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INSIDE



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# Safety Risks in Food Services Can Be Underestimated

Food services is one area in the hospital that can have a profound effect on patient safety, but which does not always get proper attention from efforts to protect patients. Risk managers should assess the policies and procedures of food services and be sure to incorporate this department into all patient safety initiatives.

Dietary errors are a more common and more serious threat to patient safety than many risk managers realize, says **Susan C. Wallace**, MPH, CPHRM, patient safety analyst with the Pennsylvania Patient Safety Authority (PPSA) in Harrisburg. She recently authored a report for PPSA on food safety risks and found that 285 dietary errors were reported to the PPSA in a five-year period, with eight events causing serious harm to patients. The most common type of error involved meals delivered to patients who were allergic to a food item on the tray. *(For more on the report, see the story on page 28. See the story on page 29 for Wallace's research on another patient safety issue involving newborns.)*

> "THERE IS PLENTY ABOUT DIETARY INFORMATION FOR PATIENTS, BUT NOT MUCH SPECIFICALLY ADDRESSING THE POTENTIAL FOR PATIENT HARM AND HOW TO PREVENT THAT HARM."

When she worked in hospitals as a risk manager, Wallace received event reports regarding dietary events and began to realize that the threat was underestimated.

"There wasn't much written about this in the literature about this risk, not a lot of studies and advice," Wallace says. "There is plenty about dietary information for patients, but not much specifically



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addressing the potential for patient harm and how to prevent that harm."

Wallace researched the issue with dietary services professionals and found that they were more aware of the issue than the risk management community and developed strategies that should be incorporated into a hospital's overall patient safety efforts. One of the professionals she consulted was **Jennifer Ross**, director of nutrition services at Abington (PA) Jefferson Health hospital, who says healthcare organizations are only now recognizing the significance of food services in keeping patients safe. Her department typically prepares up to 400 trays per meal at the hospital.

"Earlier in my career, a few decades ago, there wasn't an acknowledgment that food service plays a huge role in keeping patients safe in addition to helping patients get better and serving emotional needs also," Ross says. "We have a huge impact on both safety and the patient experience."

## Staff Play Key Role for Safety

Allergy conflicts are the most common and obvious type of dietary error, but there are other ways a simple tray of food can threaten patient safety, Ross and Wallace note. Patients may be on diet restrictions of one sort or another, diabetic patients may need to choose certain amounts of specific types of foods for each meal, others may be on only a liquid or soft food diet, and many patients will be restricted from any food before surgery.

"The risk is more than theoretical. We have seen cases in which the wrong tray was delivered to a patient with an allergy and they did have a significant allergic reaction," Wallace says. "These were events that caused harm."

Frontline staff members play a key role in preventing dietary errors, Wallace says. It may be easy to assume that the biggest threats to patient safety have passed once the meal is prepared and on its way to the patient's room, but Wallace points out that the staff members delivering a meal face more challenges than one might imagine.

Patients' dietary restrictions might have changed since the meal was prepared, for instance, or the patient may have been moved to another room or unit. Some hospitals put dietary restrictions on the white board in the patient's room, along with other common notifications such as fall risk, Wallace says. That allows the dietary service staff member another chance to confirm at the last minute that the tray is appropriate.

Hospitals also use tools such as

## EXECUTIVE SUMMARY

Food services can play an important role in patient safety, but may not receive enough attention. Specific policies and procedures should address patient safety.

- Allergy conflicts are the most common type of dietary errors.
- Encourage staff to think of dietary errors as patient safety events.
- Recipe substitutions must be carefully monitored.

a wheel posted on the patient's door that can be changed to denote the patient's dietary status, or special stickers and wristbands.

"A patient's meal tray passes through so many hands, from the conception of that meal to cooking and putting the tray together to delivering it to the patient. Every one of those steps is a possible point of error," she says. "Staff members have to be educated about the importance of dietary services in patient safety, but they also have to be given the time and authority to do their jobs right, to take the time to check double identifiers, and to ask questions if something is not right."

## Encourage Safety Approach to Diet

Risk managers should encourage staff to report dietary errors as adverse events, remembering that not everyone makes that connection automatically. A patient receiving the wrong food tray might just be seen as a simple mistake unless it results in actual harm, but staff should be encouraged to report all dietary errors and near misses, she says. Once staff begin reporting dietary errors routinely, a risk manager may realize that there are more than previously realized, she says.

Patient satisfaction surveys and similar reports from patients can reveal potential patient safety threats, Wallace says, but you sometimes have to dig to find them. Like some staff, patients often do not associate dietary errors with patient safety unless actual harm occurs, so a patient's report of a dietary error may be buried in other information about the hospital experience, either as a minor complaint or throwaway comment. The patient may report receiving a particular food item he or she was allergic to, but another might casually mention receiving a tray with someone else's name on it, for instance.

Some allergy errors occur because dietary information is entered into the electronic medical record improperly, Wallace notes.

"The information is in the record, but not where you would expect to look for it," she says. "They might have put it under medication allergies because they didn't know where else to put it. You have to have established places in the record to put food allergies so that everyone is working under the same expectations."

"CONSISTENCY IS IMPORTANT. IF THE EMERGENCY DEPARTMENT PUTS A FOOD ALLERGY BAND ON THE WRIST BUT DOESN'T NOTE THE ALLERGY IN THE SAME PLACE IN THE RECORD AS EVERYONE ELSE, IT CAN STILL BE OVERLOOKED."

Staff are more likely to overlook or improperly record food allergies for patients admitted through the ED, Wallace says. Emergency patients often are not around long enough for food to be a concern, and procedures in the ED may be different from the standard admissions process, she notes.

"Consistency is important," Wallace says. "If the emergency department puts a food allergy band on the wrist but doesn't note the allergy in the same place in the record as everyone else, it can still be overlooked."

## Situational Awareness for Safety

Some states give dieticians the authority to change dietary prescriptions without going to the patient's doctor first, Wallace notes, which she says can reduce some errors related to delays and misunderstandings.

Ross encourages situational awareness in her department. The first manager on duty each morning in food services begins by completing a checklist called "Create a Safe Day." The checklist includes the number of days since the department experienced a food safety incident, the midnight hospital census, the day's eating census, any noteworthy conditions at the hospital, or concerns with the day's menus. That checklist is posted in the department so anyone can refer to it during the day, and it also is used when Ross or another food service manager participates in the hospital's daily check-in phone call with 34 representatives from all over the hospital, Ross notes. She listens for any situations that might affect food services or in which her department can affect patient safety.

"An example would be one day when infection control reported that there was an unusually large number of patients on precautions," she says. "I took that information to my staff because we have to gown and glove like everyone else, and that can be very time-consuming. We told

our staff to take this into account and to let us know if they needed help on the floors, because we're willing to provide that extra help rather than having them feel rushed and pressured, which can affect compliance with precautions."

The food service department also holds safety huddles twice a day to go over the morning's checklist, anything learned during the check-in call, and developments during the day, supply needs, or concerns, Ross says. She also identifies any higher-risk patients, such as those with allergies that do not always transfer from the hospital's database to the computer system used for preparing meals.

