CCH Healthcare Compliance LETTER

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Letters to the Editor

The CCH Healthcare Compliance team welcomes your comments. Send them to Jeff Reinholtz, Managing Editor at reinholj@cch.com. Comments may be edited for clarity or space.

Final Privacy Rule is balanced — or not — say commentators

by Gordon R. Shea, J.D.

The decision by the Department of Health and Human Services (HHS) to codify most of its proposed changes to the Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) (*See Privacy Rule finalized; most proposed changes codified,* CCH Healthcare Compliance Letter Vol. 5, Issue 16, Aug. 19, 2002) has elicited a mixture of praise and condemnation from various players in healthcare policy circles.

Industry: balanced. Picking up a theme that the HHS struck in issuing the newly finalized rule, many commentators have focused on the issue of "balance."

In commentary accompanying the rule, HHS used the word "balance" 17 times to explain its decision to codify the rather broad changes it first proposed in March of this year. One of the first industry groups to issue a formal statement on the codification, the American Association of Health Plans (AAHP), followed this lead. Under the headline "DHHS Issues Balanced, Workable Rule," the AAHP said that in its view, HHS's final version of the privacy rule followed "a balanced, workable approach that protects the privacy of patients without undermining their health care."

Another prominent group, the Healthcare Information and Management Systems Society (HIMSS), released a letter that likewise echoed HHS's rationale for changing the Privacy Rule. HIMSS President and CEO H. Stephen Lieber said in a statement that his group believes that, under the final rule, it "appears that a balance has been successfully reached" between consent and notice and the use of protected health information for research and other purposes. Lieber said his organization is "applauding" the Bush administration for "issuing a fair final rule."

One of the most prominent industry groups to weigh in on the newly finalized rule was the American Hospital Association (AHA), which issued a statement stating its view that the "final rule strikes the right balance." The AHA statement went on to say that the rule now "guarantee[s] strong privacy rights" in a manner that "puts common sense ahead of bureaucracy."

Outside groups: unbalanced. Some groups outside of the healthcare industry likewise focused on "balance" but reacted to the codification of proposed privacy rule changes with criticism. The Citizens' Council on Health Care (CCHC), a Minnesota nonprofit group, issued a statement under the headline "Balanced Against Other Interests, Patient Privacy Lost Out in Bush Administration's Modification of Federal Medical Privacy Rule." HHS "regulators," according to CCHC's President Twila J. Brase, "have 'balanced' private interests against other interests, and the other interests won." In a unique take on the final rule, CCHC counted off the 17 times HHS's announcement of the finalized rule used the word "balance" and issued a bulleted list of issues the Department claimed to be weighing against patient privacy in each instance. According to

CCHC, rather than focusing "on the privacy needed by patients" in the healthcare system, the final rule now focuses "on the health care industry's desire" to quickly and firmly settle the controversy that has swirled over the Privacy Rule since HIPAA was first enacted.

One group that departed from the attention to balance, however, was Georgetown University's well-known Health Privacy Project (HPP).

Reacting to the rule's now-final requirement that covered entities send patients a notice of the entity's privacy protections (instead of seeking patient consent for each disclosure of private information), HPP said that "notice alone does not provide" the needed "opportunity for dialogue or understanding" between patients and doctors. In response to the rule's redefinition of what activities constitute the "marketing" of health care items and services to patients, HPP said that the new rule defines marketing "so narrowly that it does not include many of the aggressive drug marketing tactics that have recently been in the headlines." ■

CCH Chicago Bureau, August 23, 2002

States settle privacy cases

by Gordon R. Shea, J.D.

A recent series of privacy breaches by drug and pharmaceutical companies has resulted in several legal settlements with state attorneys general across the nation.

E-mail disclosures. In the largest settlement action, attorneys general from several states entered into a settlement agreement with drug company Eli Lilly. The settlement follows Lilly's disclosure of the e-mail addresses of what California Attorney General Bill Lockyer described as "hundreds" of Prozac patients.

Lilly had collected the e-mail addresses as part of the "Medi-messenger" e-mail alert service. Under the "Medi-messenger" program, Lilly collected personal data from Prozac patients on-line for the ostensible purpose of sending those patients e-mail reminders about when to take their medication. Approximately 700 Prozac takers signed up for the service.

The privacy problem occurred on June 27, 2001, when each subscriber to the e-mail service received not only their expected alert about when to take their medication, but also the e-mail addresses of everyone else who had signed up for the alerts.

Following the disclosure, attorneys general from California, Connecticut, Idaho, Iowa, Massachusetts, New York, New Jersey and Vermont initiated legal action against Lilly. In addition, the Federal Trade Commission began an inquiry that resulted in a settlement earlier this year.

In settling the legal dispute with state attorneys general, Lilly agreed to pay the eight states that took action against it a total of $160,000.

More Florida action. As reported in *Questionable marketing practices raise HIPAA concerns,* CCH Healthcare Compliance Letter Vol. 5, Issue 15, Aug. 5, 2002, the office of Florida Attorney General Bob Butterworth issued subpoenas to Lilly earlier this summer after a 59-year-old depression patient received unsolicited samples of Prozac in the mail.

