Organization works toward improving medication, patient safety

Continuing Education Objectives

After reading this article, you will be able to:

- Identify health conditions the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) teams targeted during their initial program
- Define the role of a PSPC team

Everyone in healthcare knows about the struggles of medication reconciliation and its impact on patient safety and care. The Joint Commission takes notice, building standards and safety goals around safe use of medication, and every facility must take the time to look at its policies and procedures to minimize negative outcomes.

Enter the Alliance for Integrated Medication Management (AIMM). AIMM is a nonprofit organization, which is working to expand, extend, and accelerate the work of the PSPC. The PSPC is an effort to coordinate healthcare by integrating clinical pharmacy services into the care and management of high-risk patients suffering from multiple chronic health conditions, such as:

- Diabetes
- Hypertension
- High cholesterol

The number of successful Patient Safety and Clinical Pharmacy Services Collaborative teams in operation under the Alliance for Integrated Medication Management after the first three years of the program.

$5 billion

The amount of money expected to be saved as a result of the two dozen changes announced by CMS in its March memo.

$1.4 million

The dollar amount awarded the plaintiff in a HIPAA violation suit against a Walgreens pharmacy.
 Standards proposed for new blood management certification program

The Joint Commission’s Laboratory Accreditation program announced in August 2013 that it is developing a patient blood management certification program for Joint Commission-accredited hospitals. The process of patient blood management involves providing a patient-centered approach in the hospital for blood utilization activities as well as blood conservation.


CMS renews HFAP deeming authority

The Healthcare Facilities Accreditation Program (HFAP) has received its continued status as an accrediting organization for hospitals through CMS. The notification was posted in the August 28 Federal Register and goes into effect September 25, 2013.

Accrediting organizations must reapply for deeming authority at least every six years. This decision provides HFAP with deeming authority through September 25, 2019.


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The PSPC teams use evidence-based practices that significantly improve patients’ health and safety.

The PSPC is designed to foster community partnerships to establish healthcare delivery systems specifically for patients with multiple chronic conditions who need help with adherence and monitoring of their medication regimens.

Teams of healthcare professionals integrate clinical pharmacy services with primary care services to support patients and providers with coordinating medication use and achieving desired clinical parameters, such as lower blood pressures and target A1C levels.

BOJ had a chance to chat with Todd Sorensen, PharmD, FAPhA, executive director of AIMM and a professor with the College of Pharmacy at the University of Minnesota, to find out more about the work this organization is doing nationwide.

“The collaborative started in 2008 at the direction of the Health Resources and Services Administration [HRSA],” says Sorensen.

The focus, at the beginning, was on safety net organizations, which are the HRSA’s mission. HRSA established a research team to examine the successes of 30 organizations recognized for high performance in medication management. The identified strategies were categorized and disseminated through a “Change Package”—a menu of strategies proven to support quality improvement in medication management used by teams to set their quality improvement agenda.

“They identified small groups of patients to focus on initially, and measure the differences made in those groups,” Sorensen says.

But HRSA knew this was not a process it could or should maintain forever. And so, post-HRSA, AIMM grew into a separate nonprofit, which was originally incorporated in 2011 and has grown significantly every year since.

“In year one, we had 75 teams, which grew to 125 in year two and more than 360 in year three,” says Sorensen. “We’re no longer just about safety net organizations—CMS has determined there is value in this and we have brought all Quality Improvement Organizations [QIO] into this concept.”

This involvement with QIOs has given the PSPC teams a reach they did not have before.

“This places a quality improvement expert working with us in each state,” says Sorensen. “They can go into healthcare organizations and help them. We didn’t have someone in every state before.”

The QIO experts are not staff members of the collaborative, but they are very much part of the collaborative effort.

“We have regional cluster coaches working with QIOs and teams, and facilitating regional discussions,” says Sorensen.

**Evolution of the program**

Five years in, there are a number of teams that have moved past just improving patient safety and onto more advanced concepts—such as defining the value of...
the program and building a financial system to keep it sustainable, says Sorensen.

“As teams progress, we need to adapt to them,” says Sorensen. “They’re learning what’s working in their organizations, and through them we’re learning what is working in the highest performing organizations.”

It is important to note, Sorensen says, that this was never meant to be a program that would find one perfect answer to medication safety.

“We hope to have some powerful examples of the differences that have been made as a result for these patients,” he says. “This was not designed as a research study—the measurement occurs at the community-based level.”

