June 3, 2019

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for
Health Information Technology
330 C St SW, Floor 7
Washington, District of Columbia 20201

Re: 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program (RIN 0955-AA01)

Submitted electronically

Dear Dr. Rucker,

Biocom appreciates the opportunity to offer comments on the Office of the National Coordinator (ONC) for Health Information Technology's proposed rule *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program* ("proposed rule").

Biocom is the largest, most experienced leader and advocate for California's life science sector, which includes biotechnology, pharmaceutical, medical device, genomics and diagnostics companies of all sizes, as well as research universities and institutes, clinical research organizations, investors and service providers. With more than 1,200 members dedicated to improving health and quality of life, Biocom drives public policy initiatives to positively influence the state's life science community in the research, development, and delivery of innovative products. California's life sciences industry generates nearly $317 billion in annual economic output, boosts the state's total gross product by $171.4 billion, supports more than 1.1 million jobs, and increases labor income by $92 billion per year[1].

Biocom supports regulations that promote the use of electronic health records (EHRs), digital health technologies, and patient-generated health data. Biocom acknowledges ONC's efforts to improve interoperability and clearly define exceptions to information blocking.

[1] *Biocom 2017 Economic Impact Report Databook*. 2017, issuu.com/biocom0/docs/biocom-2017-economic-impact-report-_9995632bde2e0c?e=30611789/53618285.

The proposed rule would implement key provisions in Title IV of the 21st Century Cures Act (Cures Act) that are designed to advance interoperability; support the access, exchange, and use of electronic health information; and address occurrences of information blocking. The provisions would change the Conditions and Maintenance of Certification requirements for health information technology ("health IT" or "HIT") developers, the voluntary certification of health IT for use by pediatric health providers, the reasonable and necessary activities that do not constitute information blocking, and patient access to their electronic health information (EHI).

Biocom respectfully offers the comments and recommendations below.

Recognition of Food and Drug Administration Processes

Biocom supports ONC proposal to establish processes that would provide health IT developers that are certified under the Food and Drug Administration (FDA) Software Pre-Certification Pilot Program with exemptions to ONC Health IT Certification Program requirements for "quality management systems" and "safety- enhanced design" criteria.

Biocom is supportive of FDA's efforts to modernize and streamline the medical device approval process to reduce the time to market while ensuring patient safety. FDA Software Pre-Certification Pilot Program, which Biocom members are participating in, provides a different approach to regulating digital health technology in a pathway that is better aligned with the software development cycle. Through the development of this pilot program, FDA took integral steps to include stakeholders, such as seeking public input, holding several workshops, and administering its Software Pre-Certification Pilot Program. Biocom supports ONC developing a health IT pre-certification program and recommends that ONC take a similar approach to FDA's to include stakeholder input throughout each stage of the development of the program.

Proposed Exceptions to the Information Blocking Provision

The Cures Act requires that a health IT developer, as a Condition and Maintenance of Certification under the Program, not take any action that constitutes information blocking as defined in section 3022(a) of the Public Health Service Act (PHSA). ONC's proposes to establish this information blocking Condition of Certification in § 170.401.

The Cures Act defines information blocking as a practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary of Health and Human Services (HHS) as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information (EHI)[2]. Practices that may constitute as information blocking include: implementing health IT in nonstandard ways that are likely to substantially increase the complexity or burden of accessing, exchanging, or using EHI; implementing health IT in ways that are likely to restrict the access, exchange, or use of EHI with respect to exporting complete information sets or in transitioning between health information technology systems; and implementing health IT in ways that may lead to fraud, waste, abuse, or impede innovation.

Section 3022(a)(3) of the PHSA authorizes and charges the Secretary to identify reasonable and necessary activities that do not constitute information blocking (section 3022(a)(3) of the PHSA). ONC has identified seven activities as "reasonable and necessary" exceptions to the information blocking definition. The exceptions would extend to certain activities that interfere with the access, exchange, or use of EHI but that may be

[2] Information Blocking https://www.healthit.gov/topic/information-blocking

reasonable and necessary if certain conditions are met. The proposed exceptions include: preventing harm to patients and others; promoting the privacy and security of EHI; recovering cost reasonably incurred; responding to request that are infeasible; licensing of interoperability elements on reasonable and non-discriminatory terms; and maintaining and improving health IT performance[3].

Exception – Preventing harm

Biocom generally supports this proposed exception. We believe that reliance on the U.S. Core Data for Interoperability (USCDI) standard should reduce inaccurate or corrupted data being included into a patient's EHR. In the event that two patient records are mistakenly merged and one of those patients accesses the other patient's data through API, neither patient should face liability under this rule.

