PointClickCare

The Honorable Karen B. DeSalvo, MD, MPH, MSc
Acting Assistant Secretary for Health
National Coordinator for Health Information Technology
Office of the National Coordinator for Health Information Technology
Department of Health and Human Services
Attention: 2015 Edition Health IT Certification Criteria Proposed Rule
Hubert H. Humphrey Building, Suite 729D
200 Independence Ave, S.W.
Washington, D.C. 20201

May 29, 2015

Re: 2015-06612; 2015 Edition Health Information Technology Certification Criteria, Base Electronic Health Record Definition, and ONC Health IT Certification Program Modifications

Dear Dr. DeSalvo,

PointClickCare appreciates the opportunity to comment on the proposed rule by the Office of the National Coordinator for Health Information Technology (ONC) regarding the 2015 Edition Health Information Technology (HIT) Certification Criteria, Base Electronic Health Record (EHR) Definition, and ONC HIT Certification Program Modifications. PointClickCare looks forward to actively participating in policy development and the adoption of certified HIT modules based on our experience serving providers and residents in the senior care market.

Founded in 2000 and currently employing over 900 people, PointClickCare is adopted in over 11,000 senior care facilities today, making it the North American HIT market leader for the senior care industry. PointClickCare connects healthcare providers across the senior care continuum with easy to use, regulatory compliant solutions for improved resident outcomes, enhanced efficiency and financial performance, and staff optimization. Recognizing the financial and clinical operations of the senior care market we serve, our platform is cloud-based and takes a person-centered approach to managing senior care. Our platform enables us to push regular software updates through the cloud, improving provider care delivery and business processes while avoiding the business disruption associated with lengthy licensed software upgrades. With this software delivery model, product enhancements can be made available to thousands of users immediately, enabling providers to benefit from new features and innovation without delay.

Our cloud-based solutions are accessible from any Internet-connected device. Further, PointClickCare stores all of the data in highly secure data centers, reducing the burden on providers to secure protected health information on site. In general, our cloud-based solutions are more easily adaptable to the evolving needs of residents and providers in a safe and cost-effective manner. We believe the future of HIT will continue to leverage the benefits of cloud-based solutions and, to that end, we have invested heavily in building an innovative, agile, and forward leaning cloud-based HIT offering for the senior care market.

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

As a result of our significant technology footprint in the senior care market, we believe our comments reflect the perspective of HIT vendors, providers, and residents in the long-term and post-acute care space – groups that have not previously been the focus of HIT-related rulemaking. We encourage ONC to consider our thoughts and recommendations when finalizing this rule. We hope this comment letter is the beginning of our conversation with ONC about HIT in the senior care market and we welcome the opportunity to support ONC in further policy development and adoption in this space.

General Recommendations

Base EHR Definition

PointClickCare agrees with a majority of the components that comprise the base EHR definition. One criterion that applies differently to the senior care market is the ability to "record, change, and access a list of unique device identifiers (UDIs) corresponding to a patient's implantable devices ('implantable device list')" [proposed 45 C.F.R. §170.315(a)(20) (Implantable Device List)]. Implantable devices are surgically placed in inpatient settings or outpatient clinics; therefore, this capability is most relevant to the aforementioned care settings. Residents who present in senior care settings may have a device that was implanted 10-20 years ago and may not know the details of the exact device (when it was implanted, who implanted it, where it was implanted, and so on), let alone its UDI. In order to provide the optimum healthcare services, senior care providers may wish to record this information in the EHR; accordingly, the indication of the presence of an implantable device, even without the UDI, should be part of the base EHR and the common clinical data set (CCDS). We urge ONC to broaden this capability to allow flexibility to record the existence of implanted devices, even in the absence of a UDI, to facilitate appropriate patient care management and coordination across care settings.

