ConnectedHealthInitiative

Healthcare Requires Data Interoperability

The law is clear: providers must give patients access to their own healthcare information. Accomplishing this with interoperability benefits not just patients, but the rest of the healthcare ecosystem as well.

To make interoperability a reality, Members of Congress must take two common sense steps to ensure that patients, caregivers, and providers can benefit from advances in healthcare technology:
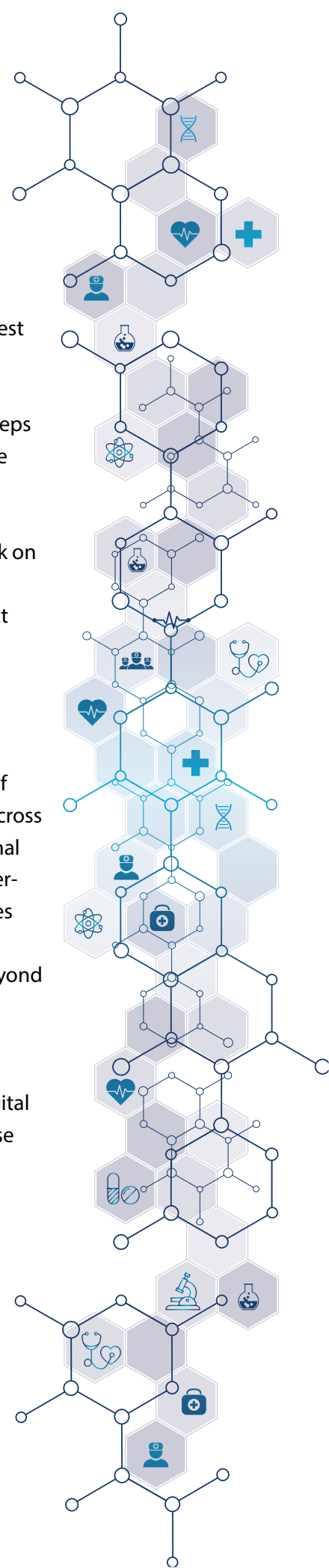
1. Demand that the Department of Health and Human Services (HHS) complete its work on the information blocking rules and enforce them; and
2. Support consideration and passage of the Better Interoperability for Devices (BID) Act (H.R. 1557).

Information Blocking Rules

Congress and HHS created a framework that promotes progress on the interoperability of electronic health records (EHRs) so that patients' data can be understood and analyzed across providers and the continuum of care. As part of that framework, HHS' Office of the National Coordinator for Health IT (ONC) oversees a process that periodically updates the interoperability standard certified EHR technology should use. Unfortunately, some EHR companies still block patients from access to their own health records to be used outside the Health Insurance Portability and Accountability Act's (HIPAA's) scope, which does not extend beyond providers and their contractors.

Congress mandated that HHS issue information blocking rules requiring EHRs to provide patients with access to their own health records in a format that is interoperable with digital health services. HHS has finalized those rules, but they are not yet being enforced because the agency is still working on a formula for civil monetary penalties to punish violations. **Congress needs to push HHS to complete its work on the information blocking rules and enforce them.**

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The Better Interoperability for Devices (BID) Act (H.R. 1557)

Although ONC has a framework to encourage data interoperability within the scope of HIPAA, no analogous framework exists at the Food and Drug Administration (FDA) to encourage data interoperability between medical devices or between medical devices and EHRs. Fortunately, Reps. Miller-Meeks (IA-1), Craig (MN-2), Murphy (NC-3), and Schrier (WA-8) introduced the Better Interoperability for Devices (BID) Act (H.R. 1557) to begin the development process for this effort. We urge Members of Congress to advance this critical legislation.

The BID Act would better position policymakers to improve conditions for patients and care-givers in these contexts by requiring:

- A review of existing device interoperability standards and the extent to which they have been adopted;
- A discussion of how interoperability could support home-based care, patient access to data, telemedicine, and data sharing, and any relevant privacy and security considerations or options associated with interoperability;
- An assessment of patients' current ability to obtain standard data from devices;
- An analysis of the cost burden on healthcare providers and others with the adoption of interoperability; and
- Recommendations to improve adoption of device interoperability, including needed guidance, regulatory, or statutory changes.

Consider a few examples that help illustrate why medical device interoperability is key:

- **Hospitals.** Hospitals are connecting devices with different functions to produce a picture of a patient's condition for physicians who may not be physically close to the patient. For example, hospital personnel benefit from infusion pumps being connected in real time with heart monitors, so that they can react to a heart monitor's reading quickly by adjusting the infusion pump. Uneven interoperability between devices impedes hospitals' ability to leverage these connected systems.
- **Telehealth and other virtual care.** Remote patient monitoring has become a critical element of prevention and treatment. As connected device sensors and analytics capabilities become more sophisticated, manufacturers are not always making them interoperable with certain kinds of EHRs or with other devices. Connected health technology has grown during the public health emergency, making interoperability more important than ever.
- **Implanted devices.** For patients to use implants like cardiac devices and insulin pumps to their full potential, they must be able to analyze the data the devices produce against other data, including from their providers or other devices.