- A. 21st Century CURES Act & Information Blocking Rules
- B. Data Breaches
- C. HIEs/HINs
- D. HIPÁA Privacy & Security
- E. 42 CFR Part 2 (+March 2020 CARES Act)
- F. Telehealth/Telemedicine

= Available

= To be Uploaded

G. Research

ССРА

I. GDPR

J.

H. Health IT & Meaningful Use

= In Development

21st Century Cures Act & Info Blocking

Checklists & T	
03.2019	TOOL: CMS Cures Act Proposed Rule Chart
03.2019	TOOL: ONC Info Blocking Proposed Rule Chart
10.05.2020	TOOL: Preventing Harm Exception (Final Rule Text & Preamble Excerpts)
10.05.2020	TOOL: Privacy Exception (Final Rule Text & Preamble Excerpts)
10.05.2020	TOOL: Security Exception (Final Rule Text & Preamble Excerpts)
10.05.2020	TOOL: Infeasibility Exception (Final Rule Text & Preamble Excerpts)
10.05.2020	TOOL: Health IT Performance Exception (Final Rule Text & Preamble Excerpts)
10.05.2020	TOOL: Content & Manner Exception (Final Rule Text & Preamble Excerpts)
10.12.2020	TOOL: Fees Exception (Final Rule Text & Preamble Excerpts)
10.12.2020	TOOL: Licensing Exception (Final Rule Text & Preamble Excerpts)
Week of 10.12.2020	CHECKLIST: ONC Info Blocking Rule Compliance (Healthcare Providers)
Week of 10.26.2020	CHECKLIST: ONC Info Blocking Rule Compliance (HIEs/HINs)
Sample Form	IS
Week of 10.19.2020	Patient Education: Privacy & Security Risks of Third-Party Health Apps (expressly permitted under Info Blocking Final Rule – preamble discussion)
Week of 10.19.2020	Documentation of Factors for Infeasibility Under the Circumstances (§171.204(a)(3)(i))
Week of 10.19.2020	Notice of Infeasibility (§171.204(b))
Week of 10.26.2020	HIPAA BA Agreement (tagged with warning language for Information Blocking)
Sample Polici	ies
HEALTH CARE PH	
10.05.2020	POLICY: Hospital ADT Notification – New CMS Medicare COP
10.05.2020	POLICY: Preventing Harm Exception
10.05.2020	POLICY: Privacy Exception
10.05.2020	POLICY: Security Exception
10.05.2020	POLICY: Infeasibility Exception
10.05.2020	POLICY: Health IT Performance Exception
10.05.2020	POLICY: Content & Manner Exception
Week of 10.12.2020	POLICY: Fees Exception
Week of 10.12.2020	POLICY: Licensing Exception
Week of 10.19.2020	POLICY: "Master" Information Blocking Policy
Week of 10.19.2020	POLICY: Privacy – Individual Rights (HIPAA CE-HCP) (amended for Info Blocking)
Week of 10.19.2020	POLICY Privacy – Individual Request for Restriction (HIPAA CE-HCP) (amended for Info Blocking)
Week of 10.19.2020	POLICY: Privacy - Uses & Disclosures of ePHI (HIPAA CE-HCP) (amended for Info Blocking)
Week of 10.26.2020	POLICY: Security – Administrative (HIPAA CE-HCP) (amended for Info Blocking)
Week of 10.262020	POLICY: Security – Technical (HIPAA CE-HCP) (amended for Info Blocking)
Week of 10.262020	POLICY: Privacy – Individual Rights (BA) (amended for Info Blocking)
HIE/HIN (BA): Co	oming soon!
PowerPoints	
10.5.2020	PPT: CMS Final Rule: Encounter Notification as Medicare Condition of Participation
10.5.2020	PPT: 21st Century CURES Act & Final Rules on Information Blocking
10.5.2020	PPT: ONC Final Rule on Information Blocking (Preventing Harm; Privacy; Content & Manner)
10.5.2020	PPT: ONC Final Rule on Information Blocking (Security; Infeasibility; Health IT Performance; Fees; Licensing)
Whitepapers	
12.2018	WHITEPAPER: 21 st Century CURES Act & MACRA