Common Clinical Data Set and Standards

We are in support of a common clinical data set (CCDS) that includes parameters which encompass all providers, including those in long-term and post-acute care settings. As proposed, the CCDS content does not include vital metrics such as pain assessment scores, activities of daily living (ADLs), functional status, modifiers on vital signs (whether the resident was sitting or standing while blood pressure was taken, etc.), non-drug allergies such as food and environmental allergies, and cognitive status. These are metrics which long-term care providers rely on when assessing resident care and support needs. Furthermore, the recently enacted Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) requires that data from patient assessments be standardized and interoperable among providers to facilitate coordinated care. As ONC expands its certification to include all HIT modules beyond hospital and physician-office EHRs, we encourage ONC to consider defining a CCDS that includes data vital to providers across the continuum when receiving and transitioning a patient to a different care setting and that also aligns with other standards and measures required by regulation or statute.

Lastly, we suggest that ONC evaluate incorporating a photo of the patient into the CCDS to improve the efficacy of patient identification. Including a photo can serve as a "second check" to primary methods of matching patients with their records in the absence of a national patient-matching standard. ONC should require this capability within EHRs and educate providers on the value of this feature as part of the CCDS,

though its use should not be mandatory. This allows providers to discuss the benefits of the photo with patients or residents and store it within the EHR with consent.

APIs

PointClickCare is committed to providing residents, providers, and third-party vendors with access to electronic medical records in an efficient and secure manner. PointClickCare has developed application program interfaces (APIs) and currently uses documented APIs to enable robust, bi-directional connections with other solution vendors to ensure that essential information flows responsibly across system boundaries.

While we support the flow of protected health information, we are concerned about the privacy and security implications that would result if the proposed regulation requiring APIs to be made publicly available were finalized. For EHR application vendors, malicious or inadvertent mishandling of protected health information poses a real risk. Exposing APIs increases such risks. Publishing an API is akin to providing one out of two keys to a safe deposit box at a bank.

If ONC is to proceed with this requirement, vendors' responsibilities for protecting protected health information will increase significantly. To minimize both the risk of malicious and inadvertent misuse of protected health information, we recommend that vendors be allowed to establish a two-part process for the management of their APIs. First, vendors should be able to institute an "application process" through which potential users of APIs can be evaluated as being "trustworthy" – an element of which is the requirement for the third party to credibly establish their identity. Those third parties who are deemed trustworthy would be granted access to the API documentation that, instead of being public, would be shared under a non-disclosure agreement.

Vendors also should be allowed to enact a certification process that allows them to evaluate whether a specific third-party developer has leveraged the API in a responsible manner and utilized quality development practices. Developers without robust quality development processes and appropriate security ultimately could jeopardize our system performance and data security through access to our APIs. As such, vendors should have the right to disqualify a third party from putting into production an API connection, and track third-party use of APIs with the ability to "cut the connection" from a third party if abnormalities are detected. Without establishing such safeguards, attempts to enable access could have significant unintended consequences for vendor products and resident data.

Furthermore, we seek clarification on how electronic medical records should be transferred across state lines with differing privacy requirements. For example, would PointClickCare be authorized to provide a resident's medical record to a third-party application for a resident who lives in a state where residents need to opt in to data sharing prior to access?

We will continue to provide a resident with access to his/her record via our cloud-based platform. The vetting process mentioned above refers only to third-party developers who request access to a multitude of resident records.

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

We recommend that ONC proceed with caution and allow sufficient time for vendors to further strengthen cybersecurity and the vetting processes prior to requiring vendors to publish APIs.

Incorporating Data from Consolidated-Clinical Document Architecture (C-CDA)

PointClickCare strives to make C-CDAs received from other EHRs/providers available to our users/customers in their EHRs. However, from our experience, most providers prefer to have those C-CDAs accessible via a link as opposed to incorporating its content as discrete data into their own EHRs. This allows them to distinguish between data captured in their own care settings from data received from other settings. While sharing information is important in coordinating care, we believe requiring the recipient EHR to incorporate data from the C-CDA is premature and we recommend delaying such a requirement until providers are more comfortable working with both their own data and data received from other providers.

Furthermore, the current format of the C-CDA contains many pages of information making it difficult for providers to find the most valuable or pertinent information quickly. In our experience, providers are concerned about their liability surrounding the receipt of C-CDAs. Specifically, they are concerned about the accuracy of the data received and the expectations of them to respond/act based upon the information. We urge ONC to re-evaluate the C-CDA as the package for data sharing and provide greater guidance surrounding provider expectations and liability in responding to information received from external/unknown sources.