During the safety huddle, Ross also asks what is working well in the department, which gives staff members a chance to recognize one another's good work or to highlight successful problem-solving, and she often reads patients' comments praising their experiences with the hospital's food service. Before the huddle ends, Ross asks for any questions or comments from the staff. Information learned from the huddles is added to the day's safety checklist, posted so that any staff on a later shift during the day can check it. *(See the story below for more strategies to reduce dietary errors.)*

The hospital's computer system generates a menu specific for each patient, and staff use the two-patient identifier rule throughout the process of preparing meals and right up to the point the tray is given to the patient. Ross cautions that no matter what computer systems a hospital uses, it is still necessary to double-check trays with any updated information that may arrive during the day. Patient menu restrictions can change quickly and significantly after food services obtains the day's menu requirements, so check the computer system for changes, and also take advantage of any information that may not have been entered into the computer system yet. Encourage nurses to notify food services of any midday changes to a patient's diet.

"Especially if you're in a hospital that is less computerized than some, the information you're working with may be old," Ross says. "The patient may have turned NPO by the time you assembled that tray. It's important to work off of some type of update list, whether that comes from the computer system or a nursing station." ■

### SOURCES


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## Allergies Most Common in Dietary Errors

Most dietary errors are related to food allergies, according to an analysis of errors reported to the Pennsylvania Patient Safety Authority over five years.

A total of 285 dietary errors were reported to the PPSA from January 2009 through June 2014, and 181 involved meals delivered to patients who were allergic to a food item on the tray. Other types of events included 50 patients receiving the wrong diet, 43 receiving meals meant for other patients, and 11 meals delivered to patients who were not to receive any food by mouth.

Delivering the right tray of food to the right patient at the right time is a complicated process that requires coordination among several departments, notes PPSA analyst **Susan C. Wallace**, MPH, CPHRM.

Wallace gathered risk-reduction strategies from dietary services professionals. The following are some of the suggested strategies:

- Educate all healthcare workers by providing continued education and training about food allergies and special diets, as well as the proper way to answer a patient's questions and concerns.
- Create a written procedure for handling food allergies and special diets for all staff members to follow.
- Encourage food service employees to consistently check for two patient identifiers before giving a patient a food tray.
- Require that cooks and chefs use only the ingredients listed on a recipe and not make substitutions.

The full PPSA report is available online at: http://bit.ly/2k0KDWW. ■

# Recipe Ingredients Must Be Monitored

In addition to the patient-specific menus, ensuring patient safety requires tracking all the recipes and ingredients used in all the food items, notes **Jennifer Ross**, director of nutrition services at Abington (PA) Jefferson Health Hospital.

Each food item or ingredient in purchased food ingredients must be tracked and cross-checked with any patient's allergies or other limitations. That is a huge task, but one that must be performed correctly to avoid inadvertently providing a patient with a harmful substance, she says.

In one case, Ross noted during the morning's safety huddle that a patient was allergic to pectin, but no one in the department was quite sure what pectin was or what food it might be in. Some quick research determined that pectin is used in jellied food but also is found naturally in apple skins and other foods.

"We serve a really good chicken parmesan on Friday nights, and our recipe calls for using our usual tomato sauce that has been chosen for specific reasons and we know all about what is in that sauce," Ross explains. "But it's not unheard of for our supplier to be out of that particular sauce, and the ingredients in the substitute sauce are not at all the same. The substitute sauce might contain corn syrup but our usual sauce doesn't, or the same with onion powder."

Any substitutions of routine ingredients are carefully noted and discussed in the safety briefing and checked against the day's patient census for conflicts. "We're all that's there between the patient and this new sauce," Ross says.

Even with all the precautions that go into monitoring allergies, menus, and ingredients, the food service department still takes precautions at the bedside. Any patient with an allergy receives a big red slash across his or her menu and tray ticket, which serves to heighten everyone's awareness. When those trays are prepared in food services, the red slash is a visual cue for each person on the tray line to stop and review what they're doing with the tray. Additionally, any tray with a red slash must be reviewed by a supervisor before it can be sent to the patient, as a set of fresh eyes to catch any potential problems.

"Our emphasis is on following the right procedures and stopping at every opportunity to confirm that you're doing the right thing, that no one in the line has slipped up somewhere," Ross says. "We trust each other to do the right thing, and we trust each other to watch out for anything that might slip by." ■

# Newborns at Risk from Tired Parents, Family

The scenario is dreadful, but it actually happens with some regularity: A mother holding her newborn child, perhaps nursing, falls asleep from exhaustion. She either accidentally smothers or drops the child, resulting in serious injury or death.

The risk first came to the attention of former hospital risk manager **Susan C. Wallace**, MPH, CPHRM, patient safety analyst with the Pennsylvania Patient Safety Authority (PPSA) in Harrisburg, when she came across an adverse event report of a mother who had been breast-feeding her newborn in the hospital when she fell asleep because she was exhausted from childbirth.

"When she woke up, unfortunately she had suffocated the baby," Wallace says. "I started looking into this and found a lot of reports over the years, not all involving suffocation but involving injury or even death because the mom, dad, or even a family member was so exhausted from being up all night and all the stress from labor and childbirth. They fall asleep, their arm relaxes, and the baby falls."

In addition to sheer exhaustion, mothers may have received pain medication that makes them sleepy or impairs judgment, Wallace notes. It is up to nurses and family members to watch these mothers carefully when breast-feeding or holding their babies.

The potential for this type of newborn injury is largely unrecognized by physicians and birthing unit staff, Wallace says, because when it happens it seems like a freak occurrence and not something preventable. After all, hospitals now encourage parents to hold their newborns soon after birth and as often as possible in the time before discharge, to foster bonding, breast-feeding, and overall wellness for the baby and parents. In many hospitals, newborns stay with the mother as much as possible rather than sleeping in the nursery.

But this tragedy happens often enough that it deserves attention from risk managers and clinicians, Wallace says. In Pennsylvania alone, Wallace's research found about 30 incidents per year in the several years she studied.

Her analysis of reports submitted to the PPSA from July 2004 to 2013 revealed almost 300 incidents of family members dropping their newborns after falling asleep, newborns slipping out of family members' arms to the floor, and newborns receiving bumps to their heads while with their families. More than 9% of the incidents resulted in serious patient harm. *(Wallace's full report on this safety risk is available online at: http://bit.ly/2kOPw8K.)*

The majority of the incidents — 85.3% — occurred when the newborn was younger than four days old. Of those falls, 42.7% occurred on day one and 32.8% occurred on day two.

"In some cases, these babies fall to the floor and they will get a brain injury," she says. "In a few instances, the baby was held in the mother's arms in such that it didn't fall, but as the mother relaxed her body as she fell asleep and the baby was caught up in the bedding or the mother's body and clothing, and suffocated."

In addition to parents falling asleep, babies can suffer other types of fall injuries while in the parents' care. PPSA records include these examples of both types from incident reports:

• "Upon entering the mom's room, the nurse found a man crying and holding a crying infant. Mom stated she was sitting in the chair feeding the newborn when she fell asleep. The infant slid to the floor off of [the mom's] lap. Mom stated the newborn's head was hit on the right side."

• "Infant was sleeping on father's chest in chair at side of bed; father fell asleep, and infant rolled to the floor face down. Infant found crying in father's arms. [Infant] returned to nursery for assessment by pediatrician."

• "Mother of [newborn] reported that her baby had fallen out of her arms and onto the floor during the night, stating that she was holding her baby and fell asleep. X-ray revealed a skull fracture."

• "Infant fell from mother's arms, landing on right side of head and body. Infant taken to NICU. Infant sustained bone skull fracture and small subdural hematoma."

• "Infant fell from mother's arms when mother bent over to pick something up from the floor."

• "Mom brought baby to the nursery [in the morning]. Mom stated that she dropped the baby onto the floor while changing breastfeeding position. Mom was sitting in her bed. Baby fell and hit back of head."

