Supporting Innovation with DFL Standards

June 9th, 2021

FDA DFL Workshop

Presenter: Stephen Konya

Senior Advisor to the Deputy National Coordinator
for Health IT and Innovation Portfolio Lead

The Office of the National Coordinator for Health Information Technology

National Strategic Priorities for Health IT

1) ONC is focused on connecting healthcare and health data through a national interoperable Health IT infrastructure.

2) ONC is working to reduce the regulatory and administrative burden related to the use of health IT, including EHRs.

3) ONC is working on ways to give clinicians more time to focus on what matters – caring for their patients.

Supporting Documents;

- ONC's Cures Act Final Rule
- Strategy on Reducing Burden Relating to the Use of Health IT and EHRs
- 2020-2025 Federal Health IT Strategic Plan

(all can be found at www.HealthIT.gov)

ONC's 21st Century Cures Act Final Rule

Putting the patient first in health technology enables the health care system to deliver:

- Transparency into the cost and outcomes of their care
- Competitive options in getting medical care
- Modern smartphone apps to provide them convenient access to their records
- An app economy that provides patients, physicians, hospitals, payers, and employers with innovation and choice

Direct Links;

- Fact Sheets
- Webinars
- Media/Press
- Blog Post
- Download Final Rule

Main Landing Page;

https://www.healthit.gov/curesrule/

Step #1 – Define Your Innovation Community

For ONC, we've defined the health IT innovation community as follows;

1. **Early adopters** who implement and test emerging technology and novel approaches
2. **Entrepreneurs** and **developers** who build new technology and bring it to market
3. **Investors** who financially support the builders and implementers of new technology and novel approaches
4. **Incubators, accelerators, bootcamps, associations and membership networks** that support any of the above 3 types of innovation stakeholder categories

Innovation Spectrum Support Stages

- **Ideation** Support (stage 1)

Purposes:
- Exploration / discovery research
- Calls to action / raise awareness
- Signal priorities
- Address pain points / areas of need

Examples:
- Research grants
- White paper solicitations
- Workshops / meetups
- Challenge competitions
- Hackathons / code-a-thons
- Think tanks

- **Development** Support (stage 2)

Purposes:
- Build
- Test
- Evaluate
- Iterate
- Validate

Examples:
- Bootcamps
- Accelerator programs
- Pilots
- Mentorship
- Resources / toolkits
- Challenge competitions

- **Deployment** Support (stage 3)

Purposes:
- Commercialization
- Market penetration
- Implementation / utilization

Examples:
- Public / private partnerships
- Connections to capital / investment
- Matchmaking / surfacing promising solutions
- Alignment with contracting opportunities
- Policy levers / incentives

Opportunities for Greater Innovation and Use of Modern Technologies and Approaches

#1 - Use of embedded QR codes

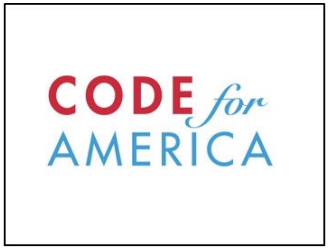
- Greater consumer engagement (for pharmacovigilance, proper use, etc.)
- Translation services / engagement
- Additional Education (informational websites, interactive media, links to peer to peer community forums, etc.)
- Obtaining consumer feedback (surveys, adverse interactions reporting, etc.)