Because the data and analysis is occurring on the community level—and is so often tailored specifically to the facility or organization in question—finding a big picture, cohesive answer is nearly impossible. But what is definitively clear is that those tailor-made processes are making a difference.

“What we know in polling the teams is that when they are put in place, they are improving the chronic health of patients,” says Sorensen.

So how is that individualized process crafted?

The teams typically start with a focused group of patients.

“They don’t take random groups,” says Sorensen. “These patients are all not at goal [meeting expectations for health].”

And although there isn’t one cookie-cutter method the PSPC groups are using, there is a uniform result: Six months later, regardless of which chronic condition or conditions they are focusing on, these teams can get at least 50% of those patients under control in terms of medication, health, and potential for readmission or further complications.

This happens through learning and doing, says Sorensen. And while the tactics are hard to measure, the results are not: One group, for example, was able to get hospitalization rates for anticoagulants down to half the national average. These patients, because of the improved safe usage of anticoagulants, were hospitalized at a significantly lower rate than patients across the country not participating in a similar improvement program.

It’s worth noting that it is not just the patients who benefit from this sort of improvement. In some cases, the organizations are able to get health plans to pay for the types of services PSPC teams are able to develop and provide when they would not previously, because they are able to show a difference in both quality and overall cost to the organization.

“We have seen payment opportunities arise because of this work,” says Sorensen.

Empowerment

The PSPC groups focus on patient care first and see a fringe benefit in terms of cost second, but it is also important to note another key word: empowerment.

“We give these groups the resources to help them find solutions that work for them,” says Sorensen.

The outpatient care providers and organizations are empowered to craft their own medication reconciliation and safety solutions without trying to fit into a national mold.

And then, by sharing positive results, other organizations are further empowered to take ideas and inspiration from similar organizations and put their own spin on those concepts.

“They might be doing it in different ways and in different places, and we collect what they’ve done so we can share it with others,” Sorensen says.

AIMM offers webinars and national learning opportunities, and while there are faculty members, most of the teaching and presentations are done by those in the field who have found a method to share.

Although the PSPC teams are primarily working with outpatient organizations, many of those outpatient facilities are part of a larger system or hospital, and so AIMM is interested in any type of group which believes it will benefit from this process.

“We may begin looking at transitions of care, chronic health management within systems as we evolve our work with our most advanced teams,” says Sorensen.

Interestingly, though, while AIMM is open to working with hospitals, there is a philosophy in the organization of trying to keep patients out of hospitals—rather than focusing on the revenue of full beds, the overall
goal is to help patients avoid hospitalization and rehospitalization.

“We’re bringing groups together to improve results in the outpatient setting,” says Sorensen. “As they build this model, it’s about keeping these patients out of the hospital, and a lot can be done in the transition of care between inpatient and outpatient.”

In addition to working with outpatient settings, AIMM has had a number of long-term care facilities join as well.

“One of the areas of focus for us is ensuring appropriate use of antipsychotic medications,” says Sorensen.

The core principles of the PSPC teams can be applied to almost any setting, however.

“Because you can focus on whatever area you want and apply the tools appropriate to it, this concept really isn’t limited by setting,” says Sorensen. “We don’t know where this is going to go yet, but we see on the horizon transitions of care and readmissions may be a focus in the future.”

The No. 1 reason patients are readmitted to the hospital is medication-related issues, he notes. For that reason, AIMM is looking at means to merge initiatives with other organizations focusing on readmission rates.

“It’s an area we should be looking into ourselves,” says Sorensen.

With the program going strong for half a decade with significant growth every year, AIMM and its participants have high hopes moving forward.

“Success has been difficult to document in traditional terms, but it’s there based on our growth, the engagement of our teams, and the benefits identified by individual teams,” says Sorensen.

These teams are improving the health of patients and expanding services to more and more patients every year. AIMM is always open to new participants and additional organizations joining the effort.

“These resources have value to them, and we welcome their involvement,” says Sorensen. “As the saying goes, a rising tide lifts all boats. What we learn across the country is that any additional participants are going to share something of value and gain something of value as well.”

What kind of results have PSPC teams seen?

