



# **Guidance on Applying to be the District Designated HIE Entity**

This document provides instructions to apply to be the District Designated HIE Entity. Please read prior to beginning the application process. The DC HIE Registration Application precedes this application.

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## **Introduction**

Sections 8708 – 8710 of *Chapter 87 (Health Information Exchange) of Title 29 (Public Welfare) of the District of Columbia Municipal Regulations* (“HIE Rule”) specifies the application requirements on applying to be the District Designated HIE Entity.

This document provides guidelines on the submission of required documents, creation and submission of several Organizational Plans, and key administrative requirements for ongoing maintenance as the District Designated HIE Entity. HIE entities interested in applying for designation are encouraged to read the HIE Rule in its entirety prior to the submission of a DC HIE Designation Application. The DC HIE Registration and Designation applications can be submitted concurrently. However, submitting a DC HIE Registration Application prior to submitting a DC HIE Designation Application is recommended and may expedite the review of the applicant’s applications.

### ***Part 1: Guidance on the Submission of the DC HIE Designation Application***

The DC HIE Designation Application consists of the submission of the following: a form, two documents, and four organizational plans.

To guide the development of plans #1-4, DHCF has provided applicants with a set of guiding questions. Applicants may choose to answer some or all of the questions posed, or provide additional information not discussed in this guide. The format of the plan is not proscribed, however DHCF recommends that applicants consider traditional business plans when drafting and include a combination of narration, graphics and bullet points to describe why the applicant should be the District Designated HIE Entity.

DHCF recommends that each plan be five (5) pages or less (double spaced, 12-point font). Visualizations are encouraged if they will help reviewers understand how the plans will be or have been implemented. Applicants may have previously adopted plans that meet or exceed the requirements of the HIE Rule; in that case applicants should describe how their plan meets those requirements and submit it as part of their application, no matter its page length.

### ***Part 2: Frequently Asked Questions on Key Administrative Requirements for Ongoing Maintenance as the District Designated HIE Entity***

The District’s Designated HIE Entity is subject to the requirements of the HIE Rule. This section of the document provides key administrative requirements and guidance related to health care consumer education materials, reporting of audits, annual reporting guidelines, and appeals and administrative review. While DHCF has addressed most policy guidance in the HIE Rule, some policies are still under development by DC’s HIE Policy Board. If you have interest in participating in the development of these pending policy guidance, please contact [dc.hie@dc.gov](mailto:dc.hie@dc.gov).

**If you have questions about the requirements for this application, please contact [dc.hie@dc.gov](mailto:dc.hie@dc.gov) or call 202-478-1470.**

## **Part 1: Guidance on the Submission of the DC HIE Designation Application**

### **1. What is the DC HIE Designation Application?**

The DC HIE Designation Application consists of the following:

A screenshot of the DC HIE Designation Form. The form is titled "DC HIE HIE Entity Designation Form" and includes sections for "Section A: General Information", "Section B: Attachments", and "Section C: Signatures". The form is a standard application form with various fields for text entry.

#### **DC HIE Designation**

**Form:** HIE entities must complete sections A-C of this form as well as read and sign the form.



**Attachments:** HIE entities must submit the required attachments (B.1 through B.6) listed in this guidance document.

### **2. What are the instructions for attachments B.1-B.6?**

If the document already exists:

- **Read** the description and instructions for the document and ensure that it accurately meets the requirements.
- **Label and save** the document with the letter, number and title of the document (e.g. B.5 Internal Revenue Service Form 990).

If the document does not exist:

- **Create the document** based on the description and instructions. The document must not exceed to more than 5 pages (double spaced with 12-point font). In addition, label and save the document with the letter, number and title of the document (e.g. B.2: Plan 2 Financial Sustainability).
- **Request a waiver or exemption on the submission of the document** by reading and reviewing the requirements on page 10 of this document and set forth in section 8712 of the HIE Rule. If the document meets these requirements, please indicate your request for waiver or exemption in your application e-mail.

### **3. How to submit the DC HIE Designation Application:**

- Submit the DC HIE Registration Application concurrently or prior to submitting the DC HIE Designation Application
- Attach the completed DC HIE Designation Form (make sure to save the content of the completed form) and all required document attachments to an e-mail
- Title the subject of the e-mail: DC HIE Designation Application
- Send e-mail to [dc.hie@dc.gov](mailto:dc.hie@dc.gov) by **5:30 pm ET on September 18, 2019**

## Descriptions and Instructions for Attachments

### B.1: Plan #1 Strategy and Operations

Per section 8708.5 (a) of the HIE Rule, an applicant applying to be the District Designated HIE Entity must develop and submit strategic and operational plans to address the needs of health providers in achieving HIE capabilities.