#2 - Realize full potential of open data opportunities

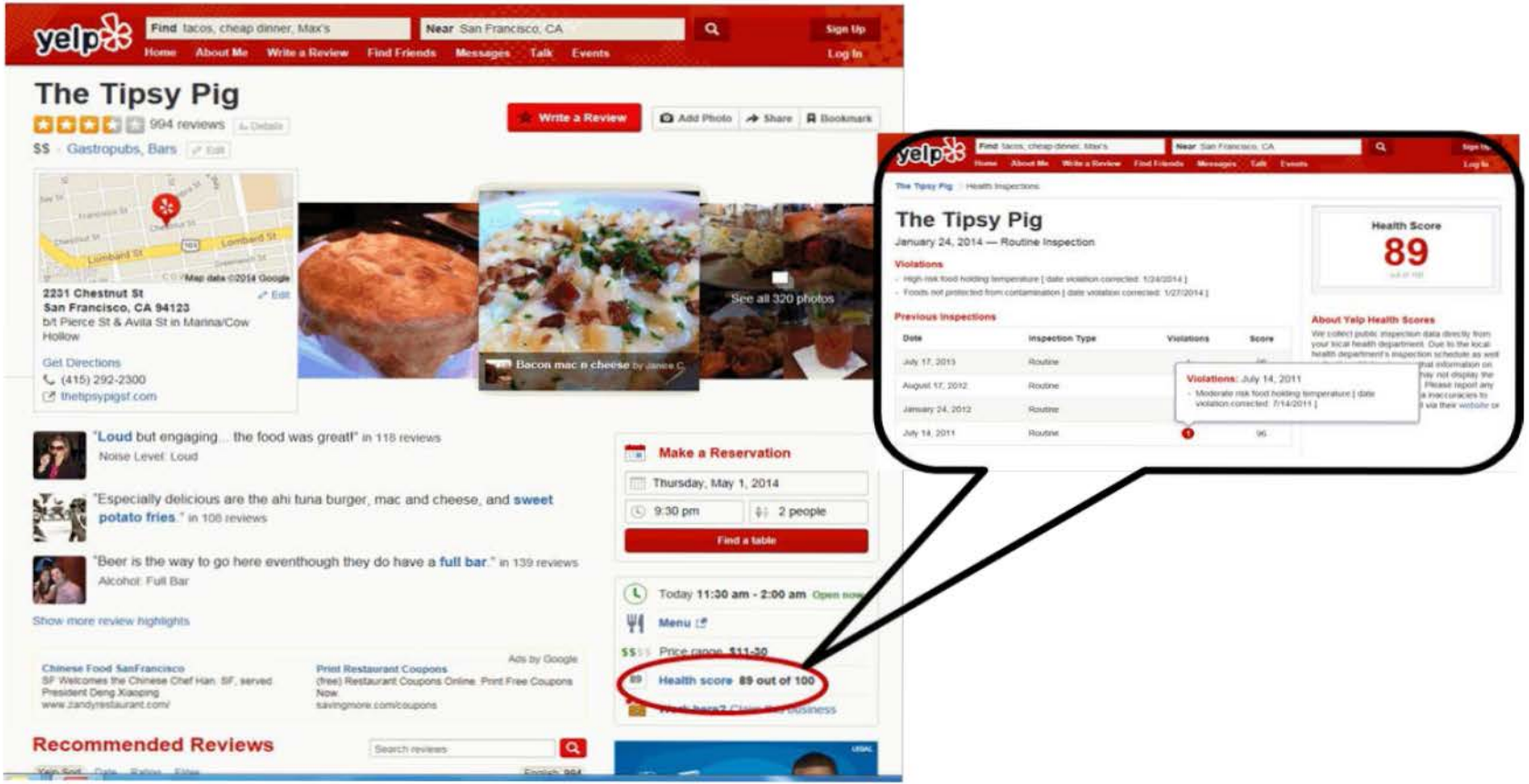
- Partner with industry to use DFL standards in the online / digital marketplace
- Work with civic coders and “big tech” companies on feedback for future development off standards and releases of API accessible/machine readable open data on DFLs/OTCs

Public Health - Restaurant Inspection Data

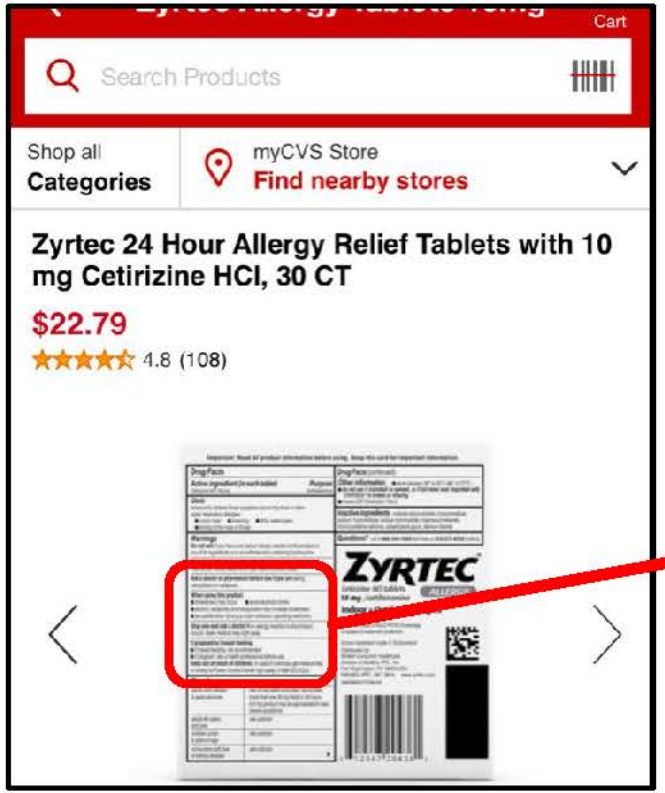
Local Inspector Value-Entry Specification (LIVES)