According to the Alliance for Integrated Medication Management (AIMM) website, the Patient Safety and Clinical Pharmacy Services Collaborative (PSPC) has seen significant results. A report released in 2011 summarizing the success of teams based on tracking the impact the team had on patient health detailed some findings worth noting:

- In diabetes patients who had A1C levels “out of control,” 35% achieved desired levels within six to 12 months
- In patients with hypertension with blood pressures above desired levels, 43% achieved desired blood pressure levels within six to 12 months
- In patients with dyslipidemia and persistently high cholesterol levels, 37% achieved desired levels within six to 12 months
- In patients taking anticoagulation medications who had International Normalized Ratio (INR) levels consistently out of control, 51% achieved INR levels in the safe range
- Improvements were also seen among patients with uncontrolled asthma (32% achieving control); depression (11% with improved depression); and HIV/AIDS (45% with improved viral levels), by the teams tracking those populations

In addition, teams reported a decrease in the average number of adverse drug events (ADE), from 0.7 to 0.5 ADEs per patient. The average number of potential errors per patient decreased from 1.5 per patient encounter at startup to 0.8. According to AIMM and PSPC, in most cases, a key change made by teams was integrating clinical pharmacists into the primary care service delivery system.

According to a report issued by the Institute of Medicine, an average of 35% of the cost contributed by patients with extremely uncoordinated care could be avoided with coordinated care that incorporates comprehensive medication management.
CMS memos every hospital should know, Part 2

Continuing Education Objectives

After reading this article, you will be able to:

• Describe adverse events related to luer misconnections
• Identify new Interpretive Guidelines premiering in 2013
• Discuss reporting adverse events into the performance improvement system

Editor’s note: Sue Dill Calloway, RN, MSN, JD, CPHRM, CCMSCP, is a frequent contributor and BOJ advisor. She can be reached at Sdill1@columbus.rr.com.

Last month in BOJ, we began our discussion of a number of key memos CMS has released impacting hospitals this year. Let’s continue our analysis by examining luer misconnections, new Interpretive Guidelines, and changes to reporting adverse events.

Luer misconnections

CMS issued a four-page memo on March 8, 2013, regarding adverse events related to luer misconnections. It is a problem when two ends fit together but don’t belong together. Nurses and others can mistakenly connect the wrong device and deliver substances through the wrong route, like putting chemotherapy into an epidural line instead of the IV line. The surveyors want to see whether the hospital has taken actions to ensure systems are in place to prevent this type of adverse event. Many hospitals have policies and procedures on this, and provide education for staff orientation. For example, after filing a report, a nurse can follow the tubing from the IV down to the insertion in the peripheral IV.

CMS encourages hospitals to report this occurrence to the FDA even if there is no adverse event. This issue has been taught in the patient safety arena for many years and was the topic of a Joint Commission Sentinel Event Alert in 2008. The ISMP published many articles on this topic, including one on July 15, 2010, that mentions oxygen tubing found connected to an IV; bladder irrigation given as IV fluid; TPN administered in enteral nutrition; and IV tubing connected to an ET tube or a tracheostomy tube. The Pennsylvania Patient Safety Authority released a toolkit on tubing misconnections in June 2010. That report found about one misconnection occurred per month.

The new Interpretive Guidelines

CMS issued a memo on March 15, 2013, detailing the new Interpretive Guidelines. Hospitals had waited for these for more than 10 months. These were based on the final regulations that went into effect July 16, 2012. CMS made more than two dozen changes that it estimated would save hospitals more than $5 billion. This is an important memo for hospitals. It included new tag numbers for the death of patients in one or two soft wrist restraints. It created the new tag number 457 for standing orders and new tag numbers 412 and 413 in the nursing standards related to self-administered medication. This memo included changes to hospitals including critical access hospitals. The new Interpretive Guidelines are included in the updated CMS hospital manual that was issued June 7, 2013. The new manual is available at www.cms.hhs.gov/manuals/downloads/som107_Appendixtoc.pdf.

Reporting adverse events into the PI system

CMS issued an eight-page memo on March 15, 2013, that reminds hospitals they are required to report adverse events into the hospital’s Quality Assessment Performance Improvement (QAPI) reporting system. The memo was titled “AHRQ Common Formats - Information for Hospitals and State Survey Agencies (SAs) - Comprehensive Patient Safety Reporting Using AHRQ Common Formats.”

