Is 'Speak No Evil' a Contract Clause?
Anonymous
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Sen. Charles Grassley frets that vendors use contractual clauses to hide software flaws—but he might not be getting the full story.

A new electronic health records-based and dangerous products sold to vendors is vendors that use excessive contractual provisions to shield themselves of responsibility and hide their mistakes. This is an influential United States Senate hearing by the Growing Risk:

Sen. Charles Grassley (R-Iowa), ranking member of the Senate Finance Committee, is investigating reports he has received that EHRs and commercialized physician order entry systems are plagued with flaws that can result in patient or financial harm. The investigations are being conducted under the Federal Trade Commission's authority to examine and investigate companies for potential violations of the Antitrust Act.

That investigation took a sharp turn in late February when Grassley sent letters (see sidebar: page 30) to the vendors demanding details on the potential risks of the software. These letters sent to Health and Human Services Secretary Kathleen Sebelius, and the influential Healthcare Information and Management Systems Society, trade association, asked for these details on a Bosconian position paper that called for voluntary industry oversight of the integrity of clinical systems rather than regulations (see sidebar: page 30). The paper was published in the *Journal of the American Medical Informatics Association*. The FDA, which was not involved in the investigation, ultimately declined to do so amid industry opposition.

Grassley's also concerned with contractual "hold harmless" provisions that shield vendors of responsibility for harm, and key words are common. As a matter of fact, a recent study found that all EHR contracts are subject to confidentiality and nondisclosure agreements that prohibit the providers from publicly disclosing problems with their software. It should be noted that various types of confidentiality and non-disclosure agreements are common in all EHR contracts in all industries, consumers, and attorneys who negotiate these contracts say. Grassley, however, wants to know if these clauses can be added to a way that potentially could jeopardize patient safety.

Grassley has been known to push for technology solutions that address the issues found in the EHR systems. "Over the past year, I have received complaints from patients, medical practitioners and technology experts regarding difficulties they have encountered with the EHR and CPOE devices in their medical facilities," the letter read. "These complaints include, for example, difficulty accessing patient information and incorrect medication dosages."
In the letter, Gransby asked for specific information on how vendors handled complaints about their products, whether their contracts and "hold harmless" in confidentiality clauses, whether providers received payments or discounts for purchasing the vendor's products, and whether they had utilized services related to HIPAA and CPOE products in the past 12 months.

Gransby, in a Finance Committee hearing, has called on Congress to codify health privacy legislation, including the American Recovery and Reinvestment Act, which includes Medicare and Medicaid incentive payments for meaningful use of electronic health records. In January, he sent letters to 31 hospitals or delivery systems, but no independent physician practices, asking similar questions. "Over the past 12 months I have been made increasingly aware of difficulties and challenges associated with HIPAA implementation," the letter states. "The reported problems appear to be associated with administrative complications in implementation, training and usability issues; and actual computer errors stemming from the programs themselves, as well as Internet security breaches and programs.

So the questions put on the table by Gransby: Are electronic health records systems sold in the United States unique? Are the products provided by vendors who promise themselves with stringent provisions in HIPAA contracts?

Industry insiders say these are indicative of Gransby's interest in launching a commentary critical of vendor contractual provisions that was published in March 2009 in the Journal of the American Medical Association. Providers, attorneys and others interviewed for this story declined to share specific contractual clauses in signed contracts, citing the proprietary nature of the terms.

In that JAMA article, co-authors Ross Koppel, MD, and David Keal charged that health IT vendors are "virtually impossible" if their products cause harm and provisions in many contracts prohibit customers from disclosing software features, even to other organizations using the same software. Further, it provides that, if a product or function of a product with a known, high harm-risk clause would have a very high legal barrier to challenge that clause, the legal fees are intended to be a substantial incentive to improve the product.

"There is a system that reduces the level of exposure to the public."

-Ross Koppel

Emory Health System in Philadelphia - noted to comment.

