The Office of the National Coordinator for Health Information Technology

ONC Policy Overview

Session 66, February 21, 2017

Elise Sweeney Anthony, Director of Policy, ONC

Conflict of Interest

Has no real or apparent conflicts of interest to report.

Learning Objectives

- Describe the relationship between the 2015 Edition certification criteria and Merit-Based Incentive Payment System and Alternative Payment Models providers under the Quality Payment Program.
- Explain ONC's new rule that enhances surveillance and transparency of health IT.
- Discuss Office of Policy Initiatives

The Office of the National Coordinator for
Health Information Technology

2015 Edition & Supporting QPP through Health IT

Supporting provider & patient needs through certification criteria focused on interoperability

Overview of the 2015 Edition Final Rule

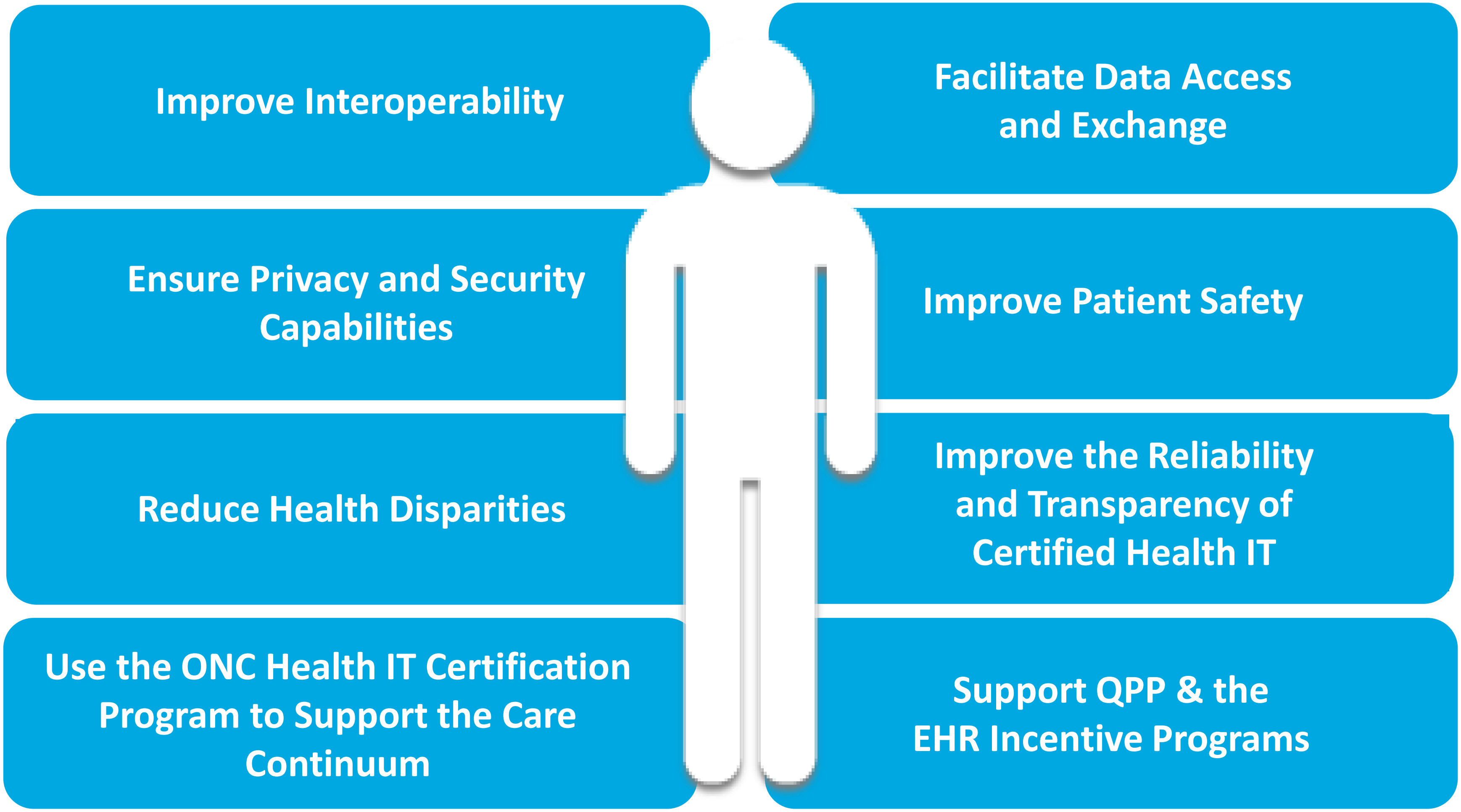
- Builds on the foundation established by the 2011 and 2014 Editions and addresses stakeholder feedback by **reducing burden as compared to the 2015 Edition proposed rule**

- Focuses on health IT components necessary to advance an interoperable nationwide health information infrastructure

- Incorporates changes designed to foster innovation, open new market opportunities, and provide more provider and patient choices in electronic health information access and exchange

- Addresses information blocking and the continued reliability of certified health IT

2015 Edition Final Rule - Health IT Goals



Improve Interoperability

Facilitate Data Access and Exchange

Ensure Privacy and Security Capabilities

Improve Patient Safety

Reduce Health Disparities

Improve the Reliability and Transparency of Certified Health IT

Use the ONC Health IT Certification Program to Support the Care Continuum

Support QPP & the EHR Incentive Programs

2015 Edition: Things to Know

- New Privacy & Security Framework
- Supportive of the broader care continuum
- New and updated vocabulary, content, and transport standards for the structured recording and exchange of health information
  - 2015 Edition Base EHR Definition
  - Common Clinical Data Set
  - Other uses are supported, for example:
    - Public Health
    - Social, Psychological, and Behavioral Health
    - Patient Capture of Health Information

2015 Base EHR Definition

BASE EHR CAPABILITIES	CERTIFICATION CRITERIA
Includes patient demographic and clinical health information, such as medical history and problem lists	Demographics § 170.315(a)(5) Problem List § 170.315(a)(6) Medication List § 170.315(a)(7) Medication Allergy List § 170.315(a)(8) Smoking Status § 170.315(a)(11) Implantable Device List § 170.315(a)(14)
Capacity to provide clinical decision support	Clinical Decision Support § 170.315(a)(9)
Capacity to support physician order entry	Computerized Provider Order Entry (medications, laboratory, or diagnostic imaging) § 170.315(a)(1), (2) or (3)
Capacity to capture and query information relevant to health care quality	Clinical Quality Measures – Record and Export § 170.315(c)(1)
Capacity to exchange electronic health information with, and integrate such information from other sources	Transitions of Care § 170.315(b)(1) Data Export § 170.315(b)(6) Application Access – Patient Selection § 170.315(g)(7) Application Access – Data Category Request § 170.315(g)(8) Application Access – All Data Request § 170.315(g)(9) Direct Project § 170.315(h)(1) or Direct Project, Edge Protocol, and XDR/XDM § 170.315(h)(2)

* Red - New to the Base EHR Definition as compared to the 2014 Edition

** Privacy and security removed – now attached to the applicable certification criteria

Common Clinical Data Set

- Renamed the "Common MU Data Set." This does not impact 2014 Edition certification.
- Includes key health data that should be accessible and available for exchange.
- Data must conform with specified vocabulary standards and code sets, as applicable.

Patient name	Lab tests
Sex	Lab values/results
Date of birth	**Vital signs (changed from proposed rule)**
Race	Procedures
Ethnicity	Care team members
Preferred language	**Immunizations**
Problems	**Unique device identifiers for implantable devices**
Smoking Status	**Assessment and plan of treatment**
Medications	**Goals**
Medication allergies	**Health concerns**

ONC INTEROPERABILITY ROADMAP GOAL

2015-2017

Send, receive, find and use priority data domains to improve health and health quality

Red = New data added to data set (+ standards for immunizations)
Blue = Only new standards for data

2015 Edition Final Rule:
Supporting the Needs of Diverse Consumers

Certification Criteria	What the Functionality Can Support
Documentation of social, psychological, and behavioral data (e.g., education level, stress, depression, alcohol use, sexual orientation and gender identity)	Allow providers and other stakeholders to better understand how these data can affect health, reduce disparities, and improve patient care and health equity
Exchange of sensitive health information (data segmentation for privacy)	Allow for the exchange of sensitive health information (e.g., behavioral health, substance abuse, genetic), in accordance with federal and state privacy laws, for more coordinated and efficient care across the continuum.
Accessibility of health IT	More transparency on the accessibility standards used in developing health IT
More granular recording and exchange of patient race and ethnicity	Allow providers to better understand health disparities based on race and ethnicity, and improve patient care and health equity.