Several reports show that nurses and others were not reporting adverse events (AE) and those AEs were not getting into the PI reporting system. The Office of Inspector General (OIG) recommends using Agency for Healthcare Research and Quality (AHRQ) Common Formats to help with the tracking. The OIG said it could help hospitals improve the reporting process, noting that 86% of all AEs are never reported to the PI program. CMS encouraged all surveyors to develop an understanding of this tool. CMS recently changed QAPI to mean quality assessment performance improvement as opposed to quality assurance.
In the CMS hospital Conditions of Participation (CoP), the PI section requires hospitals to track AEs, analyze their causes, and implement actions to prevent them in the future. In fact, CMS’ third worksheet, issued November 9, 2012, will ask hospitals to provide documentation that they conducted three separate root cause analyses. PI, discharge planning, and infection control will be hit hard during the survey process. The third and most likely final pilot runs through the end of September 2013 and is expected to be rolled out for hospitals in 2014.

CMS requirements include the reporting of near misses. The recommended AHRQ Common Formats are evidence-based. The Common Formats allow for identification and reporting of any AE, even if rare, and includes 29 National Quality Forum “never events” such as falls and medication errors. Modules in the Common Formats include blood, pressure ulcers, surgery or anesthesia, falls, perinatal, and medications. The Common Formats are located at https://psoppc.org/web/patientsafety.

In summary, there has been a lot of recent activity for hospitals regarding the CMS CoPs. There is now a new updated hospital manual. CMS has issued many memos that are important to hospitals. Hospitals need to have one person in their organization whose job it is, at least once a month, to review all memos.

### Administrative penalties: Defining and avoiding patient safety violations

**Continuing Education Objectives**

After reading this article, you will be able to:

- Describe the purpose of administrative penalties
- Identify common reasons behind the issuance of administrative penalties
- Discuss CMS’ role in administrative penalties

**Editor’s note:** The following report was authored by BOJ advisor Elizabeth Di Giacomo-Geffers, RN, MPH, CSHA, a healthcare consultant in Trabuco Canyon, Calif., and former Joint Commission surveyor.

The California Department of Public Health (CDPH) has issued 10 penalties to California hospitals after investigations that found that the facilities were noncompliant with licensing requirements that caused or was likely to cause serious injury or death to their patients. Total fines were $674,000.

The object of this column has always been to help and educate rather than to point fingers, so rather than call out these hospitals by name for their noncompliance, let’s take a look this month at what occurred and why CDPH found it necessary to weigh in with fines against them.

- **Hospital #1** received its second administrative penalty with this report, and was fined $50,000 for not following established policies and procedures for safe administration of parenteral nutrition.
- **Hospital #2** also received a $50,000 penalty, for not following established policies and procedures for telemetry monitoring.
- **Hospital #3** also was hit with a $50,000 penalty for not following established policies and procedures for cardiac catheterization.
- **Hospital #4** received its second administrative penalty for a more general finding of not following established policies and procedures related to patient safety. It was fined $50,000.
- **Hospital #5** received its fourth administrative penalty for not following established policies and procedures relating to respiratory care. This organization’s fine was more significant: $100,000.
- **Hospital #6** was also fined $100,000, for not following established policies and procedures related to patient care. This was the organization’s third administrative penalty.
- **Hospital #7** was fined $50,000 for not following surgical policies and procedures, which forced a patient to have a second procedure to remove a foreign object from his body.
- **Hospital #8** was also fined for not following surgical policies and procedures, resulting in a fine of
serious injury or death to the patient is an immediate jeopardy at the time it occurred.” However, correcting that situation does not mean it is no longer a case of immediate jeopardy. The organization can still be cited for the situation even after the incident has been abated and rectified.

Of course, with any situation where surveys are conducted and fines levied, the question must be asked: Will there be an effort to measure this law’s effectiveness—in this case, its ability to improve patient safety and healthcare?

CDPH will evaluate data collected and will be able to compare the number of violations and deficiencies to the number of immediate jeopardy deficiencies issued from year to year to determine whether the number of violations or deficiencies is changing over time, according to the department’s official FAQs. Under this law, hospitals are required to develop plans of correction for immediate jeopardy situations assessed against them.

These fines are not the only risks noncompliant hospitals face. According to CDPH, organizations can have their CMS (Medicare/Medicaid) funding terminated for noncompliance with the Conditions of

$75,000 (the organization’s third administrative penalty).
- Hospital #9, on its fifth administrative penalty, was fined $100,000 for not following surgical policies and procedures.
- Hospital #10 was fined $50,000 for not following established policies and procedures related to patient care.