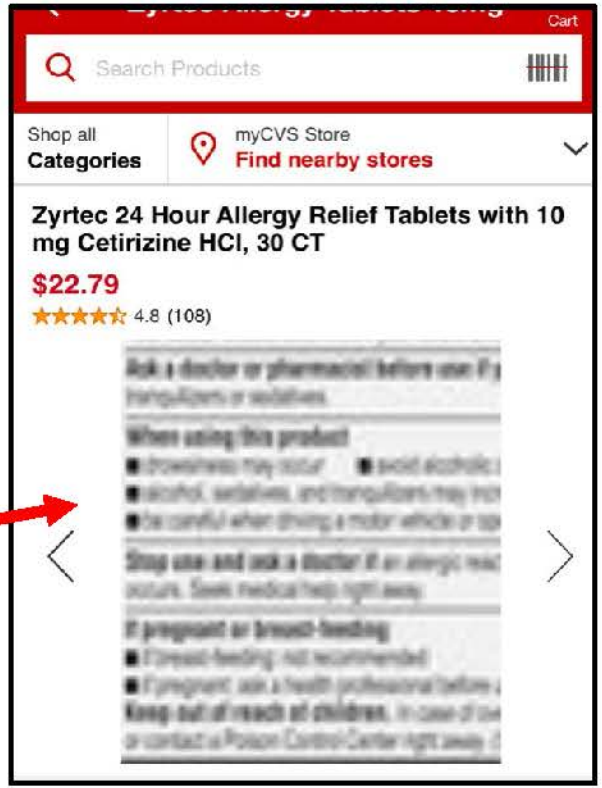


Public Health - Restaurant Inspection Data

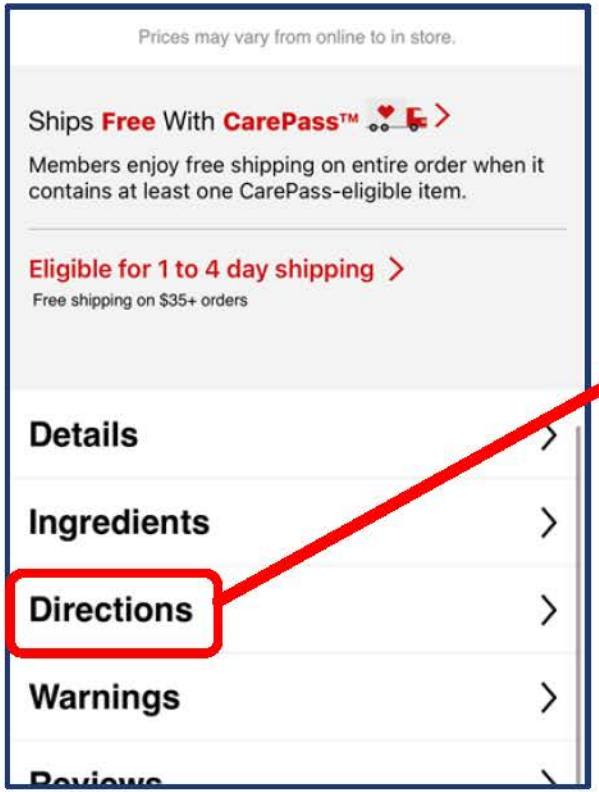