Certification Program Requirements*		2015 Edition Certification Criteria Associated with EHR Incentive Programs Stage 3 (n=38)		2015 Edition Certification Criteria Supporting the Broader Care Continuum (n=8)
2015 Edition Mandatory Certification Criteria (n=2)	2015 Edition Conditional Certification Criteria (n= 12)			
Quality Management System - (g)(4)	Authentication, Access Control, Authorization -(d)(1)	CPOE – Medications - (a)(1)	CQM – Record and Export - (c)(1)	Social, Psychological, and Behavioral Data - (a)(15)
Accessibility-Centered Design - (g)(5)	Auditable Events and Tamper-Resistance - (d)(2)	CPOE – Laboratory - (a)(2)	CQM – Import and Calculate - (c)(2)	DS4P – Send - (b)(7)
	Audit Report(s) - (d)(3)	CPOE Diagnostic Imaging - (a)(3)	CQM – Report - (c)(3)	DS4P – Receive - (b)(8)
	Amendments - (d)(4)	Drug-Drug, Drug-Allergy Interaction Checks for CPOE - (a)(4)	View, Download, and Transmit to 3rd Party - (e)(1)	Care Plan - (b)(9)
	Automatic Access Time-Out - (d)(5)	Demographics - (a)(5)	Secure Messaging - (e)(2)	CQM Filter - (c)(4)
	Emergency Access - (d)(6)	Problem List - (a)(6)	Patient Health Information Capture - (e)(3)	Accounting of Disclosures - (d)(11)
	End-User Device Encryption - (d)(7)	Medication List - (a)(7)	Transmission to Immunization Registries -(f)(1)	Common Clinical Data Set Summary Record – Create -(b)4)
	Integrity - (d)(8)	Medication Allergy List - (a)(8)	Transmission to PHA – Syndromic Surveillance - (f)(2)	Common Clinical Data Set Summary Record – Receive -(b)(5)
	Trusted Connection - (d)(9)	CDS - (a)(9)	Transmission to PHA – Reportable Laboratory Tests and Values/Results - (f)(3)	
	Auditing Actions on Health Information - (d)(10)	Drug-Formulary and Preferred Drug List Checks - (a)(10)	Transmission of Cancer Registries - (f)(4)	
	Safety Enhanced Design - (g)(3)	Smoking Status - (a)(11)	Transmission to PHA – Electronic Case Reporting - (f)(5)	
	Consolidated CDA Creation Performance - (g)(6)	Family Health History - (a)(12)	Transmission to PHA – Antimicrobial Use and Resistance Reporting - (f)(6)	
		Patient-Specific Education Resources - (a)(13)	Transmission to PHA – Health Care Surveys - (f)(7)	
		Implantable Device List - (a)(14)	Automated Numerator Recording - (g)(1) or Automated Measure Calculation - (g)(2)	
		Transitions of Care - (b)(1)	Application Access – Patient Selection - (g)(7)	
		Clinical Information Reconciliation and Incorporation - (b)(2)	Application Access – Data Category Request - (g)(8)	
		Electronic Prescribing - (b)(3)	Application Access – All Data Request -(g)(9)	
		Data Export - (b)(6)	Direct Project - (h)(1)	
			Direct Project, Edge Protocol, and XDR/XDM - (h)(2)	

KEY: Criteria are "new," "unchanged," and "revised" as compared to the 2014 Edition

Green Background = new to the 2015 Edition

Red Font = "unchanged" criteria (eligible for gap certification)

Black Font = "revised" criteria

Where have you seen Certified Health IT Provisions?

Examples:

- Medicare and Medicaid EHR Incentive Programs
- Physician Quality Reporting System (PQRS)
- Hospital Inpatient Quality Reporting (IQR)
- The Joint Commission for performance measurement initiative
- CPC alternate payment model and others
- Physician Self-Referral Law exception and Anti-kickback Statute safe harbor for certain EHR donations
- CMS chronic care management services (included in 2015 and 2016 Physician Fee Schedule rulemakings)
- Department of Defense Healthcare Management System Modernization Program
- HRSA Health Center Controlled Network Program

CMS Quality Payment Program

Established by MACRA Act of 2015; Implemented by CMS in an Oct. 2016 Final Rule

MACRA & the CMS Quality Payment Program: A Health IT Perspective

Health IT in ACI

- Closing the Health IT Referral Loop
- Bridging the Information Gap across Care Settings
- Incentivizes Public Health and Population Health Management
- Streamlining Reporting and Providing Flexibility

Health IT in Quality

- Seamless Information Exchange through Health IT
- Flexible Options for Electronic Reporting
- End-to-End Electronic Reporting Bonus

Health IT in Improvement Activities

•Includes a wide range of options that leverage certified health IT to support eligible clinicians in implementing clinical practice improvements.

•Certified EHR Technology Bonus for Improvement Activities

Health IT In APMs

- At least 50 percent of the clinicians in an Advanced APM must use certified EHR technology
- Other payer APMs will align with Medicare APMs using certified EHR technology in future years
- APM Entities must comply with HIPAA and may also include additional APM specific technology initiatives

Merit Based Incentive Program
Advancing Care Information Category

The Advancing Care Information performance category includes measurement of eligible clinicians and groups use of certified EHR technology

Protect Patient Health Information
(yes required)

Electronic Prescribing
(numerator/denominator)

Patient Electronic Access
(numerator/denominator)

Coordination of Care Through Patient Engagement
(numerator/denominator)

Health Information Exchange
(numerator/denominator)

Public Health and Clinical Data Registry Reporting
(yes required)

Merit Based Incentive Program
Advancing Care Information Category

Clinicians must use certified EHR technology to report

For those using EHR Certified to the 2015 Edition:

Option 1

Advancing Care Information Objectives and Measures

Option 2

Combination of the two measure sets

For those using 2014 Certified EHR Technology:

Option 1

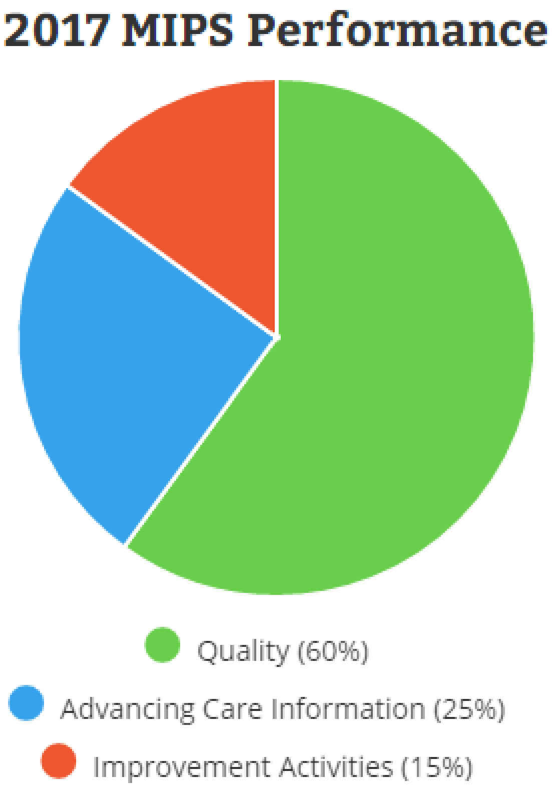
2017 Advancing Care Information Transition Objectives and Measures

Option 2

Combination of the two measure sets

Merit Based Incentive Program
Advancing Care Information Category

- Advances the goals of the HITECH Act to encourage the use of CEHRT and builds upon prior policies under Meaningful Use
- Scoring methodology emphasizes **Patient Electronic Access**, **Coordination of Care Through Patient Engagement**, and **Health Information Exchange**
- Reduced number of required measures from 11 -> 5 and improves upon prior "all or nothing" scoring
- Base reporting earns 50% credit; performance score based on the remaining optional measures
- Bonuses in ACI for completing certain Improvement Activities using CEHRT (e.g., providing 24/7 access, recording patient outcomes) and reporting to public health registries
- Hardship exemptions available



