DC HIE Secondary Use of Health Information Self-Assessment Checklist

Secondary Use Purposes (Use Cases)

SUMMARY

The DC HIE Secondary Use of Health Information Self-Assessment Checklist is to support the DC Department of Health Care Finance's governance and oversight of District Registered and Designated HIE entities as set forth in the DC HIE Rule, Chapter 87, Title 29 of the District of Columbia Municipal Regulation. The completed Checklist, by District Registered and Designated HIE entities, will support DHCF's development of its secondary use of health information policy guidance, per section 8703.4 of the DC HIE Rule.

BACKGROUND AND PURPOSE

In the DC HIE Rule, secondary use of health information is defined as "the use, access, or disclosure of health information through the registered HIE entity that is not for a Primary Use; subject to any limitations under HIPAA or federal law. A registered HIE entity shall provide DHCF with policies governing disclosure for Secondary Use in accordance with policy guidance published to the DHCF website."

This definition is quite broad; secondary use of health information can include use for research, social determinants of health, registries, health surveillance, operational improvement in quality of care and care coordination. Given the breadth and nature of these types of activities, there is often concern from patients regarding research participation and/or secondary clinical and nonclinical use of digitized information. Patients want to make sure their involvement in these activities is safe, and that the outcomes are meaningful.

A standardized framework for the secondary use of health information can help with the collection, storage, aggregation, linkage and transmission of health data, as well as with alleviating potential patient concerns. In order to develop such a framework, the DC HIE Policy Board has created this self-assessment checklist to support the eventual development of a

secondary use of health information policy guidance by DHCF and to bolster DCHF's governance and oversight of District Registered and Designated HIE entities under the DC HIE Rule.

DHCF recognizes that the DC HIE Rule excludes from its definition of "Primary Use" certain activities that otherwise satisfy the "treatment, payment and health care operations exception" under 45 CFR 154.506 of the HIPAA Rules. *DHCF is especially interested in understanding the activities of District Registered and Designated HIE entities that constitute "treatment", "payment" or "health care operations" under the HIPAA Rules but do not meet the DC HIE Rule's Primary Use requirements, to inform future policy development*. DHCF is also interested in understanding the activities of District Registered and Designated HIE entities that involve the use of PHI to create de-identified information, and the subsequent use or disclosure of de-identified information for lawful secondary purposes.

This Checklist is designed to elicit information about the written policies, practices and experiences of District Registered and Designated HIE entities for all such use cases. In addition, in an effort to understand the impact of innovations in health care delivery and payment models, DHCF seeks information about potential activities of District Registered and Designated HIE entities that support health care providers that are <u>not</u> HIPAA covered entities. These use cases apply to both identified and de-identified permitted uses.

<u>GUIDANCE AND INSTRUCTIONS</u>

Capitalized terms used and not otherwise defined have the meanings given to them in the following order of precedence: (1) the DC HIE Rule; and (2) the privacy, security, breach notification, and enforcement rules at 45 C.F.R. Part 160 and Part 164 (**"HIPAA Rules"**).

<u>CHECKLIST SUBMISSION INSTRUCTIONS:</u> Please check the boxes <u>only</u> for those use, access, or disclosure of PHI ("activities") that apply to your organization. If PHI is not used in the ways described in the checklist, please indicate 'NA'.

<u>POLICY SUBMISSION INSTRUCTIONS:</u> Once your organization has completed this Checklist, please include copies or reference sections of existing documents that cover the policies that pertain to the use cases or activities (used interchangeably) that you currently support. If the policies have not yet been developed, please indicate a timeframe in which it can be shared with DHCF.

If the relevant secondary use policies are included in documents that have already been submitted to DHCF as part of the DC HIE Registration or Designation process, you do not need to resubmit unless the documents have been updated subsequent to submission.

Please use the 'notes' field in the tables below to indicate policies that have either already been submitted to DHCF or will be submitted in response to the Checklist.