> "TELL THEM DIRECTLY THAT WHILE IT MIGHT SEEM WARM AND WONDERFUL TO FALL ASLEEP WITH YOUR BABY, IT'S ACTUALLY QUITE DANGEROUS AND SHOULD BE AVOIDED."

Hospitals are taking notice of the risk and implementing frequent checks when a mother is breastfeeding, and some are requiring parents to sign a document acknowledging that they have been warned about the risks and understand how to protect the child, Wallace says.

The best way to prevent these accidents is to educate parents, family, and clinicians about the risk and encourage vigilance, Wallace says. Nervous first-time dads may worry about dropping the baby, but those concerns are dismissed by others who assure him he will do fine. And he almost always does. But the idea of falling asleep and harming the baby does not occur to many, Wallace says.

Also, parents and family members may falsely believe that it is OK to fall asleep with the baby as long as the baby is held in such a way that there is no chance of falling. That is not safe because suffocation is always a risk, she says.

"Just making parents aware of this is the first step," Wallace says. "They need to be encouraged to let someone know if they're getting sleepy and need to hand the child to someone else or put the baby in a bassinette. Tell them directly that while it might seem warm and wonderful to fall asleep with your baby, it's actually quite dangerous and should be avoided." ■

## EXECUTIVE SUMMARY

Suffocation and falls while being held by a family member is a little-known risk to newborn babies. Nurses and other staff should be alerted to the risk so they can take precautions.

- Parent-related newborn falls are not common, but still happen more than one would expect.
- Serious injury and death have occurred.
- Prevention begins with explaining the risk to parents.

# Risk Matrix Helps Staff Make Decisions, Take Responsibility

As part of an overall project to improve quality and patient safety at Madison Memorial Hospital in Rexburg, ID, Director of Risk Management and Compliance **Nolan Bybee**, RRT, wanted to find a way to be more proactive and not wait for adverse event reports. He found solutions that accomplished that goal and draw staff into the decision-making that goes on every day in a hospital, encouraging them to take more responsibility.

In the first solution, Bybee and his colleagues developed a risk matrix that focuses on quality, patient safety, and financial issues that could lead to an unwanted result, including a malpractice lawsuit or an employee or patient injury. By using the risk matrix, staff can determine how to prioritize tasks and resources, focusing on those issues that are most likely to cause the most damage.

The matrix is an improvement over how the hospital previously tracked incidents, essentially waiting for someone to report an injury or concern and then tracking down what caused it, Bybee says. Madison Memorial implemented the new matrix in September 2015.

"The matrix helps us determine the worst possible consequence of a set of facts and the likelihood of that happening," Bybee says.

The matrix also is used to address systemic problems in the hospital. Bybee used it recently to address readmission rates. Prior to the matrix, hospital leaders waited until the readmission rates became problematic and then investigated, looking for a solution.

"With the matrix, we stepped back and identified that there are only a few reasons why patients are being readmitted," Bybee says. "One was a situation in which we discharge them to a home health agency and the agency doesn't get there until the next day, so for a long amount of time they've missed getting their meds and the care they were getting here. Once we recognized that problem, we started using a select few home health agencies, nursing homes, and medical supply companies as preferred providers, and we coordinate with them to avoid that kind of problem."

The hospital established patient care navigators that communicate with counterparts at each of the preferred providers to monitor the patient's progress.

"The risk matrix helped us identify that we have to monitor the progress of these patients quite closely for 30 to 60 days after they leave, at least, rather than saying they're out of our door and not our problem," Bybee says. "We were able to drill down and identify the potential for harm and the barriers to better care."

## Improved Safety Huddles

Madison Memorial also revamped its safety huddles. Like many hospitals, Madison Memorial holds a morning safety huddle that includes representatives from many departments, leadership, and anyone else who wants to attend. Bybee and other leaders realized that the safety huddles, while useful, weren't providing enough information to address the root problems of safety concerns.

Now, immediately following that huddle, Bybee, the department representatives, and administrators hold a second meeting to report in more detail about any issues that the whole hospital should be aware of, Bybee says.

"Med-surg might report that they have 15 patients on the floor and three are in isolation. That's not specifically a safety issue, but it can be if the staff is overwhelmed. People might realize that med-surg is really slammed, so maybe today isn't the best day to hound them about that new project," Bybee says. "That way, the whole hospital knows what's going on in a more in-depth way than just the direct safety concerns that are mentioned in the huddle.

## EXECUTIVE SUMMARY

A risk matrix can help hospital leaders and staff identify issues most likely to happen and to cause the most harm. The matrix can be used for individual problems or systemic issues.

- The matrix helped pinpoint the cause of readmissions.
- The hospital also revamped its safety huddles.
- Traditional safety huddles are followed by a more in-depth informational meeting.

This isn't intended as a way to fix problems; it's a chance to say this is what's going on, so people can get that back to their departments."

Bybee encourages risk managers to work closely with quality assurance on improvement projects like these. Many projects originating with the quality department will benefit risk management as well, he says, but only if they work cooperatively.

"As risk managers, sometimes we're quick to say 'No, we can't do that,' when actually it might be in the best interest of the patient to say yes. We just need to figure out a safe way to do it," Bybee says. "We have to be open to improvement and change." ■

### SOURCE

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# HHS Sets Conditions for Aiding Patients with Transportation, Discounts

The federal government has revised the anti-kickback statute (AKS) safe harbors and also some provisions of the civil monetary penalties (CMP) law in ways that will be significant to some healthcare providers.

The changes make clear that hospitals and other providers can provide transportation to patients under certain conditions without the HHS OIG considering it an effort to get patients from drivers or a transportation service receiving payment for the volume of patients transported. The CMP law was revised to clarify the meaning of "remuneration," which can trigger the law.

The new and revised safe harbors were required as part of the Affordable Care Act, aimed at making healthcare delivery more efficient and consistent, says **James B. Riley, Jr.**, JD, partner with the law firm of McGuireWoods in Chicago. The changes have been expected for a long time and healthcare providers can finally benefit, he says. Revisions to the transportation safe harbor were proposed in 2014, but just now made official.

"The concept of providing transportation at nominal or no cost to certain eligible patients was not something new to the OIG. Going back as far as 2009, the OIG had issued a number of advisory opinions on the issue, saying the provider could provide transportation for patients in a certain geographic area," Riley says. "The advisory opinions determined there was a limited risk of fraud and abuse under certain conditions, so the safe harbor incorporates those conditions that leaves the OIG confident there is no risk of kickbacks or other fraud."

The conditions prohibit marketing or attempts to pass the cost on to the federal government in any way, Riley says. Revisions to the CMP law include similar conditions under which a healthcare entity can provide goods and services without it being considered improper remuneration. *(See the story on page 33 for details on the safe harbors.)*

"The revisions are aimed at hospitals and other providers who were concerned about their efforts to help patients who had difficulty accessing medical care because of their transportation needs or because of their financial limitations," Riley says. "These changes are being received very well in the provider community."

The changes should alleviate some concerns that efforts to help needy patients could inadvertently land a provider in hot water with the federal government, notes **Jake A. Cilek**, JD, also an attorney with McGuireWoods in Chicago. OIG had laid out a clear path for how to provide transportation and services

### EXECUTIVE SUMMARY

Revisions to the anti-kickback statute and civil monetary penalties will affect how hospitals offer transportation and discounts to patients. The changes provide safe harbor when the hospital meets certain conditions.

