



For Immediate Release
Wednesday, January 20, 2010

Grassley asks hospitals about experiences with federal health information technology program

WASHINGTON --- Senator Chuck Grassley has sent letters to 31 hospitals nationwide asking about their experiences in implementing the \$19 billion federal health information technology program launched last year.

“Given the taxpayer investment and the investment of the health care system overall in the information technology industry, the more Congress and others overseeing implementation of this program dig into the problems and work to get them sorted out now, the better,” Grassley said. “Hospitals are on the front lines and their perspective will be very valuable in this effort, so I look forward to hearing what they have to say about expanded use of health care information technology.”

Grassley said that his survey of hospitals is based on concerns brought to his attention in recent months, including administrative complications, formatting and usability issues, errors and interoperability. Some health care providers have told him that software is producing incorrect medication dosages because it miscalculated body weights by interchanging kilograms and pounds, for example. And, some of those providers have expressed frustration about the response, or lack of, they get when they take those kinds of problems to the vendors or the hospital administration.

Last fall, Grassley wrote directly to major health information technology vendors regarding these kinds of issues and concerns. He is currently reviewing responses from the vendors who received a letter from him. The vendors are the Cerner Corporation, 3M Company, Allscripts, Cognizant Technology Solutions, Computer Sciences Corporation, Eclipsys, Epic Systems Corporation, McKesson Corporation, Perot Systems Corporation, and Philips Healthcare.

This week, Grassley sent his letter to the following hospitals: Banner Health, Brigham & Women’s Hospital, University Hospitals Case Medical Center, Catholic Healthcare West, Cedars Sinai Children’s National Medical Center, Geisinger Medical

Center, Hackensack Hospital, HCA TriStar, Intermountain Healthcare, Indiana University Hospital, Jefferson Regional Medical Center, Kaiser Permanente System, Marshfield Clinic, Massachusetts General Hospital, Mayo Clinics, Memorial Hermann Healthcare System, Methodist Hospital of Indiana, North Shore-Long Island Jewish Health System, Palo Alto Medical Foundation, Rainbow Babies and Children's Hospital, Saint Mary Mercy Hospital, Seattle Children's Hospital, Stony Brook University Medical Center, Trinity Hospital System Tufts Medical Center, University of California San Francisco Medical Center, University of Pennsylvania Health System, University of Pittsburgh Medical Center, University of Virginia Medical Center, and Vanderbilt University Hospital.

The text of Grassley's letter is below.

January 19, 2010

Dear _____:

As Ranking Member of the Senate Committee on Finance, which has jurisdiction over the Medicare and Medicaid programs, I have a special responsibility to protect the health of the programs' more than 100 million beneficiaries as well as the congressionally authorized tax dollars used to fund these programs. This includes ensuring the effective and efficient use of taxpayer money by the health care industry in implementing Health Information Technology (HIT), such as Computerized Physician Order Entry systems and Electronic Health Records.

In recent legislation, approximately \$19 billion in taxpayer funds was appropriated to encourage development and implementation of HIT systems, which further emphasizes the importance of responsible use and thorough oversight. Over the past several months, however, I have been made increasingly aware of difficulties and challenges associated with HIT implementation. The reported problems appear to be associated with administrative complications in implementation, formatting and usability issues, and actual computer errors stemming from the programs themselves, as well as, interoperability between programs. For example, I have heard from health care providers regarding faulty software that produced incorrect medication dosages because it miscalculated body weights by interchanging kilograms and pounds.

In addition, I have heard from health care providers around the country that when they report such problems to their facilities and/or the product vendors, their concerns are sometimes ignored or dismissed. Some sources recount difficulties in approaching the HIT vendor with problems and the lack of venue to discuss these issues either with the vendor or peer organizations. Often this is attributed to alleged "gag orders" or non-disclosure clauses in the HIT contract that prohibit health care providers and their facilities from sharing information outside of their facilities regarding product defects and other HIT product-related concerns.

Some HIT products, I understand, are medical devices regulated by the Food and Drug Administration (FDA). Therefore, the manufacturers of these devices are required

to meet specific reporting requirements, such as the reporting of adverse events to FDA's Manufacturer and User Facility Experience database. However, for HIT products that may not fall under FDA regulation, there appears to be a lack of a national system for reporting product errors or failures and adverse events associated with the use of such products. Thus, problems with these products may go without remedy thereby inhibiting the ability of the health care professional to provide quality care and potentially impacting patient safety. Furthermore, contractual restrictions on the sharing of experiences and information related to specific vendor products limit a health care facility's ability to make informed decisions about HIT adoption and implementation.