Merit Based Incentive Program
Advancing Care Information Category

ACI category weighted to zero for the following hardships:

- Lack of sufficient internet connectivity
- Extreme and uncontrollable circumstances (e.g., vendor issues)
- Lack of control over the availability of CEHRT
- No face-to-face interactions with patients

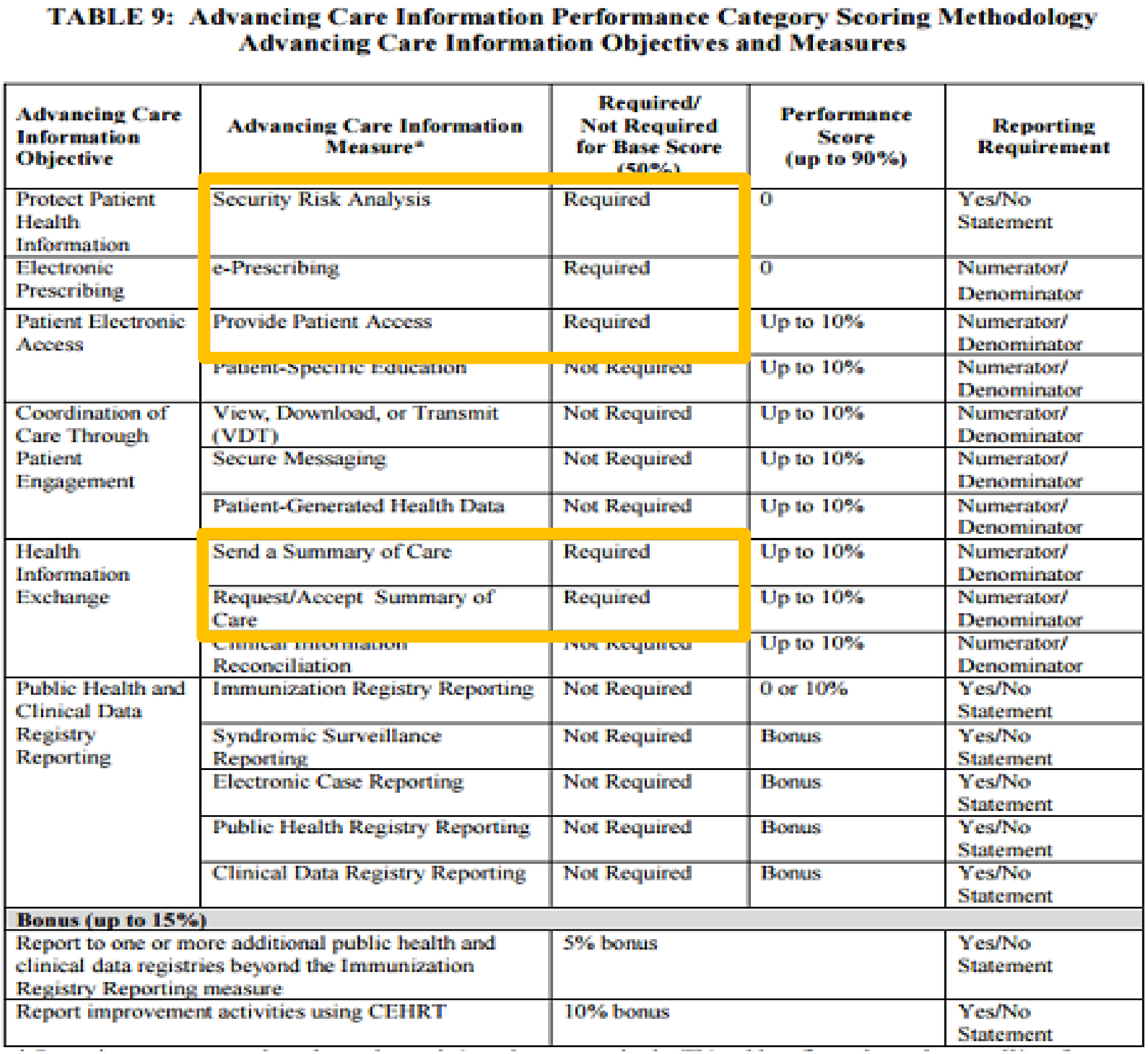


TABLE 9: Advancing Care Information Performance Category Scoring Methodology Advancing Care Information Objectives and Measures

Advancing Care Information Objective	Advancing Care Information Measure*	Required/ Not Required for Base Score (50%)	Performance Score (up to 90%)	Reporting Requirement
Protect Patient Health Information	Security Risk Analysis	Required	0	Yes/No Statement
Electronic Prescribing	e-Prescribing	Required	0	Numerator/ Denominator
Patient Electronic Access	Provide Patient Access	Required	Up to 10%	Numerator/ Denominator
	Patient-Specific Education	Not Required	Up to 10%	Numerator/ Denominator
Coordination of Care Through Patient Engagement	View, Download, or Transmit (VDT)	Not Required	Up to 10%	Numerator/ Denominator
	Secure Messaging	Not Required	Up to 10%	Numerator/ Denominator
	Patient-Generated Health Data	Not Required	Up to 10%	Numerator/ Denominator
Health Information Exchange	Send a Summary of Care	Required	Up to 10%	Numerator/ Denominator
	Request/Accept Summary of Care	Required	Up to 10%	Numerator/ Denominator
	Clinical Information Reconciliation	Not Required	Up to 10%	Numerator/ Denominator
Public Health and Clinical Data Registry Reporting	Immunization Registry Reporting	Not Required	0 or 10%	Yes/No Statement
	Syndromic Surveillance Reporting	Not Required	Bonus	Yes/No Statement
	Electronic Case Reporting	Not Required	Bonus	Yes/No Statement
	Public Health Registry Reporting	Not Required	Bonus	Yes/No Statement
	Clinical Data Registry Reporting	Not Required	Bonus	Yes/No Statement
Bonus (up to 15%)				
Report to one or more additional public health and clinical data registries beyond the Immunization Registry Reporting measure		5% bonus		Yes/No Statement
Report improvement activities using CEHRT		10% bonus		Yes/No Statement

Support for Health Information Exchange & Interoperability in Health IT Infrastructure

- Section 106(b)(2) of the MACRA requires eligible providers to demonstrate that they have not knowingly and willfully limited or restricted the interoperability of certified EHR technology.
- CMS finalized a new required attestation for health care providers using CEHRT in the EHR Incentive Programs and Merit Based Incentive Program (MIPS) to support the prevention of information blocking.

Prevention of Information Blocking

and

Cooperation with Health IT Surveillance

Quality Payment Program

Learn About the Program

Explore Measures

Education & Tools

Quality Payment Program

Modernizing Medicare to provide better care and smarter spending for a healthier America.

qpp.cms.gov

The Office of the National Coordinator for
Health Information Technology

Enhanced Oversight & Accountability Rule

Support greater accountability for health IT developers under the ONC Certification Program

Enhanced Oversight and Accountability Final Rule

- ONC Direct Review of Certified Health IT
- ONC-Authorized Testing Laboratories (ONC-ATLs)
- Transparency and Availability of Identifiable Surveillance Results

What is the EOA Final Rule?

🚫

- **Does not** create new certification criteria requirements for health IT developers
- **Does not** create new certification/health IT requirements for providers participating in HHS programs
- **Does not** establish a means for ONC to directly test and certify health IT (ONC-ACBs will continue to test and certify)
- **Does not** establish regular or routine auditing of certified health IT by ONC

✓

- **Does** establish a regulatory process for ONC to directly review already certified health IT products
- **Does** increase ONC oversight of health IT testing bodies
- **Does** increase transparency and accountability by making identifiable surveillance results of certified health IT publicly available

ONC Direct Review of Certified Health IT

- Support greater accountability for health IT developers under the Program
- Provide greater confidence to purchasers and users that health IT conforms to Program requirements when it is implemented, maintained, and used
- Sets up a process for ONC to work with health IT developers to remedy any identified non-conformities of certified health IT in a timely manner

ONC Direct Review of Certified Health IT

With the vast majority of physicians and hospitals now using certified health IT, ONC plays an important role in helping ensure that these products operate safely and reliably in the field.