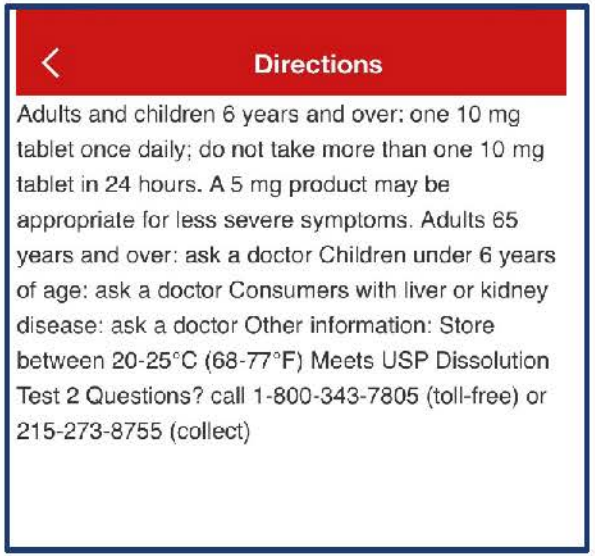
CVS Mobile App





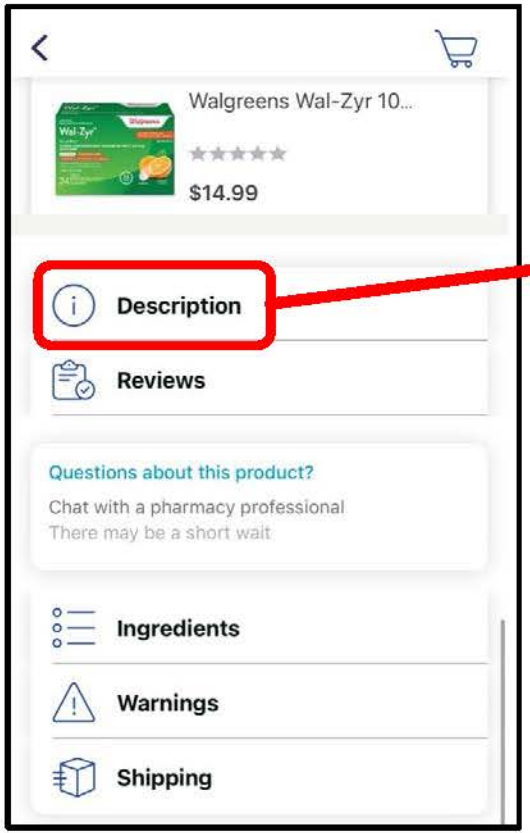
CVS Mobile App

