I. **Health Information Technology (HIT) Must Satisfy Three Criteria**: With respect to all *electronically accessible* health information, HIT must: (1) allow for secure transfer of such information to and from other HIT; (2) allow for complete access to, exchange, and use of such information; and (3) not information block, as defined below.
   A. HIPAA Privacy and Security: This provision does not preempt any federal or state law; the scope is intended to be consistent with all principles and laws pertaining to privacy and security of health information. Thus, while all HIT must be *capable* of securely transferring all electronically accessible health information, the individual transferring the information must still comply with HIPAA standards, such as disclosing or accessing only the "minimum necessary to accomplish the intended purpose".

II. **Standards**: To satisfy the criteria for interoperability, HIT must be able to exchange information using the standards adopted through the process set forth below.
   A. Categories for Interoperability: While the process leaves significant discretion to the entity or entities ultimately contracted to recommend standards appropriate for adoption on a national scale, this provision sets forth six categories of standards that are required for interoperability, which include the following: (1) vocabulary and terminology; (2) content and structure; (3) transport of information; (4) security; (5) service; and (6) querying and requesting health information for access, exchange, and use.
      i. These categories were selected based on consensus among experts that there is a need for adoption of single uniform standards in each such category to achieve interoperability, and mature standards currently exist in such categories. There is a preference for recommending standards, rather than developing them, so that standards are not adopted on a national basis before the healthcare systems is able to use them on a national scale.

III. **HIT Policy Committee (HITPC):** The HITPC will continue to prioritize policies and use-cases within the meaningful use program; however, recommendations by the HITPC must be consistent with the criteria for interoperability.

IV. **Standards Adoption**: The HIT Standards Committee will sunset and be replaced by contracting authority granted to the Secretary, thus placing primary responsibility for HIT standards with the private sector.
   A. Eligible Entities: The Secretary is authorized to award contracts to the American National Standards Institute (ANSI), *or* healthcare ANSI-accredited Standards Development Organizations.
      i. ANSI-accreditation ensures that recommendations from the contractor(s) are the product of an open, transparent process that has subjected the recommended standards and implementation specifications to real-world testing, and garnered consensus including public input.
      ii. Recognizing that there are consensus generating efforts in this area by organizations that are not ANSI-accredited, this provision allows contracts to be awarded directly to ANSI, who can then subcontract with such organizations; ANSI involvement is intended to ensure that there is still integrity in the process.
   B. Duties: Contractor(s) will recommend standards, corresponding implementation specifications, and, where appropriate, methods to test whether HIT is compatible with such standards and implementation specifications.
      i. Under HITECH, NIST is tasked with developing tests for HIT seeking certification. In order to reduce the burden on NIST's resources, contractor(s): (1) may consult with NIST on development of methods to test; and (2) must deliver their ultimate recommendation to NIST.

C. Process: Upon receipt of recommendation(s), the Secretary must review in consultation with ONC, NIST, and other relevant federal agencies, and determine whether or not to propose adoption of the recommendation(s)
   i. The Secretary's determination not to adopt, as well as the reasons for such determination, must be shared with contractor(s) and published in the Federal Register.
   ii. The Secretary's determination to adopt must be published in the Federal Register as notice of proposed rulemaking to initiate the public rulemaking process. The Secretary may not modify the standard in the resulting final rule, but the recommended implementation specification(s) may be modified to take into account information gathered during the public comment period.

D. Flexibility: to ensure that a system of national standards will not negatively affect advances in medicine and/or technology, this provision explicitly allows HIT to use additional standards, so long as the HIT remains compatible with adopted standards and associated implementation specifications.
   i. To ensure compatibility, HIT seeking or maintaining certification must be able to pass the test developed for the adopted standard and associated implementation specification, regardless of any additional standards such HIT may use.

E. Frequency: The Secretary must enter into initial contract(s) as soon as possible; subsequent contracts will be triggered based on needs for modifications and/or additions to adopted standards, implementation specifications, and/or certification criteria.
   i. To ensure that adopted standards do not remain in place once they have become outdated, the Secretary, in consultation with ONC, must periodically conduct hearings to assess whether new contracts are necessary.

V. **Information Blocking**: Information blocking is defined to include any technical, business, or organizational practices that an actor *knows,* or *should know*, prevents or materially discourages access to, exchange, or use of health information.

A. Exceptions: Information blocking excludes any practice required by law, or that the Secretary identifies as necessary to: (1) protect patient safety; (2) maintain privacy or security of health information; or (3) promote competition and consumer welfare.

B. Liability: An individual or entity is not considered to have engaged in information blocking where they were aware of the act or practice of information blocking, but did not have the ability to control the act or practice of information blocking.

VI. **Enforcement**: Compliance with interoperability criteria and standards is required for: (1) vendors of health information technology offered for use by a provider participating in Medicare or Medicaid; (2) health information systems; (3) hospitals; and (4) healthcare providers. Non-compliance will be punishable by decertification and civil monetary penalties.

A. Hardship Exemption: Providers with electronic health records (EHRs) that have been decertified will receive an automatic one-year hardship exemption from meaningful use penalties, regardless of whether they have already used the current five-year maximum; extensions may also be granted by the Secretary on a case-by-case basis.

B. Non-duplication: The Secretary is instructed to avoid duplicative penalties under this section.

VII. **Transparency**: Efforts are made to enhance transparency for consumers of HIT, including providers and patients.

A. Pricing Information: In their attestation for certification, anyone offering a qualified EHR must report additional types of costs or fees that will be imposed for particular uses of the HIT in connection with any health information such HIT generates.

i. ONC will publish such information on their website so that consumers will be aware of fees that are not included in the initial acquisition costs of a product, and make purchasing decisions based on their needs.

B. Application Programming Interfaces (APIs): APIs relevant to nationwide interoperability of health information must be made publically available.

C. Patient Safety Organizations: To increase utilization of the PSO model, information blocking is declared a reportable patient safety activity, and vendors are treated as providers so that they may make confidential reports related to patient safety.

D. Enforcement Actions: The Secretary will publish a list annually of all EHRs whose certification has been withdrawn along with the vendor of such HIT.

E. Paperwork Reduction Act Exemption: ONC is granted an exemption to the paperwork reduction act for the purposes of collecting complaints about HIT in a standardized format, which will facilitate identification of challenges to achieving nationwide interoperability.

VIII. **Patient Empowerment**: Ensuring that patients have the right to obtain their health information in the same interoperable format as providers will facilitate health information exchange and improve continuity of evidence-based care. This provision includes a *sense of Congress* on individual rights associated with health information, which includes, but is not limited to, the following:

A. Right of Access: HIPAA currently grants individuals a right to access their health information; however, it does not specify what form that access should take. HIT should contain mechanisms that allow patients electronic access to their health information, and HIT should not deny patient requests for health information or impose costs on individuals for access to such information.

B. Confidence in Accurate Assignment of Health Information: Individuals have the right to feel confident that health information in their record is actually their information, which is critical to patient safety and care coordination.

IX. **Funds Authorized for Appropriation**: $35 million

A. Private Sector Contracts: $10 million, until expended

B. NIST: $15 million, until expended

C. OIG: $10 million, until expended