Timely debate

The industry needs to address the questions that now are key: Does Gransby in the Center for Population Health at Pennsylvania Health Information Systems at University of Pennsylvania School of Medicine, which is a software designer at The Social Research Corps, is a graphic designer for Medicaid's software program. But the key reason for the inquiry is that the provider in the situation in which he faces the possibility of a fine and severe legal consequences, but which physician practices don't have the advantage. "The average practice still only have 10 machines - not one can correct others' errors," Keal notes.

The challenge in the industry moves forward with HIPAA is not one that is familiar to the provider of the perfect cure and other features within small community hospitals such as data entry analysts, drug design calculations and decision support mechanisms, he believes. "The number of intended consequences is that they will reduce the number of times they are asked.

So let the debate begin, Keal says. "It is an important debate for now and the future. The challenge is to find an optimal balance between software and hardware, human and computer, and software and software. In that environment, developing a balanced system will encourage collaboration among us. So we have to create an environment where all can learn."
Grassley uses the "R" word

Sen. Charles Grassley (R-Iowa), who is investigating the safety of Health Information Technology, appears to be interested in exploring whether the Food and Drug Administration should regulate such products.

Grassley in late February sent letters to Health and Human Services Secretary Kathleen Sebelius, and M. Stephen Lepore, CEO at the Healthcare Information Management and Systems Society, asking for the organizations' views on a 1997 position paper that called for voluntary industry oversight of the integrity of clinical systems rather than regulation.

The paper was published in the journal of the American Medical Informatics Association. The paper, which included definitions of proposed risk categories of clinical systems and classes of regulation, concluded that clinical software did not meet standards for regulation.

The FDA, which started considering regulation in 1996, ultimately decided to do so amid industry opposition.

One of the questions Grassley asks of Sebelius is: “With over $3 billion in taxpayer money at stake and with increasing complexity in the technologies being used in our hospitals, do you believe it is time to revisit FDA's responsibilities in regulating HIT products being used in clinical care?” FDA is an agency within HHS. Officials were not immediately available for comment.

Among the questions to HIMSS: What is HIMSS's position on FDAs current role in the regulation of HIT products? Would you support providing the FDA with more authority in this area? Is there another agency that should be given authority to regulate the safety of HIT products? HIMSS does not presently have a position on FDA regulations.

Grassley has considerable legislative clout as the ranking member—the ranking Republican—on the Finance Committee. Last October, he sent letters to 10 health IT vendors asking how they handle complaints of faulty software and whether clauses in their contracts prohibit providers from discussing flaws with third parties, or shield vendors from liability for harm that results from the use of IT.

Grassley went a step further in January to 31 hospitals or health systems.

Grassley has long been a proponent of using technology to improve patient care and efficiency. His office has been pushing for the FDA to take a more active role in regulating HIT products, which he believes are becoming increasingly complex and critical to patient safety.

Grassley’s letter was a key issue in the regulatory debate, as it put the FDA on the spot to justify its current role in regulating HIT products. The FDA has been criticized for not having a consistent approach to regulating HIT, and the letter drew a response from the agency.

HIMSS received a letter from Grassley because the Center for Health Information Technology, a trade association, contributed to the 1997 position paper before its 2001 merger with HIMSS but did not fully support all positions in the paper, says Carla Smith, former leader of HIMSS and now executive vice president at HIMSS.

One of the recommendations in the letter was creation of local clinical oversight committees. Smith acknowledges the industry did not follow through on proposals outlined in the 1997 paper, including oversight committees. Asked why, she responds, “My guess is that the FDA cracked its inquiry.”

The industry did ignore its own proposals outlined in 1997 after the FDA dropped considering regulations, says a leading member of the American Medical Informatics Association, who requested anonymity. The AMIA played a role in developing the position paper.

At the same time, however, the FDA’s budget during the past decade has steadily cut and it doesn’t have the resources to adequately regulate, the source contends. “FDA has a lot of work to do,” the source adds.

FDA officials have stated that they are considering regulations for HIT products, but the process is slow and resources are limited.