SUBMISSION INSTRUCTIONS TO DHCF: District Registered and Designated HIE entities are requested to complete and return the Checklist to dc.hie@dc.gov by a coordinated date announced by DHCF

Please note that this is a "living" document that can and will continue to be updated as needed or appropriate. Updated iterations will not negate previously completed Checklists, although any new requirements will be posted on the DHCF website and circulated to all District Registered and Designated Entities.

SECONDARY USE CHECKLIST

A. "Treatment" activities under the HIPAA Rules implemented by health care providers that are not subject to HIPAA.

Other Treatment Activities (Potential Secondary Uses) *Does your organization support the use, access, or disclosure of PHI by health care providers or clinical laboratories that do not participate in the National Plan and Provider Enumeration System, such as –*	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
CLIA-approved laboratories?	☐	☐	☐	☐	☐
concierge practices?	☐	☐	☐	☐	☐
worksite clinics?	☐	☐	☐	☐	☐
Please use the box below to provide any additional details or references to accompanying and attached documents related to the activities above					

B. "Payment" activities under the HIPAA Rules that are not considered "Payment of Claims and Billing" under the DC HIE Rule.

Other Payment Activities (Potential Secondary Uses) *Does your organization support the use, access, or disclosure of PHI to support the –*	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
collection of premiums for or on behalf of a health plan?	☐	☐	☐	☐	☐
determination of coverage and provision of benefits for an individual patient by a health plan?	☐	☐	☐	☐	☐
fulfillment of a health plan's responsibility for coverage and provision of benefits for an individual patient by a health plan?	☐	☐	☐	☐	☐
Please use the box below to provide any additional details or references to accompanying and attached documents related to the activities above					

C. "Health Care Operations" activities under the HIPAA Rules that do not support a "Case Management" or "Quality Assessment and Improvement Activity" under the DC HIE Rule.

Other Health Care Operations Activities (Potential Secondary Uses) *Does your organization support the use, access, or disclosure of PHI to support –*	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
Outcomes evaluation?	☐	☐	☐	☐	☐
Development of clinical guidelines (and not for purposes of generalizable knowledge)?	☐	☐	☐	☐	☐

Other Health Care Operations Activities (Potential Secondary Uses) *Does your organization support the use, access, or disclosure of PHI to support –*	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
population-based activities relating to improving health or reducing health care costs?	☐	☐	☐	☐	☐
protocol development?	☐	☐	☐	☐	☐
contacting health care providers and patients with information about treatment alternatives?	☐	☐	☐	☐	☐
reviewing the competence or qualifications of health care professionals?	☐	☐	☐	☐	☐
evaluating practitioner and provider performance?	☐	☐	☐	☐	☐
evaluating health plan performance?	☐	☐	☐	☐	☐
conducting medical education training programs?	☐	☐	☐	☐	☐
conducting training for non-health care professionals?	☐	☐	☐	☐	☐
accreditation, certification, licensing or credentialing activities?	☐	☐	☐	☐	☐
underwriting, enrollment, premium rating, and other activities related to the creation, renewal or replacement of a contract of health insurance or health benefits?	☐	☐	☐	☐	☐
ceding, securing or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance)?	☐	☐	☐	☐	☐
conducting or arranging for medical review, legal services, and auditing functions?	☐	☐	☐	☐	☐
business planning and development, such as conducting cost-management and planning-related	☐	☐	☐	☐	☐

Other Health Care Operations Activities (Potential Secondary Uses) *Does your organization support the use, access, or disclosure of PHI to support –*	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
analyses related to managing and operating the entity?					
business management and general administrative activities?	☐	☐	☐	☐	☐
Please use the box below to provide any additional details or references to accompanying and attached documents related to the activities above					

D. Other Secondary Uses That Are Authorized by HIPAA

DHCF recognizes that the HIPAA Rules set a floor for additional uses and disclosures of PHI that may be appropriately authorized as Secondary Uses.