- Transportation can be provided for the purpose of improving access to care.
- The revisions should free some hospitals to provide more help to the needy.
- The government clarifies how discounts and free services can be provided without violating remuneration prohibitions.

without running afoul of the AKS or incurring a monetary penalty.

"In terms of compliance, this should give providers some certainty to hospitals on how they would provide transportation services," Riley adds. "If they have been limited in that regard because they were awaiting OIG's final decision on some of the particulars, this should give them the go ahead. The conditions that OIG specified are not such that they would be problematic to a hospital that in good faith wants to assist patients with getting access to care." ■

### SOURCES


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# OIG Spells Out How to Provide Transport, Goods Without Penalty

This summary of the recent the Anti-Kickback Statute (AKS) safe harbors and provisions of the Civil Monetary Penalties (CMP) law is provided by **James B. Riley, Jr.**, JD, partner with the law firm of McGuire-Woods in Chicago, and **Jake A. Cilek**, JD, also an attorney with McGuire-Woods:

The revision provides safe harbor for free or discounted local transportation services provided to "established patients" by "eligible entities." An "established patient" is defined under the new rules as "a person who has selected and initiated contact to schedule an appointment with a provider or supplier … or who previously has attended an appointment with the provider or supplier." An "eligible entity" is essentially any healthcare provider except those that primarily supply healthcare items, such as durable medical equipment suppliers or pharmaceutical manufacturers, Riley and Cilek explain.

Riley notes that before the rule was finalized, OIG had received questions about patients who were not "established" but were choosing to go to the hospital for the first time. That is why the definition of "established" includes those who have initiated contact.

"The government expanded the definition of 'eligible patient' to say that if a patient calls the provider and elects to schedule an appointment, that person falls into the established patient category," Riley says. "A number of questions like that from the proposed rule were addressed in the final rule."

The transportation must meet the following conditions:

> "IN TERMS OF COMPLIANCE, THIS SHOULD GIVE PROVIDERS SOME CERTAINTY TO HOSPITALS ON HOW THEY WOULD PROVIDE TRANSPORTATION SERVICES."

- The availability of the transportation services is described in a policy not related to the past or anticipated volume or value of federal healthcare program business.
- The transportation services are not provided via air, luxury, or ambulance-level transportation.
- The transportation is not publicly marketed or advertised, and there is no marketing to patients during the trip.
- Drivers or others arranging for transportation are not paid on a per-beneficiary-transported basis.
- The transportation is made available only within 25 miles of the provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a "rural area."
- The eligible entity makes the free or discounted transportation available only for the purpose of obtaining medically necessary items and services. Round-trip transportation back to the patient's home is allowed.
- The eligible entity bears the costs of the free or discounted local transportation and does not shift the burden of such costs onto federal healthcare programs, other payers, or individuals.

The revised rule also provides a separate safe harbor for shuttle services that meet the conditions above, but HHS states that shuttle services do not have to be provided uniformly and consistently. Shuttle services also are not limited to established patients, meaning family members of a patient may ride the shuttle. However, shuttles must be local, defined as no more than 25 miles (or 50 miles in rural areas) away from the healthcare provider.

OIG also finalized a safe harbor to protect waivers and reductions

for "emergency ambulance services" furnished by a Medicare Part B ambulance provider or supplier owned or operated by a state, a political subdivision of a state, or a tribal health program. A new safe harbor also protects discounts for "applicable drugs" furnished to an "applicable beneficiary," as those terms are defined in the Medicare Coverage Gap Discount Program statute.

Changes to the CMP law include the implementation of ACA-mandated exceptions to the definition of "remuneration" that would not trigger application of the CMP law. The final rule exempts from the definition of remuneration under the CMP law "items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs."

"Low risk of harm" items or services are defined as unlikely to interfere with, or skew, clinical decision-making; unlikely to increase costs to federal healthcare programs or beneficiaries through overutilization or inappropriate utilization; and not raising patient safety or quality-of-care concerns, the attorneys say.

OIG explains that items or services intended to help patients access care or make it convenient are covered by the safe harbor, but "inducements to comply with treatment or rewards for compliance with treatment" are not.

OIG also provides an exemption to the definition of "remuneration" for offers or transfers of items or services for free or below fair market value. If the provider determines in good faith that the individual is in financial need, the items or services can be provided free or below market value if they are not offered as part of any advertisement or solicitation, not tied to other services reimbursed under Medicare or a state healthcare program, and if there is a "reasonable connection" between the items or services and the medical care of the individual. Cash or instruments that can be converted into cash are excluded. ■

# UPMC Settles Neurosurgery Malpractice Cases

The University of Pittsburgh Medical Center (UPMC) has settled two medical malpractice lawsuits against the hospital's neurosurgeons, cases that stemmed from a federal false claims lawsuit alleging surgeons were incentivized to perform unnecessary procedures.

The *Pittsburgh Post-Gazette* reports that the lawsuits were settled shortly before the trials were to begin in the Allegheny County Court of Common Pleas, but the settlement terms were not released. *(The* Post-Gazette *story is available online at: http://bit.ly/2kntc5x.)*

The federal false claims lawsuit is still pending in the U.S. District Court for the Western District. The government claims that UPMC paid improper bonuses to neurosurgeons for the number of procedures performed and promoted medically unnecessary procedures. UPMC has denied the allegations.

One of the medical malpractice cases that were settled involved a patient suing a UPMC neurosurgeon over back operations performed on him in July and November 2010, procedures the plaintiff said were not medically necessary, according to court records. In the second lawsuit, a patient sued another UPMC neurosurgeon after a December 2008 back operation.

The federal whistleblower lawsuit alleged that those physicians and 11 others received improper financial inducements for increasing the complexity and number of procedures performed. UPMC denied impropriety, saying its "effort-based incentive compensation system" is employed by many hospitals. ■

# Study: Apology Laws Don't Reduce Malpractice Claims

Laws that allow doctors to apologize to patients after an adverse event are intended to protect physicians who want to say they're sorry but not have that considered an admission of guilt, but their effectiveness is questionable, according to a new study.

The research from Vanderbilt University in Nashville, TN, indicates that apology laws are "intuitively appealing but empirically unfounded," says **Benjamin J. McMichael**, JD, PhD,

a postdoctoral scholar at Vanderbilt's Owen Graduate School of Management. Medical and legal professionals have been hopeful that apology laws would reduce the incidence of patients suing for malpractice because many such lawsuits are prompted by anger and feelings of neglect, he notes.

Thirty-two states and the District of Columbia passed apology laws, but the Vanderbilt research suggests they have not been successful in reducing claims. The researchers used a data bank that includes all malpractice claims from 2004 to 2011 for 90% of physicians practicing in a single specialty across the country, attained from a national malpractice insurer. Seventy-five percent were surgeons. *(An abstract of the study is available online at: http://bit.ly/2khVYBY.)*

The researchers assumed that apology laws increase the number of apologies, since the data did not reveal whether the doctor actually apologized. Analysis of 3,517 claims revealed that 2.6% of doctors per year face a malpractice lawsuit a year, and of those, 65.4% of those sued end up in court. Of those sued, 51.4% pay the claimant something and 34.6% settle a claim without involving the courts.

Of that 34.6%, 7.1% settle out of court and pay the claimant something and 27.5% have claims dropped without paying the claimant anything.