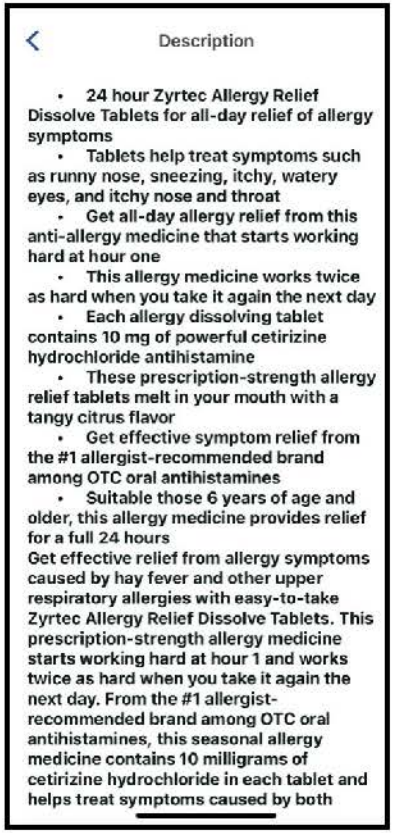




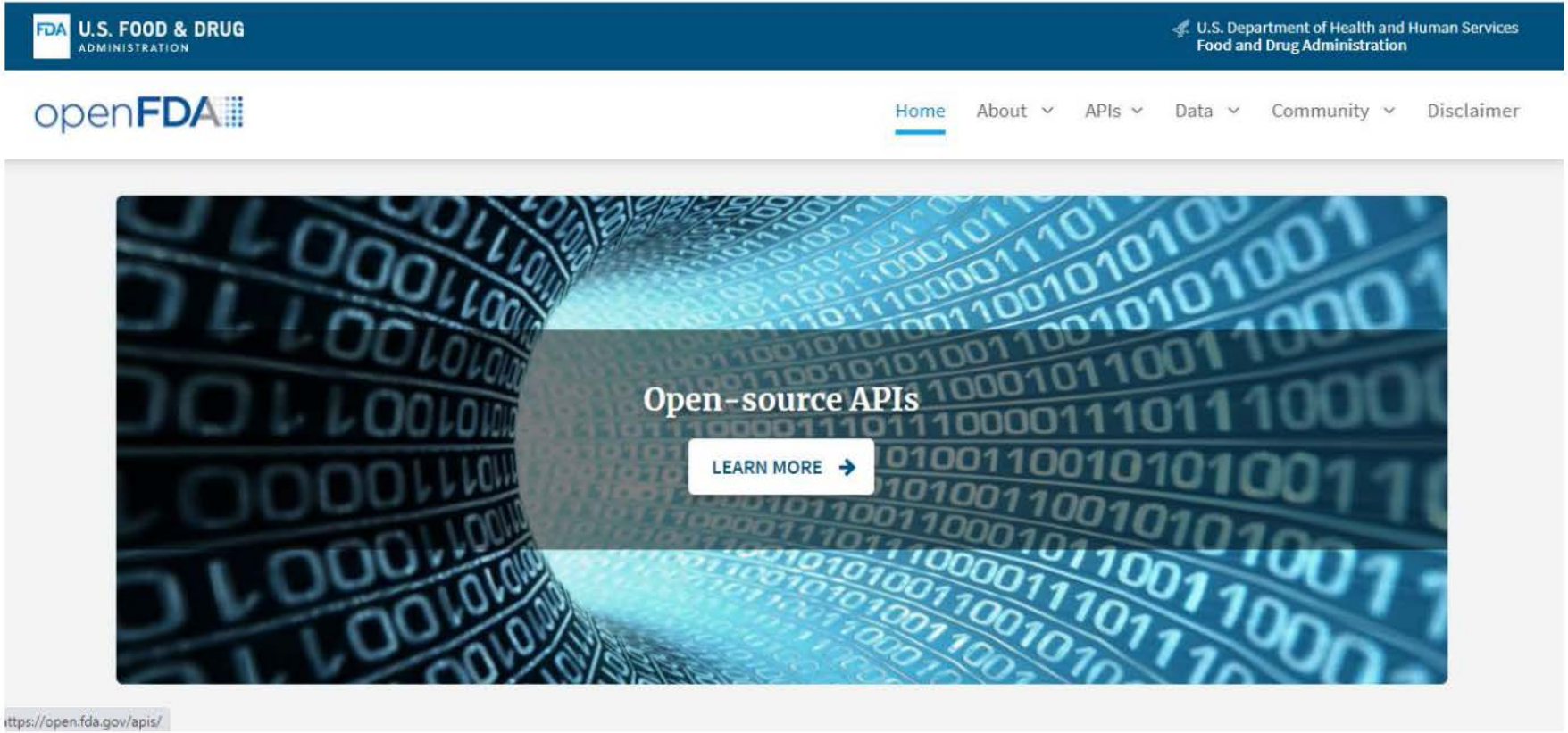
Walgreens Mobile App

Walgreens Mobile App