Certification Process

PointClickCare supports the need for thorough testing of HIT to ensure patient safety. All of our products are subjected to a rigorous testing process that evaluates system functionality and safety. In fact, PointClickCare was tested and certified for the Safety Enhanced Design (SED) criterion in 2013.

We have concerns about the new certification requirements under SED. For cloud-based solutions, such as PointClickCare's EHR platform, the proposed requirements have the potential to create development process redundancy and possible delays in releasing functionality enhancement updates. All vendors value user input; our engineers and developers translate this input into product design and conduct robust testing, including seeking feedback from users. However, the SED certification requirement as proposed places heavy reliance on users providing guidance on design components. In reality, users do not always have the vision of what technology can do for them. Consider Apple. If they had left it to users to describe their ideal phone, we would not have smartphones today. Accordingly, we encourage ONC to reduce the onerous user experience testing requirements of the SED certification.

Further, the proposed certification rule appears to be designed for the development cycles of traditional EHRs, which generally are static and go through periodic updates. It also overlooks the realities of cloud-based solutions, which are dynamic and provide regular updates to improve functionality and user experience. As written, certification requirements involve testing and certification of the whole system instead of only testing the changes/new capabilities added to the system. This philosophy of testing the entire system each time may be appropriate for traditional, static EHRs but negatively impacts EHR developers, such as PointClickCare, which offer cloud-based, dynamic and regularly updated solutions that

are in use for several months/years before the next certification cycle. Under the proposed rule, cloud-based developers would be forced to undergo testing and certification for a dynamically updated platform as if the entire platform were new and had never been used or tested before.

We believe that demonstrating SED as part of the certification process for new products/modules is justified. However, we request ONC to reconsider the requirement to demonstrate SED for systems which our customers have been using effectively for years (as a result of the fact that we previously obtained certification for those systems). Similarly, once systems are implemented, developers may make minor modifications to the functionality but we do not believe each upgrade warrants reporting to the Authorized Certification Body (ACB) or re-testing. We encourage ONC to consider only requiring SED testing in newly developed systems, not systems which already are in use, to avoid increasing costs of the systems, especially those used in sectors – such as the senior care market – where meaningful use incentive payments do not exist and healthcare providers are required to support the entire cost of EHR technology without any assistance from CMS.

Finally, PointClickCare encourages ONC to reduce vendors' reporting requirements. The future of HIT involves adoption of cloud-based solutions, which reduces costs while allowing providers to take advantage of rapid innovation. As a cloud-based provider, PointClickCare issues software updates very frequently and the proposed requirement to update ACBs as updates are rolled out adds unnecessary administrative burdens on vendors, which ultimately impacts the providers relying on the availability of new feature sets. In fact, such reporting requirements are more likely to deter innovation and regular feature updates, and force developers to perform batch upgrades instead, which would entail more complex rollout efforts for providers and vendors alike.

Future Certification Criteria/Tracks

PointClickCare fully supports ONC's vision of expanding certification beyond ambulatory and inpatient EHRs to include all HIT. We received certification for a number of our products/functionalities in 2013 and intend to seek certification for the 2015 Edition as well. We believe certification provides greater assurance to our customers that our platform meets industry standards and works in concert with other certified products, which is particularly important when our clients expand their networks of care partners across the continuum. However, as highlighted in many of our comments above, the 2015 Edition certification requirements primarily focus on ambulatory and inpatient EHR scenarios – such as requiring capture of the unique device identifier and not capturing key data used by post-acute care providers, such as pain assessments in the CCDS. While we support core capabilities, common data, and transport standards that span across the continuum, we believe EHR systems across settings will not have identical functionality and/or data fields due to differing needs of patients and residents, as well as the differing priorities that are specific to each care environment. We recognize that standardization is a key element not only for quality care delivery but also for interoperability. Therefore, it would be beneficial to patients, residents, providers, and vendors to institute distinct sub-certification tracks specific to each care setting, thereby ultimately encouraging innovation and assuring suitable care delivery and patient/resident engagement.