“The posting of the administrative penalties should be used as a learning tool. It is important to review your hospital’s processes to ensure they protect against making similar errors,” says Lynne Whaley-Welty, RN, MS, chief nurse executive and senior vice president of clinical operations with the CDHP. “To err is human. By developing a deliberate process to review errors provides another layer of safety for our patients.”

It is important to note that prior to 2009, these incidents carried a fine of $25,000, but new legislation that went into effect in 2009 increased fines after that date: $50,000 for first violation; $75,000 for a second; and $100,000 for any subsequent one. Findings occurring before January 1, 2009, did not count toward this total.

Hospitals are required to provide CDPH with a plan of correction to prevent repeated incidents following their survey. They can also appeal penalties up to 10 days after notification of the findings.

But what are these administrative penalties and what do they mean on a larger scale? Let’s take a look.

Definitions and FAQs
An administrative penalty is defined as a civil, monetary penalty in the amount specified above per violation or deficiency constituting immediate jeopardy in the health and safety of a patient. Those penalties, according to the CDPH, are assessed against general acute care hospitals, acute psychiatric hospitals, and special hospitals after an investigation of the facility’s noncompliance of licensure.

Immediate jeopardy is a term in the accreditation world with which we are familiar. For clarity’s sake, let’s look at the CDPH definition: “A situation in which the hospital’s noncompliance with one or more requirements of licensure has caused, or is likely to cause We’re seeking experts for books, audio conferences, and seminars

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—Matt Phillion
Senior Managing Editor
CDPH does have the ability to levy fines of up to $25,000 for deficiencies or violations not on the immediate jeopardy level, but this will not take effect until CDPH develops regulations for various potential levels of fines. There is no timetable currently available for implementation.

**Adverse events**

All of this ties in directly to California Senate Bill 1301, which requires general acute care, acute psychiatric, and special hospitals to report adverse events as a means to heighten awareness of preventable medical errors in hospitals. The relatively new law is intended to increase oversight and raise public awareness.

These hospitals must report adverse events to CDPH within five days of detecting the event. They are also required to report ongoing urgent or emergent threats to the welfare, health, or safety of patients, personnel, or visitors no later than 24 hours after detection. The Licensing and Certification Program is required to conduct on-site investigations of all reported events.

**Lessons learned**

It is recommended that organizations review these administrative penalties to see what, if anything, can be done to prevent this from occurring in their hospitals. You should review plans of correction for opportunities to improve, and look for knowledge and/or system defects that may need redesign. Then implement changes accordingly and in a timely manner. And educate those who need to know and do ongoing audits, as applicable, for sustained compliance.

Links are provided below where California Administrative Penalties can be reviewed. The statute 2567 statement of deficiencies and plans of correction can be found at the links below. 

**References**

CDPH Issues Penalties to Ten Hospitals
[www.cdph.ca.gov/Pages/NR13-036.aspx](http://www.cdph.ca.gov/Pages/NR13-036.aspx)

Hospital Administration Penalties by County Summary
[www.cdph.ca.gov/certlic/facilities/Pages/Counties.aspx](http://www.cdph.ca.gov/certlic/facilities/Pages/Counties.aspx)

CDPH Frequently Asked Questions
CIHQ receives deeming authority

Continuing Education Objectives

After reading this article, you will be able to:

- Discuss the state of accreditation organizations and deeming authority for hospitals in the U.S.

A new player has entered the field for hospital accreditation: The Center for Improvement in Healthcare Quality (CIHQ) has received deeming authority from CMS for acute care hospitals. CIHQ joins The Joint Commission, DNV, Inc., and the Healthcare Facilities Accreditation Program (HFAP) in this arena.

Deeming authority allows an organization to accredit healthcare facilities, thus providing the hospital or healthcare organization an alternative to working directly with CMS or its home state to be accredited.

CIHQ announced its intention to pursue deeming authority two years ago.

“We believe that the fundamental purpose of a deemed-status agency is to ensure that an accredited organization is in compliance with the Medicare Conditions of Participation (CoP),” CIHQ executive director Richard Curtis, RN, MS, HACP, said in the organization’s official announcement. “We have the tools and resources to do so. The core of a deemed-status accreditation process should be to ensure that patients receive care in a safe environment by an organization that complies with the minimum standards set forth by the federal government. Your deemed-status provider should ensure this; provide you with the tools and support you need, engage with you in a collegial, respectful, and educational manner, and perform these services at a reasonable cost.”