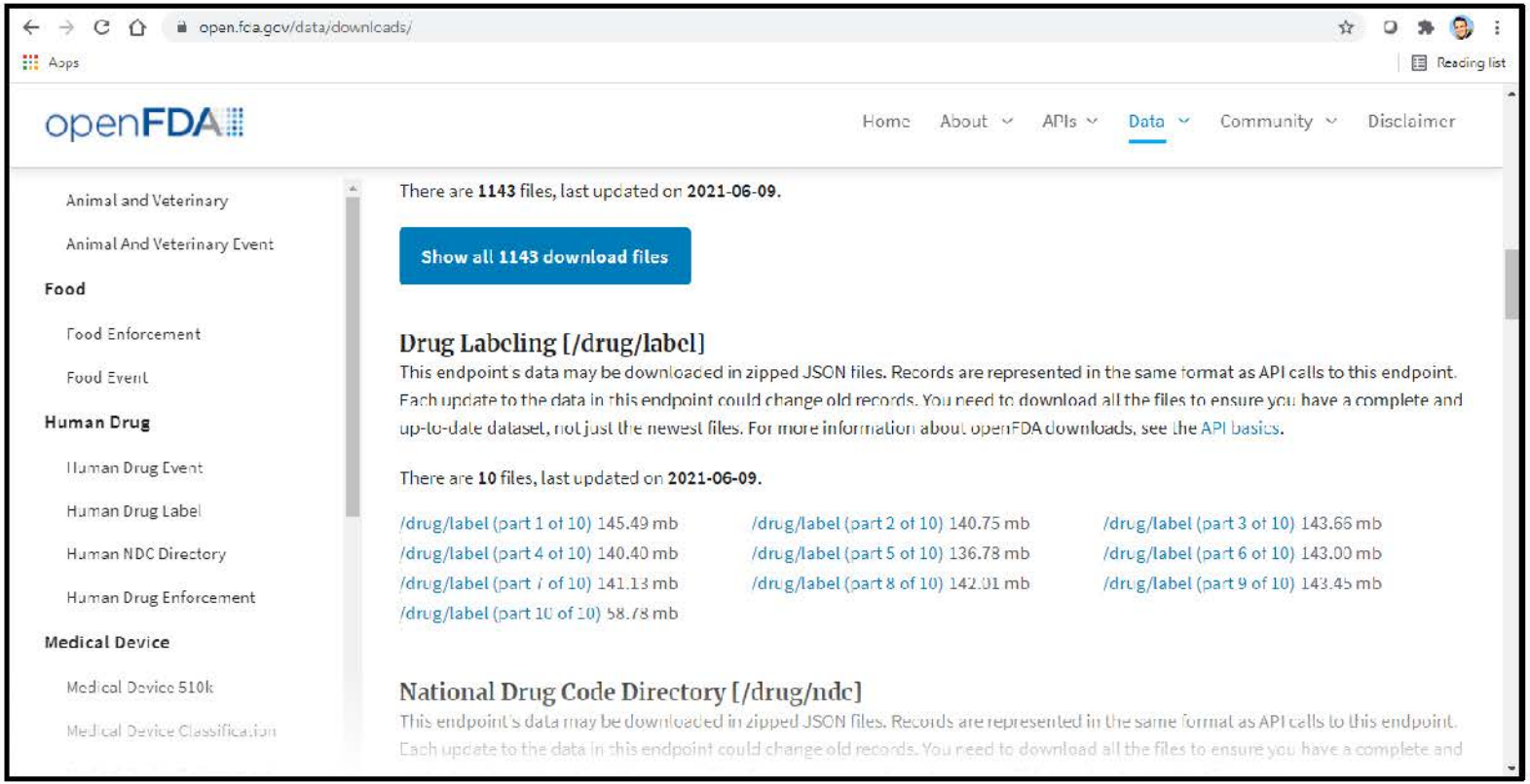




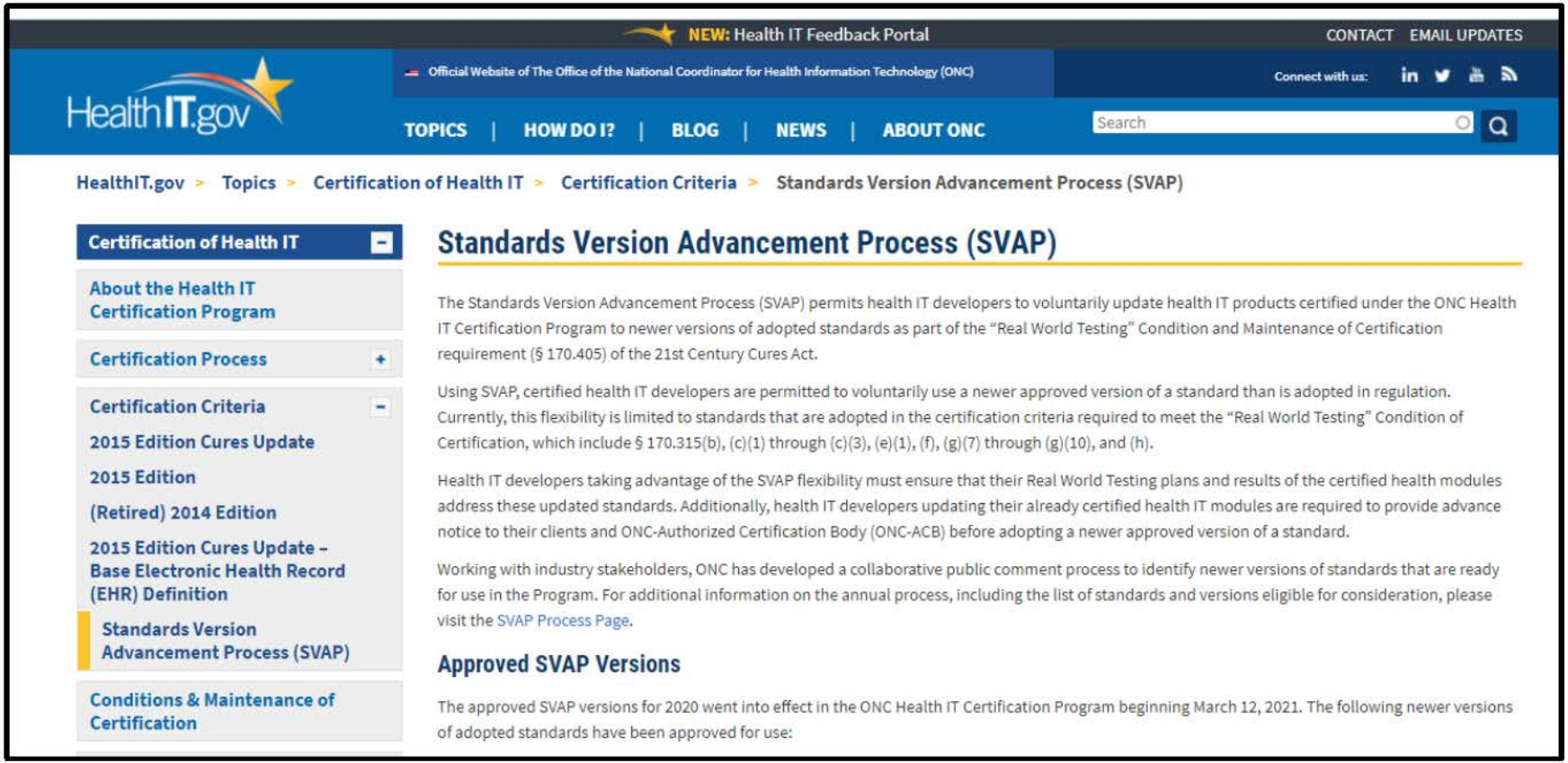
Leveraging Open Data (open.FDA.gov)