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

To that end, we encourage ONC to develop a common set of certification criteria for all EHRs that enable recording, sharing and using of a robust CCDS (to include data relevant not just to acute care settings but also to long-term care, behavioral health and other care settings) using common interoperability and security standards. Beyond the common set of criteria/capabilities, each EHR should be required to seek additional certification based on which segment of the provider market it serves. For the additional certification, we encourage ONC to develop separate certification tracks for each different segment of the provider market (including lab providers, behavioral health, long-term care, etc.) with a close eye for alignment/consistency and interoperability across certifications. Certification tracks for different provider care settings would give purchasers confidence that their EHR is designed for their target market and patient population. It also would foster innovation by enabling EHR vendors to develop functionality that best meets the needs of specific provider types. Additionally, it would prevent EHR vendors from falsely marketing their certified, yet non-setting appropriate EHR to providers who are unable to distinguish capabilities. For example, EHR functionality in the senior care market differs based on the type of facility. The nursing wing requires clinical functionality whereas the assisted living wing, where group activities take place, requires capabilities for tracking social activity. And these capabilities are distinct from those used in acute care hospitals. Hence it makes most sense to have separate certification tracks by provider segment, while maintaining a common set of criteria/capabilities required for all EHRs to support care coordination across the continuum.

Finally, all certification processes should allow leeway for innovation and acknowledge that technology changes significantly faster than the regulatory process. Given our 15 years of experience serving the senior care provider market, we are available and welcome the opportunity to collaborate with ONC to develop the certification track for this segment of the healthcare industry.

Specific Recommendations

Proposed 45 C.F.R. §170.315(g)(8) Accessibility-centered design
Included in 2015 Edition Base EHR Definition? No, but a mandatory certification requirement
Stage 3 Meaningful Use Objective N/A

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

Proposed 45 C.F.R. §170.315(g)(8) Accessibility-centered design

2015 Edition Health IT Certification Criterion

(8) *Accessibility-centered design.* For each capability that a Health IT Module includes and for which that capability's certification is sought, the use of a health IT accessibility-centered design standard or law in the development, testing, implementation and maintenance of that capability must be identified.

(i) If a single accessibility-centered design standard or law was used for applicable capabilities, it would only need to be identified once.

(ii) If different accessibility-centered design standards and laws were applied to specific capabilities, each accessibility-centered design standard or law applied would need to be identified. This would include the application of an accessibility-centered design standard or law to some capabilities and none to others.

(iii) If no accessibility-centered design standard or law was applied to all applicable capabilities such a response is acceptable to satisfy this certification criterion.

FR Citation: 80 FR 16914 **Specific questions in preamble?** Yes, at 80 FR 16861-2.

Public Comment Field: PointClickCare believes that limiting this criterion to specific modules is appropriate. For example, cloud-based desktop solutions used in post-acute facilities may require certain accessibility requirements which are different from the accessibility requirements for solutions offered via mobile applications available on patient-owned devices (personal iPhone, iPad, etc.). Hence, we encourage ONC to not attempt to create a 'one size fits all' requirement for accessibility-centered design that is applied to the entire EHR.

Proposed 45 C.F.R. §170.315(a)(7) Problem list

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 Meaningful Use Objective

N/A

2015 Edition Health IT Certification Criterion

(7) *Problem list*. Enable a user to record, change, and access a patient's active problem list:

(i) *Ambulatory setting***.** Over multiple encounters in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4); or

(ii) *Inpatient setting*. For the duration of an entire hospitalization in accordance with, at a minimum, the version of the standard specified in § 170.207(a)(4).

FR Citation: 80 FR 16907 **Specific questions in preamble?** No. *See* 80 FR 16819.

Public Comment Field: In long-term and post-acute care (LTPAC), a resident's problem list is constantly evolving during the facility stay. This is significantly different when comparing the problem list in acute care or in ambulatory settings, where the problem(s) generally are the reason for the visit. In LTPAC, the problem(s) upon admission may evolve and change over the residents' length of stay and may be completely different upon discharge. This complicates the creation of the C-CDA because the C-CDA only provides a snapshot of the resident at the point of discharge. It does not accurately capture the various problems a resident may have experienced during the stay in the LTPAC setting.