For decades, the only accreditation options for hospitals outside of working directly with CMS had been The Joint Commission or HFAP, with The Joint Commission holding the lion’s share of the market.

In addition to acute care hospital accreditation, CIHQ also received approval for three disease-specific certification programs, which are as follows:

- Heart failure
- Hip and knee replacement surgery
- Primary stroke center

Standards based on CoPs

According to the organization’s FAQs, CIHQ has joined the growing trend in hospital accreditation of staying very close to the requirements set forth in the CMS Conditions of Participation.

According to the official FAQs page, “since the fundamental responsibility of a deeming authority is to ensure that a hospital meets the Medicare CoPs, it makes sense to assure that our standards are consistent with those regulations.”

CIHQ has also developed what it calls a “reasonable and modest set of additional standards” to address gaps in the CoPs and CMS Interpretive Guidelines.

Similar to other accrediting bodies, CIHQ has stated it will conduct full surveys on a three-year cycle, with a focused, mid-cycle survey occurring around the 18-month mark.

CIHQ anticipates a full survey will take three or four days and involve two to four surveyors, including a facilities specialist, which once again brings the organization in line with the arrangements of other accreditors. Mid-cycle focused surveys, meanwhile, are expected to be one day in length with a single surveyor.

CIHQ will not require reporting of core measure or quality measure data, though hospitals will need to comply with CMS requirements for data reporting. CIHQ will also not require reporting of sentinel events or root cause analyses for sentinel events. Additionally, the organization will not require internal self-assessments of standards compliance.

And finally, while ISO certification has become more and more common among accrediting organizations, CIHQ has elected not to require ISO or additional certifications, nor will it “mandate adoption of a particular performance measure or improvement program,” according to the FAQs.

More information on the new program can be found by visiting the official CIHQ website at www.cihq.org.
Continuing Education Objectives

After reading this article, you will be able to:
• Describe the risks and impact of HIPAA violations on a national organization

Editor’s note: Roger Shindell is CEO of Carosh Compliance Solutions, which specializes in HIPAA compliance consulting with small to mid-sized U.S. companies (www.carosh.com). He can be reached at rshindel@Carosh.com.

We talk often about the cost of Health Insurance Portability and Accountability Act (HIPAA) violations in terms of regulatory fines and penalties, and we may also mention that similar privacy regulations with their own fines and penalties exist at the state level.

But in the words of the late great Paul Harvey, “Now, the rest of the story.”

At the end of July 2013, a six-person jury awarded an Indiana woman $1.4 million in a civil action based on a HIPAA-type claim (Hinchy v. Walgreen Co., et al., No. 49D06 11 08 CT029165, Marion Co. Sup. Ct., Ind., filed August 1, 2011).

The complaint named Walgreens and a single Walgreens™ pharmacy employee as defendants and a single customer as a plaintiff.


Consider this: In 2012 the California State Legislature passed, and Governor Jerry Brown signed, a bill to amend the California Confidentiality of Medical Information Act (CMIA) (California Assembly Bill No. 439 Chapter 437). The CMIA provides for nominal damages of $1,000 even in the absence of actual damages to the individual whose medical information has been disclosed.

Now consider that in one study (Ponemon Institute, LLC, Second Annual Benchmark Survey on Patient Privacy and Data Security, December 8, 2011), the median-size medical record breach consists of 2,575 records.

You do the math. Is $1.44 million so out of line? Does anyone think the plaintiff attorneys aren’t taking notice?

Recently the company Lifelock™ has begun running commercials on medical record breaches and the fear of identity theft.

Would a company like Lifelock expend advertising resources if this fear didn’t resonate with the public?

Do you hear those plaintiff attorney hoofbeats a bit louder?

And we’ve only just begun. The hidden or “soft” costs of a breach of electronic personal health information far outweigh the costs from federal fines and penalties, as onerous as those might already seem.

Recent study results

According to a recent Ponemon Institute study (The True Cost of Compliance, A Benchmark Study of Multinational Organizations, January 2011—see Table 1), penalties and fees accounted for only about 15% of the total cost of a breach to the organization.

The majority of the costs were “soft” costs (i.e., those for which you don’t sign a check, but are real nonetheless).

Another survey by the Ponemon Institute (2013 Cost of Data Breach Study: United States; this study is not limited to medical record breaches) breaks down the non-regulatory costs associated with a medical record breach.