1. Explain how the HIE entity addresses the known needs of District health providers in achieving HIE capabilities, including but not limited to:
  - a. Community health providers
  - b. Individual and small group practices
  - c. Public health agencies
2. Explain how the HIE entity is capable of supporting the four (4) use cases in the [DC State Medicaid Health IT Plan](#) for District Medicaid providers.
3. Explain how the HIE entity has the necessary technical capacity to operate and implement publicly funded DC HIE infrastructure and tools.
4. Describe how the HIE entity's organizational capacity and capability supports to operationalize the DC HIE in the following categories:
  - a. **Administration**, including how filing, recordkeeping, and information systems provide accountability for assurances for safeguarding sensitive information.
  - b. **Financial Management**, including how the HIE entity maintains fiduciary accountability for the organization and plans and implements its budgets.
  - c. **Governance**, including how the HIE entity's vision, mission, and values set expectations for its users and partners and provides accountability to the community it serves. Describe the HIE entity's: governing and advisory bodies, the influence and voices of local stakeholders, and the executive leadership team's experience and expertise.
  - d. **Human Resources**, including current and planned staffing models and personnel policies that contribute to accountability, security, growth and technical needs.
  - e. **Organizational Management**, including how the HIE entity involves community stakeholders in planning and implementation efforts, how the HIE entity fosters consensus and decides what to invest in.

- f. **Program Management**, including how the HIE entity manages design, development and implementation projects, monitors and evaluates implementation of projects and maintains and operates existing services.

## **B.2: Plan #2 Financial Sustainability**

Per section 8708.5 (d) of the HIE Rule, an applicant applying to be the District Designated HIE Entity must develop and submit financial sustainability plan that includes public and private financing strategies, projected utilization, and rates structures.

1. Provide the HIE entity's financial sustainability model:
  - a. A description of how the HIE entity plans to be sustainable and to grow (develop and implement new services) without substantial government grant funding;
  - b. A description of current streams of income and any plans to diversify or grow in the future; and
  - c. A market analysis of the District's growth opportunities for known services and expected services that the HIE entity could provide to be sustainable absent of government grant funding.

## **B.3: Plan #3 Access and Auditing**

Per section 8708.5 (h) of the HIE Rule, an applicant applying to be the District Designated HIE Entity must develop and submit its access and auditing plan as defined in sections 8709.4 – 8709.6 of the HIE Rule.

1. Describe the manner used to identify, report and take reasonable steps to promptly mitigate the impact of a non-HIPAA violation and a HIPAA breach, as defined and outlined in the rule.
2. Describe the process used to review access logs to ensure that only an authorized user who is appropriately authenticated is granted access to HIE information through a participating organization's third-party system.
3. Describe any outside privacy or security audits that the HIE entity engages in regularly or on an ad hoc basis.
4. Describe the plan to ensure that the HIE entity's enrolled participating organizations conduct their own audit or review the HIE access logs relating to the participating organization within ten (10) days of receipt from the HIE entity.

## **B.4: Plan #4 Health Care Consumer Education**

Per section 8708.5 (i) of the HIE Rule, an applicant applying to be the District Designated HIE Entity must develop and submit a consumer education plan as defined in section 8710.4 of the HIE Rule.

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1. Consumer-facing education materials are required to be produced after a District Registered HIE Entity receives District Designated HIE Entity status and do not need to be included in the application. However, the plan to develop those materials must be included.
2. The Health Care Consumer Education Plan should outline how the HIE entity as the District Designated HIE Entity will meet the requirements of section 8710 of the HIE Rule and *actively promote* the education of consumers about health information exchange, their health information accessible via HIE, and their rights as consumers. The plan should:
  - a. Provide the plain English definitions of the key terms and concepts underlying health information technology, including electronic health records and the exchange of electronic health information for a consumer audience.
  - b. Describe how the District Designated HIE Entity ensures access to information to health care consumers.
  - c. Provide information on how the District Designated HIE Entity will make the following information available to health care consumers:
    - i. A description of each type of PHI that is accessed or disclosed through the District Designated HIE Entity;
    - ii. The health information maintained by the District Designated HIE Entity;
    - iii. The specific details concerning who may access, use, or disclose a health care consumer's health information and for what purpose;
    - iv. The privacy and security measures that the District Designated HIE Entity has implemented to protect health information, and a detailed explanation of what happens if there is a breach that results in unauthorized access to PHI;
    - v. A health care consumer's access and participation options regarding health information exchange and the control over, protection of, use of, and correction of each type of health information;
    - vi. The process provided for a health care consumer to exercise the health care consumer's access and participation options, including a detailed description of the steps a health care consumer can to opt out of participation in health information exchange;
    - vii. The implications of a health care consumer's decision to opt out of participation in health information exchange and not permit the disclosure of that consumer's PHI to authorized users, except as otherwise permitted under applicable law; and,
    - viii. The District Designated HIE Entity's policies and procedures, including without limitation, policies and procedures consistent with these