"In general, the results are not consistent with the intended effect of apology laws, as these laws do not generally reduce either the total number of claims or the number of claims that result in a lawsuit," according to the study. "Apology laws have no statistically significant effect on the probability that surgeons experience either a non-suit claim or a lawsuit." ■

# Lost Devices Lead to OCR Finding More Noncompliance

A hospital's loss of a BlackBerry and a laptop containing unsecured electronic protected health information (ePHI) led to an investigation by the Department of Health and Human Services, Office for Civil Rights (OCR) that found more widespread HIPAA violations.

OCR imposed a civil monetary penalty against Children's Medical Center of Dallas based on its "impermissible disclosure of and noncompliance over many years with multiple standards of the HIPAA Security Rule," the office reports.

Children's paid the full civil monetary penalty of $3.2 million. The penalty came after the hospital filed a breach report with OCR in 2010 indicating the loss of an unencrypted, non-password-protected BlackBerry device with the ePHI of approximately 3,800 individuals at the Dallas/Fort Worth International Airport. In 2013, Children's filed a separate HIPAA Breach Notification Report with OCR after the theft of an unencrypted laptop from its premises. That contained the ePHI of 2,462 individuals.

OCR's investigation determined that Children's implemented some physical safeguards to the laptop storage area, including badge access and a security camera at one of the entrances, but it also provided access to the area to workers not authorized to access ePHI.

OCR cited the hospital for failing to implement risk management plans, contrary to prior external recommendations to do so, and a failing to deploy encryption or an equivalent alternative measure on all of its laptops, work stations, mobile devices, and removable storage media until after the theft of the laptop.

"Despite Children's knowledge about the risk of maintaining unencrypted ePHI on its devices as far back as 2007, Children's issued unencrypted BlackBerry devices to nurses and allowed its workforce members to continue using unencrypted laptops and other mobile devices until 2013," OCR reports. "Ensuring adequate security precautions to protect health information, including identifying any security risks and immediately correcting them, is essential. Although OCR prefers to settle cases and assist entities in implementing corrective action plans, a lack of risk management not only costs individuals the security of their data, but it can also cost covered entities a sizable fine." ■

## COMING IN FUTURE MONTHS

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HEALTHCARE RISK MANAGEMENT™



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# CME/CE QUESTIONS

1. **In dietary error reports submitted to the Pennsylvania Patient Safety Authority over a five-year period, what was the most common type of error?**

   a. Meals delivered to patients who were allergic to a food item on the tray.
   b. Meals delivered to patients about to undergo surgery.
   c. Meals with an excessive amount of fat or salt.
   d. Meals delivered to the wrong patient.

2. **In research conducted by Susan C. Wallace, MPH, CPHRM, about how many incident reports were there per year in Pennsylvania of baby injuries related to parents or family members?**

   a. 15
   b. 30
   c. 60
   d. 80

3. **In the revised anti-kickback statute safe harbors, what is one condition that must be for transportation services?**

   a. Drivers or others arranging for transportation are not paid on a per-beneficiary-transported basis.
   b. Drivers are not employed by the hospital.
   c. Passengers are charged a reasonable and customary rate.
   d. Passengers are not provided transportation back home.

4. **In the revision to the civil monetary penalties law, what is covered by the remuneration safe harbor?**

   a. Items or services intended to help patients access care or make it convenient.
   b. Inducements to comply with treatment or rewards for compliance with treatment.
   c. Cash.
   d. Instruments that can be converted into cash.

LEGAL REVIEW & COMMENTARY
EXPERT ANALYSIS OF RECENT LAWSUITS AND THEIR IMPACT ON HEALTHCARE RISK MANAGEMENT

# $14.5 Million Verdict for Premature Infant's Injuries

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**News:** On May 14, 2008, a child was born prematurely at a hospital in Las Vegas. She suffered from anemia and was placed under the care of a physician for 11 weeks until she was discharged to the care of her parents and pediatrician on Aug. 2, 2008. The hospital physician did not inform the baby's parents of the anemia and treated her incorrectly due to a misdiagnosis of anemia of prematurity.

After the child's discharge, the pediatrician failed to timely administer a follow-up test that the initial physician ordered. The pediatrician eventually ordered blood testing on Oct. 24, 2008, and carried it out on Oct. 28, and the child went into anemic shock the next day. The shock caused diffuse brain damage, which led to developmental delays as well as cortical visual impairment, which made her unable to walk or speak and caused her to be mostly blind. The subsequent lawsuit ultimately yielded a $14.5 million verdict.

**Background:** On May 14, 2008, a baby was born prematurely at 29 weeks at a Las Vegas hospital. She was placed under the care of a physician for 11 weeks. The premature child was born with anemia, but the physician failed to inform her parents of the disease and treated her incorrectly. The child's anemia was due to a bone marrow disorder known as Diamond-Blackfan anemia, but the physician incorrectly diagnosed her with anemia of prematurity.

After 11 weeks, the child was discharged from the hospital on Aug. 2, 2008, and put in the care of her parents and a pediatrician. After her discharge, the pediatrician allegedly failed to administer a follow-up test ordered by the initial physician. Blood testing was later ordered at the pediatrician's practice on Oct. 24, 2008, and carried out on Oct. 28. The next day, the child went into anemic shock, which caused diffuse brain damage that led to developmental delays, leaving her unable to walk or speak. The shock also caused cortical visual impairment, rendering her mostly blind.

THE CHILD WENT INTO ANEMIC SHOCK, WHICH CAUSED DIFFUSE BRAIN DAMAGE THAT LED TO DEVELOPMENTAL DELAYS, LEAVING HER UNABLE TO WALK OR SPEAK.

The child sued the physician, the pediatrician, and the hospital. The hospital settled out of the case for $500,000. Shortly before trial, the plaintiff made an offer of judgment (i.e., a formal offer to settle the case) for $850,000, which was rejected. At trial, the initial physician argued that his care met the requisite standards and that he did not harm the child. The pediatrician thought the follow-up testing ordered by the hospital physician at discharge was unnecessary. The pediatrician died by the date of trial, but settled the case against him prior to his death for $2 million. The suit only proceeded against the initial physician.

On Dec. 2, 2016, the Nevada jury awarded the plaintiff $14.5 million in damages, allocating 40% liability to the initial physician and 60% liability to the pediatrician. The

award covered $1.8 million for past medical expenses, $9.2 million for future medical expenses, and $3.6 million for pain and suffering. The pain and suffering portion will be reduced to $350,000 under the Nevada medical malpractice cap.

Prior to the court verdict, the defendant was granted a hearing by the Nevada Supreme Court following a motion *in limine* (a procedural motion usually filed shortly before trial in an effort to exclude or limit anticipated evidence). The trial judge rejected the remaining defendant's position that he was entitled to argue the percentage of fault of settled defendants and to include the settled defendants' names on the verdict form where the jury could conclude that the settled defendants' negligence caused some or all of the plaintiff's injury. The Nevada Supreme Court relied on a 2004 law, Keep Our Doctors in Nevada. However, the statute carved out an exception relating to a defendant's ability to litigate the comparative fault of parties who previously settled out of a suit. The physician was thus permitted to litigate the comparative fault of the pediatrician, but the ultimate trial verdict, again, was in favor of the plaintiff.

**What this means to you:** Given the recency of this verdict, the matter may yet be appealed. Nonetheless, this case still illustrates the need for proper follow-up testing, especially with genetic diseases like anemia. The pediatrician believed that the follow-up tests ordered by the initial physician were unnecessary, and this child suffered tremendously as a result. The pediatrician's decision against testing may well have been caused by a lack of information provided by the other physician.