Other Secondary Uses under the HIPAA Rules (Potential Secondary Uses) Does your organization support –	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
disclosures to a coroner, medical examiner, or funeral director (CFR 164.512(g))?	☐	☐	☐	☐	☐
Uses or disclosures that facilitate organ, eye or tissue donation and transplantation (45 CFR 164.512(h))?	☐	☐	☐	☐	☐
Uses or disclosures in research conducted to obtain generalizable knowledge (45 CFR 164.512(i))?	☐	☐	☐	☐	☐
Uses or disclosures of PHI in preparation of research protocols or similar purposes preparatory to research?	☐	☐	☐	☐	☐
The individual right to request privacy protection (45 CFR 164.522)?	☐	☐	☐	☐	☐

Other Secondary Uses under the HIPAA Rules (Potential Secondary Uses) Does your organization support –	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
The Individual right of access (45 CFR 164.524)?	☐	☐	☐	☐	☐
The individual right to amend their PHI (45 CFR 164.526)?	☐	☐	☐	☐	☐
The individual right to an accounting of disclosures (45 CFR 164.528)?	☐	☐	☐	☐	☐
The individual right to receive a notice of privacy practices, on behalf of third parties?	☐	☐	☐	☐	☐
The individual right to authorize other uses or disclosures (45 CFR 164.508)?	☐	☐	☐	☐	☐
Disclosures to an individual's personal representative?	☐	☐	☐	☐	☐
Disclosures to a family member, other relative or close personal friend of the individual, or any other person identified by the individual and involved with the individual's health care or payment related to the individual's care (45 CFR 164.510(b))?	☐	☐	☐	☐	☐
Disclosures between HIPAA covered entities that support fraud and abuse detection or compliance (45 CFR 164.506(b)(4))?	☐	☐	☐	☐	☐
Disclosures that support the health care operations activities of an organized health care arrangement (45 CFR 164.506(b)(5))?	☐	☐	☐	☐	☐
Population-based activities relating to improving health or reducing health care costs?	☐	☐	☐	☐	☐
Protocol development?	☐	☐	☐	☐	☐
Contacting health care providers and patients with information about treatment alternatives; and related functions that do not include treatment?	☐	☐	☐	☐	☐

Other Secondary Uses under the HIPAA Rules (Potential Secondary Uses) Does your organization support –	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
Reviewing the competence or qualifications of health care professionals?	☐	☐	☐	☐	☐
Evaluating practitioner and provider performance or health plan performance?	☐	☐	☐	☐	☐
Conducting training programs in which students, trainees, or practitioners in areas of health care learn under supervision to practice or improve their skills as health care providers?	☐	☐	☐	☐	☐
Training of non-health care professionals?	☐	☐	☐	☐	☐
Accreditation, certification, licensing, or credentialing activities?	☐	☐	☐	☐	☐
Underwriting, premium rating, and other activities relating to the creation, renewal or replacement of a contract of health insurance or health benefits, and ceding, securing, or placing a contract for reinsurance of risk relating to claims for health care (including stop-loss insurance and excess of loss insurance)?	☐	☐	☐	☐	☐
Business planning and development, such as conducting cost-management and planning-related analyses related to managing and operating the entity, including formulary development and administration, development, or improvement of methods of payment or coverage policies?	☐	☐	☐	☐	☐
Management activities relating to implementation of and compliance with the requirements of the HIPAA privacy rule?	☐	☐	☐	☐	☐

Other Secondary Uses under the HIPAA Rules (Potential Secondary Uses) Does your organization support –	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
Customer service, including the provision of data analyses for policy holders, plan sponsors, or other customers, provided that protected health information is not disclosed to such policy holder, plan sponsor, or customer?	☐	☐	☐	☐	☐
Resolution of internal grievances?	☐	☐	☐	☐	☐
The sale, transfer, merger, or consolidation of all or part of the covered entity with another covered entity, or an entity that following such activity will become a covered entity and due diligence related to such activity?	☐	☐	☐	☐	☐
Consistent with the applicable requirements of §164.514, creating deidentified health information or a limited data set, and fundraising for the benefit of the covered entity?	☐	☐	☐	☐	☐
Marketing, including: • Communication about a product or service that encourages recipients of the communication to purchase or use the product or service • Arrangement between a covered entity and any other entity whereby the covered entity discloses protected health information to the other entity, in exchange for direct or indirect remuneration, for the other entity or its affiliate to make a communication about its own product or service that encourages recipients of the	☐	☐	☐	☐	☐

