This appendix provides the statutory language for the study and key terms used in this study. In addition, it provides summary information about the certification process for EHR technology and the regulatory definition for a Base EHR.

A. HITECH Act Section 4104(a) Requirements

Section 4104(a) \(^1\) of the HITECH Act, which requires the Secretary of Health and Human Services (HHS) to conduct a study to determine the extent to which, and manner in which, payment incentives and other funding for implementing and using certified EHR technology should be made available to those providers who receive minimal or no payment incentives or other funding under the HITECH Act, Medicare, Medicaid, or otherwise, for such purposes. The Secretary is required to submit a report to Congress on the findings, addressing the following factors:

SEC. 4104. STUDIES AND REPORTS ON HEALTH INFORMATION TECHNOLOGY.
(a) STUDY AND REPORT ON APPLICATION OF EHR PAYMENT INCENTIVES FOR PROVIDERS NOT RECEIVING OTHER INCENTIVE PAYMENTS.
(1) STUDY.

(A) IN GENERAL. The Secretary of Health and Human Services shall conduct a study to determine the extent to which and manner in which payment incentives (such as under title XVIII or XIX of the Social Security Act) and other funding for purposes of implementing and using certified EHR technology (as defined in section 1848(o)(4) of the Social Security Act, as added by section 4101(a)) should be made available to health care providers who are receiving minimal or no payment incentives or other funding under this Act, under title XIII of division A, under title XVIII or XIX or such Act, or otherwise, for such purposes.

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\(^1\) Section §4104(a): “The Secretary of Health and Human Services shall conduct a study to determine the extent to which and manner in which payment incentives (such as under title XVIII or XIX of the Social Security Act) and other funding for purposes of implementing and using certified EHR technology (as defined in section 1848(o)(4) of the Social Security Act, as added by section 4101(a)) should be made available to health care providers who are receiving minimal or no payment incentives or other funding under this Act, under title XIII of division A, under title XVIII or XIX or such Act, or otherwise, for such purposes.”
(B) DETAILS OF STUDY. Such study shall include an examination of--

i. the adoption rates of certified EHR technology by such health care providers;

ii. the clinical utility of such technology by such health care providers;

iii. whether the services furnished by such health care providers are appropriate for or would benefit from the use of such technology;

iv. the extent to which such health care providers work in settings that might otherwise receive an incentive payment or other funding under this Act, under title XIII of division A, under title XVIII or XIX of the Social Security Act, or otherwise;

v. the potential costs and the potential benefits of making payment incentives and other funding available to such health care providers; and

vi. any other issues the Secretary deems to be appropriate.²

(2) REPORT. Not later than June 30, 2010, the Secretary shall submit to Congress a report on the findings and conclusions of the study conducted under paragraph (1).

B. Definition of Providers

The complexity of the U.S. health care delivery and payment system, variability in classifying healthcare providers across the states, and overlap in services between providers creates challenges in identifying the types of providers who are the focus of this study. The methodology used to determine which health care provider types are the focus of this study was:

- Identify and define the health care provider types in section 3000(3) of the Public Health Service Act (PHSA) as modified in section 13101 of HITECH.

- Identify which of these providers in section 3000(3) could participate in either Medicare or Medicaid programs.

- Which of these provider types are eligible to receive EHR incentive payments under HITECH, and which of these providers are not eligible for such incentive payments.

- For those providers who were determined to be eligible to participate in Medicare and/or Medicaid programs but not eligible for the EHR Incentive Program, we considered whether any of these provider types received other funding (e.g., in the form of grants) to support their use of EHR technology. In brief, with one exception, any available “other funding” was not found to be sufficient to support wide-spread adoption and use of EHR technology by any of these ineligible provider types thus this report focuses on those provider types who are ineligible to participate in the EHR Incentive Program.

² The Secretary has not specified any additional issues to be addressed in the report (item vi).
See Section II.A (Identifying Ineligible Providers) of the report for a complete description of the methodology and criteria used to identify the types of health care providers that were the focus of this study.

