INTELICHART

Regulatory FAQs

Q1. **How often are these FAQs updated?**
A1. Updates are be assessed in a timely manner upon the receipt of the information from the ONC and our ACB-Drummond.

Q2. **What Value-Based Care and what does it mean for my organization?**
A2. Value-Based payment programs reward healthcare providers with incentive payments for the quality of care they give to people with Medicare. These programs are part of CMS's larger quality strategy to reform how healthcare is delivered and paid for. Value-Based programs support better care for individuals, better health for populations, and lower costs.

Q3. How do I know if I am required to comply with an ONC criterion?
A3. Drummond Group is our ONC Authorized Certification Body (ONC-ACB) and Test Lab within the Office of the National Coordinator Health IT Certification Program. Drummond specializes in working with healthcare information technology (Health IT) developers to evaluate and/or certify their Health IT software for use by healthcare providers in regulatory programs.
InteliChart and our designated ONC-ACB will continue to collaborate and update our clients on all ONC mandatory changes in a timely manner as they are communicated.

Q4. **Who is responsible for creating certificates for standardized EHR technology?**
A4. The requirements for creating certificates for standardized EHR technology are generated and regulated by the federal government. Both the Centers for Medicare & Medicaid Services (CMS). as well as the Office of the National Coordinator for Health Information Technology (ONC), determine the regulatory requirements for certified EHR systems.

Q5. **What is the HITECH Act?**
A5. The HITECH Act includes incentives to purchase certified EMR systems and create privacy standards and regulations. Also, it authorizes Medicare and Medicaid to provide payments to hospitals and physicians who demonstrate "meaningful use" of electronic health records.

Q6. What is the HITECH Act updates from 2024?
A6. The HTECH Act encourage healthcare providers to adopt electronic health records and improve privacy and security protections for healthcare data through financial incentives for adopting EHRS.

Q7. **How is the ONC Health IT Certification Program structured?**
A7. ONC Health IT Certification Program

Q8. **Where can I find information regarding mobile device requirements from the ONC?**
A8. ONC Mobile Device Requirements

Q9. **What is inherited certification status as defined by the ONC?**

A9. An ONC-Authorized Certification Body (ONC-ACB) must accept requests for a newer version of a previously certified Complete EHR or EHR Module(s) to inherit the certified status of the previously certified Complete EHR or EHR Module(s) without requiring the newer version to be recertified.

Q10. **Where can I find the ONC-Approved Test Method?**
A10. ONC Approved Test Method

Q11. What is the CHPL?
A11. Certified Health IT Product List is often referred to as CHPL is a comprehensive and authoritative listing of all certified Health Information Technology which has been successfully evaluated and certified by the ONC Health IT Certification program.

- All about CHPL
- Quick CHPL Access

Q12. How often is this the CHPL updated?
A12. At a minimum, once per week.

Q13. What does "Additional Software Required" mean? How does it affect me?
A13. "Additional Software Required" includes any additional software that a certified Complete EHR or Health IT Module relied upon to demonstrate its compliance with a certification criterion, or criteria adopted by the Secretary of the United States Department of Health and Human Services.

Q14. What if I am an EHR who relies on a 3rd party software program to demonstrate my compliance with a specific certification criterion. Does this 3rd party software program need to be independently certified?
A14. No, the 3rd party software program that your EHR technology relies upon does not need to be independently certified.

Q15. What are eCQMS?
A15. Electronic Clinical Quality Measure (eCQMS) are included in the Medicare Promoting Interoperability Program. Electronic clinical quality measures (eCQMs) use data electronically extracted from EHRs and/or health information technology systems to measure the quality of health care services that are provided.

The benefits of using eCQMs:

- eCQMs use clinical data to assess the outcomes of treatment by measured entities.
- eCQMs reduce the burden of manual abstraction and reporting for measured entities.
- eCQMs foster the goal of access to real-time data for point of care quality improvement and clinical decision support.

CMS requires that Medicare Promoting Interoperability Program participants report on eCQM.