Exception – Promoting the privacy of electronic health information

Biocom urges ONC to ensure that information blocking rule adherence does not undercut necessary patient privacy.

Biocom is supportive of ONC's approach to exempt Business Associates (BA), as defined under Health Insurance Portability and Accountability Act (HIPAA), from information blocking rules being developed in this rule making. We urge ONC to provide clarity that BAs will not be included in the Office of Inspector General (OIG) information blocking investigations due to their roles as BAs.

Electronic Health Information (EHI) Export

ONC proposes a new 2015 Edition certification criterion for "electronic health information (EHI) export" that would replace the 2015 Edition "data export" certification criterion and become part of the 2015 Edition Base EHR definition. This criterion would: (1) enable the export of EHI for a single patient upon a valid request from that patient or a user on the patient's behalf, and (2) support the export of EHI when a health care provider chooses to transition or migrate information to another health IT system.

Biocom generally supports the proposed rule. Biocom requests clarity on the statement "We do not propose that the export must be executed according to any particular standard, but propose to require that the export must be accompanied by the data format, including its structure and syntax, to facilitate interpretation of the EHI therein." This leaves open the possibility of requiring complex interpretation methods. Biocom recommends that ONC provide some standard options for data export to encourage interoperability. Biocom also urges ONC to implement reasonable timelines for compliance for developer requirements, as these updates can be costly and time-consuming for both developers and users.

Standardized API for Patient and Population Services

ONC's proposed rule explicitly mandates the adoption and use of application programming interface (API) technology. APIs have achieved powerful, scalable and efficient interoperability by making it easier for different applications to connect, exchange data and collaborate. ONC is proposing that certified health IT applications use a specific API based on the Fast Healthcare Interoperability Resources (FHIR) specifications.

[3]21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program https://www.regulations.gov/document?D=HHS-ONC-2019-0002-0001

FHIR is an interoperability standard for the electronic exchange of healthcare information developed and maintained by Health Level Seven International (HL7), a not-for-profit organization accredited by the American National Standards Institute that develops and provides frameworks and standards for the sharing, integration, and retrieval of clinical health data and other electronic health information[4]. Mandating the use of the FHIR standard API helps to ensure foundational compatibility and basic interoperability.

Biocom generally supports ONC's proposal to adopt the HL7 Fast Healthcare Interoperability Resources (FHIR) standard as a foundational standard for its proposals. We appreciate that ONC is seeking feedback on the appropriate FHIR Release version to mandate. We recommend that ONC pursue "Option 4" to utilize FHIR Release 4 (R4)[5]. While "Option 3" provides developers with flexibility in adopting R2 and R4, Biocom believes that using one version of FHIR would be more conducive to realizing a true interoperable ecosystem.

ONC proposes to require that APIs, and the health care ecosystem in which they are deployed, have three attributes: standardized, transparent, and pro-competitive. The standardized attribute requires all health IT developers seeking certification to implement the same technical advanced planner and optimizer (APO) capabilities in their products, using modern, computing standards such as RESTful interfaces and eXtensible markup language (XML)/JavaScript Object Notation (JSON).

Biocom believes that ONC should select a computing standard that is cleaner and more condensed than JSON. Large table formats using comma or tab as delimiter are most common for data storage because they allow easier parsing and table manipulation. JSON works well for websites but when data becomes larger, it is much less suitable.

Biocom is dedicated to improving patient access to innovative therapies and thanks you again for the opportunity to provide these comments. We look forward to a continued dialogue with ONC. If you have any questions about these comments, please contact Brittany Blocker, Manager of Regulatory Affairs at bblocker@biocom.org.

Sincerely,

Joe Panetta
President and CEO
Biocom

[4] FHIR Overview https://www.hl7.org/fhir/overview.html
[5] FHIR Release 4 (R4) http://www.hl7.org/FHIR/

Office of the National Coordinator for Health IT Proposed Rule Public Comment Template