Leveraging Open Data (open.FDA.gov)



Standards Version Advancement Process (SVAP)



NEW: Health IT Feedback Portal

CONTACT EMAIL UPDATES

Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

Connect with us:

HealthIT.gov

TOPICS | HOW DO I? | BLOG | NEWS | ABOUT ONC

Search

HealthIT.gov > Topics > Certification of Health IT > Certification Criteria > Standards Version Advancement Process (SVAP)

Certification of Health IT

About the Health IT Certification Program

Certification Process

Certification Criteria

2015 Edition Cures Update

2015 Edition

(Retired) 2014 Edition

2015 Edition Cures Update – Base Electronic Health Record (EHR) Definition

Standards Version Advancement Process (SVAP)

Conditions & Maintenance of Certification

Standards Version Advancement Process (SVAP)

The Standards Version Advancement Process (SVAP) permits health IT developers to voluntarily update health IT products certified under the ONC Health IT Certification Program to newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement (§ 170.405) of the 21st Century Cures Act.

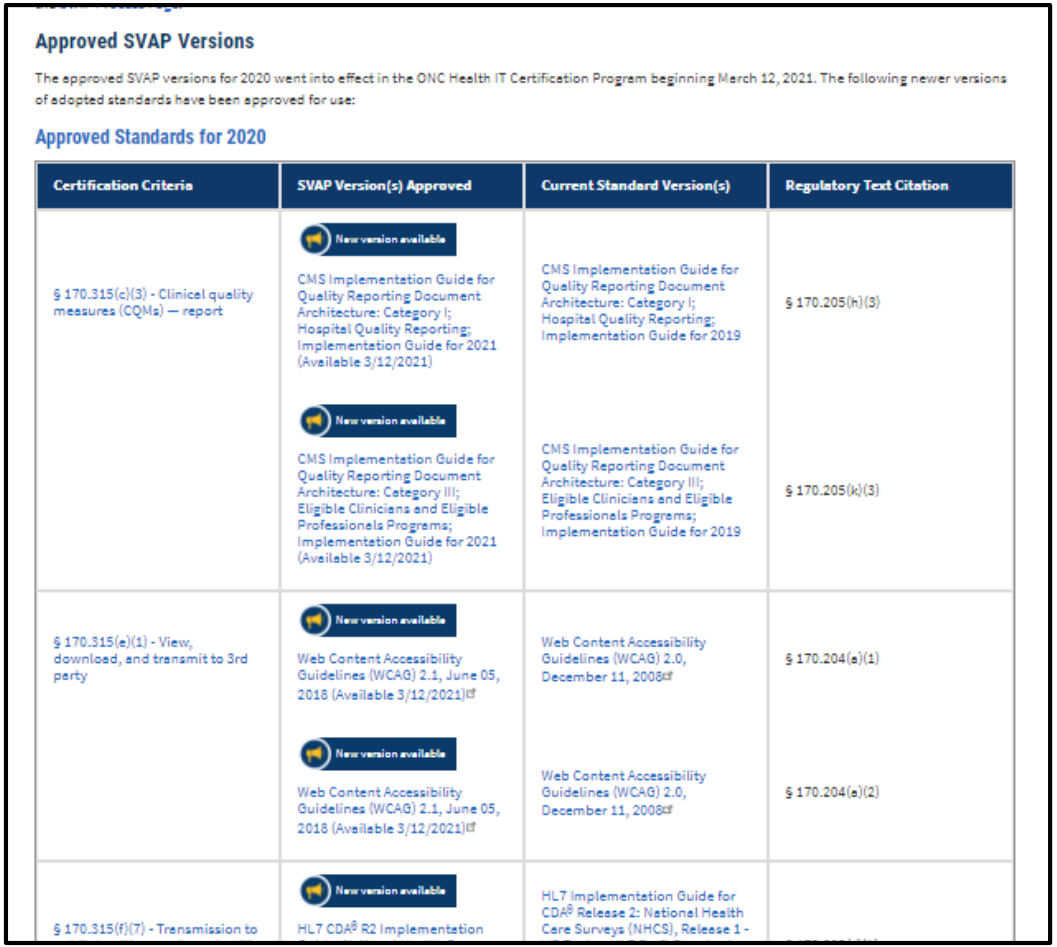
Using SVAP, certified health IT developers are permitted to voluntarily use a newer approved version of a standard than is adopted in regulation. Currently, this flexibility is limited to standards that are adopted in the certification criteria required to meet the "Real World Testing" Condition of Certification, which include § 170.315(b), (c)(1) through (c)(3), (e)(1), (f), (g)(7) through (g)(10), and (h).

