



ONC Regulatory Activities

Regulatory activities are listed in reverse chronological order

#	Name of Regulation	Date	Action	Focus of Regulation
41	Updates, Algorithm Transparency, and Information Sharing; Correction	March 2024	Final Rule; Correction	This document corrects technical and typographical errors in the final rule entitled, “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” that was published in the Federal Register on January 9, 2024, and has a stated effective of February 8, 2024.
40	Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing; Correction	February 2024	Final Rule; Correction	This document corrects technical and typographical errors in the final rule entitled, “Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing” that was published in the Federal Register on January 9, 2024, and has a stated effective of February 8, 2024.
39	Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing	January 2024	Final Rule	This final rule implements the Electronic Health Record (EHR) Reporting Program provision of the 21st Century Cures Act by establishing new Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program). This final rule also makes several updates to certification criteria and standards recognized by the Program. The Program updates include revised certification criteria for “decision support interventions,” “patient demographics and observations,” and “electronic case reporting,” as well as a new baseline version of the United States Core Data for Interoperability (USCDI) standard to Version 3. Additionally, this final rule provides enhancements to support information sharing under the information blocking regulations. The implementation of these provisions advances interoperability, improves algorithm transparency, and supports the access, exchange, and use of electronic health information (EHI). This final rule also updates numerous technical standards in the Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs for health IT developers and users of health IT.
38	21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking	November 2023	Proposed Rule (Joint ONC/CMS)	This proposed rule would implement the provision of the 21st Century Cures Act specifying that a health care provider determined by the HHS Inspector General to have committed information blocking shall be referred to the appropriate agency to be subject to appropriate disincentives set forth through notice and comment rulemaking. In



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				particular, this rulemaking would establish for such health care providers a set of appropriate disincentives using authorities under applicable Federal law.
37	Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing	April 2023	Proposed Rule	<p>This proposed rule would implement the Electronic Health Record (EHR) Reporting Program provision of the 21st Century Cures Act by establishing new Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program). This proposed rule would also make several updates to certification criteria and implementation specifications recognized by the Program, including a revised certification criterion for decision support and revised certification criteria for patient demographics and observations and electronic case reporting. This proposed rule would establish a new baseline version of the United States Core Data for Interoperability (USCDI). Additionally, this proposed rule would provide enhancements to support information sharing under the information blocking regulations. The implementation of these provisions would advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information. The proposed rule would also update the Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.</p>
36	Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications	December 2022	Proposed Rule (Joint ONC/CMS)	<p>This proposed rule would revise the Medicare Advantage (Part C), Medicare Prescription Drug Benefit (Part D), Medicare cost plan, and Programs of All-Inclusive Care for the Elderly (PACE) regulations to implement changes related to Star Ratings, medication therapy management, marketing and communications, health equity, provider directories, coverage criteria, prior authorization, passive enrollment, network adequacy, identification of overpayments, formulary changes, and other programmatic areas. This proposed rule would also codify regulations implementing section 118 of Division CC of the Consolidated Appropriations Act, 2021, section 11404 of the Inflation Reduction Act, and includes a large number of provisions that would codify existing sub-regulatory guidance in the Part C, Part D, and PACE programs. This proposed rule would also amend the existing regulations for Medicare Parts A, B, C, and D regarding the standard for an identified overpayment.</p>
35	Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria	January 2022	Request for Information	<p>This request for information seeks input from the public regarding electronic prior authorization standards, implementation specifications, and certification criteria that could be adopted within the ONC Health IT Certification Program. Responses to this Request for Information will be used to inform potential future rulemaking.</p>



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34	Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency; Correction	December 2020	Final Rule; Correction	This correction notice corrects typographical errors found in the interim final rule entitled "Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency" that was published in the Federal Register on November 4, 2020.
33	Information Blocking and the ONC Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID-19 Public Health Emergency	November 2020	Interim Final Rule with Comment Period	This interim final rule with comment period (IFC) gives health IT developers and health care providers flexibilities to effectively respond to the public health threats posed by the spread of the coronavirus disease 2019 (COVID-19). Recognizing the urgency of this situation, and understanding that caring for patients with COVID-19 is of utmost importance, ONC is issuing this IFC to extend certain compliance dates and timeframes adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (ONC Cures Act Final Rule), including compliance and applicability dates for the information blocking provisions, certain 2015 Edition health IT certification criteria, and Conditions and Maintenance of Certification requirements under the ONC Health IT Certification Program. In this IFC, we are also making programmatic changes to the Program by updating standards. In addition, we are making corrections and clarifications to the ONC Cures Act Final Rule, which was published in the Federal Register on May 1, 2020.
32	21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program	August 2020	Final Rule; OFR Correction	This correction notice corrects errors the Office of the Federal Register (OFR) made when adding the compliance dates to the final rule entitled "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program."
31	21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program	July 2020	Final Rule; OFR Correction	This correction notice corrects errors OFR made when adding the compliance dates to the final rule entitled "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program."
30	21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program	May 2020	Final Rule	This final rule implements certain provisions of the 21st Century Cures Act, including Conditions and Maintenance of Certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions will advance interoperability and support the access, exchange, and use of electronic health information. The rule also finalizes certain modifications to the 2015 Edition health IT certification criteria and



