health information (PHI). This information will be kept strictly confidential and not included in reports such as the regular surveillance reports to the ONC or in the corrective action notifications submitted to the CHPL. SLI endeavors not to retain any PHI and shall adhere to its internal procedures to protect any sensitive information if it must be recorded.

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 potential nonconformity is the non-disclosure of material information about additional types of costs associated with a certified health IT product. For more information, see the SLI Certification Program Manual section "Suspension, Withdrawal, or Revocation of Certification."

2.2 Proactive Surveillance

As part of SLI's certification program and depending on current ONC guidance, SLI may conduct random surveillance of a percentage of certified products for which SLI is

responsible (beyond routine surveillance as described below). The selection method is described below under Random Surveillance. For each selected product, SLI will 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.*

2.2.1 Routine Oversight

Each quarter, SLI requires developers to provide a list of all complaints relevant to each product's certification. SLI reviews these reported complaints for information regarding compliance with the certification criteria and program requirements. SLI will evaluate and follow up on complaints that are relevant to the certification requirements and the respective resolutions, which will include requesting additional information from the developer and/or initiating reactive surveillance where appropriate. For instance, SLI will gather more information and may initiate surveillance if there is a suspected non-conformity that has not been fully resolved (or the resolution is not adequately described) or when the problem may have additional impacts beyond the ones the developer has addressed.

If SLI becomes aware of a complaint related to the Conditions and Maintenance of Certification, SLI will gather the relevant information and pass the complaint along to the ONC, which enforces the Conditions and Maintenance of Certification.

In addition, SLI conducts routine oversight on each actively certified product annually, within each 12-month period after certification, covering the areas marked with "*" above, as well as any URLs identified in the associated CHPL listing. This routine oversight involves monitoring websites related to the certified health IT (which will always include the Mandatory Disclosures URL linked from the CHPL for the product, plus other developer web pages describing the product) and will also include review of other publicly available materials required by the ONC Program, including but not limited to URLs required for 170.315(b)(10) and the API criteria. For follow-up purposes or based on SLI's knowledge

about a particular product, SLI may request information from the product developer regarding certified products.

SLI also tracks developer compliance with ONC program requirements and deadlines. SLI will track the following and communicate with developers who are at risk of missing an ONC attestation deadline, or where issues are found in submitted materials reviewed by SLI:

- Adding or updating criteria prior to specific deadlines as applicable and required in the relevant regulation; this includes updating the product to conform to more recent standards, code sets, etc. where required.

- Submission of complete Real Word Test plans and results reports, covering the relevant criteria and including product updates as applicable.

- Submission of attestations required by the ONC twice annually.

- Addressing nonconformities that developers identify when conducting their Real World Testing.

If a developer misses an ACB or ONC deadline for a required submission (e.g., a Real World Test Results Report, Semi-annual attestation, or attestation pertaining to a standard update required by regulation), SLI will issue a warning and will follow up with surveillance where warranted. SLI will follow ONC guidance and cooperate with the ONC, providing requested information for ONC inquiries and direct reviews.

2.2.2 Random Surveillance

Random surveillance by ACBs is no longer mandatory in the ONC program. However, as needed to maintain the integrity of the SLI Health IT Certification Program, SLI may conduct random surveillance. In such case, 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 implementations 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 as indicated by difficulty in 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 the certified products and how many retests were needed during the testing phase. 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 the customer lists provided by the developers of SLI Certified products to determine the number of providers using each vendor's certified product(s). Based on the numbers of implementations, SLI will enter products and their 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 sites where the product is in use. SLI will inform the developer of the surveillance and will contact the selected sites. SLI will attempt to gather information from those sites using emailed surveys and/or calls. Any issues identified in the surveys will be followed up with further information gathering. (More details on surveys follow below.)

2.2.3 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 ONC's "Prioritized Elements of Surveillance." Any other certified areas may be assessed at the discretion of the SLI assessor.

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.

2.2.4 Exclusion and Exhaustion

When a certified product has been selected for randomized surveillance, SLI shall make a good faith effort to conduct remote information gathering for the selected product at the first set of randomly selected locations (typically up to 5). If, after making this good faith effort, SLI cannot complete the surveillance at the selected locations for reasons beyond our control, SLI may exclude such locations and substitute another set of locations (also typically up to 5) that meet 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 or of 2 unsuccessful attempts at getting information from the randomly selected users, the excluded certified product will be counted towards the minimum number of products SLI is required to surveil during the calendar year surveillance period (if applicable). SLI shall 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.