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

Proposed 45 C.F.R. §170.315(b)(3) Electronic prescribing

Included in 2015 Edition Base EHR Definition?

No

Stage 3 Meaningful Use Objective

EP must generate and transmit permissible prescriptions electronically, and eligible hospitals and CAHs must generate and transmit permissible discharge prescriptions electronically (eRx).

2015 Edition Health IT Certification Criterion

(3) Electronic prescribing.

(i) Enable a user to prescribe, send, and respond to prescription-related transactions for electronic transmission in accordance with the standard specified at § 170.205(b)(2), and, at a minimum, the version of the standard specified in § 170.207(d)(3), as follows:
- (A) Create new prescriptions (NEWRX);
- (B) Change prescriptions (RXCHG, CHGRES);
- (C) Cancel prescriptions (CANRX, CANRES);
- (D) Refill prescriptions (REFREQ, REFRES);
- (E) Receive fill status notifications (RXFILL); and
- (F) Request and receive medication history information (RXHREQ, RXHRES).

(ii) Enable a user to enter, receive, and transmit structured and codified prescribing instructions for the transactions listed in paragraph (b)(3)(i) of this section for electronic transmission in accordance with the standard specified at § 170.205(b)(2) and, at a minimum, for at least the following component composites:
- (A) Repeating Sig;
- (B) Code System;
- (C) Sig Free Text String;
- (D) Dose;
- (E) Dose Calculation;
- (F) Vehicle;
- (G) Route of Administration;
- (H) Site of Administration;
- (I) Sig Timing;
- (J) Duration;
- (K) Maximum Dose Restriction;
- (L) Indication; and
- (M) Stop.

(iii) Technology must limit a user's ability to prescribe all medications in only the metric standard.

(iv) Technology must always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

FR Citation: 80 FR 16909 **Specific questions in preamble?** Yes, at 80 FR 16835-7.

Public Comment Field: The requirement indicates that the metric unit of measure should be used for ordering all medications. As ONC is aware, many drugs are prescribed and dispensed as capsules/tablets and while they may have a metric standard associated with them (such as milligrams), prescriptions are often written in number of units (capsules or tablets) and not by number of milligrams. The example used in the proposed rule involves liquids and uses 'mL', which in most scenarios is appropriate. However, there are some liquid medications which are not ordered in mL, such as insulin, which is prescribed in units. As such, PointClickCare requests that ONC clarify the requirement and create sufficient flexibilities in certification criteria to account for clinical practice and current industry safety standards associated with drug manufacturing and packaging.

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

Proposed 45 C.F.R. §170.315(c)(1) Clinical quality measures – record and export

Included in 2015 Edition Base EHR Definition?

Yes

Stage 3 Meaningful Use Objective

N/A

2015 Edition Health IT Certification Criterion

(1) Clinical quality measures – record and export.

(i) *Record.* For each and every CQM for which the technology is presented for certification, the technology must be able to record all of the data that would be necessary to calculate each CQM. Data required for CQM exclusions or exceptions must be codified entries, which may include specific terms as defined by each CQM, or may include codified expressions of "patient reason," "system reason," or "medical reason."

(ii) *Export.* A user must be able to export a data file formatted in accordance with the standard specified at § 170.205(h) for one or multiple patients that includes all of the data captured for each and every CQM to which technology was certified under paragraph (c)(1)(i) of this section. A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

FR Citation: 80 FR 16910 **Specific questions in preamble?** Yes, at 80 FR 16842-3.

Public Comment Field: The certification requirements surrounding clinical quality measures (CQMs) primarily take into account CQMs in the acute care setting. Only a few of the currently required CQMs under Meaningful Use are specific to the LTPAC sector. Despite this fact, there are several critical measures used in the LTPAC sector. We encourage ONC and CMS to work together to adapt existing LTPAC measures for reporting using EHRs (e.g. MDS, resident assessment charting, etc.).

Proposed 45 C.F.R. §170.315(a)(18) Electronic medication administration record

Included in 2015 Edition Base EHR Definition?

No

Stage 3 Meaningful Use Objective

N/A

2015 Edition Health IT Certification Criterion

(18) Electronic medication administration record.