ONC direct review will:

- **Be independent of (and may be in addition to) ONC-ACBs' surveillance** and other functions under the Program
- **Focus on capabilities and aspects of health IT that are certified under the Program** (i.e., "**certified capabilities"**), taking into consideration other relevant functionalities or products to the extent necessary to determine whether certified health IT is functioning in a manner consistent with Program requirements
- **Focus on circumstances involving:**
  1. **Potential risks to public health or safety; or**
  2. **Practical challenges that may prevent ONC-ACBs from carrying out their surveillance responsibilities**

ONC Direct Review of Certified Health IT

- **Serious Risk to Public Health or Safety**
  - ONC may initiate direct review if it has a reasonable belief that certified health IT may not conform to Program requirements because the certified health IT may be causing or contributing to conditions that present a serious risk to public health or safety
  - ONC will consider:
    - The potential nature, severity, and extent of the suspected conditions;
    - The need for an immediate or coordinated government response; and
    - If applicable, information that calls into question the validity of the health IT's certification or maintenance thereof under the Program.

- **Impediments to ONC-ACB Oversight**
  - ONC may initiate direct review if it has a reasonable belief that certified health IT may not conform to Program requirements **and** the suspected non-conformity presents issues that:
    - May require access to confidential or other information that is unavailable to an ONC-ACB;
    - May require concurrent or overlapping reviews by multiple ONC-ACBs; or
    - May exceed an ONC-ACB's resources or expertise.

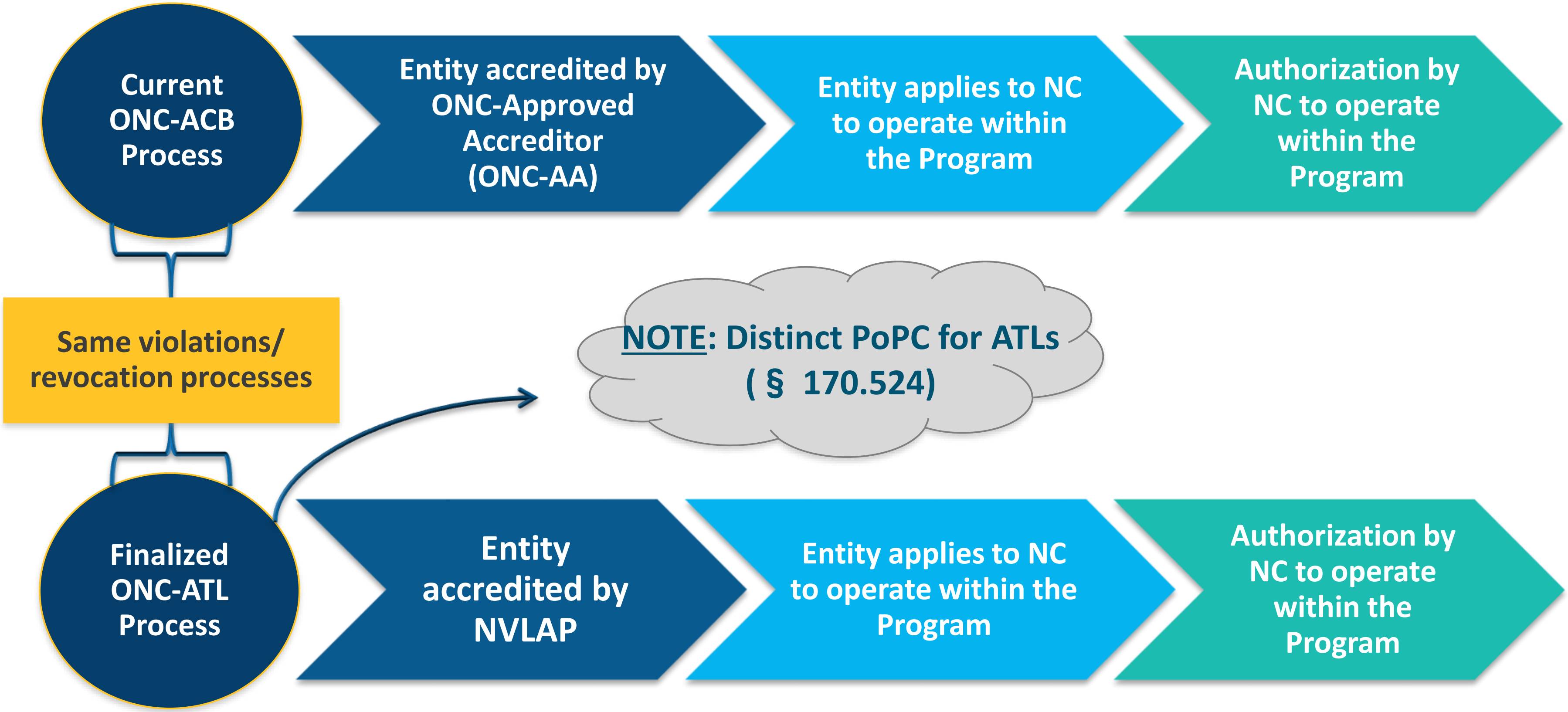
- **Examples – Six examples in the final rule (A through F (3-part example)) (81 FR 72420-25)**

ONC-Authorized Testing Laboratories

- Establishes regulatory processes for ONC to have more direct oversight of testing labs under the Program. These processes are similar to the ONC-ACB processes.

- Provision enables ONC to oversee and address testing and certification performance issues throughout the entire continuum of the Program in an immediate, direct, and precise manner, including by:
  - Authorizing testing labs as ONC-ATLs.
    - Does not require labs applying for ONC-ATL status to obtain additional accreditation beyond NVLAP accreditation for health IT testing
  - Specifying requirements for retaining ONC-ATL status and means for ONC to suspend and revoke ONC-ATL status under the Program.

Comparison of ONC-ATL and ONC-ACB Processes



Current ONC-ACB Process

Entity accredited by ONC-Approved Accreditor (ONC-AA)

Entity applies to NC to operate within the Program

Authorization by NC to operate within the Program

Same violations/ revocation processes

NOTE: Distinct PoPC for ATLs (§ 170.524)

Finalized ONC-ATL Process

Entity accredited by NVLAP

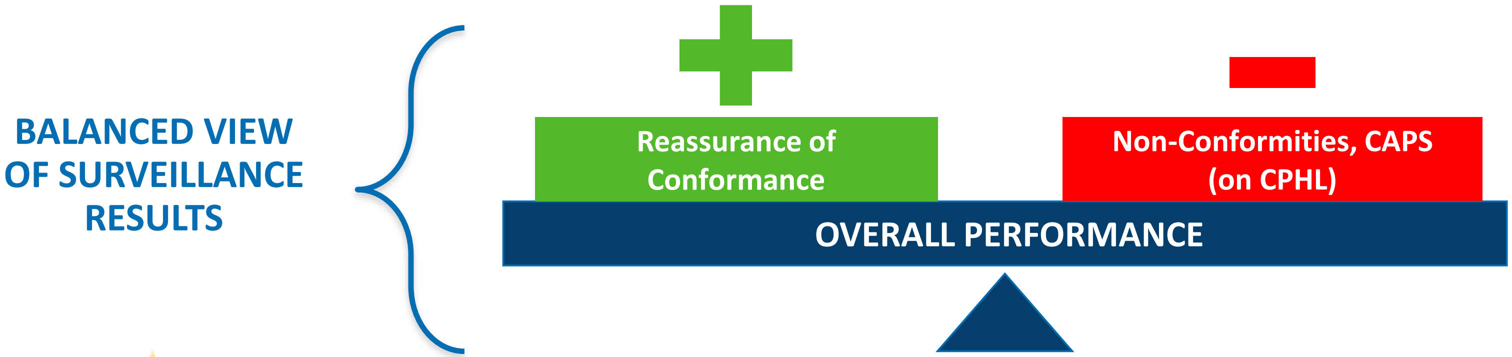
Entity applies to NC to operate within the Program

Authorization by NC to operate within the Program

Transparency and Availability of Identifiable Surveillance Results

Before this rule, ONC only lists corrective action plans for non-conformities found by ONC-ACBs on the CHPL. Through this final rule, ONC will provide more complete information that illuminates good performance and continued conformity with Program requirements for certified health IT

- Requires ONC-ACBs to make identifiable surveillance results publicly available on the web-based Certified Health IT Product List (CHPL) on a quarterly basis.
- Further enhances transparency and provide customers and users of certified health IT with valuable information about the overall conformity of certified health IT to Program requirements.