Quick Access Links

- Statute: 21st Century Cures Act (Public Law 114-255) (December 13, 2016)
- Statute: <u>42 USC 300jj-52</u> (Information Blocking)
- Final Regulation: [See TOOLS for a combined copy of final federal regulatory text]
- Rule: ONC Final Rule: Info Blocking & Health IT Certification Program 85 Fed Reg 25642 (May 1, 2020)
- Rule: ONC Proposed Rule: Info Blocking, & Health IT Certification Program 42 Fed Reg 7424 (March 4, 2019)
- Rule: CMS Final Rule: Interoperability and Patient Access 85 Fed Reg 25510 (May 1, 2020)
- Rule: CMS Proposed Rule: Interoperability and Patient Access 84 Fed Reg. 7610 (March 4, 2019) Rule: OIG Proposed Rule: Civil Monetary Penalties for Information Blocking 80 Fed Reg. 22979 (April 24, 2020)
- *Future Rule:* [OIG Final Rule: Civil Monetary Penalties for Information Blocking]
- Future Rule: [HHS Notice and Rulemaking re: "Appropriate Disincentives" for Health Care Provider engaged in Information Blocking] Agency Action: ONC Announcement of Enforcement Discretion (April 21, 2020) (3-month delay in enforcement)
- Agency Action: CMS Announces Enforcement Discretion (April 21, 2020) (6-month delay in enforcement)
- Agency Resource: ONC Cures Act Rule Fact Sheets
- Agency Resource: ONC Enforcement Dates & Timeline
- Agency Resource: ONC Proposed Rule & Final Rule Summary of Changes
- Agency Resource: ONC Regulatory Deadlines Dates
- Agency Resource: CMS Cures Act Rule Fact Sheet
- [Future Reporting to HHS]

Data Breaches

Tools & Checklists

Tools & Check	lists		
4.21.2020	TOOL: HIPAA Incident Report with Log		
4.21.2020	TOOL: HIPAA Breach Assessment (+Low Probability scoring Tool)		
Week of 10.19.2020	TOOL: NJ-HIPAA Breach Decision Tree		
Week of 10.19.2020	TOOL: NY-HIPAA Breach Decision Tree		
Week of 10.19.2020	TOOL: PA-HIPAA Breach Decision Tree		
Week of 10.19.2020	TOOL: Template_HIPAA-State Breach Law Decision Tree		
Coming soon!	TOOL: 50 State Survey of Data Breach Laws		
Coming soon!	TOOL: Final HITECH Breach Rule in FULL (CFR version)		
Coming soon!	TOOL: Checklist to Reviewing Your HIPAA Breach Policy & Procedures		
Sample Form	S		
4.19.2020	FORM: Breach Notification Letter to Patient (CE-HealthCare Provider)		
4.19.2020	FORM: Certification by Entity PHI Destroyed (BA)		
4.19.2020	FORM: Certification by Entity PHI Destroyed (CE-HealthCare Provider)		
Sample Polic	ies		
4.19.2020	POLICY: HIPAA Breach Response & Notification (BA)		
4.19.2020	POLICY: HIPAA Breach Response & Notification (CE-HealthCare Provider)		
PowerPoints			
Coming soon!	Managing a Data Breach from Beginning to End		
Coming soon!	Big Data Breaches & Class Action Lawsuits		
Coming soon!	Training Your Workforce to Report Breaches		
Whitepapers			
Coming soon!	WHITEPAPER: HIPAA Breach Preemption with State Law (05.06.2011)		
Quick Access	Links		
	CH Statute H.R.1-114		
	Omnibus Final Rule (+Breach Notification) 78 Fed Reg 5566 (January 25, 2013) [compliance by September 23, 2013]		
Rule: <u>HITECH</u>	Act Proposed Rule 75 Fed Reg 40868 (July 14, 2010)		
	 Rule: <u>HITECH Breach Notification Interim Final Rule</u> 74 Fed Reg 42740 (August 24, 2009) [effective September 23, 2009] 		
	 Rule: FTC Health Breach Notification Rule 74 Fed Reg 42962 (August 25, 2009) Rule: FTC Health Breach Notification Rule 74 Fed Reg 42962 (August 25, 2009) 		
	TC: <u>Federal Trade Commission (FTC) Breach Notification Form</u> for vendors of PHR to notify FTC IHS: <u>HHS Portal to Report HIPAA Breaches</u> (Annual reporting and immediate reporting of Breaches 500+)		
	 Reporting to HHS: <u>HHS Portal to Report HIPAA Breacnes</u> (Annual reporting and immediate reporting of Breacnes 500+) Agency Guidance: <u>OCR Encryption Guidance</u> See also <u>74 Fed Reg 19006</u> (April 27, 2009) 		
 Agency Guidan 	 Agency Guidance: <u>Ransomware Guidance</u> Agency Guidance: <u>Ransomware Guidance</u> 		
 Agency Guidance: <u>Update on Preventing, Mitigating & Responding to Ransomware</u>. (Fall 2019) 			
	rce: Guidance for Media Sanitization (<u>NIST Special Publication 800-88</u>) (12/17/2014)		
Resource: 50-State Catalog of State Security Breach Notification Laws assembled by the National Conference of State Legislatures			