(3) HEALTH CARE PROVIDER.--The term ‘health care provider’ includes a hospital, skilled nursing facility, nursing facility, home health entity or other long-term care facility, health care clinic, community mental health center (as defined in section 1913(b)(1)), renal dialysis facility, blood center, ambulatory surgical center described in section 1833(i) of the Social Security Act, emergency medical services provider, federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1861(r) of the Social Security Act), a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-Determination and Education Assistance Act), tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), a rural health clinic, a covered entity under section 340B, an ambulatory surgical center described in section 1833(i) of the Social Security Act, a therapist (as defined in section 1848(k)(3)(B)(iii) of the Social Security Act), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary. (PHSA §3000(3))

C. Definitions of Certified EHR Technology

HITECH Section 4104(a) requires, among other things, a study of what is known about the ineligible provider’s adoption of certified EHR technology. This study applies the definition of certified EHR technology and qualified EHR from Section 3000(1) and (13) of the PHSA as added by the HITECH Act:3

(1) CERTIFIED ELECTRONIC HEALTH RECORD TECHNOLOGY. The term “certified EHR technology” means a qualified electronic health record that is certified pursuant to section 3001(c)(5) as meeting standards adopted under section 3004 that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(13) QUALIFIED ELECTRONIC HEALTH RECORD. The term “qualified electronic health record” means an electronic record of health-related information on an individual that--

(A) includes patient demographic and clinical health information, such as medical history and problem lists; and

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B-3
(B) has the capacity—
   i. to provide clinical decision support;
   ii. to support physician order entry;
   iii. to capture and query information relevant to health care quality; and
   iv. to exchange electronic health information with, and integrate such
      information from other sources.

D. Certification and Certification Criteria for Ineligible Providers

ONC provided guidance to other health care settings (including ineligible providers) on the types of certified EHR technology that support electronic health information exchange with EPs, EHs, and CAHs in the ONC Final Rule for Standards, Implementation Specifications, and Certification Criteria for EHR Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health IT.  

The ONC Final Rule provides the following guidance to other health care settings:

We appreciate the interest in other health care settings expressed by commenters. We agree that it makes good policy sense to support interoperability and the secure electronic exchange of health information between all health care settings. We believe the adoption of EHR technology certified to a minimal amount of certification criteria adopted by the Secretary can support this goal. To this end, we encourage EHR technology developers to certify EHR Modules to the transitions of care certification criteria (§ 170.314(b)(1) and (2)) as well as any other certification criteria that may make it more effective and efficient for EPs, EHs, and CAHs to electronically exchange health information with health care providers in other health care settings. The adoption of EHR technology certified to these certification criteria can facilitate the secure electronic exchange of health information. We concur with commenters that there are currently private sector organizations that are addressing requests for certification programs for other health care settings.

Transition of Care Criteria (§ 170.314(b)(1) and (2)):  

(1) Transitions of care—receive, display, and incorporate transition of care/referral summaries.

   i. Receive. EHR technology must be able to electronically receive transition of care/referral summaries in accordance with:

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ii. Display. EHR technology must be able to electronically display in human readable format the data included in transition of care/referral summaries received and formatted according to any of the following standards (and applicable implementation specifications) specified in: § 170.205(a)(1), § 170.205(a)(2), and § 170.205(a)(3).

iii. Incorporate. Upon receipt of a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3), EHR technology must be able to:

(A) Correct patient. Demonstrate that the transition of care/referral summary received is or can be properly matched to the correct patient.

(B) Data incorporation. Electronically incorporate the following data expressed according to the specified standard(s):

1. Medications. At a minimum, the version of the standard specified in § 170.207(d)(2);
2. Problems. At a minimum, the version of the standard specified in § 170.207(a)(3);
3. Medication allergies. At a minimum, the version of the standard specified in § 170.207(d)(2).

(C) Section views. Extract and allow for individual display each additional section or sections (and the accompanying document header information) that were included in a transition of care/referral summary received and formatted in accordance with the standard adopted at § 170.205(a)(3).

(2) Transitions of care—create and transmit transition of care/referral summaries.7

i. Create. Enable a user to electronically create a transition of care/referral summary formatted according to the standard adopted at § 170.205(a)(3) that includes, at a minimum, the Common Meaningful Use Data Set and the following data expressed, where applicable, according to the specified standard(s):

(A) Encounter diagnoses. The standard specified in § 170.207(i) or, at a minimum, the version of the standard specified § 170.207(a)(3);

(B) Immunizations. The standard specified in § 170.207(e)(2);

(C) Cognitive status;

(D) Functional status; and

(E) Ambulatory setting only. The reason for referral; and referring or transitioning provider’s name and office contact information.

(F) Inpatient setting only. Discharge instructions.

ii. Transmit. Enable a user to electronically transmit the transition of care/referral summary treated in paragraph (b)(2)(i) of this section in accordance with:

(A) The standard specified in § 170.202(a).