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

Recognition of Food and Drug Administration Processes
We propose to establish processes that would provide health IT developers that can document successful certification under the Food and Drug Administration (FDA) Software Pre-Certification Pilot Program with exemptions to the ONC Health IT Certification Programs requirements for testing and certification of its health IT to the 2015 Edition "quality management systems" criterion and the 2015 Edition "safety-enhanced design" criterion, as these criteria are applicable to the health IT developer's health IT presented for certification. We also believe that such a "recognition" could be applicable to the functionally-based 2015 Edition ''clinical'' certification criteria.
Preamble FR Citation: 84 FR 7438-39 **Specific questions in preamble?** *No*
Regulatory Impact Analysis: Not Applicable
Public Comment Field: Biocom supports ONC proposal to establish processes that would provide health IT developers that are certified under the Food and Drug Administration (FDA) Software Pre-Certification Pilot Program with exemptions to ONC Health IT Certification Program requirements for "quality management systems" and "safety- enhanced design" criteria. Biocom is supportive of FDA's efforts to modernize and streamline the medical device approval process to reduce the time to market while ensuring patient safety. FDA Software Pre-Certification Pilot Program, which Biocom members are participating in, provides a different approach to regulating digital health technology in a pathway that is better aligned with the software development cycle. Through the development of this pilot program, FDA took integral steps to include stakeholders, such as seeking public input, holding several workshops, and administering its Software Pre-Certification Pilot Program. Biocom supports ONC developing a health IT pre-certification program and recommends that ONC take a similar approach to FDA's to include stakeholder input throughout each stage of the development of the program.

§ 171.201 Exception – Preventing harm

To qualify for this exception, each practice by an actor must meet the following conditions at all relevant times.

(a) The actor must have a reasonable belief that the practice will directly and substantially reduce the likelihood of harm to a patient or another person arising from—

(1) Corrupt or inaccurate data being recorded or incorporated in a patient's electronic health record;

(2) Misidentification of a patient or patient's electronic health information; or

(3) Disclosure of a patient's electronic health information in circumstances where a licensed health care professional has determined, in the exercise of professional judgment, that the disclosure is reasonably likely to endanger the life or physical safety of the patient or another person, provided that, if required by applicable federal or state law, the patient has been afforded any right of review of that determination.

(b) If the practice implements an organizational policy, the policy must be—

(1) In writing;

(2) Based on relevant clinical, technical, and other appropriate expertise;

(3) Implemented in a consistent and non-discriminatory manner; and

(4) No broader than necessary to mitigate the risk of harm.

(c) If the practice does not implement an organizational policy, an actor must make a finding in each case, based on the particularized facts and circumstances, and based on, as applicable, relevant clinical, technical, and other appropriate expertise, that the practice is necessary and no broader than necessary to mitigate the risk of harm.

Preamble FR Citation: 84 FR 7523-26 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Not applicable

Public Comment Field:

Biocom generally supports this proposed exception. We believe that reliance on the U.S. Core Data for Interoperability (USCDI) standard should reduce inaccurate or corrupted data being included into a patient's EHR. In the event that two patient records are mistakenly merged and one of those patients accesses the other patient's data through API, neither patient should face liability under this rule.

§ 171.202 Exception – Promoting the privacy of electronic health information

provide access, exchange, or use of electronic health information provided that the actor's practice—

(1) Complies with applicable state or federal privacy laws;

(2) Implements a process that is described in the actor's organizational privacy policy;

(3) Had previously been meaningfully disclosed to the persons and entities that use the actor's product or service;

(4) Is tailored to the specific privacy risk or interest being addressed; and

(5) Is implemented in a consistent and non-discriminatory manner.

(d) Denial of an individual's request for their electronic protected health information in the circumstances provided in 45 CFR 164.524(a)(1), (2), and (3). If an individual requests their electronic protected health information under 45 CFR 164.502(a)(1)(i) or 45 CFR 164.524, the actor may deny the request in the circumstances provided in 45 CFR 164.524(a)(1), (2), or (3).

(e) Respecting an individual's request not to share information. In circumstances where not required or prohibited by law, an actor may choose not to provide access, exchange, or use of an individual's electronic health information if—

(1) The individual requests that the actor not provide such access, exchange, or use;

(2) Such request is initiated by the individual without any improper encouragement or inducement by the actor;

(3) The actor or its agent documents the request within a reasonable time period; and

(4) The actor's practice is implemented in a consistent and non-discriminatory manner.

Preamble FR Citation: 84 FR 7526-35 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Not applicable

Public Comment Field:

Biocom urges ONC to ensure that information blocking rule adherence does not undercut necessary patient privacy.

Biocom is supportive of ONC's approach to exempt Business Associates (BA), as defined under Health Insurance Portability and Accountability Act (HIPAA), from information blocking rules being developed in this rule making. We urge ONC to provide clarity that BAs will not be included in the Office of Inspector General (OIG) information blocking investigations due to their roles as BAs.

§ 170.315(b)(10) Electronic health information export

Included in 2015 Edition Base EHR Definition? *Yes*

Electronic health information export.

(i) Single patient electronic health information export.

(A) Enable a user to timely create an export file(s) with all of a single patient's electronic health information the health IT produces and electronically manages on that patient.

(B) A user must be able to execute this capability at any time the user chooses and without subsequent developer assistance to operate.

