



In February 2017 the Massachusetts Executive Office of Health & Human Services (EOHHS) promulgated the state regulation *101 CMR 20.00: Health Information Exchange*, which is also known as the *Mass HIway Regulations*. These regulations implement key components of Massachusetts General Law (M.G.L.) Chapter 118I, pertaining to the Mass HIway, which is the state-sponsored, statewide health information exchange (HIE) for the Commonwealth of Massachusetts.

This document provides Frequently Asked Questions (FAQs) and answers that can help stakeholders understand how the regulations apply to them. Terms that are defined in Section 20.04 of the regulations, such as HIway Direct Messaging, are capitalized in this FAQ document.

The full regulations, this FAQ document, a 2-page *Mass HIway Regulations Summary*, and the *Mass HIway Policies & Procedures* are available on the [Mass HIway website](#).

## **Frequently Asked Questions (FAQs):**

### **1. Background about the Mass HIway Regulations and M.G.L. Chapter 118I:**

#### **a) Q: How were the Mass HIway Regulations developed?**

**A:** The regulations were developed through an open, transparent process, during which EOHHS gathered feedback from the state's Health Information Technology (HIT) Council, the Council's advisory groups, and other stakeholders from across the state. The process included a public comment period and public hearing held in the fall of 2016.

### **2. The HIway connection requirement: Who and when**

#### **a) Q: Who do the Mass HIway Regulations apply to?**

**A:** The regulations apply to all Mass HIway Users (which are defined in 101 CMR 20.04). Under the regulations, (101 CMR 20.05) certain Provider Organizations are required to meet the HIway connection requirement, while other categories of eligible Mass HIway Users (e.g., Provider Organizations that do not have specified HIway connection dates in the regulations, local departments of public health, or health insurance plans) are eligible but not currently required to connect to the Mass HIway.

#### **b) Q: Are individual providers, such as a physician, nurse practitioner, pharmacist, or laboratory technician, required to connect to the Mass HIway?**

**A:** No, not at this time. Under the regulations (101 CMR 20.08) specified Provider Organizations are required to connect to the Mass HIway, rather than individual health care providers who hold a professional license in the state.

#### **c) Q: Why do the Mass HIway Regulations set required HIway connection dates for certain Provider Organizations, and not others?**

**A:** The regulations set HIway connection dates for three groups of Provider Organizations (i.e., Acute Care Hospitals, Large and Medium Medical Ambulatory Practices, and Community Health Centers) and not for other types of Provider Organizations (e.g., nursing homes, dental clinics, behavioral health entities, Small Medical Ambulatory Practices, solo practices). The regulations implement this approach because these three Provider Organizations are more likely to have adopted health information technology earlier than other provider organizations, as they may have had access to federal funding to adopt EHR systems, and have more resources than other organizations to implement regulatory requirements. (continued on page 2)

Also, connecting these three organizations to the Mass HIway will create stronger clinical and business reasons for other provider organization types to connect at a later time.

M.G.L. Chapter 118I Section 7 requires that all providers connect to the Mass HIway. EOHHS anticipates that Provider Organizations which are not specified in the regulations will be required to connect at a date that will be specified in the future. The regulations (in 101 CMR 20.08(1b)) specify that future guidance will provide at least one year notice for affected provider organizations to connect to the Mass HIway.

**d) Q: How does a Medical Ambulatory Practice determine if it is large, medium, or small for the purposes of the Mass HIway Regulations?**

**A:** The regulations (101 CMR 20.06) establish that Large and Medium Medical Ambulatory Practices have 10 or more licensed providers participating in providing health care. The number of participating licensed providers is determined by calculating the number of licensed providers that provide health care services to patients on behalf of the provider organization, regardless of employment status (e.g., including the organization's full-time and part-time licensed providers).

The threshold of 10 licensed providers varies slightly from the threshold of 15 that exists in the 2016 Medicare Access and CHIP Reauthorization Act (MACRA). The regulations take this approach in order to increase the number of practices connecting to the Mass HIway, and advance the goals of care coordination and interoperability.