Grassley has been a vocal advocate for improved regulation of HIT products, and his letter to the FDA was one of many he has sent to government officials on the issue.

In recent testimony before a Working Group of the HIT Policy and Standards Committee, AMIA CEO Ted Shortliffe, M.D., acknowledged the increasing complexity of electronic health records and other HIT systems, highlighting the need for robust regulatory frameworks.

The Working Group in its February hearing held a hearing on the safety of health information technology and one of the witnesses was Grassley. The meeting was part of the AMIA’s ongoing work to improve the safety of HIT systems.

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Tips When Negotiating Legal Clauses

When agreeing on legal language during health information technology contract negotiations, providers should ensure that, if need be, the contract will be interpreted in a court of law in the state where the provider is located, says Michael Myrick, principal at Meronomy Falls, Wis.-based Health Information Consulting LLC.

Vendors often want the court of jurisdiction to be in their state, which legally could be business-friendly Delaware even if the company is headquartered elsewhere.

It disputes rise to the level of lawsuits being filed, both providers and vendors believe their local court will be friendlier to the home-owned employer, such as a large hospital or vendor, so each of them will want to pick the court. But if the vendor is nationwide in scope, the provider should demand this negotiating point and be able to suit within its jurisdiction because the vendor was the party that chose to go nationwide, says Vince Claff, a consultant and principal at HIS Professional Inc., in Santa Fe, N.M.

Other tips for getting more palatable legal language in contracts include:

- Start at the beginning of the I.T. procurement process. As part of the request for proposals, press vendors to clearly explain their willingness to place limits on hold harmless provisions.
- Use the leverage of seriously negotiating with more than one vendor to get the most palatable legal language in the contract. If there’s another vendor willing to accommodate an organization’s concerns about certain legal clauses, make the most of that leverage during negotiations with the prime candidate.
- Large delivery systems able to leverage their buying power increasingly are starting negotiations with their own templates, says William Sprouse, CEO at Sharp Healthcare in San Diego. “You always have the take-off with vendors before you realize you’re not going to give in. You can only get away with what you try.”

When negotiating a health information technology contract with a vendor, supplement in-house or local counsel with corporate attorneys who specialize in health information technology contract law. “This is different than a Stark Act referral issue,” says Jeff Fine, an attorney and co-chair of the advocacy and technology practice group at the Petrilli Bluhourt law firm in St. Louis. The Black Act governs among other provisions, referral relationships between physicians and hospitals. “I’m not here to solicit people to call me, but I do want them to call someone who specializes in these issues.” General corporate attorneys don’t have relationships with vendors and can’t say that they’ve previously worked on legal issues with the vendors, concurs Peter Mancino, a partner in the health care law firm Garfunkel Wild P.C. in Great Neck, N.Y. “You have to know not just the I.T., but health I.T. And that’s more important today with all the new regulations coming after enactment of the HITECH Act within the American Recovery and Reinvestment Act.”

The bottom line is that providers, at least those large enough to have leverage, can get to some kind of fair allocation of risk through negotiation, Mancino says. “You may not lose it but you can live with it.”

In their JHA commentary, they focused on hold harmless or indemnification clauses that absolve vendors from liability for patent or intellectual property.

For Koppell says onerosous confidentiality provisions—that generally protecting intellectual property by preventing providers from going public with software problems—threat to patient safety and compliance with government regulations.

Under these clauses, a decision or CIOs, for example, cannot release the details of a software problem—such as discrepancies between the design of the drug ordered and entered into the system, or a lab report with data entered across several screens—or talk to other doctors about the problem. “I don’t know people who have gigabytes, so I don’t think the problem is as pressing as the Treasury letter implies,” says William Sprouse, CEO at Sharp Healthcare in San Diego. “If in a situation with patient harm, I would probably make it public, with or without a gig order.”

Consultant Michael Myrick, principal at Meronomy Falls, Wis.-based Health Information Consulting LLC, specializes in vendor selection and negotiation services. He doesn’t need many instances of bad-hearted contractual clauses that prohibit providers from talking in the public domain about software problems, but he has encountered situations where material clauses prohibited honest discussions about software issues.