2.2.5 Developer Customer Lists

SLI may obtain and integrate health IT developers' customer lists into its randomized sampling and other aspects of proactive and reactive surveillance. SLI reserves the right to request customer lists as needed. Additionally, before initiating any in-the-field surveillance activities, SLI may obtain 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/IEC 17065, to suspend or withdraw the health IT certification per the ONC's Certification Standards and Regulations.

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:

- in response to complaints from end user customers or other interested parties regarding certified health IT product(s),

- in response to developer self-reported nonconformities

- when SLI becomes aware of a confirmed or suspected nonconformity with ONC program requirements (where the ACBs enforce such requirements), and

- where there are repeated inheritance requests (products with 4 inherited certified status requests and every fourth ICS request after the first such surveillance).

Reactive surveillance may include in-the-field surveillance as needed.

ONC Prioritized Criteria: This approach applies when a certified product is the subject of reactive surveillance due to a confirmed or suspected nonconformity with certified criteria and/or the program's disclosure requirements (excluding minor website issues found under Routine Surveillance). If the product's certification scope includes one or more of the ONC's prioritized criteria, SLI will select at least one prioritized criterion to include in the surveillance per the ONC's direction. Selection of the area(s) is based on risk of noncompliance per SLI's estimation, and the criterion not having been included in surveillance of the same product in the last 2 years. This is in addition to the issue that triggered the surveillance. SLI will determine a method for confirming compliance, which might include a live demonstration or screen captures for example.

ICS: In the case of a product having 4 inherited certified status requests, SLI will select from the ONC's prioritized elements that apply to the product and will focus mainly on at least two of those areas (where applicable), along with any other areas that SLI deems appropriate for surveillance based on risk and sampling of the product's capabilities. Selection of the areas is based on risk of noncompliance per SLI's estimation, and the criterion not having been included in surveillance of the same product in the last 2 years. The same process will apply to each additional 4th inherited certified status request (i.e., 8th, 12th, etc.). If ICS surveillance had already been done earlier, such as on the 3rd request, it would then be done after the 7th, 11th, etc.

Complaints: When SLI becomes aware of a complaint that may be related to the certification criteria or other certification requirements applicable to a health IT product, SLI will investigate it to determine whether the complaint is substantive and the matter is in scope for the product's certification. Where a complaint appears related to conformity with any criteria in the certification's scope and/or relevant to applicable Program requirements, SLI will initiate surveillance. The developer's complaint log and complaint handling procedure will be reviewed as part of this surveillance.

SLI will obtain and analyze information of various types depending on the nature of a complaint or suspected nonconformity. This information includes but is 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).

- Other relevant facts and circumstances of which SLI is aware or has concerns – in particular, information relevant to ONC prioritized elements.

SLI will conduct a thorough investigation of the issue. This will include examining all data relevant to the complaint/issue and may also include interviewing developer personnel. SLI will review health IT developers' disclosures related to the requirements at 45 CFR 170.523(k)(1) when performing reactive surveillance and, where applicable, will also examine developers' complaint logs and responses to complaints relevant to the issue.

Complaint logs: If SLI's ACB requests a developer to submit their complaint handling procedure and complaint log, SLI will provide a time period for the log based on the information around any known complaints or suspected nonconformities and their severity. SLI will generally ask for complaint logs covering the past 6 months; however, if we are aware of any issues that fall outside that time range, we will adjust the time window to include the time the issue was identified.

SLI will scan the complaint log from the selected time period to determine which complaints are relevant to ONC Program requirements and will examine those in more detail. SLI will determine whether there have been complaints made to the developer that are related to ONC prioritized elements, along with the extent to which the developer adhered to their complaint process for such complaints, the timeline for addressing each complaint, and any deficiencies observed in that process (e.g., treating customers differently rather than following a consistent complaint handling process or failing to respond to a complaint in the time window required by the developer's complaint handling process). SLI will determine whether to conduct additional surveillance of any applicable Program criteria/requirements based on this analysis.

SLI, as an accredited ONC-ACB, will review complaint logs in an impartial manner and in accordance with our internal surveillance procedures. SLI reviews the complaint log information relevant to ONC Certification Program criteria/requirements, along with the developer's complaint handling process. The purpose of this review is to determine whether the developer is adhering to their own complaint handling procedures when processing complaints that may be relevant to the ONC Certification Program. For instance, if the procedures state that all complaints will be followed up within a defined timeframe or escalated in a specific manner, SLI's ACB will evaluate whether the developer consistently adheres to these guidelines. If SLI determines that there are 50 or more complaints that

may be relevant to the ONC Program requirements, SLI will randomly select at least 10 such complaints or 5%, whichever is higher, to review and may choose to review more if problems are identified as described above.