Q16. Are we required to participate in in the Medicare Promoting Interoperability Program?
A16. The program is open to eligible hospitals and critical access hospitals (CAHs) that receive federal funds from Medicare. Those who are eligible but do not participate are subject to a downward payment adjustment.

Q17. What are the requirements for successfully reporting data for the Medicare Promoting Interoperability Program?
A17. To be considered a Meaningful User in the program, eligible hospitals and CAHs must:

- Use the appropriate edition of Certified Electronic Health Record Technology (CEHRT),
- Attest to the required objectives and their measures for the required EHR reporting period,
- Satisfy the minimum score requirement,
- Report on the required number of Electronic Clinical Quality Measures (eCQM), and
- Attest to the following:
    - The annual self-assessment of the SAFER Guides measure, with a "yes/no" attestation;
    - The Security Risk Analysis measure Office of the National Coordinator (ONC) Direct Review Attestation;
    - The Actions to limit or restrict the compatibility or interoperability of CEHRT attestation.

Q18. What if I have more questions about eCQMS?
A18. Please contact the CCSQ Help Desk at 1 (866) 288-8912 or qnetsupport@cms.hhs.gov.

Q19. What is CEHRT?
A19. To efficiently capture and share patient data, health care providers need *certified electronic health record (EHR) technology (CEHRT)* that stores data in a structured format. Structured data allow health care providers to easily retrieve and transfer patient information and use the EHR in ways that can aid patient care.

Q20. How do I align CEHRT requirements for Shared Shaving Program ACOs with MIPS?
A20. The Merit-based Incentive Payment System (MIPS) is a performance-based program where eligible clinicians may earn positive (up to 9%, not including additional positive adjustments for exceptional performance) or negative (up to -9%) payment adjustments for the services they provide to Medicare patients. The 2024 performance year has set the performance threshold to a score of 75 points to earn a neutral payment adjustment for fiscal year 2026 reimbursements. Review more details at CMS.gov.

CMS incentives provider adoption through:

- For eligible clinicians: The CMS quality payments program (MIPs)
- For hospitals: The Medicare Promoting Interoperability Program.

Quality Measures
Promoting Interoperability
Improvement Activities

Q21. How can I verify my MIPS participation status?
A21. Access this link and enter your individual NPI at https://cmsqualitysupport.servicenowservices.com/ccsq_support_central

You could be eligible if you answer "yes" to all three of the following questions:

1. Do you invoice $90K or more in Medicare Part B allowed charges?
2. Do you have more than 200 Medicare Part B patients?
3. Do you provide more than 200 covered professional services to Medicare Part B beneficiaries?

Q22. What is MACRA or Quality Payment Program (QPP) for Medicare Providers?

A22. MACRA stands for Medicare Access and CHIP Reauthorization Act and outlines the Quality Payment Program (QPP) was implemented on January 1, 2017. MACRA replaces and consolidates previous incentive programs like PQRS and Meaningful Use under the new MACRA umbrella for Medicare providers.

MACRA has two tracks, Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs).

Who is eligible to participate?

- Physician (Doctor of Medicine or Osteopathy, Doctor of Dental Surgery or Dental Medicine, Doctors of Podiatric Medicine, Doctor of Optometry, Chiropractors)
- Physician Assistant
- Nurse Practitioner
- Clinical Nurse Specialist
- Certified Registered Nurse Anesthetist
- Physical Therapist
- Occupational Therapist
- Clinical Psychologist
- Qualified speech-language pathologist
- Qualified Audiologists
- Registered dietitians or Nutrition Professionals

Q23. What does APMs mean?

A23. An Alternative Payment Model (APM) is an approach to payment, developed in partnership with clinician communities, providing incentives to clinicians to provide high-quality and cost-effective care. Clinicians must apply or be invited to participate in an APM.

Examples of the approved MIPS-APMs and Advanced APMs for 2023 include:

- Bundled Payments for Care Improvement Advanced Model (BPCI Advanced)
- Kidney Care Choices: Comprehensive Kidney Care Contracting (CKCC) Global Option
- Oncology Care Model (OCM) - Two-Sided Risk, One-Sided Risk

Q24. What is USCDI?