(i) In combination with an assistive technology that provides automated information on the "rights" specified in paragraphs (a)(18)(i)(A) through (E) of this section, enable a user to verify the following before administering medication(s):

(A) *Right patient.* The patient to whom the medication is to be administered matches the medication to be administered.

(B) *Right medication.* The medication to be administered matches the medication ordered for the patient.

(C) *Right dose.* The dose of the medication to be administered matches the dose of the medication ordered for the patient.

(D) *Right route.* The route of medication delivery matches the route specified in the medication order.

(E) *Right time.* The time that the medication was ordered to be administered compared to the current time.

(ii) *Right documentation.* Record the time and date in accordance with the standard specified in § 170.210(g), and user identification when a medication is administered.

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

Proposed 45 C.F.R. §170.315(a)(18) Electronic medication administration record

FR Citation: 80 FR 16908 **Specific questions in preamble?** No. *See* 80 FR 16823.

Public Comment Field: The requirement indicates that an assistive technology for verifying the 5-rights of medication administration is necessary (i.e. barcoding). Although we agree that this technology would reduce medication administration incidents/errors, this is not entirely under the control of long-term and post-acute care providers who may rely on smaller long-term care (LTC) pharmacies for medications needed by their patients/residents. These LTC pharmacies deliver medications to LTPAC providers but typically the medications are not barcoded. Medications may be unit dose strip-packed, blister packaged or even administration time-based packaged (with multiple medications for a given administration time packaged together). Meeting this requirement would force pharmacies to barcode medications which are packaged in a variety of ways: a time-consuming and costly endeavor. We do not believe it is the responsibility of LTPAC providers to barcode medications prior to administration since this process is part of prescription labeling, which based on best practices and is completed by the pharmacy. We urge ONC to work with other relevant agencies to require pharmacies sending medications to providers using electronic medication administration to place barcodes on all medications.

Proposed 45 C.F.R. §170.315(b)(7) Data segmentation for privacy – send

Included in 2015 Edition Base EHR Definition?

No

Stage 3 Meaningful Use Objective

N/A

2015 Edition Health IT Certification Criterion

(7) *Data segmentation for privacy – send.* Technology must enable a user to create a summary record formatted in accordance with each of the standards adopted in § 170.205(a)(3) and (4) that is tagged as restricted and subject to restrictions on re-disclosure according to the standard adopted in § 170.205(o)(1).

FR Citation: 80 FR 16910**Specific questions in preamble?** No. *See* 80 FR 16840-2.

Public Comment Field: PointClickCare requests clarification from ONC. The way this regulation is written, it could be interpreted to require that an EHR system create a separate file whenever a provider receives a document from a third party (e.g., whenever a pharmacy sends information related to a prescription) and then tag that individual file in a manner which will enable the provider to ensure that the record has not been changed/tampered. While PointClickCare endorses the importance of proving the validity of a third-party record, being required to create separate, self-contained records would be complicated and costly. The additional burden of these requirements could add unnecessary cost to providers. Accordingly, PointClickCare encourages ONC to clarify that the purposes of this proposed regulation can be served within a database (as an alternative to a self-contained document), by requiring a digital signature or "e-signature," whereby the third-party's document can have a cryptographic algorithm applied to it which creates a "hash value" that represents the contents of the document. Providers can ensure that a document has not been tampered with by comparing the hash value of the document they are viewing at any given moment with the hash value of that document as it was originally saved into the EHR system.

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9
www.pointclickcare.com

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Conclusion

At PointClickCare, we share the same ultimate goal as the customers we serve – striving to reduce the overall cost-burden on healthcare while providing better care for our seniors. HIT has great potential to revolutionize the delivery of care. Working in collaboration with vendors and providers to develop regulations will ensure success for the entire healthcare industry and a healthier senior population.

PointClickCare looks forward to partnering with ONC to ensure the power and potential of HIT is harnessed to the fullest. Please feel free to contact me at 905-858-8885, Ext. 240 or at dave.w@pointclickcare.com if you have any questions about our comments.

Sincerely,

Dave Wessinger
Chief Technology Officer

6975 Creditview Road, Unit 4
Mississauga, ON Canada
L5N 8E9

www.pointclickcare.com