Application Programming Interfaces in the Regulatory Context

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Key Ingredients

- **ONC Regulatory Provisions**

  » Base EHR Definition

  » Common Clinical Data Set (CCDS)

  » API certification criteria

  » Certified Health IT Product List (CHPL)

- **CMS Regulatory Provisions**

  » CMS Payment programs

    – Meaningful Use "Stage 3" for Eligible Hospitals/Medicaid

    – Merit-based Incentive Payment System (MIPS) for eligible clinicians

  » Certified EHR Technology Definition

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ONC Regulatory Provisions (1) – Base EHR Definition

- Required by law (HITECH Act refers to it as "Qualified EHR")

- ONC links specific certification criteria to functionality that is described in HITECH definition

- 2015 Edition Base EHR means an electronic record of health-related information on an individual that:

  » (1) Includes patient demographic and clinical health information, such as medical history and problem lists;

  » (2) Has the capacity:

    – (i) To provide clinical decision support;

    – (ii) To support physician order entry;

    – (iii) To capture and query information relevant to health care quality;

    – (iv) To exchange electronic health information with, and integrate such information from other sources; and

  » (3) Has been certified to the certification criteria adopted by the Secretary in §170.315(a)(1), (2), or (3); (a)(5) through (9); (a)(11); (a)(14); (b)(1) and (6); (c)(1); **(g)(7) through (9);** and (h)(1) or (2);

ONC Regulatory Provisions (2) – CCDS

- Replaced the "MU Common Data Set"

- Serves as shorthand (regulatory equivalent of a method/function call in programming)

- Lists 21 data types/categories and (as applicable) terminology/vocabulary bindings

ONC Regulatory Provisions (3) – API Certification Criteria & CHPL

- 45 CFR 170.315(g)(7) through (g)(9) & referenced in the Base EHR definition

- 3 criteria overall – Why are there three?

  - » (g)(7) – focuses on patient selection/identification/token provision

  - » (g)(8) focuses on individual data requests from within all of the data listed in the CCDS

  - » (g)(9) focuses on response to request for patient data with a C-CDA response containing the CCDS data

- All three criteria require that the technical documentation associated with them be publicly accessible via hyperlinks, which are also available on ONC's CHPL website where the product is listed.

  - » chpl.healthIT.gov

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CMS Regulatory Provisions

- Set the CEHRT definition = Base EHR criteria + CMS prioritized extras

- So what impact does that have?

  » All providers participating in a CMS program that references CEHRT will need to have in their possession heath IT with certified API functionality.

    – For general use by the provider

    – In specific to address MU/MIPS measures related to patient access

  » For example, MIPS "Provide Patient Access"

    – For at least one unique patient seen by the MIPS eligible clinician: (1) The patient (or the patient authorized representative) is provided timely access to view online, download, and transmit his or her health information; **and** (2) The MIPS eligible clinician **ensures the patient's health information is available for the patient** (or patient-authorized representative) **to access using any application of their choice** that is configured to meet the technical specifications of the Application Programing Interface (API) in the MIPS eligible clinician's certified EHR technology.

In conclusion

- Investments already made/in the process of to include API functionality in health IT systems

- ONC certification criteria do not mandate FHIR, but are FHIR friendly

- Deployment will pick up pace and be strong in 2017 leading into 2018

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