(C) Limit the ability of users who can create such export file(s) in at least one of these two ways:

(1) To a specific set of identified users.

(2) As a system administrative function.

(D) The export file(s) created must be electronic and in a computable format.

(E) The export file(s) format, including its structure and syntax, must be included with the exported file(s).

(ii) Database export. Create an export of all the electronic health information the health IT produces and electronically manages.

(A) The export created must be electronic and in a computable format.

(B) The export's format, including its structure and syntax must be included with the export.

(iii) Documentation. The export format(s) used to support single patient electronic health information export as specified in paragraph (b)(10)(i) of this section and database export as specified in paragraph (b)(10)(ii) of this section must be made available via a publicly accessible hyperlink.

Preamble FR Citation: 84 FR 7446-49 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Please see 84 FR 7568-70 for estimates related to this proposal.

Public Comment Field:

Biocom generally supports the proposed rule. Biocom requests clarity on the statement "We do not propose that the export must be executed according to any particular standard, but propose to require that the export must be accompanied by the data format, including its structure and syntax, to facilitate interpretation of the EHI therein." This leaves open the possibility of requiring complex interpretation methods. Biocom recommends that ONC provide some standard options for data export to encourage interoperability. Biocom also urges ONC to implement reasonable timelines for compliance for developer requirements, as these updates can be costly and time-consuming for both developers and users.

§ 170.315(g)(10) Standardized API for patient and population services (Certification Criterion)

Included in 2015 Edition Base EHR Definition? *Yes*

Standardized API for patient and population services. The following technical outcomes and conditions must be met through the demonstration of application programming interface technology.

(i) Data response. Respond to requests for data (based on an ID or other token) for each of the resources referenced by the standard adopted in § 170.215(a)(1) and implementation specifications adopted in § 170.215(a)(2) and (3).

(ii) Search support. Respond to search requests for data consistent with the search criteria included in the implementation specification adopted in § 170.215(a)(4).

(iii) App registration. Enable an application to register with the technology's "authorization server."

(iv) Secure connection. Establish a secure and trusted connection with an application that requests data in accordance with the standard adopted in § 170.215(a)(5).

(v) Authentication and app authorization – 1st time connection. The first time an application connects to request data the technology:

(A) Authentication. Demonstrates that user authentication occurs during the process of authorizing the application to access FHIR resources in accordance with the standard adopted in § 170.215(b).

(B) App authorization. Demonstrates that a user can authorize applications to access a single patient's data as well as multiple patients data in accordance with the implementation specification adopted in § 170.215(a)(5) and issue a refresh token that is valid for a period of at least 3 months.

(vi) Authentication and app authorization – Subsequent connections. Demonstrates that an application can access a single patient's data as well as multiple patients data in accordance with the implementation specification adopted in § 170.215(a)(5) without requiring re-authorization and re-authentication when a valid refresh token is supplied and issue a new refresh token for new period no shorter than 3 months.

(vii) Documentation.

(A) The API(s) must include complete accompanying documentation that contains, at a minimum:

(1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns.

(2) The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s).

(3) All applicable technical requirements and attributes necessary for an application to be registered with an authorization server.

(B) The documentation used to meet paragraph (g)(10)(vii)(A) of this section must be available via a publicly accessible hyperlink.

Preamble FR Citation: 84 FR 7481-84 **Specific questions in preamble?** *Yes*

Regulatory Impact Analysis: Please see 84 FR 7570-75 for estimates related to our proposals regarding APIs.

§ 170.315(g)(10) Standardized API for patient and population services (Certification Criterion)

Public Comment Field:

Biocom generally supports ONC's proposal to adopt the HL7 Fast Healthcare Interoperability Resources (FHIR) standard as a foundational standard for its proposals. We appreciate that ONC is seeking feedback on the appropriate FHIR Release version to mandate. We recommend that ONC pursue "Option 4" to utilize FHIR Release 4 (R4). While "Option 3" provides developers with flexibility in adopting R2 and R4, Biocom believes that using one version of FHIR would be more conducive to realizing a true interoperable ecosystem.

ONC proposes to require that APIs, and the health care ecosystem in which they are deployed, have three attributes: standardized, transparent, and pro-competitive. The standardized attribute requires all health IT developers seeking certification to implement the same technical APO capabilities in their products, using modern, computing standards such as RESTful interfaces and XML/JSON.

Biocom believes that ONC should select a computing standard that is cleaner and more condensed than JSON. Large table formats using comma or tab as delimiter are most common for data storage because they allow easier parsing and table manipulation. JSON works well for websites but when data becomes larger, it is much less suitable.