BALANCED VIEW OF SURVEILLANCE RESULTS
+
Reassurance of Conformance
−
Non-Conformities, CAPS (on CPHL)
OVERALL PERFORMANCE

Snapshot of Office of Policy Initiatives

- Model Privacy Notice
- EHR Contract Guide
- Public Health - Zika Response
- Patient Generated Health Data
- Patient Access Resources

An Updated Model Privacy Notice

- There is now a broad range of consumer health technologies beyond PHRs.
- More and more individuals are obtaining access to their electronic health information and using consumer health technology to manage this information.
- Users are concerned about privacy and security of their data.
- Existing privacy policies can be long, complex, and confusing.
- Not all users read the privacy policy and those that do may not fully understand the content in the policy.

What if…

•… Privacy practices were as easy to understand as a nutrition label?

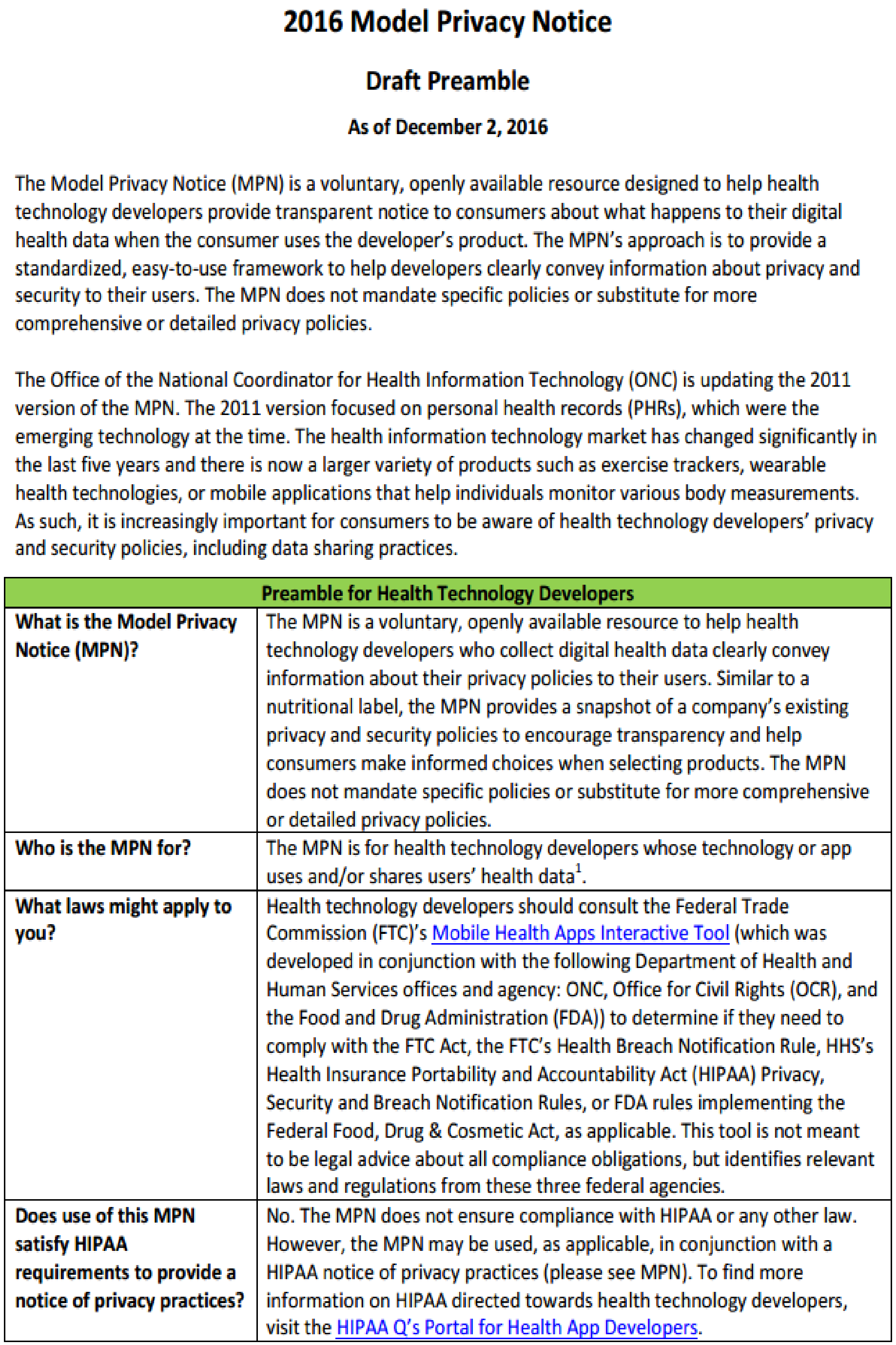
•… Users were provided with a snapshot of the privacy practices that they are most concerned about in terms that they understand?

Model Privacy Notice

- Model Privacy Notice (MPN): a voluntary, openly available resource designed to help developers provide transparent notice to consumers about what happens to their data.

- The MPN's approach is to provide a standardized, easy-to-use framework to help developers clearly convey information about privacy and security to their users.

- The 2011 version of the MPN was developed in collaboration with the Federal Trade Commission and focused on Personal Health Records (PHRs), which were the emerging technology at the time.



2016 Model Privacy Notice

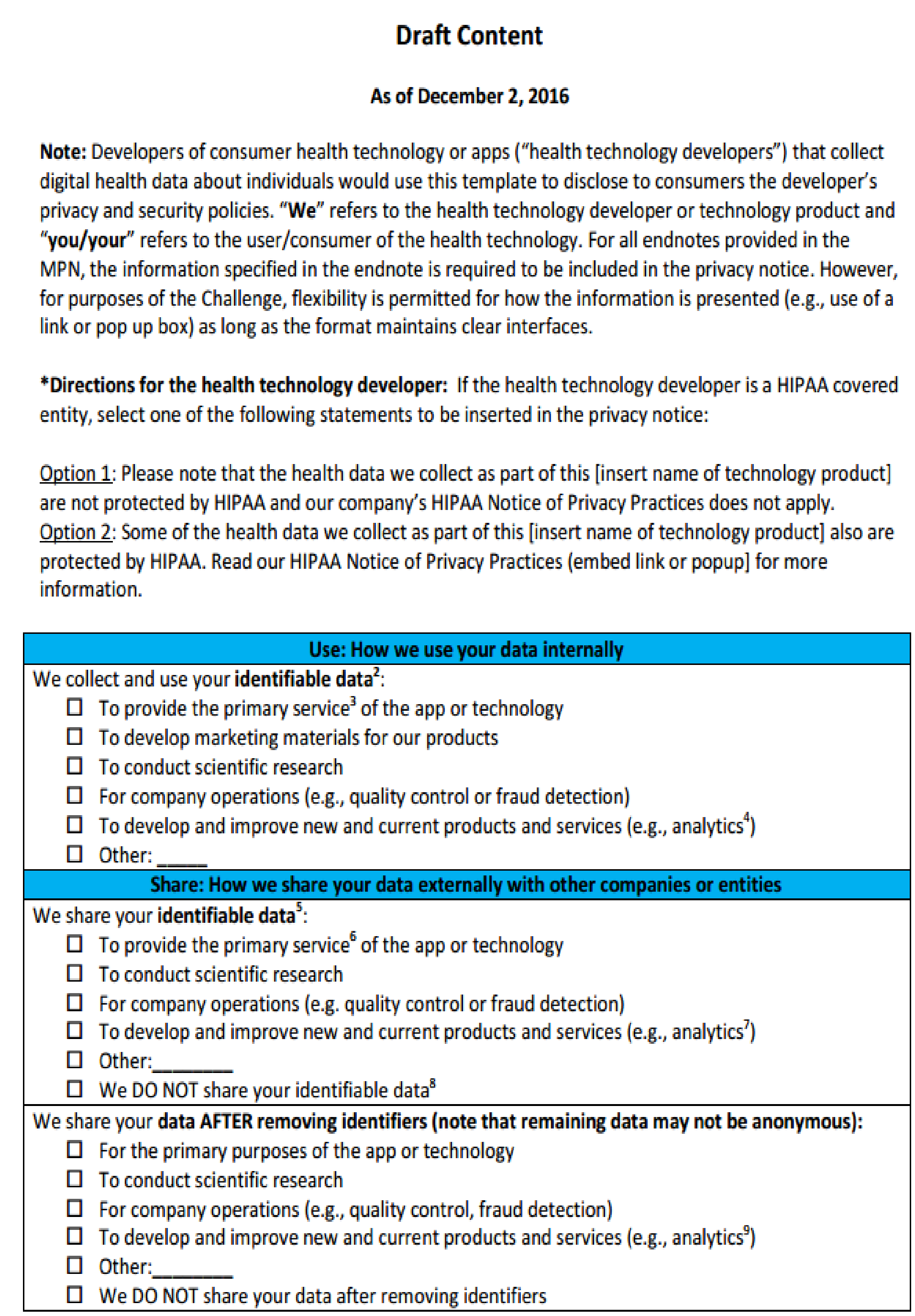
Draft Preamble

As of December 2, 2016

The Model Privacy Notice (MPN) is a voluntary, openly available resource designed to help health technology developers provide transparent notice to consumers about what happens to their digital health data when the consumer uses the developer's product. The MPN's approach is to provide a standardized, easy-to-use framework to help developers clearly convey information about privacy and security to their users. The MPN does not mandate specific policies or substitute for more comprehensive or detailed privacy policies.