Resource: 50-State Catalog of State Security Breach Notification Laws assembled by the National Conference of State Legislatures

HIE & HI	N/HIO
Checklists & "	•
03.2020	TOOL_Incorporating Part 2 Records in HIOs
4.2020	TOOL_Pros & Cons Worksheet for Selecting a Governing HIO Entity
4.2020	CHECKLIST: Participant HIE Readiness
4.2020	CHECKLIST: Evaluating HIT Vendor Contracts
4.2020	CHECKLSIT: Evaluating Cyber Insurance for HIE
4.2020	CHECKLIST: Decision Matrix for Developing Policies for Health Information Exchange
4.2020	CHECKLIST: Considertions for Development of an HIO or HIE
4.2020	CHECKLIST: Decision Matrix for Organizations Evaluting HIE Activities
4.2020	CHECKLIST: De-identifying PHI and Creating Limited Data Sets
4.2020	CHECKLSIT: Identifying Business Associates and Need for BAA
Coming soon!	TOOL: Poster Diagram of Opt-Out
Coming soon!	TOOL: 50-State Chart of HIO Issues & Standards (Opt-In/Out; Consent; Use of De-identified Data etc.)
Coming soon!	CHECKLIST: Privacy Requiremenst for DURSA and the eHealth Exchange
Coming soon!	CHECKLIST: Developing Personal Health Record Policies
Sample Form	15
Sample Polic	ies
Coming soon!	HIE Policies
PowerPoints	
4.19.2020	HIE Registration Training and End User Agreement (Clinician)
Whitepapers	
07.2015	Minors Emancipated Treatment Challenges with Electronic HIE and Patient Portals (written July 2015)
04.2014	When do HIE Conduits Cross the HIPAA BA Line? (prepared April 2014)
2014	Sensitive Information, Consent and HIE (prepared in 2014)
10.2012	Workforce Access to Personal PHI & FamilyPHI from Covered entity HER (prepared October 2012)
09.2012	Recommendations for Patient HIE Education and "Meaningful Consent" (prepared September 2012)
05.2012	Implementing an Opt-Out Consent Framework for HIE – a Case Example (prepared May 2012)
02.2012	Patient Consent & Opt-Out Under the Medicare ACO Rule (prepared Feb 2012)
2012	HIEs as Bas for Data Loading and Storage (prepared in 2012)
2011	Sequestration of Sensitive Information (prepared in 2011)
2011	Starting up Electronic Health Information Exchange (prepared in 2011)
Quick Access	Links
• Statute:	
 Regulation: 	
 Agency Activ Agency Reso 	
 Agency Kest Other Resou 	
	rivacy & Security
Tools & Check	klists
4.19.2020	CHECKLIST: Assessing your Organization for HIPAA Covered Entity Status [Legal HIE]
4.19.2020	CHECKLIST: Business Associates & When a HIPAA BAA is Needed
4.19.2020 4.19.2020	CHECKLIST: Business Associate HIPAA Compliance Checklist
4.19.2020	CHECKLIST: Destruction of ePHI Checklist CHECKLIST: Health Care Provider HIPAA Compliance Checklist
4.19.2020	CHECKLIST: De-Identification of PHI and Limited Data Set (LDS) Standards
4.19.2020	CHECKLIST: Required Elements of a HIPAA Authorization
4.19.2020	CHECKLIST: Required Elements of a HIPAA BAA
4.19.2020	TOOL: Security Reminders (samples)
03.2020	TOOL: HIPAA Primer and "Train the Trainer"
10.19.2020	TOOL: OCR HIPAA Enforcement Agreements – Learn from Others' Past Mistakes [Running Summary of ALL Enforcement Cases]
Coming soon!	TOOL: EASY REFERENCE_Combined Privacy, Security & Breach Rules