American taxpayers and health care facilities across the country will be investing substantially in the HIT industry, and it is important that their monies are appropriately spent on effective and interoperable HIT systems. In October 2009, I wrote to ten major HIT companies regarding similar issues and concerns. The purpose of today's letter is to gather information from hospitals regarding their perspective and experiences with HIT. Accordingly, I would appreciate your response to the following questions and requests for information regarding the HIT products being implemented at your facility and any issues or concerns that have been raised by your health care providers. Unless otherwise noted, the requests cover the period of January 1, 2007 through December 31, 2009. In responding to this letter, please repeat the enumerated question and follow with the appropriate response and documentation.

1. Please describe in detail your facility's process for identifying HIT products for purchase and choosing an HIT vendor(s).
 - a. What is the personnel structure of those involved in the purchase?
 - b. To what extent do physicians and other health care providers within your facility provide input regarding the specific HIT items to be implemented within your facility?
 - c. Who or what department within your facility is responsible for making HIT purchase decisions?
2. Three of the companies that I wrote to in October 2009 informed me that they do not manufacture HIT software or hardware, but instead assist their health care clients, such as hospitals, with the implementation and management of HIT systems. To what extent do you contract with such entities to assist with the purchase, implementation and/or management of HIT products in your facility?
3. Please describe the training process implemented in your facility to familiarize employees with new technology systems.
 - a. How does your facility budget for HIT training?

- b. What are the vendors' roles in helping your facility train in the use of their products?
4. Does your facility have any policies or processes governing the reporting of problems or concerns by your health care employees related to the HIT products or systems implemented in your facility? If so, please provide a description of the policies or processes. If not, please explain why not.
5. When patient care and/or safety problems related to HIT systems arise, how are these problems reported within the facility and what is the process or mechanism for addressing them?
 - a. Are these problems also reported to the HIT vendor, and if so, what is the process for reporting them?
 - b. If patient care and/or safety problems related to HIT systems are not routinely reported to the HIT vendors, please explain how your facility decides which problems or issues are reported to a vendor and/or addressed by a vendor and which problems are addressed internally by the facility.
6. Please describe in detail any system your facility has in place to document, track, catalogue, and maintain complaints, concerns or issues related to HIT products that may directly or indirectly involve or impact the delivery of care or patient safety.
7. Please provide a list of HIT problems or complaints that have been identified by or reported to your facility since January 2008 that directly or indirectly impacted patient safety or the delivery of care, including any complications or adverse events that have occurred as a result of HIT product design and/or usability. Please describe whether and how each of those problems or complaints was resolved and whether these issues have resulted in a change in policy to prevent the problem in the future.
8. Does your facility have policies regarding the discussion of problems in your HIT systems with other health care facilities or with government officials or any individuals or entities outside your facility? If so, please describe those policies. To what extent are these policies driven by contractual agreements with the HIT vendors, and to what extent do they stem from internal processes? Please provide examples of contracts with HIT vendors that include non-disclosure clauses.
9. Some of the HIT vendors stated specifically in their responses to me that they do not include language that would hold them harmless for failures of their products or for the company's own negligence or recklessness. However, they may include provisions that spell out the vendor's and the health care client's respective legal responsibilities and obligations in the use of the product. For

example, one vendor stated that it is accountable for the performance of its product as long as the client uses the product appropriately. Another vendor stated that it is not liable when harm or loss results from the client's use of the product in diagnosing and/or treating patients.

- a. Do any of the HIT vendors include language in their contracts with your facility that could be considered "hold harmless" provisions, i.e., the transferring of liability associated with the services or products provided to your facility, or otherwise limit their liability? If so, please provide a copy of sample contracts containing such provisions.

10. What is the relationship between your facility and any HIT vendors?

- a. HIT vendors that manufacture software, hardware and/or other products purchased by health care facilities have stated in their responses to me that they do not offer any financial incentives for purchasing their products, such as shares in the company or financial interests in a particular product. At least one vendor stated, however, that it does offer financial incentives in the form of discounts based on purchase size. Another vendor said that health care clients may receive royalty payments when the clients collaborate with the vendor to develop a product. What financial interest, if any, does your facility have in HIT vendors and/or their products?
- b. Do the vendors offer your facility and/or any of your health care providers any financial incentives for purchasing the vendors' products? If so, please describe the types and value of the incentives.

11. Did your staff, health care providers and/or facility receive any payments, product discounts, or other items of value from any vendor for discussing and/or promoting that vendor's HIT products? If so, please list the different types of payments and discounts and their value.

I look forward to your cooperation and assistance on this important matter. Please provide your response to the questions and requests set forth in this letter by no later than February 16, 2010.

Sincerely,

Charles E. Grassley
United States Senator
Ranking Member