The Office of the National Coordinator for Health Information Technology (ONC) is updating the 2011 version of the MPN. The 2011 version focused on personal health records (PHRs), which were the emerging technology at the time. The health information technology market has changed significantly in the last five years and there is now a larger variety of products such as exercise trackers, wearable health technologies, or mobile applications that help individuals monitor various body measurements. As such, it is increasingly important for consumers to be aware of health technology developers' privacy and security policies, including data sharing practices.

Preamble for Health Technology Developers	
What is the Model Privacy Notice (MPN)?	The MPN is a voluntary, openly available resource to help health technology developers who collect digital health data clearly convey information about their privacy policies to their users. Similar to a nutritional label, the MPN provides a snapshot of a company's existing privacy and security policies to encourage transparency and help consumers make informed choices when selecting products. The MPN does not mandate specific policies or substitute for more comprehensive or detailed privacy policies.
Who is the MPN for?	The MPN is for health technology developers whose technology or app uses and/or shares users' health data[1].
What laws might apply to you?	Health technology developers should consult the Federal Trade Commission (FTC)'s Mobile Health Apps Interactive Tool (which was developed in conjunction with the following Department of Health and Human Services offices and agency: ONC, Office for Civil Rights (OCR), and the Food and Drug Administration (FDA)) to determine if they need to comply with the FTC Act, the FTC's Health Breach Notification Rule, HHS's Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security and Breach Notification Rules, or FDA rules implementing the Federal Food, Drug & Cosmetic Act, as applicable. This tool is not meant to be legal advice about all compliance obligations, but identifies relevant laws and regulations from these three federal agencies.
Does use of this MPN satisfy HIPAA requirements to provide a notice of privacy practices?	No. The MPN does not ensure compliance with HIPAA or any other law. However, the MPN may be used, as applicable, in conjunction with a HIPAA notice of privacy practices (please see MPN). To find more information on HIPAA directed towards health technology developers, visit the HIPAA Q's Portal for Health App Developers.



Draft Content

As of December 2, 2016

Note: Developers of consumer health technology or apps ("health technology developers") that collect digital health data about individuals would use this template to disclose to consumers the developer's privacy and security policies. "**We**" refers to the health technology developer or technology product and "**you/your**" refers to the user/consumer of the health technology. For all endnotes provided in the MPN, the information specified in the endnote is required to be included in the privacy notice. However, for purposes of the Challenge, flexibility is permitted for how the information is presented (e.g., use of a link or pop up box) as long as the format maintains clear interfaces.

***Directions for the health technology developer:** If the health technology developer is a HIPAA covered entity, select one of the following statements to be inserted in the privacy notice:

Option 1: Please note that the health data we collect as part of this [insert name of technology product] are not protected by HIPAA and our company's HIPAA Notice of Privacy Practices does not apply.
Option 2: Some of the health data we collect as part of this [insert name of technology product] also are protected by HIPAA. Read our HIPAA Notice of Privacy Practices (embed link or popup) for more information.

Use: How we use your data internally

We collect and use your **identifiable data**[2]:

□ To provide the primary service[3] of the app or technology
□ To develop marketing materials for our products
□ To conduct scientific research
□ For company operations (e.g., quality control or fraud detection)
□ To develop and improve new and current products and services (e.g., analytics[4])
□ Other: ____

Share: How we share your data externally with other companies or entities

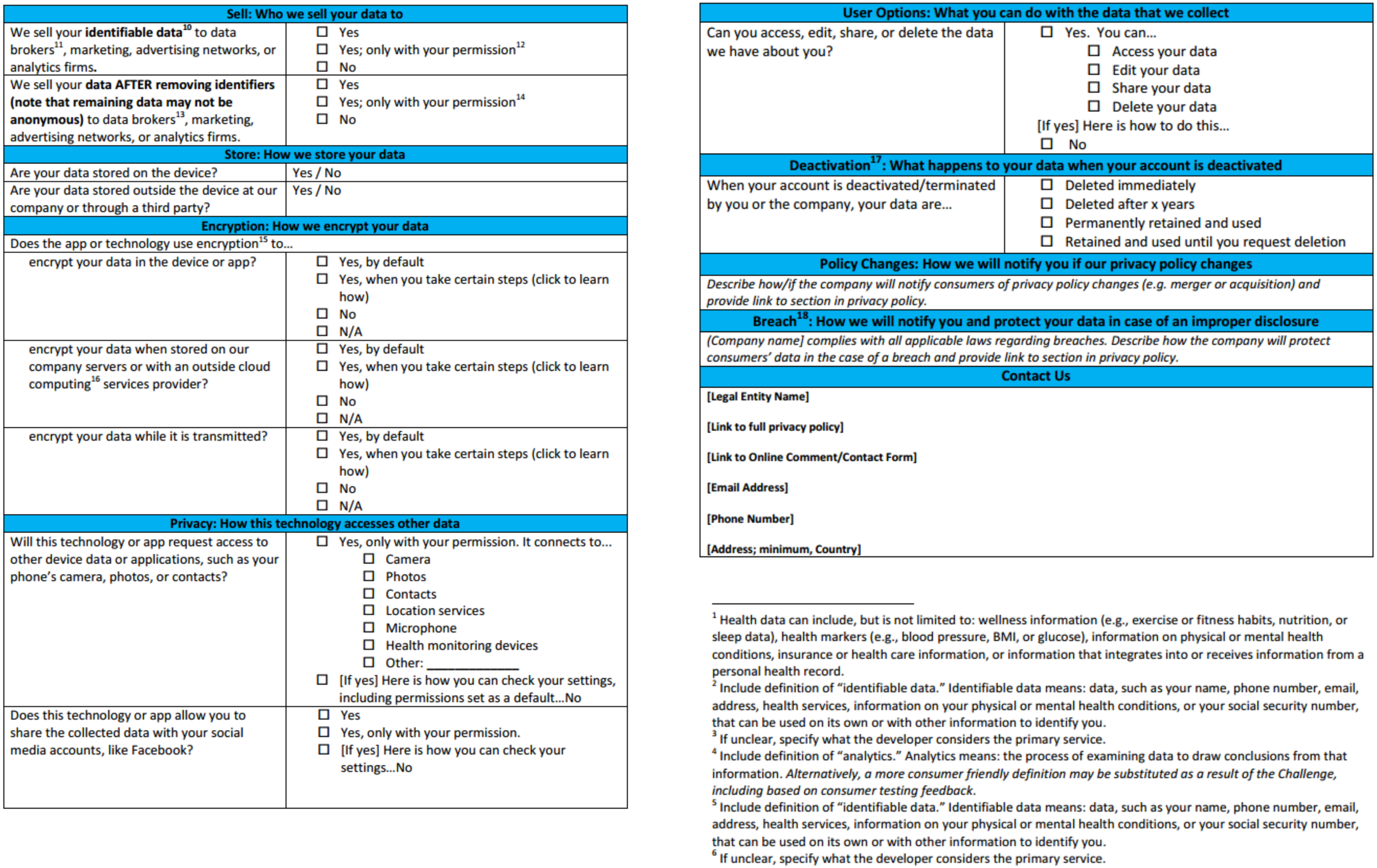
We share your **identifiable data**[5]:

□ To provide the primary service[6] of the app or technology
□ To conduct scientific research
□ For company operations (e.g. quality control or fraud detection)
□ To develop and improve new and current products and services (e.g., analytics[7])
□ Other:________
□ We DO NOT share your identifiable data[8]

We share your **data AFTER removing identifiers (note that remaining data may not be anonymous):**

□ For the primary purposes of the app or technology
□ To conduct scientific research
□ For company operations (e.g., quality control, fraud detection)
□ To develop and improve new and current products and services (e.g., analytics[9])
□ Other:________
□ We DO NOT share your data after removing identifiers

ONC' S 2016 Model Privacy Notice (MPN)



Sell: Who we sell your data to	
We sell your **identifiable data**[10] to data brokers[11], marketing, advertising networks, or analytics firms.	□ Yes □ Yes; only with your permission[12] □ No
We sell your **data AFTER removing identifiers (note that remaining data may not be anonymous)** to data brokers[13], marketing, advertising networks, or analytics firms.	□ Yes □ Yes; only with your permission[14] □ No
Store: How we store your data	
Are your data stored on the device?	Yes / No
Are your data stored outside the device at our company or through a third party?	Yes / No
Encryption: How we encrypt your data	
Does the app or technology use encryption[15] to…	
encrypt your data in the device or app?	□ Yes, by default □ Yes, when you take certain steps (click to learn how) □ No □ N/A
encrypt your data when stored on our company servers or with an outside cloud computing[16] services provider?	□ Yes, by default □ Yes, when you take certain steps (click to learn how) □ No □ N/A
encrypt your data while it is transmitted?	□ Yes, by default □ Yes, when you take certain steps (click to learn how) □ No □ N/A
Privacy: How this technology accesses other data	
Will this technology or app request access to other device data or applications, such as your phone's camera, photos, or contacts?	□ Yes, only with your permission. It connects to… □ Camera □ Photos □ Contacts □ Location services □ Microphone □ Health monitoring devices □ Other: _____________ □ [If yes] Here is how you can check your settings, including permissions set as a default…No
Does this technology or app allow you to share the collected data with your social media accounts, like Facebook?	□ Yes □ Yes, only with your permission. □ [If yes] Here is how you can check your settings…No

User Options: What you can do with the data that we collect	
Can you access, edit, share, or delete the data we have about you?	□ Yes. You can… □ Access your data □ Edit your data □ Share your data □ Delete your data [If yes] Here is how to do this… □ No
Deactivation[17]: What happens to your data when your account is deactivated	
When your account is deactivated/terminated by you or the company, your data are…	□ Deleted immediately □ Deleted after x years □ Permanently retained and used □ Retained and used until you request deletion
Policy Changes: How we will notify you if our privacy policy changes	
Describe how/if the company will notify consumers of privacy policy changes (e.g. merger or acquisition) and provide link to section in privacy policy.	
Breach[18]: How we will notify you and protect your data in case of an improper disclosure	
(Company name] complies with all applicable laws regarding breaches. Describe how the company will protect consumers' data in the case of a breach and provide link to section in privacy policy.	
Contact Us	
[Legal Entity Name] **[Link to full privacy policy]** **[Link to Online Comment/Contact Form]** **[Email Address]** **[Phone Number]** **[Address; minimum, Country]**	

[1] Health data can include, but is not limited to: wellness information (e.g., exercise or fitness habits, nutrition, or sleep data), health markers (e.g., blood pressure, BMI, or glucose), information on physical or mental health conditions, insurance or health care information, or information that integrates into or receives information from a personal health record.

[2] Include definition of "identifiable data." Identifiable data means: data, such as your name, phone number, email, address, health services, information on your physical or mental health conditions, or your social security number, that can be used on its own or with other information to identify you.

[3] If unclear, specify what the developer considers the primary service.

[4] Include definition of "analytics." Analytics means: the process of examining data to draw conclusions from that information. *Alternatively, a more consumer friendly definition may be substituted as a result of the Challenge, including based on consumer testing feedback.*

[5] Include definition of "identifiable data." Identifiable data means: data, such as your name, phone number, email, address, health services, information on your physical or mental health conditions, or your social security number, that can be used on its own or with other information to identify you.

[6] If unclear, specify what the developer considers the primary service.

Steps to Update the MPN

- ONC put out a request for information on March 1, 2016 and sought comment on what information practices health technology developers should disclose to consumers and what language should be used to describe those practices.

- Further engage stakeholders, including our federal advisory committees, federal partners, privacy organizations, developers and developer associations, and, of course, consumers

- An updated MPN

- “Privacy Policy Snapshot” Challenge

Privacy Policy Snapshot Challenge

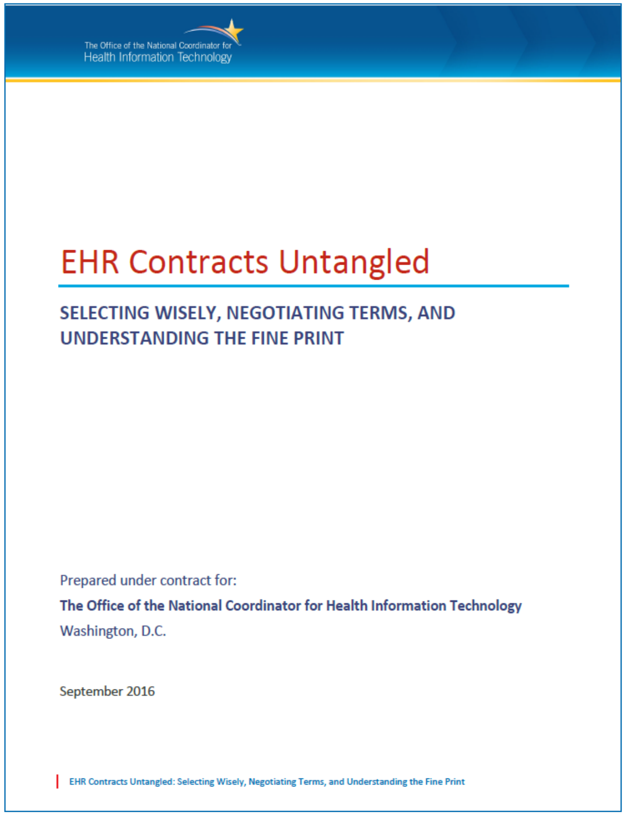
Privacy Policy
Snapshot Challenge

- The Privacy Policy Snapshot Challenge calls upon developers, designers, health data privacy experts, and creative, out-of-the-box thinkers to use ONC’s Model Privacy Notice template to create an online tool that can generate a user-friendly “snapshot” of a product’s privacy practices.
- ONC will award a total of $35,000 in prizes through this challenge.
- The deadline for submission is **April 10, 2017** with winners expected to be announced in mid-2017. Submissions can be entered here.
- The Federal Register Notice announcing the challenge can be viewed here.
- For more information on the MPN, please visit: https://www.healthit.gov/policy-researchers-implementers/model-privacy-notice-mpn

EHR Contract Guide

EHR Contracts Untangled: Selecting Wisely, Negotiating Terms, and Understanding the Fine Print

- Updates a guide released by ONC in 2013
- Prepared for ONC by private sector attorneys who have extensive experience negotiating EHR contracts
- A resource for diverse audiences



The Office of the National Coordinator for
Health Information Technology

EHR Contracts Untangled

SELECTING WISELY, NEGOTIATING TERMS, AND
UNDERSTANDING THE FINE PRINT

Prepared under contract for:

The Office of the National Coordinator for Health Information Technology

Washington, D.C.

September 2016

EHR Contracts Untangled: Selecting Wisely, Negotiating Terms, and Understanding the Fine Print

The EHR Contract Guide should not be construed as legal advice and does not address all possible legal and other issues that may arise with the acquisition of an electronic health record or other health information technology product or service. Each health care provider organization is unique and will need to consider its particular circumstances and requirements, which cannot be contemplated or addressed in this guide. A health care provider organization should obtain the advice of an experienced attorney whenever it proposes to enter into a legally binding contract.