Sample Forn			
4.19.2020	FORM: Workforce Acknowledgement of HIPAA Obligations		
4.19.2020	POLICY: Business Associates (BA) and BAAs		
4.19.2020	POLICY: HIPAA Compliance Program (CE-Health Care Provider)		
4.19.2020	POLICY: HIPAA Compliance Program (BA)		
4.19.2020	POLICY: Use of Email to transmit ePHI		
4.19.2020	POLICY: Use of Mobile Devices		
Coming soon!	POLICY: Remote Access POLICY: Social Media		
Coming soon!			
Coming soon!	POLICY: Ransomware Response		
Coming soon!	POLICY: Cloud Providers (square BA peg in circle BA hole)		
D			
PowerPoints			
4.2020	PPT: HIPAA Workforce Training (PowerPoint)		
TATI. "1			
Whitepapers			
06.2013	Granting Access to Care Coordinators in Accordance with HIPAA		
10.2012	Workforce Access to Personal PHI & Family PHI from Covered Entity's EHR (prepared October 2012)		
02.2012	Patient Consent & Opt-Out Under the Medicare ACO Rule (prepared Feb 2012)		
Quick Access			
	Statute (Public Law 104-191) (August 21, 1996)		
	<u>H Statute</u> (H.R. 1-2) (Feb 17, 2009) Iodifying <u>HIPAA Rules to Improve Coordinated Care</u> . 83 Fed Reg 64302 (12/14/2018)		
	IAL HITECH Omnibus Rule. 78 Fed Reg 5566 (01/25/13)		
Rule: Proposed	<u>d HITECH Omnibus Rule</u> . 75 Fed Reg 40868 (07/14/10)		
	I <u>AL Rule – Modifications to the Privacy Rule</u> . 67 Fed Reg 53181 (08/14/2002) <u>d Rule-Modification to the Privacy Rule</u> . 67 Fed Reg 14776 (03/27/2002)		
	on of Effective & Compliance Dates for Privacy Rule. 66 Fed Reg 12434 (02/26/01)		
	IAL Privacy Rule. 65 Fed Reg 82462 (12/28/2000)		
	<u>d Privacy Rule</u> . 64 Fed Reg 59918 (11/03/99)		
	on of Authority to OCR. 74 Fed Reg 38630 (08/04/09)		
	IAL Security Rule, 68 Fed Reg 8334 (02/20/03)		
	 Rule: Proposed Security Rule. 63 Fed Reg 43242 (08/12/98) Final Rule: <u>HIPAA Enforcement Rule</u>. 71 Fed Reg 8390 (02/16/2006) 		
	Enforcement Discretion. 83 Fed Reg 18161 (04/30/2019)		
	ce: OCR Regional Offices for HIPAA		
	ce: <u>OCR HIPAA Complaint Portal</u> ce: <u>Combined Text of Final Privacy Rule, Security Rule & HITECH Omnibus Rule (</u> through March 26, 2013)		
	ce: <u>HHS Security Risk Assessment Tool</u>		
	ce: <u>SECURITY Rule Guidance Material</u> (includes guidance on: <u>Remote Use</u> ; <u>Mobile Devices</u> ; <u>Ransomware</u> ; NIST Special Publications; FTC Guidance on <u>Peer-to-Peer</u>		
	plications; Digital Copiers; Medical Identity Theft; Cloud Computing)		
	ce: <u>PRIVACY Rule Guidance Material</u> (includes guidance on: <u>Access Rights, Apps & APIs; Patients' Right of Access; Workplace Wellness Programs; De-identification</u> & Behavioral Health Info; <u>Research; Public Health; Emergency Response; GINA; CLIA; Ryan White & HIV/AIDS</u>)		
	ce: <u>HIPAA FAQs</u>		
42 CFR P	art 2 (+March 2020 CARES Act Amendments)		
Checklists &			
02.2020	CHECKLIST _Authorization&Consent form requirements under HIPAA and 42 CFR Part 2		
03.2020	TOOL_Incorporating Part 2 Records in HIOs		
Sample Form			
Coming soon!	42 CFR Part 2 Policies and Procedures for Part 2 Providers and Programs		
PowerPoints			
Whitepapers			