Health IT developers taking advantage of the SVAP flexibility must ensure that their Real World Testing plans and results of the certified health modules address these updated standards. Additionally, health IT developers updating their already certified health IT modules are required to provide advance notice to their clients and ONC-Authorized Certification Body (ONC-ACB) before adopting a newer approved version of a standard.

Working with industry stakeholders, ONC has developed a collaborative public comment process to identify newer versions of standards that are ready for use in the Program. For additional information on the annual process, including the list of standards and versions eligible for consideration, please visit the SVAP Process Page.

Approved SVAP Versions

The approved SVAP versions for 2020 went into effect in the ONC Health IT Certification Program beginning March 12, 2021. The following newer versions of adopted standards have been approved for use:



Approved SVAP Versions

The approved SVAP versions for 2020 went into effect in the ONC Health IT Certification Program beginning March 12, 2021. The following newer versions of adopted standards have been approved for use:

Approved Standards for 2020

Certification Criteria	SVAP Version(s) Approved	Current Standard Version(s)	Regulatory Text Citation
§ 170.315(c)(3) - Clinical quality measures (CQMs) — report	New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2021 (Available 3/12/2021)	CMS Implementation Guide for Quality Reporting Document Architecture: Category I; Hospital Quality Reporting; Implementation Guide for 2019	§ 170.205(h)(3)
	New version available CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2021 (Available 3/12/2021)	CMS Implementation Guide for Quality Reporting Document Architecture: Category III; Eligible Clinicians and Eligible Professionals Programs; Implementation Guide for 2019	§ 170.205(k)(3)
§ 170.315(e)(1) - View, download, and transmit to 3rd party	New version available Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018 (Available 3/12/2021)	Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008	§ 170.204(a)(1)
	New version available Web Content Accessibility Guidelines (WCAG) 2.1, June 05, 2018 (Available 3/12/2021)	Web Content Accessibility Guidelines (WCAG) 2.0, December 11, 2008	§ 170.204(a)(2)
§ 170.315(f)(7) - Transmission to	New version available HL7 CDA® R2 Implementation	HL7 Implementation Guide for CDA® Release 2: National Health Care Surveys (NHCS), Release 1 -	

ONC's Standards Version Advancement Process (SVAP)

Setting a New Vision for the Future

To Participate:

1) Go to www.HealthIT.gov/HealthInterop2030

2) Chat us up on Twitter @ONC_HealthIT with #HealthInterop2030 to send your response

(Submissions will be accepted through July 30, 2021!!!)

Contact Information:

Stephen Konya

Senior Advisor and Innovation Portfolio Lead
U.S. Department of Health and Human Services (HHS),
Office of the National Coordinator for Health IT (ONC)

Email: Stephen.Konya@hhs.gov

www.HealthIT.gov