**e) Q: How do health care systems with multiple provider organizations fulfill the HIway connection requirement?**

**A:** If a health care system consists of multiple Provider Organizations, then each Provider Organization must meet the requirements in the regulations. For example, if a health care system contains multiple Acute Care Hospitals and Medical Ambulatory Practices with 10 or more licensed providers participating in health care, then each Acute Care Hospital within that system has a required HIway connection date in 2017, and each of those Medical Ambulatory Practices has a required HIway connection date in 2018.

There is flexibility in how Provider Organizations establish the technical connection to the Mass HIway. For example, one health care system may choose to connect to the Mass HIway via a single technical connection, whereas a different system may choose to have separate connections for each of its different hospitals.

**f) Q: Is there help for Provider Organizations who want to connect to the Mass HIway?**

**A:** Yes, the Mass HIway Account Management team can assist your organization through the process of enrollment, onboarding, and connection to the Mass HIway. Contact the team via email at [masshiway@state.ma.us](mailto:masshiway@state.ma.us) or call 1-855-MA-HIway (624-4929) option 1 to get started.

**3. The HIway connection requirement: How organizations fulfill the requirement**

**a) Q: Why do the Mass HIway Regulations use a 4-year phased-in approach for using HIway Direct Messaging?**

**A:** The regulations implement the M.G.L. Chapter 118I's requirement that providers implement interoperable EHR systems that connect to the Mass HIway by using a phased-in approach in recognition of the following several factors:

(1) Phasing in the requirements recognizes that technical and operational readiness among Providers, as well as the availability of interoperable systems, varies widely;

(2) The regulations require the implementation of HIway Direct Messaging for at least one use case, instead of just requiring a technical connection to the Mass HIway. The regulations focus on use cases in order to emphasize that the use of HIway Direct Messaging should be meaningful, and that the messages are being used by the recipient;

(3) The regulations call for using HIway Direct Messaging for at least one use case in Years 1, 2 and 3, rather than requiring a certain number of transactions. This avoids setting a target number that would be appropriate for some provider organizations and not for others, and sets a minimum level of interoperability without burdening providers with a specific number of transactions that they need to meet;

(4) In Year 1, the connection requirement is fulfilled by sending or receiving HIway Direct Messages for at least one use case within any category of use cases. This includes public health and quality reporting. In Year 2 there must be at least one use case of sending or receiving within the category of Provider-to-Provider communications. This approach progressively encourages using the Mass HIway to implement Provider-to-Provider communications in clinical practice.

(5) In Year 1 and Year 2, Provider Organizations must either send or receive HIway Direct Messages for at least one use case to fulfill the connection requirement, while in Year 3 they must both send and receive HIway Direct Messages for at least one use case. This approach implements the goal of bi-directional exchange of health information, and addresses stakeholder input that requiring both sending and receiving of information will help avoid two situations: (1) the scenario where a Provider Organization is ready to send information (e.g., a hospital ready to send discharge summaries to primary care providers), but is unable to find organizations ready to receive; (2) the scenario where a Provider Organization is sending information electronically in compliance with a state or federal requirement, but these messages are not being used by the recipient because the same information is simultaneously being sent over less secure methods such as by fax.

In order to attest to the HIway connection requirement, Provider Organizations must confirm that they have coordinated with the sending and/or receiving organization to establish that the organization is able to use the transmission. The goal is to use HIway Direct Messaging in order to replace less secure methods of sending and/or receiving information, such as fax or mail. See the *Mass HIway Policies & Procedures* (in Appendix B) for the attestation form that Provider Organizations shall use to report information about how they have fulfilled the HIway connection requirements.