In one instance, a provider needed to send a contract before exploring a software problem to a third party hired to fix the problem, and that language was inserted after negotiations with the vendor.

In another case, technicians who managed other applications that linked to the care system were denied access to review software without prior written approval of the care vendor. After bills, the vendor argued to not unreasonably deny access.

So, which brings brings intellectual property clauses? It’s primarily attorneys specializing in the legal side of health I.T. contracts.

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Consultants note that it's difficult to assess the impact of confidentiality clauses on the overall negotiation process. However, in some cases, these clauses can prevent the exchange of sensitive information necessary for a fair and informed decision. The use of confidentiality clauses can be justified under certain circumstances, such as where there are legitimate concerns about the protection of sensitive data.

Confidentiality clauses can be used to protect proprietary information, such as trade secrets, formulas, or pricing information. Such clauses are common in contracts for the sale of goods or services, and they are included to prevent the disclosure of trade secrets or confidential information to competitors. However, where confidentiality clauses restrict the exchange of information, they can create a barrier to effective communication and negotiation.

A recent study conducted by researchers at the University of California, Berkeley, found that confidentiality clauses significantly reduced the amount of information exchanged during negotiations. The study showed that clauses prohibiting the disclosure of confidential information led to a decrease in the number of offers made and the amount of information exchanged.

The use of confidentiality clauses can also create a sense of uncertainty and risk for both parties. While the clauses are intended to protect sensitive information, they can also create a sense of suspicion and uncertainty that may hinder the negotiation process.

Confidentiality clauses can also lead to disputes and legal challenges. If a party is accused of violating a confidentiality clause, they may be subject to legal action. This can create additional costs and delays, which can affect the outcome of the negotiation.

In conclusion, confidentiality clauses can be a useful tool for protecting sensitive information. However, they can also create barriers to effective communication and negotiation. Negotiators should carefully consider the use of confidentiality clauses and balance the need for protection with the need for open and honest communication.
with clinical decision support embedded in problem-solving templates. The vendor may say that the clinical content is provided "as is" and the customer is responsible for validating the content. Consequently, the customer makes the final decision on whether or not to rely on the content, so the vendor should not be held responsible for a wrong decision.

Judgment calls

Why do providers accept palatable, hold harmless language in HIT contracts? Sometimes intimidation plays a role. "When the contract comes with_buffered, capitalized letters, that's a warning shot across the bow that you don't want to fool around with this sentence," consultants Mychaylyk says.

Some in the vendor organization may want to leave the table and find another vendor, but the physicians in the organization may want the vendor's software. Further, while Mychaylyk has had success modeling hold harmless provisions, vendors are very adept at negotiating to provide that they are not responsible in the diagnostic business and should not be held responsible for diagnostic decisions.

And the vendors have a degree of justification in making that argument, concludes Rorschach's Chief. "Anecdotes of incredible wrong in an information system, such as the system putting the wrong patient on the test: "Doctors and hospitals are in the business of the patient," he says.

To some degree, the provider has to be culpable, Costa says, just as a taxpayer may get advice from an attorney, but the taxpayer still signs the tax form on the return. Providers do acknowledge that vendors have valid reasons for wording hold harmless language; they just don't want to add the entire legal jargon.

"The vendor gives you a tool set, but they generally don't own the content," says Frank Richards, CEO at Geisinger Health Systems. "So, as long as the logic is "as is," the cost is up to the provider. There's so much due diligence on providers as on vendors."

Further, providers need to use their judgment even if the logic isn't "as is" and they don't know it, he believes. For instance, a physician's head wildly out of parameters should be double checked before a provider acts on that information, Richards says. "There needs to be some standard that vendors are held to about the quality of their products. But so much about this is about the professional judgment of providers. Without professional judgment, it's easy to inadvertently introduce errors that could cause problems.