Quick Access Links

- Statute: <u>42 USC 290dd-2</u> (as amended March 27, 2020 by the CARES Act)
- Rule: <u>42 CFR Part 2</u> (Confidentiality of Substance Use Disorder Patient Records)(through 01/18/17)
- Rule: <u>SAMHSA Final Rule</u> (Confidentiality of SUD Records) 82 Fed Reg 6052 (01/18/17)
- Rule: <u>SAMHSA Proposed Rule</u> (Confidentiality of SUD Records) 84 Fed Reg 44568 (08/26/2019)
 Rule:
- Rule:
- Agency Resource: FAQ: Applying 42 CFR Part 2 to Health Information Exchange (HIE)
- Agency Resource:
- Agency Resource: <u>Does 42 CFR Part 2 Apply to Me?</u> Excellent SAMHSA whitepaper evaluating applicability of Part 2 to various networked cared settings, including HIEs & ACOs
- Other Resource: <u>Legal Action Center</u>

Telehealth/Telemedicine

Checklists & Tools

Coming soon!

Sample Forms & Policies

Coming soon!

PowerPoints

Coming soon!

Whitepapers

Quick Access Links

- Statute:
- Rule:
- Agency Guidance:
- Agency Resource: <u>SAMHSA-HRSA Tele-behavioral Health Training & Technical Assistance</u>
- Agency Resource:

GDPR

UDFK		
Checklists and Tools		
05.2018	TOOL_GDPR Compliance Matrix	
05.2018	TOOL_GDPR Principles	
05.2018	TOOL_GDPR Scope and Activities	
Sample Form	s & Policies	
Coming soon!	SAMPLE_IRSG_Data Protection Addendum	
PowerPoints		
Whitepapers		
May 2018	GDPR Summary (written May 2018)	
Quick Access	Links	
Privacy Shield	1 Framework	
EU GDPR Quic	:k Links	

Research
Checklists and Tools
O4.2020 CHKLST_De-identifying PHI and Creating Limited Data Sets
04.2020 CHKLST_De-Identifying PHT and Creating Limited Data Sets
Sample Forms & Policies
04.2020 POLICY: Research
PowerPoints
4.2020 Research under HIPAA & Common Rule
Whitepapers
Quick Access Links
Statute:
 Statute: Statute:
 Rule:
 Rule:
 Agency Resource: <u>OCR Guidance on 21st Century Cures Act Mandate re: Individual Authorization of Uses/Disclosures of PHI for Research</u>
 Agency Resource: <u>HHS HIPAA Guidance on Research</u>
Agency Resource: <u>HIPAA Privacy Rule Booklet for Research</u>
Agency Resource: <u>Clinical Research Fact Sheet</u>
 Agency Resource: <u>Institutional Review Boards Fact Sheet</u>
 Agency Resource: <u>HIPAA Authorization Fact Sheet and Sample Language</u>
 Agency Resource: <u>Health Services Research Fact Sheet</u>
Agency Resource: <u>Research Repositories and Databases Fact Sheet</u>
Agency Resource: <u>Frequently Asked Questions</u>
 Agency Resource:
Certified Health IT & Meaningful Use
Checklists & Tools
Sample Forms & Policies
PowerPoints
Whitepaper
Quick Access Links
Quick Access Links
Statute: Degulation:
Regulation: Begulation:
 Regulation: Regulation:
 Agency Action:
 Agency Action. Agency Resource:
 Agency Resource:
 Agency Resource:
 Other Resource:
SOCIAL MEDIA
Checklists & Tools
Sample Forms & Policies
4.2020 POLICY: Social Media Use (incl PHI)
PowerPoints
Coming soon! PPT_Social Media & Internet Training

Legal Health information exchange"

TCPA		
Checklists & Tools		
Sample Forms & Policies		
PowerPoints		
Whitepaper		
4.2020 Background to the TCPA		
Quick Access Links		
Statute:		
Regulation:		
Regulation:		
Regulation:		
Agency Action: Agency Resource:		
 Agency Resource: Agency Resource: 		
 Agency Resource: 		
 Other Resource: 		