**b) Q: Do the Mass HIway Regulations allow Provider Organizations to fulfill the HIway connection requirement with health information exchanges outside the Mass HIway?**

**A:** All Provider Organizations with a HIway connection date that is specified in the regulations are required to connect to the Mass HIway even if they are connected to other health information exchanges. However, under the regulations (101 CMR 20.15(1d)) a Provider Organization may be granted a waiver if it successfully implements provider-to-provider direct messaging outside of the Mass HIway (e.g., using a non-Mass HIway HISP) and does not have any trading partners on the Mass HIway to implement a provider-to-provider communications use case. In this case, the Provider Organization still must demonstrate the technical capability to send and receive HIway Direct Messages with a HIway Participant. This provision supports the Mass HIway's mission to provide interoperability across the state and provide health information exchange that is accessible to all eligible Provider Organizations statewide regardless of size, location or level of technology.

#### 4. Penalties for non-compliance with the HIway connection requirement

**a) Q: When do the penalties for non-compliance with the HIway connection requirement take effect?**

**A:** Under the phased-in approach implemented by the regulations (101 CMR 20.13 and 20.14), penalties for non-compliance with the HIway connection requirement do not take effect until Year 4 of the connection requirement (i.e., in January 2020, at the earliest).

**b) Q: What are the penalties for not meeting the HIway connection requirement?**

**A:** Under the regulations (101 CMR 20.14) penalties range from \$1,000 to \$30,000 per year for different Provider Organizations. While flexible penalty amounts (e.g., penalties up to a maximum amount) were considered, the regulations describe fixed penalty amounts in order to provide a clear, efficient penalty determination process.

**c) Q: What is the waiver process for Provider Organizations that are unable to fulfill the requirement to connect to the Mass HIway?**

**A:** Under the regulations (101 CMR 20.15) EOHHS may grant a waiver to certain Provider Organizations who are unable to fulfill the HIway connection requirement by their initial connection date. Waiver criteria include, but are not limited to, catastrophic events, extenuating circumstances, or an organization not having trading partners on the Mass HIway to implement a HIway Direct Messaging use case within the category of Provider-to-Provider Communications.

**d) Q: What is the appeals process related to penalty determinations made by EOHHS?**

**A:** Under the regulations (101 CMR 20.16) there is a "Reconsideration and Appeals Process" which includes the method by which: (a) EOHHS will notify Provider Organizations that fail to comply with the HIway connection requirement, (b) Provider Organizations can request EOHHS to review and reconsider their penalty determination, and (c) Provider Organizations can appeal EOHHS' final determination to assess a penalty for not meeting the HIway connection requirement.

#### 5. The opt-in opt-out mechanism for the Mass HIway

**a) Q: How does the opt-in opt-out mechanism impact HIway Direct Messaging?**

**A:** Under the regulations (101 CMR 20.07(1)) Mass HIway Users may transmit information via HIway Direct Messaging in compliance with applicable federal privacy laws and regulations (such as HIPAA and 42 CFR Part 2) and state privacy laws and regulations (such as M.G.L. Chapter 93H), similar to sending such information via fax message.

HIway Participants may elect to implement local opt-in and/or opt-out processes that apply to their organization's use of HIway Direct Messaging. This option was provided in recognition of stakeholder input that some organizations wanted to implement a local process.

**b) Q: What information for patients is available about HIway Direct Messaging?**

**A:** There is a *Mass HIway Fact Sheet for Patients* available on the Mass HIway website at [www.masshiway.net](http://www.masshiway.net). Provider Organizations that use HIway Direct Messaging are not required to give this document to each patient, but Provider Organizations can make the document available to patients if they chose to do so. For more information, patients can also visit the "Patients and Families" section on the Mass HIway website. (continued on page 5)

Patients can contact the Mass HIway directly by calling 1-855-MA-HIway (624-4929) Option 3 or emailing [masshiway@state.ma.us](mailto:masshiway@state.ma.us) with questions about the Mass HIway.