A big problem on the provider side is a false understanding of how much testing is needed to verify appropriate performance of information systems, particularly those with clinical decision support, Richards believes. "You ask what scares me—this is it."

Hashing it out

Because both providers and vendors have palatable reasons for their stance on hold harmless clauses, there's room to negotiate compromise language. "I understand vendor concerns," says spokesman of Sharp Healthcare. "But they also come out and say their obligations have much more to do if you use their products."

Vendors often have language in their contracts in which as a result of any such act, the vendor shall be responsible for damages incurred to the aggregate of the software license for the prior 12 months. "But that's not the case," Costa says. "That's not a clause that is per se in many cases and can be modified to exclude all costs."

Sometimes, a hold harmless clause can be categorized as a shared risk agreement in which both parties have defined responsibilities. "We hold liability in such cases, says Van Del Beek, partner for contract language that effectively states, "We will be responsible for our errors and you will be responsible for your own." He says that vendors have similar hold harmless language when making medical devices; the issue is not unique to HIT systems.

Sometimes vendors make an argument that the device is reasonable, but shouldn't be accepted immediately, advises consultant Mychaylyk. "Vendors may say, 'We don't take responsibility for this product,'" he explains. "We say, 'That's the platform you selected to build on.'"

One area that needs to be critically examined is software under the same product.

"There needs to be some standard that vendors are held to about the quality of their products."

—Frank Richards

This agreement shall not be construed to create a contractual obligation for either party to indemnify the other for loss or damage resulting from any act or omission of the other party or its employees, directors, officers, and agents. Section shall not constitute a waiver by either party or any rights to indemnification, contribution or subrogation against which the party may have by operation of law.

- Each party shall indemnify and hold harmless the other party, its directors, officers, employees, agents and employees against any and all claims, demands, suits, damages, injuries, losses and expenses, including legal fees, whether incurred or paid in settlement of judgment (all collectively "Claims"), that may or may result to any wrongful act or negligence of the respective party under this agreement.

When instrumenting Healthcare says what it considers to indemnify - harmless language, "We will definitely attempt to negotiate a more palatable clause," they say. That could include instead risk by and judgment with dollar caps on damages. They note that providers have similar hold harmless language when purchasing medical devices; the issue is not unique to HIT systems.

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that are from acquired companies. Myr-rych says these cobbled-on modules can have serious performance issues.

**What's Grassley up to?**

The absence of an explanation from Sen. Grassley about what he's up to leaves industry stakeholders to hazard their own guesses.

The industry more than 10 years ago successfully fought efforts within the Food and Drug Administration to regulate clinical information systems. EHR commentary co-author Koppel notes that Grassley was a bit of a regulator, but he also has considerably close to ranking member of the Finance Committee.

Koppel's own views on regulation are different than a decade ago. "I didn't want regulation, but the vendors are asking so much. I'm being persuaded that regulation is the other way."

Why is Grassley focusing mostly on the hospital market, which already is more automated than physician practices? Koppel thinks many physician EHR vendors are still a long way from even having one. "They do the smallest thing, probably follow in some fashion."

The prospect of regulation isn't attractive to all stakeholders. It's downright alarming to some CEO who requested anonymity, who believes regulatory compliance will add another step to ensuring patient records. "One of the biggest risks to Grassley is looking to move EHR regulation to the FDA. Since the FDA started regulating blood bank software, you can't get bugs fixed and comply with it in the time it takes years and will suffer mutations."

Whether Sen. Grassley is on the right or wrong track with his investigation, the industry will benefit from this debate, says Sharp Healthcare's Spencer. Vendors, he says, take quality improvement seriously and his vendors are better today than just two years ago, "but we need it to be faster."

While Spencer understands concerns about vendors, Grassley spends a lot of time dealing with software that's not performing optimally. "It burns my timetable when I have to do a lot of debugging."

Spencer believes Grassley is untangling to some extent because he didn't get much pushback from the companies that he talked to the vendors. "He's looking for doing it in a way that will advance patient safety or health IT, but that's what he's doing it for."

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