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ONC HIT Certification Program

Section 3001(c)(5) of the PHSA, as added by HITECH, requires the Office of the National Coordinator to keep or recognize a program for the voluntary certification of health information technology as being in compliance with applicable certification criteria. ONC established the ONC HIT Certification Program, under which health information technology products are tested and certified by authorized entities. ONC established both temporary and permanent testing and certification programs through rulemaking. The temporary program authorized ONC Authorized Testing and Certification Bodies (ONC-ATCBs). In subsequent rulemaking, ONC sunset the temporary program which referred to ONC-ATCBs and launched the ONC HIT Certification Program, which now includes ONC-Authorized Certification Bodies (ONC-ACBs) and Accredited Testing Laboratories (ATLs).

The ONC HIT Certification Program requires that ONC-ACBs certify health IT including complete EHRs and/or EHR modules. Section 170.102 of the Code of Federal Regulations includes the following definition of base, complete and modular EHR:

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

1. Includes patient demographic and clinical health information, such as medical history and problem lists;
2. Has the capacity:
   i. To provide clinical decision support;
   ii. To support physician order entry;
   iii. To capture and query information relevant to health care quality;
   iv. To exchange electronic health information with, and integrate such information from other sources;
   v. To protect the confidentiality, integrity, and availability of health information stored and exchanged; and
3. Has been certified to the certification criteria adopted by the Secretary at: § 170.314(a)(1), (3), and (5) through (8); (b)(1), (2), and (7); (c)(1) through (3); (d)(1) through (8).

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Has been certified to the certification criteria at § 170.314(c)(1) and (2):
   i. For no fewer than 9 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible professionals, including at least 6 clinical quality measures from the recommended core set identified by CMS; or
   ii. For no fewer than 16 clinical quality measures covering at least 3 domains from the set selected by CMS for eligible hospitals and critical access hospitals.

Certified EHR Technology means:

(1) For any Federal fiscal year (FY) or calendar year (CY) up to and including 2013:
   i. A Complete EHR that meets the requirements included in the definition of a Qualified EHR and has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria; or
   ii. A combination of EHR Modules in which each constituent EHR Module of the combination has been tested and certified in accordance with the certification program established by the National Coordinator as having met all applicable certification criteria adopted by the Secretary for the 2011 Edition EHR certification criteria or the equivalent 2014 Edition EHR certification criteria, and the resultant combination also meets the requirements included in the definition of a Qualified EHR; or
   iii. EHR technology that satisfies the definition for FY and CY 2014 and subsequent years specified in paragraph (2);

(2) For FY and CY 2014 and subsequent years, the following: EHR technology certified under the ONC HIT Certification Program to the 2014 Edition EHR certification criteria that has:
   i. The capabilities required to meet the Base EHR definition; and
   ii. All other capabilities that are necessary to meet the objectives and associated measures under 42 CFR 495.6 and successfully report the clinical quality measures selected by CMS in the form and manner specified by CMS (or the States, as applicable) for the stage of meaningful use that an eligible professional, eligible hospital, or critical access hospital seeks to achieve.

Common MU Data Set means the following data expressed, where indicated, according to the specified standard(s):
(1) Patient name.
(2) Sex.
(3) Date of birth.
(4) Race--the standard specified in § 170.207(f).
(5) Ethnicity--the standard specified in § 170.207(f).
(6) Preferred language--the standard specified in § 170.207(g).
(7) Smoking status--the standard specified in § 170.207(h).
(8) Problems--at a minimum, the version of the standard specified in § 170.207(a)(3).
(9) Medications--at a minimum, the version of the standard specified in § 170.207(d)(2).
(10) Medication allergies--at a minimum, the version of the standard specified in § 170.207(d)(2).
(11) Laboratory test(s)--at a minimum, the version of the standard specified in § 170.207(c)(2).
(12) Laboratory value(s)/result(s).
(13) Vital signs--height, weight, blood pressure, BMI.
(14) Care plan field(s), including goals and instructions.
(15) Procedures--
   i. At a minimum, the version of the standard specified in § 170.207(a)(3) or § 170.207(b)(2).
   ii. Optional. The standard specified at § 170.207(b)(3).
   iii. Optional. The standard specified at § 170.207(b)(4).
(16) Care team member(s).

**Complete EHR, 2011 Edition** means EHR technology that has been developed to meet, at a minimum, all mandatory 2011 Edition EHR certification criteria for either an ambulatory setting or inpatient setting.

**Complete EHR, 2014 Edition** means EHR technology that meets the Base EHR definition and has been developed to meet, at a minimum, all mandatory 2014 Edition EHR certification criteria for either an ambulatory setting or inpatient setting.