Other Secondary Uses under the HIPAA Rules (Potential Secondary Uses) Does your organization support –	Select all that apply				
	Currently Support	Plan to Support	Identifiable	De-identified	N/A
communication to purchase or use that product or service					
Any other use of PHI for subsequent use or re-disclosure	☐	☐	☐	☐	☐
Please use the box below to provide any additional details or references to accompanying and documents related to the activities above					

Assessment of Policy and Procedures

This Section of the DC HIE Secondary Use of Health Information Checklist is designed to elicit information about the written policies, practices and experiences of District Registered HIEs and Designated HIEs for each secondary use case the organization has indicated it supports or plans to support.

Use, Access, Disclosure, and Redisclosure

Secondary Use Policy Evaluation Question	Select All that Apply			
	Yes (please use the last column to reference the name of the accompanying document)	No	N/A	Document / Policy Name:
Do you have a policy that specifies whether data for the use case must be deidentified?	☐	☐	☐	
If your use cases require deidentified data, do you have a policy that specifies how data is deidentified?	☐	☐	☐	

Does your policy indicate whether data shared for each use case may be redisclosed by the data requestor, recipient, or data holder/provider?	☐	☐	☐	
If data may be redisclosed by the data requestor or recipient, does your policy specify the conditions under which it may be redisclosed, I.e. with or without patient consent, with or without notification to the data holder/originator?	☐	☐	☐	
Does your policy indicate whether data shared for each use case may be sold or shared with partners by the data requestor?	☐	☐	☐	
For each secondary use case, does your policy specify what data will be available to data requestors or providers to ensure minimum necessary requirements are met?	☐	☐	☐	

Permitted Users

Secondary Use Policy Evaluation Question	Yes (please use the last column to reference the name of the accompanying document)	No	N/A	Document / Policy Name:
For each use case, does your policy define who the permitted users are, I.e. payers, public health agencies, healthcare providers, patients, vendors, etc.?	☐	☐	☐	
Does your policy specify security protocols that permitted users must follow for data?	☐	☐	☐	

Patient/Individual Choice

Secondary Use Policy Evaluation Question	Yes (please use the last column to reference the name of the accompanying document)	No	N/A	Document / Policy Name:
For each use case, does your policy specify if patient/individual consent/authorization must be obtained prior identified data can be shared?	☐	☐	☐	
For each use case, does your policy specify if patient/individual consent/authorization must be obtained prior to deidentified data be shared?	☐	☐	☐	
For each use case, does your policy specify if patient/individual consent can be revoked and if yes, does it specify the procedure for patients/individuals to follow?	☐	☐	☐	
If consent is not required, does your policy specify if patients must be notified of their data being used for the secondary use case?	☐	☐	☐	
Does your policy specify if patients can request an accounting for disclosures for secondary use cases?	☐	☐	☐	
Does your policy specify if patients can request privacy protection for secondary use cases?	☐	☐	☐	
Does your policy specify individual's options for access and the control over, protection of, use of, and correction of each type of health information?	☐	☐	☐	

Other Secondary Use Practices Under OCR's Notifications of Enforcement Discretion during Public Health Emergencies

During public health related emergencies, the Office of Civil Rights with the U.S. Department of Health and Human Services may issue guidance and notifications for its intent to exercise enforcement discretion with respect to the HIPAA Rules[1].   If applicable at times of a public health emergency, District Registered and Designated HIE entities are invited to share information about the impact of these notifications on their policies, practices and experiences, and any observations that would inform the DHCF's development of policy guidance for Secondary Uses during or after public health emergencies.

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[1] https://www.hhs.gov/hipaa/for-professionals/special-topics/hipaa-covid19/index.html, last accessed May 26, 2020.