Costs are designated as direct costs, those that refer to the direct expense outlay to accomplish a given activity such as engaging forensic experts, hiring a law firm, or offering victims identity protection services.

And indirect costs—those which include the time, effort, and other organizational resources spent during the data breach resolution—include the use

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<td>Cost of noncompliance for four consequences</td>
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<tr>
<td>Business disruption</td>
<td>35%</td>
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<tr>
<td>Productivity loss</td>
<td>26%</td>
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<tr>
<td>Revenue loss</td>
<td>23%</td>
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<td>Fines, penalties, and other</td>
<td>15%</td>
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of existing employees to help in the data breach notification efforts or in the investigation of the incident. Indirect costs also include the loss of goodwill and customer turnover. In the Ponemon study, 32% of the costs were direct, and 68% were indirect, as detailed in Table 2.

**An accounting of costs**

As you can see, a breach disrupts not only the operations of the organization, but also its revenue cycle. Lost customers account by far for the largest cost component, at 36% of the total cost.

Before delving into the details of these costs, it is interesting to note that while the average per record breach, across all industries, is $188 per record, for healthcare the per record cost is $305.

This is not only the highest industry segment, but 62% higher than the average, and more than twice as much as the technology sector at $150 and 20% higher than the financial sector at $254.

In the above referenced study, Ponemon reports the median number of breaches as 27,724 (breaches in excess of 100,000 records were not included as not being representative) giving us the non-regulatory median cost of a healthcare breach as $8,455,820, as presented in Table 2.

What jumps out of this table is the expense associated with lost customer business. At 36% of the total, non-regulatory costs far outpace any of the other costs by more than 2 to 1.

If we add in additional customer acquisition costs, the revenue impact constitutes almost 50% of the total costs of a breach, not associated with a fine or penalty.

So how does the cost of compliance stack up against the totality of costs associated with a medical data breach? According to the Ponemon Institute study *The True Cost of Compliance*, noncompliance costs are 2.65 times higher than compliance costs.

In other words, for every dollar spent on compliance, the organization will see a $2.65 return in savings on deferred costs from data breaches that did not occur. I would challenge any organization to find this kind of return on investment from other investments.

Taken as a whole, the message is clear. Although we tend to focus on the fines and penalties associated with a health record breach, they tell only a small portion of the story, 15%.

More significant are the business-related costs, 85%. Layer on top of these costs the wave of costs related to civil litigation, investments in such activities as conducting internal audits, implementing and enabling technologies, compliance training, and expert staffing among other activities would be seen as a necessity, not a luxury for any organization looking to thrive in today’s business environment.

And by failing to prepare for PHI security, you are preparing to fail. Can you afford to?

### Table 2

<table>
<thead>
<tr>
<th>Median cost by breach cost categories</th>
<th>Percentage</th>
<th>Dollar amount</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigations and forensics</td>
<td>12%</td>
<td>1,014,698</td>
</tr>
<tr>
<td>Audit and consulting services</td>
<td>8%</td>
<td>676,466</td>
</tr>
<tr>
<td>Outbound contact costs</td>
<td>5%</td>
<td>422,791</td>
</tr>
<tr>
<td>Inbound contact costs</td>
<td>5%</td>
<td>422,791</td>
</tr>
<tr>
<td>Public relations/communications</td>
<td>1%</td>
<td>84,558</td>
</tr>
<tr>
<td>Legal services—defense</td>
<td>15%</td>
<td>1,268,373</td>
</tr>
<tr>
<td>Legal services—compliance</td>
<td>4%</td>
<td>338,233</td>
</tr>
<tr>
<td>Free or discounted services</td>
<td>1%</td>
<td>84,558</td>
</tr>
<tr>
<td>Identity protection services</td>
<td>4%</td>
<td>338,233</td>
</tr>
<tr>
<td>Lost customer business</td>
<td>36%</td>
<td>3,044,095</td>
</tr>
<tr>
<td>Customer acquisition cost</td>
<td>9%</td>
<td>761,024</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100%</strong></td>
<td><strong>8,455,820</strong></td>
</tr>
</tbody>
</table>

**Questions? Comments? Ideas?**

We at BOJ value and welcome your feedback and opinions. Do you have a response to any of this month’s articles? An idea for a best practice or success story you’d like to share, or a recent survey experience you would like to recount? We would love to hear from you.

Contact Senior Managing Editor Matt Phillion at mphillion@hcpro.com.