regulations regarding how the health care consumer may gain access to the health care consumer's health information.

### **B.5: Internal Revenue Service Form 990**

Per section 8708.5 (e) of the HIE Rule, an applicant applying to be the District Designated HIE Entity must submit to DHCF a copy of the HIE entity's most recently filed Internal Revenue Service Form 990.

### **B.6: Accreditation or Certification**

Per section 8708.5 (f) of the HIE Rule, an applicant applying to be the District Designated HIE Entity must submit to DCHF copies of any accreditation(s) or certification (s) by a nationally recognized accreditation and certification organization for entities that electronically exchange health care data.

## **Part 2: Frequently Asked Questions on Key Administrative Requirements for Ongoing Maintenance as the District Designated HIE Entity**

### **Reporting Guidance**

#### ***Q1: What are additional audit reporting requirements for the District Designated HIE Entity?***

A1: At the request of DHCF and consistent with the specifications in such request, the District Designated HIE Entity will:

- Provide the results of any audit that is required under section 8709 of the HIE Rule, and any supporting documentation to DHCF; and
- Conduct an additional unscheduled audit and provide the results of the audit within the time frame specified by DHCF.
- The District Designated HIE Entity will post a publicly available summary report of the audit on its website within thirty (30) calendar days after the completion of the audit and DHCF will also post the report on its website.

### **District Designated HIE Entity Term**

#### ***Q1: What is the District Designated HIE Entity term?***

A1: The District Designated HIE Entity status is awarded for a term of five (5) years.

#### ***Q2: How does the District Designated HIE Entity renew its status post its five-year term?***

A2: DHCF will review the District Designated HIE Entity status every five (5) years from the date of term to determine whether the HIE entity will be renewed for an additional five (5) year term. DHCF may request an HIE entity to submit updated information related to the requirements set forth in section 8708.5 during review of the District Designated HIE Entity status.

#### ***Q3: Are there additional reporting or requirements for the District Designated HIE Entity?***

A2: Yes. The District Designated HIE Entity must submit an annual report for review by DHCF that addresses:

- Updates to the Strategic and Operational plans developed and submitted in section 8708.5(a), including plans for ensuring the necessary capacity to support clinical transactions;
- Rates of adoption, utilization, and transaction volume, and mechanisms to support health information exchange; and,
- Other information as requested by DHCF.

## **Appeals and Administrative Review**

***Q1: Are there appeal rights for HIE entity's applying for the District Designated HIE Entity status?***

A1: Within thirty days (30) of receipt of notice of a DHCF enforcement action in accordance with 8711 or notice from DHCF denying an HIE entity's application for designation pursuant to 8708.7, an HIE entity may request an administrative review of the action taken by DHCF. The request for administrative review will be made in writing to DHCF. For more information, please read section 8713 of the HIE Rule.

## **Exemptions**

***Q1: In what scenarios does DHCF exempt a HIE entity from requirements in the HIE Rule?***

A1: In scenarios when an exemption will not pose substantial risks to the privacy or security of health care consumers, and:

- The HIE entity's infrastructure does not allow the HIE Entity to maintain compliance with a section of the HIE Rule; or
- The requirements in the HIE Rule would cause an undue burden or hardship on the HIE Entity.

***Q2: How can a HIE entity request an exemption for the requirements in the HIE Rule?***

A2: A District Registered and or Designated HIE Entity can request a one (1) year exemption from requirements set forth in the HIE Rule. An exemption request must:

- Be written in the e-mail application to DHCF;
- Identify each specific requirement of the HIE Rule from which the HIE entity is requesting an exemption;
- Identify the requested time period of the exemption;
- State the reason for each exemption request; and
- Include information that justifies the exemption request.