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				Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.
29	21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program	March 2019	Proposed Rule	This proposed rule would implement certain provisions of the 21st Century Cures Act, including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking. The implementation of these provisions would advance interoperability and support the access, exchange, and use of electronic health information. The proposed rule would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs.
28	ONC Health IT Certification Program: Enhanced Oversight and Accountability	October 2016	Final Rule	This final rule finalizes modifications and new requirements under the ONC Health IT Certification Program ("Program"), including provisions related to the Office of the National Coordinator for Health Information Technology (ONC)'s role in the Program. The final rule creates a regulatory framework for ONC's direct review of health information technology (health IT) certified under the Program, including, when necessary, requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The final rule also sets forth processes for ONC to authorize and oversee accredited testing laboratories under the Program. In addition, it includes provisions for expanded public availability of certified health IT surveillance results.
27	Office of the National Coordinator for Health Information Technology; Medicare Access and CHIP Reauthorization Act of 2015; Request for Information Regarding Assessing Interoperability for MACRA	April 2016	Request for Information	Soliciting input on the following three topics: (1) measurement population and key components of interoperability that should be measured; (2) current data sources and potential metrics that address section 106(b)(1) of the MACRA; and (3) other data sources and metrics ONC should consider with respect to section 106(b)(1) of the MACRA or interoperability measurement more broadly.
26	Request for Information on Updates to the ONC Voluntary Personal Health Record Model Privacy Notice	March 2016	Request for Information	Seeks comments on the scope and content of the voluntary Personal Health Record Model Privacy Notice (MPN) developed by ONC and published in 2011. In response to stakeholder requests for an electronic means to inform consumers about how health technology products store, use, and share health information (especially products of health technology developers not covered by the Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191), we have initiated a process to update the MPN to better align with the current consumer health technology landscape.



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25	Health IT Certification Program: Enhanced Oversight and Accountability	March 2016	Proposed Rule	Proposes to establish processes for ONC to directly review health IT certified under the Program and take action when necessary, including requiring the correction of non-conformities found in health IT certified under the Program and suspending and terminating certifications issued to Complete EHRs and Health IT Modules. The proposed rule includes processes for ONC to authorize and oversee accredited testing laboratories under the Program. It also includes a provision for the increased transparency and availability of surveillance results.
24	2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications; Corrections and Clarifications	December 2015	Final Rule; Corrections and Clarifications	Corrects errors in the 2015 Edition final rule and also clarifies requirements of the Common Clinical Data Set, the privacy and security certification framework, and the mandatory disclosures for health IT developers.
23	2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications	October 2015	Final Rule	Finalizes a new edition of certification criteria (the 2015 Edition health IT certification criteria or “2015 Edition”) and a new 2015 Edition Base Electronic Health Record (EHR) definition, while also modifying the ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings.
22	2015 Edition Health Information Technology (Health IT) Certification Criteria, Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications	March 2015	Proposed Rule	Introduces a new edition of certification criteria (the 2015 Edition health IT certification criteria or “2015 Edition”), proposes a new 2015 Edition Base EHR definition, and proposes to modify the ONC Health IT Certification Program to make it open and accessible to more types of health IT and health IT that supports various care and practice settings.
21	Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record (EHR) Incentive Program for 2014 and	September 2014	Final Rule (Joint ONC/CMS)	This final rule changes the meaningful use stage timeline and the definition of certified electronic health record technology (CEHRT) to allow options in the use of CEHRT for the EHR reporting period in 2014. It also sets the requirements for reporting on meaningful use objectives and measures as well as clinical quality measure (CQM) reporting in 2014 for providers who use one of the CEHRT options finalized in this rule for their EHR reporting period in 2014. In addition, it finalizes revisions to the Medicare and Medicaid EHR Incentive Programs to adopt an alternate measure for the Stage 2 meaningful use objective for hospitals to provide structured electronic laboratory results to ambulatory providers; to correct the regulation text for the measures associated with