**c) Q: What is the opt-in component of the Mass HIway's opt-in opt-out mechanism?**

**A:** Under the regulations (101 CMR 20.07(2a)), all HIway Participants must provide each patient and/or their legal representative with written notice of how the organization uses HIway-Sponsored Services, and that written notice must be provided by at least one of the following methods: (a) inclusion in the HIway participant's privacy notice; (b) patient handout; or (c) letter, email, or other personal electronic communication to patients.

**d) Q: Will EOHHS provide a sample written notice?**

**A:** Yes. EOHHS intends to provide a sample written notice closer to the time that HIway-Sponsored Services are launched.

**e) Q: What languages will the written notice need to be provided in?**

**A:** Under the regulations (101 CMR 20.07(2a)) written notice must be available in languages as established by EOHHS in the *Mass HIway Policies & Procedures*. EOHHS anticipates providing more detailed guidance once the HIway-Sponsored Services are launched.

**f) Q: Why was a centralized opt-out mechanism implemented, instead of a localized opt-out mechanism?**

**A:** Under the regulations (101 CMR 20.02(2b)) there will be a forthcoming centralized opt-out mechanism for HIway-Sponsored Services. A *centralized* opt-out mechanism is being implemented for several reasons, including: (1) operating the opt-out mechanism centrally can increase efficiency and help reduce the burden on Provider Organizations; and (2) having a single central record of who has opted-out of the HIway-Sponsored Services avoids conflicting records among various Provider Organizations.

**g) Q: What is an Event Notification Service (ENS), and when will it be launched?**

**A:** ENS is defined as a HIway-Sponsored Service that would allow provider organizations (e.g., a primary care physician) to receive notifications about important medical encounters such as when their patient is admitted to a hospital (101 CMR 20.04). The regulations do not provide a date by which the ENS will be launched. EOHHS and the Mass HIway are actively in the planning stages, and anticipate a launch in early 2018.

To support the ENS, Acute Care Hospitals are required to send Admission Discharge Transfer notifications (ADTs) to the Mass HIway within 12 months of the ENS' launch as a part of the HIway connection requirement.

**h) Q: When will operational details of the centralized opt-out be available?**

**A:** EOHHS anticipates that operational details of the centralized opt-out mechanism will be provided closer to the launch of HIway-Sponsored Services.

**i) Q: Are Provider Organizations allowed to implement local opt-in or opt-out processes?**

**A:** Yes. HIway Participants may elect to implement additional local opt-in and/or opt-out processes that apply to their organization's use of HIway-Sponsored Services (101 CMR 20.07(2c)). If a Mass HIway Participant chooses to implement a local process, then it must supplement, and not replace the HIway's opt-in and opt-out mechanism. (continued on page 6)

For example, a Provider Organization may decide to require its patients to sign an opt-in form for HIway-Sponsored Services, while another Provider Organization may allow patients to opt-in through an internet-based patient portal. These local processes could *supplement* the written notice and centralized opt-out mechanism.

**j) Q: Does the opt-in opt-out provisions of the regulations apply to local or regional health information exchanges?**

**A:** No. The opt-in opt-out provisions of the regulations (101 CMR 20.07) apply to use of the Mass HIway, which is the state-sponsored, statewide health information exchange. These provisions do not apply to local, regional, or private health information exchanges.

## 6. The requirements regarding Electronic Health Records (EHRs)

**a) Q: Do the Mass HIway Regulations require that all providers in the Commonwealth have an interoperable EHR by January 2017? Do the regulations require that all providers have an interoperable EHR that connects to the HIway?**

**A:** In order to implement Section 7 of M.G.L. c118I that calls for providers to have an interoperable EHR system that connects to the Mass HIway, the regulations (101 CMR Section 20.10(1)) state that the Provider Organizations that have HIway connection dates specified in the regulation shall establish interoperability by implementing HIway Direct Messaging.