The records of complaint procedure/complaint log reviews and outcomes are communicated to the developer and retained by SLI along with the developer-specific surveillance records.

If SLI determines that one or more nonconformities exist in a developer's handling of program relevant complaints, SLI will follow ONC guidance about reporting, following up and (when appropriate action has been taken and confirmed) closing out 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 any other data collected. In-the-field surveillance will be employed if SLI determines that this approach is the best way to gather the needed information for one or more criteria/requirements, or if other methods to gather data prove insufficient.

Even where a product is shown to have the required capabilities, in some cases the developer may interfere with the user's ability to exercise these capabilities or may impose undisclosed limitations. SLI will investigate such claims, including as appropriate the contract between the developer and user, the developer's communications and disclosures, and any limitations imposed by the developer that may hinder use, potentially causing a nonconformity with certification requirements.

Late responses to ONC program deadlines: When a developer misses the ACB deadline for providing a Real World Test Plan or Report, misses an ONC attestation deadline, or is 30 days late providing the quarterly report and the issue is not resolved quickly after reaching out to the developer, SLI will initiate reactive surveillance.

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

3 Disclosure and Public Info Requirements

As part of proactive and reactive surveillance, SLI will obtain information to ensure developer compliance with mandatory disclosure requirements and requirements to make certain information publicly available. Routine surveillance is carried out by monitoring

developer websites and may include reviews of other publicly available materials. SLI reviews each developer's website and assesses whether the information shown meets ONC requirements and corresponds to the scope and details of the product certification.

SLI may begin reviewing websites for certified products any time after certification is posted on the CHPL and will typically wait at least one month to allow for developer updates. 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)

- SLI Certified Mark (if used – use is not required but if the mark is used, the usage must conform to SLI Compliance requirements)

- ONC disclaimer and certification information

- Disclosure of additional costs in a clear and accessible manner

- Maintenance of current and historical Real World Test Plans and Reports, where applicable to the product's scope and timing of certifications

- Based on the scope of the certification, information that developers are required to post on publicly available hyperlinks:

  o 170.315(b)(10) EHI export: The documentation required for the export format(s) used to support (b)(10)(i) and (ii) functionality

  o 170.315(b)(11) Intervention risk management practices: Health IT developers supplying predictive decision support interventions (PDSIs) provide a hyperlink to summary documentation of the intervention risk management practices applied for each PDSI supplied by the Health IT developer as part of the Health IT module

  o 170.315(d)(13) Multi-factor authentication: Health IT developers attesting "yes" to supporting MFA must provide a hyperlink to any required use cases (or if attesting "no," optional documentation, if any, must be maintained)

  o 170.315 (g)(7), (9), (10), (31) and (33) APIs: Developers with a certification to any of these criteria must publish both complete business and technical documentation **and** all terms and conditions for the certified API technology including material information and API fees; developers certified to 170.315 (g)(10) must also publish a list of certified API service base URLs

SLI also evaluates disclosures as part of all reactive surveillance. SLI may ask developers for their marketing materials, communications and statements, and other assertions related to the product so SLI can review these for compliance. When SLI identifies instances in which failures to disclose additional types of costs have substantially impaired their use (or could), SLI will follow up with the developer and, where appropriate, will initiate surveillance or a corrective action.

SLI will communicate any apparent issues with the above information to the developer and may invoke SLI's Corrective Action Procedure. SLI will provide the developer an opportunity to correct any issues. Please see the SLI Certification Program Manual 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 additional types of costs that a person may encounter or incur to implement or use certified health IT capabilities, whether to meet objectives and measures for specified (e.g., CMS) programs 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 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.

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 … 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 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.

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 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 withdraw the health IT's certification. In addition, if a CAP is submitted to SLI and is not completed within the timeframe specified in the CAP, SLI will follow up with the developer. Lack of timely response to the follow up will lead to suspension of the certification. SLI's ONC-ACB Certification Program Manual has additional details about the suspension and withdrawal process.

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

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 #18-03, section Submission and Reporting of Surveillance and 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 the calendar year 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 the calendar year. 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 #18-03, section Submission and Reporting of Surveillance and Corrective Action Information).

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 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

Surveillance results are due to ONC quarterly in the agreed upon template. ONC will only accept electronic submissions of surveillance results (transmitted as instructed by the ONC).

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. When the current year's surveillance plan is finalized, SLI Compliance posts it on our website: https://slicompliance.com/services/testing-certification-health/.

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