Traditional communication systems, such as discharge summaries, often are inadequate to communicate patient needs to outpatient physicians. Here, the initial physician failed to communicate the gravity of the anemia to the pediatrician. The fact that the physician failed to inform the parents of the anemia in the first place only exacerbated the situation. To avoid suits similar to this case, it is imperative that hospitals and medical professionals consider moving toward more effective and comprehensive communication mechanisms. The electronic medical record is one mechanism that, if shared by all treating practitioners, can prevent communication errors. Another, more basic tool is the telephone, in conjunction with taking the time to stop and make a critical call to parents, caregivers, or fellow medical professionals. Additionally, consultation with a neonatologist with an expertise in genetic-related prematurity would have been helpful in bringing to light the nature of the infant's disease and treatment options to all parties.

This case shows that medical professionals ought to take extra care when treating premature babies. Preemies are exceptionally vulnerable and society will likely always feel the need to protect them as especially sympathetic plaintiffs in court when things go wrong in the doctor's office. Therefore, to conform to the appropriate standard of care, physicians and other medical professionals must exercise the utmost care with premature babies. Additionally, from a strictly financial perspective, future medical costs and pain and suffering often are much costlier for a newborn child with many years to live than for an adult (especially an elderly person).

With respect to litigation procedures, the appeal of the motion *in limine* makes an interesting point about medical liability. Nevada voters overwhelmingly passed the Keep Our Doctors in Nevada ballot measure in 2004 to deal with a statewide medical crisis. Other states, including California, have enacted similar statutes to secure quality medical treatment for citizens. Knowledge of statutes that give an edge in court is critical for a sound defense and reduction of financial effect for judgments against hospitals and medical professionals, so working with local, experienced, and specialized medical malpractice defense counsel is important.

Statutory damage caps were at play in this case as well. Statutory caps can both help determine the value of cases and act as a bargaining chip for the defense. Juries can be quick to award unjustifiably high judgments in medical malpractice cases, but legislatures may offer protection against the emotionally charged jury.

Here, the offer of judgment from the child's family was in the amount of $850,000, but the final, reduced verdict against the defendant was still more than $9.5 million. The physician was liable for 40% of that amount, leaving him responsible for approximately $4 million. In contrast, the pediatrician settled for $2 million, even though he was found to be more culpable for the child's injuries. Clearly, the physician would have been more successful in this case if he settled earlier.

Finally, this case demonstrates the obligation of physicians to discover genetic diseases through comprehensive family-related inquiries. The physician's misdiagnosis of the child's Diamond-Blackfan anemia as anemia of prematurity prevented him and the pediatrician from administering appropriate treatment. A standardized, in-depth questionnaire for the parents may

have led to a proper diagnosis and prevention of catastrophic brain dysfunction. Hospitals should adopt such surveys to ensure they are shielded from liability by properly diagnosing genetic diseases before they cause irreparable damage to patients. ■

## REFERENCE

District Court of Clark County, Nevada, Case No. A-10-616728, Dec. 2, 2016.

# Hospital Ordered to Pay $1.7 Million for Fatal Excessive Fluid Administration

**News:** In early 2011, a middle-aged woman presented to an ED, complaining of nausea and vomiting over the previous four days. X-rays showed a bowel obstruction. Due to her dehydration and low urine output, she was given three liters of normal saline and taken to surgery. During the four- to five-hour surgery, the patient continued to produce low urine output. To promote urine output, saline fluid was regularly administered, for a total of 6,900 mL, with only 95 mL of urine output. The surgery successfully addressed her bowel obstruction and diverticulosis by removing three-quarters of her large bowel.

Following the surgery, the patient continued to receive aggressive fluid. She experienced increased respiratory depression as fluid entered her lungs and abdomen. That resulted in abdominal compartment syndrome and organ failure. The patient was put on a ventilator and became acidotic. The medical staff thought she was septic and performed another surgery to see if she was suffering from a dead bowel. It was determined that the surgical connections were intact. However, during the procedure, she went into cardiac arrest and suffered hypoxic-ischemic encephalopathy. She remained unconscious until her death on March 23, 2011. The subsequent lawsuit resulted in a verdict of $1.7 million for the plaintiff.

**Background:** On Jan. 12, 2011, a 54-year-old woman arrived at the ED complaining of nausea and vomiting over four days. Analysis of X-rays revealed a bowel obstruction. She was also suffering from dehydration and low urine output, so she received three liters of normal saline and taken to surgery. The patient continued to produce a low urine output during the surgery, which lasted roughly four to five hours. Saline fluid was regularly administered, eventually totaling 6,900 mL, but with only 95 mL of urine output. Surgeons removed three-quarters of her large bowel and successfully addressed the bowel obstruction and diverticulosis.

Significant amounts of fluid were administered postoperatively in the ICU. Over the next two days, her condition deteriorated, leading to increased respiratory depression as fluid entered her lungs and abdomen due to excess saline solution, which in turn caused abdominal compartment syndrome and organ failure. She went on a ventilator, and still became acidotic. This resulted in another surgery on Jan. 14 to see if she was suffering from a dead bowel. The surgery revealed that the surgical connections were intact, but the patient went into cardiac arrest during the surgery and suffered hypoxic-ischemic encephalopathy. She remained unconscious until her death on March 23, 2011.

The woman's estate sued the hospital, hospital owner, umbrella entities, and the surgeon, alleging they were negligent in excessively administering saline fluid and in failing to consult with a nephrologist. The estate also sued a resident doctor, a vascular surgeon who took part in the second surgery and that surgeon's practice, the managing resident, and another resident who took part in the initial surgery. The first surgeon settled for an undisclosed amount. He and all other defendants, save for the hospital, were dismissed prior to trial. Thus, the case proceeded against the hospital only.

At trial, the plaintiff's expert in critical care opined that, given the patient's significantly low urine output during the surgery relative to the high-saline input, the hospital's medical staff should have consulted with a nephrologist. According to the expert, it is not unusual to use aggressive amounts of fluid during surgery on a dehydrated patient. However, surgeons must be cognizant of the patient's urine output in relation to the administered fluid. The fact that the patient's urine output was 95 mL and the fluid input was 6,900 mL was a major red flag that the medical staff overlooked.

However, the hospital's expert in critical care surgery opined that the amount of fluids administered was not overabundant or overly aggressive because it was necessary to address possible sepsis and to maintain her cardiac output and blood pressure.

He also stated that the medical staff properly monitored her vitals and lab work following the surgery, and opined that she had become septic. The hospital's expert in general surgery also testified that the medical staff adhered to the standard of care in their fluid administration. The expert stated that the woman was seriously ill with an obstructed bowel and diverticulosis and the amount of fluids given to her allowed her to remain alive. Had the fluids been discontinued, her blood pressure would have dropped.

After the conclusion of the five-day trial, the jury deliberated for one-and-a-half hours before awarding the plaintiff more than $1.7 million for past medical costs, pain and suffering, and loss of past and future companionship.

**What this means to you:** Neglecting a postoperative patient can cost healthcare professionals and hospitals a great deal. Hospitals have an ongoing duty to their patients. For most, it goes without saying that patients are under the care of hospitals until they are discharged. However, it bears repeating for some, and the reminder can be helpful to reduce the number of medical malpractice cases. Hospitals should periodically remind their nurses and physicians of their duties to ensure they are properly ingrained in the professionals' minds.

This case also shows the importance of carefully monitoring patients and their symptoms. Once the medical staff recognized that the patient's urine output was abnormally low relative to the fluid input, they should have re-evaluated her input. Patients receiving intravenous fluids require frequent assessment to reduce risks of over- or under-administration, electrolyte imbalance, and other complications. The risks associated with cases like this are so high that failure to properly monitor a patient can easily result in a malpractice suit. Therefore, it is imperative that hospitals articulate the importance of patient monitoring to medical professionals.