**Discussion of the Relationship of EHR Certification for an Ineligible Provider**

This section includes excerpts from the HHS/ASPE report “Opportunities for Engaging LTPAC Providers in Health Information Exchange”, a study in which the relationship and challenges of EHR certification related to ineligible providers was discussed.¹⁰

HITECH requires the use of certified EHR technology for certain providers (e.g., physicians and short-term acute care hospitals) to qualify for incentive payments under the Medicare and Medicaid EHR Incentive Programs (“EHR Incentive Programs”). For purposes of the EHR Incentive Programs, two types of certifications can be issued to EHR technology that meets certification criteria adopted by the Secretary of HHS: (1) Complete EHR, or (2) EHR Module. To be eligible for meaningful use incentive payments, eligible hospitals (EHs) and eligible professionals (EPs) must use EHR technology that has been certified by an entity authorized by ONC. To date, four ONC-Authorized Certification Bodies (ONC-ACBs)¹¹ have been authorized to test and certify

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EHR technology that can be used by eligible professionals and hospitals in the EHR Incentive Programs.\textsuperscript{12} For example, EHR certification criteria include (but are not limited to) vocabulary standards (e.g., Systematized Nomenclature of Medicine (SNOMED), International Classification of Diseases (ICD), Logical Observation Identifiers Names and Codes (LOINC)) and content exchange standards (e.g., Clinical Document Architecture (CDA) and Continuity of Care Document (CCD)).

While some EHR technology certification criteria used for the EHR Incentive Programs for EPs and EHs would be applicable to the workflow in LTPAC setting, there is growing concern and awareness that not all of the certification criteria are applicable to EHR technology used by LTPAC providers. For example, the capability to plot growth charts or submit to immunization registries would not be a typical feature of a LTPAC EHR technology. Additionally, the adopted EHR technology certification criteria do not reflect the requirements that are uniquely needed by LTPAC providers.

For several years, the LTPAC provider and vendor community worked with Health Level 7 (HL7) (a Standards Development Organization) to produce an EHR Functional Profile for LTPAC. This Profile was used by LTPAC stakeholders and the Certification Commission for Health Information Technology (CCHIT) to identify LTPAC EHR certification criteria.\textsuperscript{13} It should be noted that the CCHIT LTPAC EHR Certification Program has not been recognized by ONC. While there is significant overlap in the EHR criteria that have been adopted for the EHR Incentive Programs and the LTPAC EHR Certification Criteria, there are also differences in the criteria that have been identified in these two programs. This misalignment has created confusion and uncertainty among LTPAC providers regarding whether they should purchase certified EHRs and if so, what type of certified EHR product would support the workflow of the LTPAC provider. ONC is aware of the uncertainties and questions regarding EHR certification confronting LTPAC and other providers that are ineligible under the EHR Incentive Programs and is working with stakeholders to better understand their EHR technology needs.

During the discussion at the 2011 LTPAC HIT Summit at the session on “Moving LTPAC Providers in the Nationwide Health IT Infrastructure,” providers and vendors concluded that there is likely a core set of EHR criteria that will be common across all EHR products (e.g., requirements related to privacy/security, medication reconciliation, problem list, etc.).\textsuperscript{14} During this discussion, providers and vendors suggested that ONC consider: (1) meeting with LTPAC providers and vendors to identify what EHR certification criteria are needed to support the workflow in LTPAC; and (2) working with the Meaningful Use Workgroup of the Health IT Policy Committee to identify the types of HIE activities that are needed in and from LTPAC. The Longitudinal Coordination of Care Workgroup (LCCWG) created through the ONC-sponsored S&I Framework (described in more detail below) is beginning to examine the health IT standards needed to support HIE on behalf of persons receiving LTPAC. The HIE activities targeted in this S&I effort are expected to advance the meaningful use of EHRs and shed some light on some of the EHR certification criteria needed by LTPAC providers.

\textsuperscript{12} Establishment of the Permanent Certification Program for Health Information Technology. 45 CFR Part 70. 2011.

\textsuperscript{13} The CCHIT is the only entity to date that has established criteria for LTPAC EHR products.

\textsuperscript{14} Harvell, J. Moving LTPAC Providers in the Nationwide Health IT Infrastructure Boardroom Session at the 2011 LTPAC HIT Summit. June 2011.
Experts interviewed as part of this study noted that there is growing discussion about the need to integrate LTPAC providers in HIE activities to support quality, continuity, and collaborative care (Appendix A: Stakeholder Interview Summary). To support efficient and interoperable HIE, some LTPAC providers and EHR vendors believe that it is important to use EHR products that support at least some of the standards incorporated in certification criteria for the Meaningful Use Incentive Program.