EHR Contract Guide

Helps Health IT Purchasers:

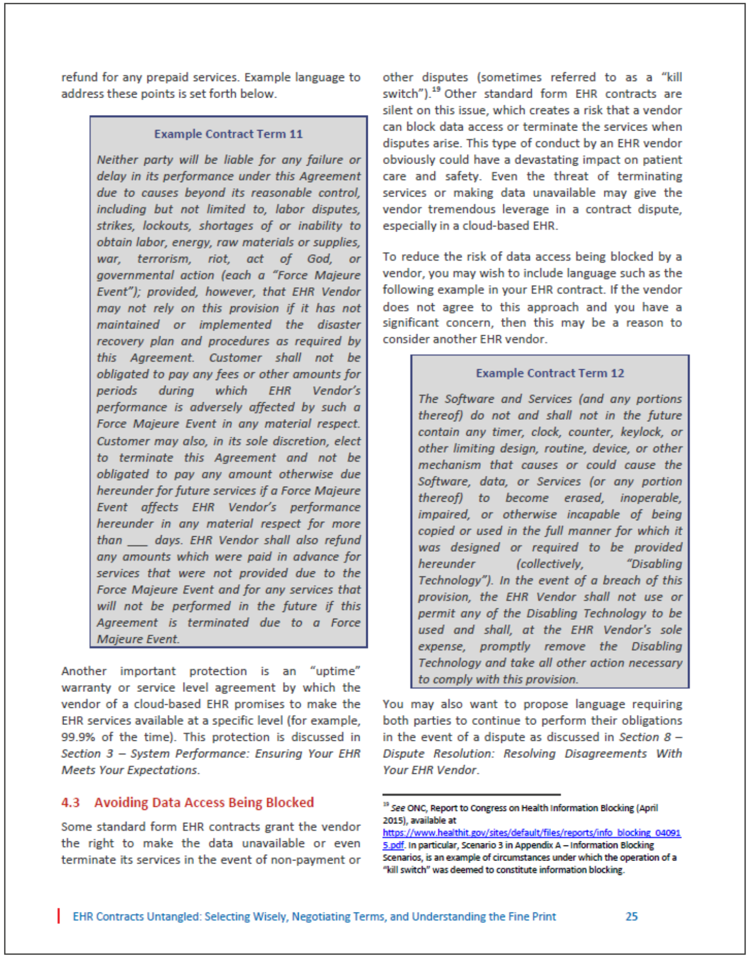
- Understand the “fine print”
- Consider contract provisions that impact whether the technology they are contracting for will meet their needs and expectations
- Ask the right questions when selecting an EHR and better communicate their requirements to potential vendors
- Consider and manage expectations and offer a framework for negotiating reasonable contract terms that reflect best practice contracting principles

Part A: The Importance of Planning: Putting Your Best Foot Forward

- Highlights the critical planning steps that providers should take to properly understand and communicate their requirements to potential vendors. Areas addressed include:
  - Types of EHR products and service models
  - Researching and comparing EHR products and vendors
  - Identifying and prioritizing technical and operational requirements
  - Understanding certification and regulatory requirements
  - Procurement strategy, planning and resourcing

Part B: Negotiating EHR Contracts: Key Terms and Considerations for Providers

- Focuses on the negotiation and contracting phase of acquiring an EHR
- Contains strategies and recommendations for negotiating best practice EHR contract terms
- Addresses the practical issues important to providers
- Illustrates how legal issues might be addressed in a contract by providing **example contract language**



refund for any prepaid services. Example language to address these points is set forth below.

Example Contract Term 11

Neither party will be liable for any failure or delay in its performance under this Agreement due to causes beyond its reasonable control, including but not limited to, labor disputes, strikes, lockouts, shortages of or inability to obtain labor, energy, raw materials or supplies, war, terrorism, riot, act of God, or governmental action (each a "Force Majeure Event"); provided, however, that EHR Vendor may not rely on this provision if it has not maintained or implemented the disaster recovery plan and procedures as required by this Agreement. Customer shall not be obligated to pay any fees or other amounts for periods during which EHR Vendor's performance is adversely affected by such a Force Majeure Event in any material respect. Customer may also, in its sole discretion, elect to terminate this Agreement and not be obligated to pay any amount otherwise due hereunder for future services if a Force Majeure Event affects EHR Vendor's performance hereunder in any material respect for more than ___ days. EHR Vendor shall also refund any amounts which were paid in advance for services that were not provided due to the Force Majeure Event and for any services that will not be performed in the future if this Agreement is terminated due to a Force Majeure Event.

Another important protection is an "uptime" warranty or service level agreement by which the vendor of a cloud-based EHR promises to make the EHR services available at a specific level (for example, 99.9% of the time). This protection is discussed in *Section 3 – System Performance: Ensuring Your EHR Meets Your Expectations.*

4.3 Avoiding Data Access Being Blocked

Some standard form EHR contracts grant the vendor the right to make the data unavailable or even terminate its services in the event of non-payment or other disputes (sometimes referred to as a "kill switch").[19] Other standard form EHR contracts are silent on this issue, which creates a risk that a vendor can block data access or terminate the services when disputes arise. This type of conduct by an EHR vendor obviously could have a devastating impact on patient care and safety. Even the threat of terminating services or making data unavailable may give the vendor tremendous leverage in a contract dispute, especially in a cloud-based EHR.

To reduce the risk of data access being blocked by a vendor, you may wish to include language such as the following example in your EHR contract. If the vendor does not agree to this approach and you have a significant concern, then this may be a reason to consider another EHR vendor.

Example Contract Term 12

The Software and Services (and any portions thereof) do not and shall not in the future contain any timer, clock, counter, keylock, or other limiting design, routine, device, or other mechanism that causes or could cause the Software, data, or Services (or any portion thereof) to become erased, inoperable, impaired, or otherwise incapable of being copied or used in the full manner for which it was designed or required to be provided hereunder (collectively, "Disabling Technology"). In the event of a breach of this provision, the EHR Vendor shall not use or permit any of the Disabling Technology to be used and shall, at the EHR Vendor's sole expense, promptly remove the Disabling Technology and take all other action necessary to comply with this provision.

You may also want to propose language requiring both parties to continue to perform their obligations in the event of a dispute as discussed in *Section 8 – Dispute Resolution: Resolving Disagreements With Your EHR Vendor.*

[19] *See* ONC, Report to Congress on Health Information Blocking (April 2015), available at https://www.healthit.gov/sites/default/files/reports/info_blocking_040915.pdf. In particular, Scenario 3 in Appendix A – Information Blocking Scenarios, is an example of circumstances under which the operation of a "kill switch" was deemed to constitute information blocking.

Supporting Public Health Interoperability & Response

- Working with Public health specialists, health IT stakeholders and industry
- Federal Advisory Committee - Public Health Task Force (Pregnancy Status)
- Community of Practice - Designed to build a communication pathway between the public health and health IT developer communities to identify and share promising practices around public health
- Zika Response Support
  - ONC/CMS Health IT- Focused Webinars with stakeholders on Zika response
  - Build on lessons learned from Ebola, MERS & H1N1
  - Algorithm for developers (clinical decision support)
  - Create vocabulary sets to support Zika-related terminology

PGHD: What are patient-generated health data?

Patient-generated health data (PGHD) are **health-related data** created, recorded, or gathered by or **from patients** (or family members or other caregivers) **to help address a health concern.**

PGHD include, but are not limited to:

- Health history
- Treatment history
- Biometric data
- Symptoms
- Lifestyle choices

PGHD are distinct from data generated in clinical settings and through encounters with providers in two important ways:

Patients, not providers, are **primarily responsible for capturing** or recording these **data**.

Patients decide how to share or distribute these **data to** health care **providers** and others.

PGHD: Draft White Paper and Pilot Demonstrations

- ## Draft White Paper
  - Developed by Accenture Federal Services t
  - Draft white paper considers best practices, gaps, and opportunities for progress in the collection and use of PGHD for research and care delivery through the year 2024
  - Available for review at:
    https://www.healthit.gov/sites/default/files/Draft_White_Paper_PGHD_Policy_Framework.pdf

- ## Pilot Demonstrations
  - The concepts in the draft white paper will be tested and refined through real world application in pilot demonstrations
  - The results will inform updates to the white paper at the end of the two-year project
  - Accenture Federal Services has established two pilot demonstrations with:
    - TapCloud in partnership with Amita Health
    - Validic in partnership with Sutter Health

HIPAA Access Guidance

AVAILABLE ONLINE AT WWW.HHS.GOV/HIPAA

Fact Sheet

Scope FAQs

Form and Format and Manner of Access FAQs

Timeliness FAQs

Other (Clinical Labs) FAQs