What happened here arose from the failures of both treating physicians and nurses to go back to the basics of fluid balance, which is learned by both in their first year of their respective training. Urine output must be closely monitored at all times for patients receiving supplemental fluids. It is expected that a dehydrated patient will initially exhibit a lower output than input as the body redistributes lost fluid. However, there should be a steady increase in output as the body's need is satisfied. If, as in this case, there is no recovery of output, the first thought should have been renal failure, often a temporary and very reversible consequence of dehydration. A nephrologist's consultation and intervention would have had a significant effect, and perhaps a life-saving one, on this case.

While it is true septic patients may require more aggressive fluid delivery, the staff determined in this case that the patient was not septic; thus, fluid levels should have been kept lower. The estate's general surgery expert noted that the excessive amount of fluid was inappropriate given the patient's vital signs and other parameters of cardiac output and cardiac function. Such relatively high fluid levels should not have gone unchecked.

When medical professionals are unsure about patient treatment, they should be directed to consult specialists. The estate's expert in nephrology contended that a nephrologist should have been contacted immediately, so the physician could administer diuretics to streamline the fluids in the patient's body or dialysis to jump-start the kidneys. In doing so, according to the estate's expert in general surgery, the woman's condition would have improved steadily. This would have prevented organ failure and the second surgery, which caused her cardiac arrest. To avoid litigation, hospitals must ensure that specialists are available for consultation.

According to the counsel for the estate, the patient also experienced pain prior to passing. Rather than discover the cause of the pain, the medical staff stopped at the administration of pain medication. If the patient's discomfort was caused by the surgery rather than a medical condition, pain medication would have been appropriate, but here the staff negligently overlooked the root of the patient's pain. Pain medication certainly is a useful tool, but blind administration creates more problems than solutions. Pain management is a basic patient right regardless of the patient's condition or level of consciousness. There are multiple signs of pain recognizable by trained caregivers that indicate an unconscious patient is uncomfortable. Grimacing, high pulse rate, and high blood pressure are a few of them. Pain is expected and must be treated following a major surgery, especially after opening the abdomen. It should have been addressed earlier.

This case also shows the jury value of objective pain and suffering. The patient was unconscious until she passed, but winced and was given pain medication. The plaintiff's counsel used this to appeal to the jury's empathy. The jury clearly felt moved by the patient's suffering, evidenced by the $500,000 pain and suffering award. ■

## REFERENCE

Wayne County, Circuit Court, Case No. 14-004174-NH, November 1, 2016.

HIPAA REGULATORY ALERT

CUTTING-EDGE INFORMATION ON PRIVACY REGULATIONS

# Presence Settlement Shows Need for Timely Notification When Breach Occurs

For the first time ever, the Department of Health and Human Services, Office for Civil Rights (OCR), is settling a HIPAA violation based on failure to report a breach in a timely fashion. The case illustrates how it can be difficult to determine the timeline for a breach, but it could be just the first case of this type.

The breach occurred at a facility owned by Presence Health, one of the largest healthcare networks serving Illinois with 150 locations, including 11 hospitals and 27 long-term care and senior living facilities. Presence agreed to pay $475,000 and implement a corrective action plan, OCR announced recently.

Unlike any other HIPAA breach case, OCR focused on Presence when company officials reported the problem. On Jan. 31, 2014, OCR received a breach notification report from Presence indicating that it had discovered on Oct. 22, 2013, that paper-based OR schedules containing the protected health information (PHI) of 836 individuals were missing from the Presence Surgery Center at the Presence Saint Joseph Medical Center in Joliet, IL. The information consisted of the affected individuals' names, dates of birth, medical record numbers, dates of procedures, types of procedures, surgeon names, and types of anesthesia.

OCR's investigation revealed that Presence Health, without unreasonable delay and within 60 days of discovering the breach, failed to notify OCR and each of the 836 individuals affected by the breach, as well as prominent media outlets. Media notification is required for breaches affecting 500 or more individuals.

The resolution agreement and corrective action plan are available online at: http://bit.ly/2iX7ZjQ.

Assuming good faith from Presence, the delay in notification may have been related to the time administrators confirmed the breach and investigation afterward, suggests **Jeff Drummond**, JD, an attorney with the Dallas office of the law firm Jackson Walker.

> THE CASE ILLUSTRATES HOW IT CAN BE DIFFICULT TO DETERMINE THE TIMELINE FOR A BREACH, BUT IT COULD BE JUST THE FIRST CASE OF THIS TYPE.

"A lot of these breaches are slow-moving train wrecks," he says. "Something happens, it takes time for anybody to realize it happened, and it may take longer for everyone to confirm that yes, it really did happen, even if there's no discernible damage from the breach. So sometimes you can have a breach and it takes a long while for anybody to do anything or make notifications, and that seems odd when you're looking back at that first initial date."

OCR took that into consideration in the past and was not strict about using that initial date as the starting point, Drummond explains. This settlement suggests OCR has changed its position, he says.

"People have not been in any hurry to get their notifications out and they've been getting away with taking long times to investigate," he says. "I think this case is an indication that OCR decided people were taking a little too much for granted that they could get away with that. This case gave OCR an opportunity to make an example of somebody."

Timely notification will join other issues that OCR can bring up if they want to put the screws to a provider

for some reason, Drummond says, along with hard-to-define deficiencies like "insufficient" risk analysis or insufficient policies and procedures, he says.

"Not only were your safeguards insufficient and that's why you had the breach, but you had these other problems as well, and timely notification will be one of those things they can throw in," Drummond says. "It can be one more thing they use to justify imposing a penalty."

Drummond also cautions that the 60 days in the breach notification requirement is not necessarily what OCR will consider acceptable in all cases. It is theoretically possible, though it hasn't happened yet, to notify the appropriate parties within 60 days from the earliest date and still be penalized for a timely notification failure, he says.

"People throw the 60 days around as if that's the time you have to report, and that's not accurate," Drummond says. "You're required to report as soon as is practical. The 60 days is just a drop-dead date you have to report by."

Even if you notify at 60 days or 55 days, OCR could still claim that you should have been ready and able to notify at 35 days, Drummond explains.

Drummond advises marking the 60-day date from the date you first learned of the incident, or the possibility of an incident, rather than using a date further down the line when you determined that a breach definitely occurred, or some other determination is made. Play conservatively with that time frame.

"You could make the argument that it's not until you're certain you have a reportable breach that the 60 days begins to tick, but I wouldn't be comfortable with that," he says. "The only way that might be reasonable is if between the time you discovered a problem and determined it was a reportable breach, you had reason to have a very high level of confidence that it would not be reportable."

## Poor Risk Assessment

The breach itself probably occurred because there was inadequate risk assessment, says **Denise Bloch**, JD, an attorney with Sandberg Phoenix & von Gontard in St. Louis.

"While breaches may happen no matter what the preventive measures and policies and procedures are in place, such as workforce members failing to follow policy or procedure, the likelihood of this particular breach might have been reduced if a risk assessment had been conducted and identified the risk the paper operating room records posed," she says. "As a result of risks identified, the covered entity could have implemented stronger policies and procedures requiring that the records be kept in a locked location, with access limited solely to those individuals needing the information and required the individuals to replace the records to the locked location following use."

Even better, the records could have been kept electronically, Bloch says.