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	Other Changes to the EHR Incentive Program; and Health Information Technology: Revisions to the Certified EHR Technology Definition and EHR Certification Changes Related to Standards			the objective for hospitals to provide patients the ability to view online, download, and transmit information about a hospital admission; and to set a case number threshold exemption for CQM reporting applicable for eligible hospitals and critical access hospitals (CAHs) beginning with FY 2013. Finally, this rule finalizes the provisionally adopted replacement of the Data Element Catalog (DEC) and the Quality Reporting Document Architecture (QRDA) Category III standards with updated versions of these standards.
20	2014 Edition Release 2 Electronic Health Record (EHR) Certification Criteria and the ONC HIT Certification Program; Regulatory Flexibilities, Improvements, and Enhanced Health Information Exchange	September 2014	Final Rule	Finalizes regulatory flexibilities and general improvements for certification to the 2014 Edition EHR certification criteria (2014 Edition). It also codifies a few revisions and updates to the ONC HIT Certification Program for certification to the 2014 Edition and future editions of certification criteria as well as makes administrative updates to the Code of Federal Regulations.
19	Medicare and Medicaid Programs; Modifications to the Medicare and Medicaid Electronic Health Record Incentive Programs for 2014; and Health Information Technology: Revisions to the Certified EHR Technology Definition	May 2014	Proposed Rule (Joint ONC/CMS)	Proposes to change the meaningful use stage timeline and the definition of certified electronic health record technology (CEHRT). It would also change the requirements for the reporting of clinical quality measures for 2014.
18	Proposed Risk-Based Regulatory Framework and Strategy for Health Information Technology Report; Notice to Public of Availability of the Report and Web Site Location; Request for Comments	April 2014	Request for Comments (Issued by FDA on behalf of FDA, FCC, and ONC)	Announces the availability of the report and Web site location where the Agency has posted the report entitled "Food and Drug Administration Safety and Innovation Act (FDASIA) Health IT Report: Proposed Risk Based Regulatory Framework." In addition, FDA established a docket where stakeholders could provide comments.
17	Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and	March 2014	Proposed Rule; Correction	Provides minor corrections to the gap certification table for the Voluntary 2015 Edition proposed rule.



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	Regulatory Improvements; Correction			
16	Voluntary 2015 Edition Electronic Health Record (EHR) Certification Criteria; Interoperability Updates and Regulatory Improvements	February 2014	Proposed Rule	Improves on the 2014 Edition EHR certification criteria. The 2015 Edition EHR certification criteria proposed in this rule would be voluntary. Also includes revisions to the ONC HIT Certification Program. These proposals focus on: Improving regulatory clarity; simplifying the certification of EHR Modules that are designed for purposes other than achieving meaningful use; and discontinuing the use of the Complete EHR definition starting with the 2015 Edition.
15	2014 Edition Electronic Health Record Certification Criteria: Revision to the Definition of "Common Meaningful Use (MU) Data Set	November 2013	Interim Final Rule w/Comment Period	Revises one paragraph in the Common Meaningful Use (MU) Data Set definition at 45 CFR 170.102 to allow more flexibility with respect to the representation of dental procedures data for electronic health record (EHR) technology testing and certification.
14	Food and Drug Administration Safety and Innovation Act (FDASIA): Request for Comments on the Development of a Risk-Based Regulatory Framework and Strategy for Health Information Technology	May 2013	Request for Comments (Joint ONC/FDA/FCC)	Seeks broad input from stakeholders and experts on the elements we should consider as we develop a report that contains a proposed strategy and recommendations on an appropriate, risk-based regulatory framework for health IT, including mobile medical applications, that promotes innovation, protects patient safety, and avoids regulatory duplication.
13	Advancing Interoperability and Health Information Exchange	March 2013	Request for Information (Joint ONC/CMS)	Seeks input on a series of potential policy and programmatic changes to accelerate electronic health information exchange across providers, as well as new ideas that would be both effective and feasible to implement. To further accelerate and advance interoperability and health information exchange beyond what is currently being done through ONC programs and the EHR Incentive Program, HHS is considering a number of policy levers using existing authorities and programs.
12	Health Information Technology: Revisions to the 2014 Edition EHR Certification Criteria; and Medicare and Medicaid Programs; Revisions to the Electronic Health Record Incentive Program	December 2012	Interim Final Rule w/Comment Period (Joint ONC/CMS)	Replaces the Data Element Catalog (DEC) standard and the Quality Reporting Document Architecture (QRDA) Category III standard adopted in the final rule. Also revises the Medicare and Medicaid EHR Incentive Program by adding an alternative measure for Stage 2 MU, and also provides notice of CMS's intention to issue technical corrections to the electronic specifications for CQMs released on October, 25, 2012.
11	Health Information Technology: Standards, Implementation	September 2012	Final Rule	Adopts certification criteria that support the achievement of MU under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in fiscal