***Q3: How long will it take DHCF to respond to an HIE entity on the status of their exemption request and what types of actions will DHCF take?***

A3: Within forty-five (45) days after receipt of complete information from an applicant requesting an exemption, applying for District Registered and or Designated HIE Entity, DHCF will take one of the following actions:

- Grant the exemption by providing written notification; or

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- Deny the exemption request by providing written notification that enumerates the reasons for the denial to the HIE entity.

For good cause shown, DHCF may renew a one (1)-year exemption for an additional one (1) year period, as requested by the HIE entity.

### ***Q4: Are there any exemption requests that are excluded?***

A4: An exemption may not be made for any requirements within the HIE Rule that is otherwise required of District Registered and or Designated HIE Entity by federal or other District law.

## **Oversight and Enforcement**

DHCF will take enforcement actions as necessary, including the suspension or revocation of a District Registered and or Designated HIE Entity status in accordance with the requirements set forth below:

- When DHCF is considering suspension or revocation of an HIE entity's District Registered and or Designated HIE Entity status as set forth in section 8711, all investigatory data that are collected, created, or maintained related to the suspension or revocation are classified as confidential data on persons and as protected nonpublic data; and
- DHCF may disclose data classified as protected nonpublic or confidential under section 8711.1 (a) if disclosing the data, as permissible under 45 C.F.R. § 164.512(j), will protect the health, privacy, or safety of health care consumers.

### ***Q1: In what situations or scenarios, does DHCF revoke or suspend a District Registered and or Designated HIE Entity's status?***

A1: DHCF may suspend or revoke a District Registered and or Designated HIE Entity status issued to an HIE entity or issue a requirement for corrective action if DHCF finds that:

- The HIE entity is operating outside of nationally recognized standards identified by DHCF in policy guidance, or in a manner contrary to that described in any other information submitted under sections 8702.2 and 8708.5, unless amendments to the submissions have been filed with and approved by DHCF;
- The HIE entity is unable to fulfill its obligations to furnish comprehensive HIE services as required under its agreements with DHCF or with its participating organizations;
- The HIE entity is no longer financially solvent or may not reasonably be expected to meet its obligations to DHCF or its participating organizations;
- The HIE entity, or any person acting with its sanction, has advertised or merchandised its services in an untrue, misleading, deceptive, or unfair manner;
- The continued operation of the HIE would pose risks to its participating organizations or the privacy and security of health care consumers served by the participating organizations;

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- The HIE entity improperly discloses any PHI, or health information derived from PHI, that is available through the registered or designated HIE entity's infrastructure, except as consistent with or otherwise permitted by the HIE Rule and applicable federal or District law; and
- The HIE entity has otherwise failed to substantially comply with the requirements of the HIE Rule or other applicable federal or District law.

DHCF retains its authority to enforce other generally applicable Medicaid requirements outlined in District laws and regulations, as applicable to District Registered and Designated HIE Entities.

### ***Q2: How will DHCF notify the HIE entity of a corrective action, suspension, or revocation of an HIE entity's District Registered and or Designated HIE Entity status?***

A2: DHCF will notify the HIE entity in writing stating the grounds for the action taken. Notice will include:

- A reference to the regulatory basis for the action;
- A description of the findings of fact regarding the violations with respect to which the action is proposed;
- The nature of the action;
- Any circumstances that were considered in determining the amount of the proposed action;
- Instructions for responding to the notice, including a statement of the HIE entity's ability to request administrative review and date which response or corrective action must occur; and
- The address to which the request for review must be sent.

If DHCF suspends or revokes the District Registered and or Designated HIE Entity status, the HIE entity will not, during the period of suspension or revocation, engage in any new advertising or solicitation while holding itself out as a District Registered and or Designated HIE Entity.

### ***Q3: What does a DHCF written request for corrective action include?***

A3: All suspensions of District Registered and or Designated HIE Entity status will be accompanied by a requirement for corrective action. A DHCF written request for corrective action will include:

- Nature and scope of corrective action requested;
- Date by which corrective action must be completed by the District Registered and or Designated HIE Entity; and
- Details on how DHCF will evaluate the District Registered and or Designated HIE Entity correction of underlying issues.

### ***Q4: What is the timeline for requesting an administrative review of DHCF's action?***

A4: Within thirty days (30) of receipt of notice of enforcement action from DHCF, a HIE entity may request an administrative review of the action taken by DHCF in accordance with the procedures set forth in 8713 of the HIE Rule.