Bloch notes that the notification requirements differ according to the amount of information compromised. For all breaches, notification to the affected individuals must occur without unreasonable delay and in no case later than 60 days following the discovery of the breach. In cases with 500 or more affected individuals of a state or jurisdiction, notification must be given to media outlets serving the state or jurisdiction and OCR without unreasonable delay, and no later than 60 days following the discovery of a breach.

In cases affecting fewer than 500 individuals, the notification is due to the OCR secretary no later than 60 days after the end of the calendar year in which the breaches are discovered.

Although there can be some confusion about timing, there is no doubt that notification was not timely in this case, Bloch says. The breach was not reported to OCR until Jan. 31, 2014, 101 days after the discovery of the breach. Affected individuals were not notified until Feb. 3, 2014, 104 days after discovery of the breach. Presence did not notify the media until Feb. 5, 2014, 106 days after discovering the breach.

"The key lesson to learn is to timely investigate possible breaches and timely report any breaches according to the breach notification rule, but another lesson is the importance of training workforce

## EXECUTIVE SUMMARY

For the first time, a healthcare provider is settling a HIPAA violation based on failure to quickly report a breach. It can be difficult to determine when to start the clock for the deadline.

- The breach involved paper records of OR schedules.
- Notification is required within 60 days of discovering a breach.
- The provider waited more than 100 days after the breach to notify appropriate parties.

members to not only be aware of their obligations under HIPAA to avoid breaches, but if one occurs, to know who to report any incidents to, and what circumstances require such reporting," Bloch says.

Providers need to specifically train their workforce on how to report breaches and ensure the breach response team understands their responsibilities, says **Kelli Fleming**, JD, partner with the law firm of Burr & Forman in Birmingham, AL. Tabletop exercises are a great tool to identify weak links in breach response process, she says.

## Other Deficiencies Found

Each day that notification was not made to the individuals, OCR, or the media constituted three separate violations, notes **Stacey Gulick**, JD, partner with the law firm of Garfunkel Wild in Great Neck, NY, and co-chair of the firm's HIPAA compliance practice group.

"When questioned about the failure to notify in a timely fashion, Presence claimed internal miscommunication," Gulick says. "Also relevant was that when the OCR investigated the breach, it reviewed other Presence breach reports and found other instances of failure to meet the notification time frames. This is the first settlement for failure to notify in a timely fashion, and could very well be the first of many."

The fact that paper records were involved is noteworthy, says **Kristin Jones**, JD, an attorney with the law firm of Stradley Ronon in Malvern, PA. Many providers are so focused on the risks associated with electronic medical records that they forget to protect traditional paper records as well, she says.

"OCR is unquestionably cracking down on HIPAA breaches as a whole, and we see announcements of record settlements regularly. Healthcare providers have had nearly four years to implement their policies, and OCR is no longer tolerating preventable mistakes," Jones says. "Not only should providers expect more enforcement actions related to timely notification, but they should expect other procedural deficits to catch OCR's eye during breach reporting and HIPAA audits."

Fleming agrees that providers should expect greater scrutiny on timely notification.

"The message this enforcement sends is that OCR is taking these breach notification time frames seriously, and that strict compliance with the deadline is mandatory," she says. "While Presence had a history of not reporting breaches in a timely manner, which probably contributed to the level of enforcement taken by OCR, I would not be surprised if we were to see similar action taken against other providers in the future, especially in situations where additional areas of noncompliance are discovered following an OCR investigation."

## State Laws Vary

It is important to understand the distinction between federal and state notification requirements, says **Brian Lapidus**, managing director for identity theft and breach notification with the fraud consulting firm Kroll

### CAP Requires HIPAA Policy Review

After the Presence Health settlement, healthcare providers are now more likely to see settlements and corrective action plans (CAPs) related to timely notification, says **Denise Bloch**, JD.

"It is likely that the OCR will take more enforcement actions against untimely breach reports in the future," Bloch says. "In the current enforcement action, the OCR has given a clear message that late notification is not acceptable, as a significant fine was imposed as well as requiring the covered entity to enter a [CAP] for a two-year period."

The CAP places many requirements on Presence, including revision of its existing policies and procedures related to complying with the breach notification rule, including proper procedures for handling potential breaches and completing risk assessments, as well as providing timely notification should there be a breach of unsecured personal health information. The CAP also requires revising existing policies and procedures related to appropriate sanctions against workforce members that fail to comply with such policies and procedures.

Presence also is required to forward such policies and procedures within 60 days of the CAP effective date to HHS, within 30 days of HHS' approval of the policies and procedures, and officially adopt and distribute policies to all workforce members and within 30 days of any new workforce member providing services.

The CAP also calls for training workforce members within 60 days of the approval of the policies and procedures, as well as annual certified retraining and written compliance reports confirming the training. ■

in Nashville, TN. The definition of "timely" notification varies from state to state, he says. For example, Connecticut requires notification within 90 days, but Florida sets notification within 30. California states notification must occur "within the most expedient time possible and without unreasonable delay."

"Notification can be a juggling act for organizations, because the process of conducting a thorough investigation to identify all affected individuals is critical and often takes time," Lapidus says. "The timing of notification is a big issue for any organization because releasing incorrect information about a breach can create needless anger, worry, and fear, and in healthcare can be even more critical given the type of information stored."

A plan is not enough. Kroll encourages organizations to regularly review, update, and drill their plans. These exercises help identify security gaps, address employee training needs, strengthen communication structures, and adapt plans to ever-changing nature of cyber threats. By conducting drills, organizations should give themselves a better chance to respond to breaches effectively and meet notification timing requirements.

Aside from the specific violation of the notification rule, the settlement also signals that OCR expects more of healthcare providers. Failure to understand the requirements will be accepted as an excuse less often, he says.

"I think as data breaches continue to occur and evolve, the expectation that an organization is prepared ahead of time and be able to demonstrate movement and notification efficiently and in a reasonable amount of time will be the expected norm," Lapidus says. "That said, every breach is different; it often takes time to understand what happened and to determine next steps."

Lapidus says the lessons in the Presence case include more than just reporting in a timely manner.

"The key lessons are to take proactive incident response planning measures and define the necessary internal roles and responsibilities determined before a breach occurs to help increase the chances of a timely investigation and notification," he says. "And remember, a breach can involve one individual to millions of personal records, so organizations need to plan ahead for a range of scenarios." ■

### SOURCES


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# USB Drive Containing ePHI Stolen

The OCR recently announced a HIPAA settlement based on the theft of a USB data storage device with unsecured electronic protected health information (ePHI).

MAPFRE Life Insurance Company of Puerto Rico will pay $2.2 million and implement a corrective action plan, OCR reported. MAPFRE underwrites and administers a variety of insurance products and services in Puerto Rico, including personal and group health insurance plans.

MAPFRE filed a breach report with OCR in September 2011 indicating that a portable USB device containing ePHI was stolen when it was left unsecured in the IT department overnight. The device included complete names, dates of birth, and Social Security numbers of 2,209 people.

MAPFRE reported that it was able to identify the breached ePHI by reconstituting the data on the computer on which the device was attached. OCR's investigation determined the company was not in compliance with HIPAA rules, specifically a failure to conduct its risk analysis and implement risk management plans contrary to its prior representations, and a failure to deploy encryption or an equivalent alternative measure on its laptops and removable storage media until Sept. 1, 2014.

MAPFRE also failed to implement, or delayed implementing, other corrective measures it informed OCR it would undertake.

The resolution agreement and corrective action plan may be found online at: http://bit.ly/2jaf5MZ. ■