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	Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology			year and calendar year 2014. This rule also makes changes to the permanent certification program for health IT, including changing the program's name to the ONC HIT Certification Program.
10	Nationwide Health Information Network: Conditions for Trusted Exchange	May 2012	Request for Information	Requests public comment on draft proposals the Office of the National Coordinator for Health Information Technology (ONC) is considering in anticipation of developing a notice of proposed rulemaking (NPRM) to establish such a governance mechanism. This RFI seeks broad input on a range of topics, including: The creation of a voluntary program under which entities that facilitate electronic health information exchange could be validated with respect to their conformance to certain ONC-established "conditions for trusted exchange (CTEs);" the scope and requirements included in the initial CTEs; the processes that could be used to revise, adopt new, and retire CTEs, including but not limited to the standards development and adoption process provided in section 3004 and other relevant sections of the PHSa; and a process to classify the readiness for nationwide adoption and use of technical standards and implementation specifications to support interoperability related CTEs.
9	Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology	March 2012	Proposed Rule	Proposes new and revised certification criteria would establish the technical capabilities and specify the related standards and implementation specifications that Certified Electronic Health Record (EHR) Technology would need to include to, at a minimum, support the achievement of meaningful use by eligible professionals, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs beginning with the EHR reporting periods in fiscal year and calendar year 2014. This notice of proposed rulemaking also proposes revisions to the permanent certification program for health information technology, which includes changing the program's name.
8	Permanent Certification Program for Health Information Technology: Revisions to ONC-Approved Accreditor Processes	November 2011	Final Rule	Establishes a process for addressing instances where the ONC-Approved Accreditor (ONC-AA) engages in improper conduct or does not perform its responsibilities under the permanent certification program. This rule also addresses the status of ONC-Authorized Certification Bodies (ONC-ACBs) in instances where there may be a change in the accreditation organization serving as the ONC-AA and clarifies the responsibilities of the new ONC-AA.
7	Permanent Certification Program for Health Information Technology: Revisions to ONC-Approved Accreditor Processes	May 2011	Proposed Rule	Proposes a process for addressing instances where the ONC-Approved Accreditor (ONC-AA) engages in improper conduct or does not perform its responsibilities under the permanent certification program. This rule also proposes to address the status of ONC-Authorized Certification Bodies (ONC-ACBs) in instances where there may be a



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				change in the accreditation organization serving as the ONC-AA and clarifies the responsibilities of the new ONC-AA.
6	Establishment of the Permanent Certification for Health Information Technology	January 2011	Final Rule	Establishes a permanent certification program for the purpose of certifying health information technology (HIT). This final rule is issued pursuant to the authority granted to the National Coordinator for Health Information Technology (the National Coordinator) by section 3001(c)(5) of the Public Health Service Act (PHSA), as added by the Health Information Technology for Economic and Clinical Health (HITECH) Act. The permanent certification program will eventually replace the temporary certification program that was previously established by a final rule. The National Coordinator will use the permanent certification program to authorize organizations to certify electronic health record (EHR) technology, such as Complete EHRs and/or EHR Modules. The permanent certification program could also be expanded to include the certification of other types of HIT.
5	Health Information Technology: Revisions to Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology	October 2010	Interim Final Rule w/Comment Period	Request for comment to remove the implementation specifications related to public health surveillance.
4	Health Information Technology: Initial Set of Standards, Implementation Specifications and Certification Criteria for Electronic Health Record Technology	July 2010	Final Rule	Finalizes the adoption of an initial set of standards, implementation specifications, and certification criteria, and to more closely align such standards, implementation specifications, and certification criteria with final meaningful use Stage 1 objectives and measures.
3	Establishment of the Temporary Certification Program for Health Information Technology	June 2010	Final Rule	Establishes a temporary certification program for the purposes of testing and certifying health information technology.
2	Proposed Establishment of Certification Programs for Health Information Technology	March 2010	Proposed Rule	Proposes the establishment of two certification programs for purposes of testing and certifying health information technology.
1	Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for	January 2010	Interim Final Rule w/Comment Period	Request for comments to adopt an initial set of standards, implementation specifications, and certification criteria, as required by section 3004(b)(1) of the Public Health Service Act. This interim final rule represents the first step in an incremental approach to adopting standards, implementation specifications, and certification criteria to enhance the interoperability, functionality, utility, and security of health information technology and



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	Electronic Health Record Technology			to support its meaningful use. The certification criteria adopted in this initial set establish the capabilities and related standards that certified electronic health record (EHR) technology will need to include in order to, at a minimum, support the achievement of the proposed meaningful use Stage 1 (beginning in 2011) by eligible professionals and eligible hospitals under the Medicare and Medicaid EHR Incentive Programs.