A24. The United States Core Data for Interoperability (USCDI) is a standardized set of data elements for nationwide, interoperable health information exchange. It establishes a baseline set of data that can be commonly exchanges across care settings for a wide range of uses. InteliChart is currently certified for the 21st Century Cures Act using USCDI v1 (45 CFR 170.213)

- ONC has released and approved three more versions of USCDI for the two have been approved under the ONC Standard Version Advancement Process.

Q25. What is exactly is SVAP?

A25. The ONC Standard Version Advancement Process (SVAP), permits health IT developers with health IT products certified under the ONC Health IT Certification Program to voluntarily update their conformance to newer versions of adopted standards as part of the "Real World Testing" Condition and Maintenance of Certification requirement.

Q26. Where can I find LOINC codes?
A26. Home – LOINC

Q27. Where can I find information about the CMS EHR Incentive Programs?
A27. CMS EHR Incentive Programs

Q28. Who is our assigned Accredited Certification Body, also known as an ACB?
A28. Drummond Group

Q29. What is HTI-1 and what does it mean for me?
A29. Health Data, Technology, and Interoperability is an ONC Certification Program Updates, Algorithm Transparency, and Information Sharing. The final rule was published in the Federal Register on January 9, 2024, which amends provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official provisions are contained in the final rule and 45 C.F.R. Parts 170 and 171.

Ruling Highlights:

- Implements the Cures Act's "EHR Reporting Program" to require transparent reporting on multiple types of certified health IT metrics through the new "Insights" Condition and Maintenance of Certification.
- Provides updates to the information blocking regulations in response to feedback from affected parties.
- Adopts United States Core Data for Interoperability (USCDI) Version 3 to replace USCDI Version 1 as the baseline USCDI standard as of January 1, 2026.
- Updates the Certification Program's standards, criteria, and requirements, including:
    - Standardized application programming interfaces (APIs), including adoption of the SMART App Launch Implementation Guide v2;
    - Electronic case reporting using HL7® Consolidated Document Architecture (CDA) and HL7 Fast Healthcare Interoperability Resources (FHIR ®)-based specifications.
    - A revised decision support intervention (DSI) certification criterion based on the prior clinical decision support certification criterion that includes new capabilities and transparency requirements for Health IT Modules; and
    - New functionality that enables an "internet-based method" for a patient to request a restriction on the use and disclosure of their EHI.

Discontinuing "Year-Themed Editions" for Health IT Certifications Criteria:

- To simplify the Certification Program and support more modular and extensible future updates, the HTI-1 final rule discontinues year-themed editions of certification criteria. This change also supports broader use of **certification criteria and standards adopted by ONC for other federal agencies and programs.**

Revised Standards and Criteria

- Most revisions are adopted in 45 CFR Part 170 which is included in part of HTI-1 will:
    - Improve interoperability through more modern standards and newer versions of existing standards

- Assist partner agencies such as CMS and the CDC in fulfilling their missions through certified health IT
- Improve care delivery for clinicians and care experience for individuals by improving access to more interoperable data – consistently and reliably – for patient care and individual access
- Require greater transparency regarding the decision support interventions included in certified health IT.

Q30. What does TEFCA stand for and what do they do?
A30. The Trusted Exchange Framework and Common Agreement commonly referred to as (TEFCA) was a requirement of the 2016 21st Century Cures Act. TEFCA designated Qualified Health Information Networks (QHINs) are designed to become the "on ramp" known as a point of access for all electronically accessible health information without special effort on the part of the user.

Q31. Who are "actors" as defined by the ONC?
A31. There are three categories of "actors" that are regulated by the information blocking section of the ONC Cures Act Finale Rule:

- Health Care Provider
- Health Information Network (HIN) or Health Information Exchanges (HIE)
- Health IT Developer of Certified Health IT

Q32. Which Health IT Legislations does the ONC mandate?
A32. The ONC mandates health IT legislations at the federal level and collaborates with CMS. These health IT legislations include:

- 21st Century Cures Act
- MACRA
- HITECH Act
- FDASIA
- HIPAA
- Affordable Care Act

Q33. What are the standard annual mandatory requirements for the ONC?
A33. Here is what you can expect from BAU perspective for each year for Attestations and Real World Testing.