As reported at the 2011 LTPAC Health IT Summit, some vendors expressed an interest in obtaining certification for their EHR products as either: (1) meeting the meaningful use requirements; and/or (2) complying with the LTPAC CCHIT comprehensive EHR criteria. At least one LTPAC vendor has obtained hospital modular EHR certification (through an ONC-ATCB) for their product to support the interoperable and secure exchange of health information such as demographics, problem lists, physician order entry, medication lists, medication reconciliation, and advance directives. This LTPAC health IT vendor and one other have also obtained LTPAC CCHIT EHR certification.

To support widespread adoption of appropriate and interoperable EHRs for LTPAC, the LTPAC health IT Collaborative recommended in the LTPAC 2010-2012 Health IT Roadmap that policy guidance be provided for the EHR certification criteria needed to enable the exchange of health information between hospitals, physicians and LTPAC providers. The members of the Collaborative believe that such criteria would facilitate HIE with and by LTPAC providers, support the meaningful use of EHRs by a wide array of health care providers, and support the emerging nationwide infrastructure.

At this time the ONC has not established a specialty EHR certification program (e.g., a certification and testing program for EHR products for LTPAC providers (or other specialty providers)) or identified EHR certification criteria that are unique to the workflow requirements in LTPAC or other specialty providers. Establishing such a program or identifying EHR certification criteria is complex, could be costly, and requires careful consideration of the advantages and disadvantages. An objective in the draft roadmap of the recently established LCCWG under the ONC-sponsored S&I Framework is to “develop certification requirements for EHR and LTPAC vendors in anticipation of LTPAC pilots.” As described above, in Section D “Certification and Certification Criteria for Ineligible Providers,” in the Final Rule for EHR Standards, Implementation Specifications, and certification Criteria for the Stage 2 EHR Incentive Programs, ONC encouraged EHR technology developers to certify EHR Modules to the transitions of care certification criteria as well as any other certification criteria that may make it more effective and efficient for EPs, EHs, and CAHs to electronically exchange health information with health care providers in other health care settings.”

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EHR PAYMENT INCENTIVES FOR PROVIDERS
INELIGIBLE FOR PAYMENT INCENTIVES
AND OTHER FUNDING STUDY

Files Available for This Report

Main Report
http://aspe.hhs.gov/daltcp/reports/2013/EHRPI.shtml
http://aspe.hhs.gov/daltcp/reports/2013/EHRPI.pdf

APPENDIX A. Medicare and Medicaid EHR Incentive Programs
http://aspe.hhs.gov/daltcp/reports/2013/EHRPIap.shtml#appendA
http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendA.pdf

APPENDIX B. Definitions and Certification of EHR Technology
http://aspe.hhs.gov/daltcp/reports/2013/EHRPIap.shtml#appendB
http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendB.pdf

APPENDIX C. Public Health Service Act Section 3000(3) as Added by HITECH
Section 13101 -- Provider Analysis
http://aspe.hhs.gov/daltcp/reports/2013/EHRPIap.shtml#appendC
http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendC.pdf

APPENDIX D. Ineligible Provider Characteristics
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APPENDIX E. Long-Term and Post-Acute Care Provider Profiles
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APPENDIX F. Behavioral Health Provider Profiles
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http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendF.pdf

APPENDIX G. Safety Net Provider Profiles
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APPENDIX H. Other Health Care Provider Profiles
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APPENDIX I. Table Summary of Patient Protection and Affordable Care Act Provisions with Relationship to Ineligible Providers and Health IT Use
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APPENDIX L. Loan Programs
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APPENDIX M. Technical Assistance Programs
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APPENDIX N. Administrative Infrastructure Building Programs
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APPENDIX O. Anti-Kickback Statute EHR Safe Harbor Regulations
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APPENDIX P. Private Sector Programs to Advance Certified EHR Technology
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http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendP.pdf

APPENDIX Q. Regulations for Medical Records
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APPENDIX R. Technical Advisory Group Summary
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http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendR.pdf

APPENDIX S. Evaluating Benefits and Costs of New Incentives for EHR Adoption by Ineligible Providers
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http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendS.pdf
APPENDIX T. CIO Consortium EMR Cost Study Data
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APPENDIX U. Abbreviations and Acronyms
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http://aspe.hhs.gov/daltcp/reports/2013/EHRPI-appendV.pdf