The regulations reference the *Mass HIway Policies & Procedures* which specify the different methods for implementing HIway Direct Messages. Under Section 4.1.4 of the *Mass HIway Policies & Procedures*, those different implementation methods include via: (a) an EHR's Direct XDR connection, (b) a Local Access for Network Distribution (LAND) appliance connection, or (c) a Webmail connection, which does not require an EHR. In other words, the regulations give Provider Organizations flexibility to connect to the Mass HIway via an EHR or via other means. This flexibility is being provided in recognition that some Provider Organizations (e.g., some small Provider Organizations or an imaging center) may not have a traditional EHR system such as what a hospital may have.

**b) Q: What information will Provider Organizations need to provide the Mass HIway regarding their EHR, if they have one?**

**A:** Under the regulations (101 CMR 20.10(2)) Provider Organizations with required dates for connecting to the Mass HIway must submit information regarding: (a) whether or not they have an EHR, and (b) how their EHR, if any, connects to the Mass HIway. The attestation form, instructions, and dates to report this information is in the *Mass HIway Policies & Procedures* (in Appendix B).

## 7. The Mass HIway Policies & Procedures

**a) Q: What changes were made to the updated *Mass HIway Policies & Procedures*?**

**A:** The *Mass HIway Policies & Procedures* is the detailed document that provides the rules that govern access to and use of the Mass HIway. Version 3 of the *Mass HIway Policies & Procedures*, and a summary of the changes from Version 2, were released in February 2017 and are available on the [Mass HIway's webpage](#). Changes in Version 3 were made to align with the Mass HIway Regulations, to streamline Mass HIway documentation and contracts, and to update procedures and practices to reflect changes in the healthcare information technology environment.

**b) Q: What fees are associated with the use of the Mass HIway?**

**A:** The fee schedule for using the Mass HIway is provided in the *Mass HIway Policies & Procedures*. This fee schedule establishes different tiers of HIway Participants, with larger participants (e.g., a large hospital) having higher fees than smaller ones (e.g., a small ambulatory practice). The current fees for using the Mass HIway are less than typical fees for health information exchange services, in order to achieve the HIway's mission of enabling health information exchange by all health care providers in the state, regardless of affiliation, location, or differences in technology.

**8. Other FAQs**

**a) Q: Can patients access their electronic health records via the Mass HIway?**

**A:** No. At this time, the Mass HIway does not include a function for patients to access their electronic health records via the Mass HIway. The Mass HIway does not currently function as a clinical data repository that holds electronic medical records for individuals. Patient's electronic health record(s) are held by specific provider organizations, and these records are not made available to the Mass HIway.

Therefore, as provided in *Mass HIway Policies & Procedures* (Section 9.1.1), patients may request a copy of their medical record from the healthcare provider that holds the record.

**b) Q: How do the Mass Regulations protect patient privacy?**

**A:** The regulations maintain protection of patient privacy in several important ways. Any disclosure made over the Mass HIway must comply with state and federal privacy rules. Impermissible use or disclosure of individually identifiable patient health information by or through the Mass HIway is prohibited, and violators may be subject to penalties established under applicable state or federal law regarding the protection and privacy of personal information. The *Mass HIway Policies & Procedures* (Section 12.4.6) authorize the Mass HIway to suspend a HIway Participant's access to the Mass HIway as required to prevent impermissible uses of the Mass HIway.

In addition, under the regulations (101 CMR 20.07) the opt-in opt-out mechanism for the Mass HIway ensures that each patient receives written notice describing how a Provider Organization uses HIway-Sponsored Services, and also provides a mechanism by which patients can opt-out of participating in these services.

**c) Q: How can stakeholders keep up to date regarding the Mass HIway Regulations and forthcoming updates from the Mass HIway?**

**A:** The best way to stay informed on the regulations and issues related to the Mass HIway is to sign up for the Mass HIway newsletter at [www.masshiway.net](http://www.masshiway.net). In addition, meetings of the state's [HIT Council](#) often discuss the Mass HIway, and are open to the public.

Visit [www.masshiway.net](http://www.masshiway.net) - Email [MassHIway@state.ma.us](mailto:MassHIway@state.ma.us)