The list below includes ONC compliance activities for **2024:**

- **January Quarterly Attestation**
  - Attest to changes to certified functionality for the previous quarter and other updates.
  - Due two weeks from notification of Quarterly Attestation required to avoid a corrective action for your ONC certification.
- **February 1, Real World Testing Results**
  - Submit 2023 RWT Results to Drummond by February 1st (results based on 2023 RWT Plan)
  - Developers must submit their RWT Results by February 1st to allow the Drummond ACB sufficient time to review and post to the ONC CHPL by the regulation deadline.

- **April Quarterly Attestation**
  - Attest to changes to certified functionality for the previous quarter and other updates.
  - Due two weeks from notification of Quarterly Attestation required to avoid a corrective action for your ONC certification.
  - The Drummond Certification Body will email the compliance contact on file for the certified product alerting when the quarterly attestation link is available.
- **April 1-30 Semi-Annual Attestation**
  - Attest compliance to applicable Conditions and Maintenance of Certification for the past 6 months
  - 30-day window to submit the semi-annual attestation(s) via the ONC CHPL website
- **July Quarterly Attestation**
  - Attest to changes to certified functionality for the previous quarter and other updates.
  - Due two weeks from notification of Quarterly Attestation required to avoid a corrective action for your ONC certification.
- **October, Quarterly Attestation**
  - Attest to changes to certified functionality for the previous quarter and other updates.
  - Due two weeks from notification of Quarterly Attestation required to avoid a corrective action for your ONC certification.
- **October 1-30 Semi-Annual Attestation**
  - Attest compliance to applicable Conditions and Maintenance of Certification for the past 6 months
  - 30-day window to submit the semi-annual attestation(s) via the ONC CHPL website
- **November 1 Real World Test Plan**
  - Submit 2025 RWT Plan to Drummond by November 1st (plan for RWT to occur in 2025).
  - Developers must submit their RWT Plan by November 1st to allow the Drummond ACB sufficient time to review and post to the ONC CHPL by the regulation deadline.
- **December 1 Real World Test Results**
  - Submit 2025 RWT Plan to Drummond by November 1st (plan for RWT to occur in 2025).
  - Developers must submit their RWT Plan by November 1st to allow the Drummond ACB sufficient time to review and post to the ONC CHPL by the regulation deadline.
- **December 1 (b.11) Decision Support Interventions**
  - For any health IT product that is currently certified to 170.315 (a)(9) Clinical Decision Support must be certified to 170.315 (b)(11) Decision Support Interventions. This criterion replaces (a)(9) Clinical decision support. Remove all reference to (a)(9) Clinical decision support from website and marketing materials.
  - Developers must submit their (b)(11) Decision Support Interventions attestation by December 1st to allow the Drummond ACB sufficient time to review and post to the ONC CHPL by the regulation deadline.
- **December 31 Standardized "FHIR Endpoints"**
  - By December 31, 2024, Certified API Developers must publish their customers' service base URL information (FHIR Endpoints) according to specific adopted standards.
- **January 2025 Quarterly Attestation**
  - Attest to changes to certified functionality for the previous quarter and other updates.

- Due two weeks from notification of Quarterly Attestation required to avoid a corrective action for your ONC certification.

- **2025 USCDI v3**
  - By December 31, 2025, developers with health IT certified to the clinical decision support certification criterion adopted at at17 0.315(a)(9) must:
    - Update their certificate(s) for the decision support interventions certification criterion at 170.315(b)(11) and
    - Provide such certified health IT to customers.
  - ACB deadline is December 1, 2025 (subject to change) for attestation. All required paperwork must be submitted by this deadline to be processed by the deadline.

Q34. What should I do if the answer to my question is not included in the FAQ?
A34. Email compliance@intelichart.com.

Additional resources:

1. U.S. Department of Health and Human Services
2. Centers of Medicare & Medicaid Services
3. Acronyms
4. Glossary
5. Medicare Learning Network (MLN) Compliance
6. Developer.cms.gov
7. HTI-1 Certification Final Ruling

Last update on 4/30/2024