But Lilly is not the only drug industry player who has come within Butterworth's sites. Following another case of a possible privacy breach, this time by a drug retailer, Butterworth's office announced that it entered into a settlement agreement with that retailer, the Eckerd Corporation.

Butterworth's office began its investigation of Eckerd last December. Eckerd had pharmaceutical customers sign an acknowledgement when they picked up their prescribed drugs. The form seemed uncontroversial until customers began to notice the fine print on it that authorized Eckerd to use patient prescription information for future marketing purposes.

Under the rather unusual terms of Butterworth's settlement with Eckerd, Eckerd has endowed a new ethics chair at Florida A&M University at a cost of one million dollars. It has also agreed to discontinue use of combined acknowledgement forms and marketing permissions.

HIPAA implications. Had these companies obtained the patient information they received from HIPAA-covered entities rather than from patients themselves, the entities might well have been exposed to legal action. The Eckerd example provides a good cautionary tale for any healthcare entity that hopes to save administrative hassles by combining patient consent forms with other forms of required patient paperwork. Furthermore, the Lilly case strongly suggests caution for any covered entity that looks to communicate private health information via e-mail. ■

CCH Chicago Bureau, July 25, 2002

CCH Healthcare Compliance Letter

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Discount program — "ok" if uniform, "no" if purchase-based

by Geraldine S. Stroka J.D., R.N.

Despite failing to qualify under the discount safe harbor regulation, a dialysis manufacturer's proposed discount arrangement, based on a uniform discount for aggregate annual purchases, would not be subject to administrative sanctions under the antikickback statue. However, the manufacturer's second discount proposal, necessitating minimal purchases of certain items, could be subject to sanctions by the Office of Inspector General (OIG).

Proposed discount program. A national manufacturer and distributor of dialysis — both hemodialysis and peritoneal — equipment and supplies proposed these arrangements for its customers. Its customers utilized either hemodialysis equipment which is utilized primarily in dialysis facilities and hospitals, or peritoneal equipment which was utilized by patients primarily in their home or at work.

The manufacturer proposed two discount programs for purchasers of its dialysis equipment and supplies: (1) a uniform discount based on the aggregate annual purchases, and (2) a discount based on total annual purchases of certain designated or all items if the purchaser bought a minimum quantity of certain items. The manufacturer certified that it would meet all the requirements of the discount safe harbor.

Reimbursement methodologies. Under Medicare Part B maintenance dialysis is reimbursed under three different methodologies, one for dialysis in a facility — usually hemodialysis — and the other two for home dialysis — usually peritoneal. While different, all of the methodologies are capped at almost the same amount. The dialysis facility and one of the home methods are composite rate payments and receive almost the same amount while the other at-home method is based on reasonable cost or charges but has a cap similar to Medicare's composite rate.

Discount safe harbor inapplicable. The dialysis manufacturer would be required to comply with the requirements for "sellers" under the discount safe harbor, 42 CFR §1001.952(h)(2). The 1999 final rule, 42 CFR §1001.952(h)(5)(ii), defined "discount" so that the discount safe harbor does not apply in circumstances in which the goods or services that are being discounted are reimbursed under different methodologies. Here, because Medicare reimburses some of the dialysis customers under two or even three different payment methodologies, the discounted sales to these customers would not qualify for this safe harbor.

The discount safe harbor does not protect bundled goods where reimbursement is under different payment methodologies because such discounts may (1) allow parties to cost shift among reimbursement systems, (2) distort true cost or (3) force parties to order more goods than needed, thereby passing this cost on to the federal government.

Uniform discount minimal risk. The payment methods, although different, result in almost identical payments for dialysis equipment and supplies; Part B pays the same composite rate on a per treatment basis. Although another payment procedure uses two different methods, reasonable cost and reasonable charges related to costs, the reimbursement caps equalize the reimbursment for all three methods. In addition, the dialysis manufacturer has certified that it would meet all the requirements applicable to it as a seller under the safe harbor regulation.

The OIG found that the uniform discount proposal posed a minimal risk of fraud and abuse because the applicable payment methods result in almost identical payments. In addition, the dialysis manufacturer certified that it would comply with all discount safe harbor requirements for sellers. Therefore, OIG determined that would not impose administrative sanctions on this proposed discount program. However, OIG warned, this discount program could become illegal if it is considered among other related arrangements.

Minimum quantity purchase-fraud potential. This proposed plan requires minimum quantity purchase of certain items. Because the products would vary, the payment method is unknown; the discounts might be "tiered" with more

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The Power Behind Payment Data to Strengthen Hospital Compliance and Increase the Bottom Line

by Jacqueline T. Hodges, MBA, RHIA

For hospitals trying to make it in a competitive health care market, their success may have more to do with tracking and trending their services than with all the beds they can fill or rates they can raise. It's the data–payment data in fact! With the myriad of other payer obligations hospitals contend with everyday, it's more important than ever for them to know where they've been so they can predict where they are going.

Hospitals really don't spend a lot of time looking at their payment data. They use it to post to their accounts receivable but they really don't look at the detail. That's unfortunate because there is a wealth of information there and it's easy to access.

The payment files are basically the result of provider coding and billing accuracy. Facilities send a string of numbers on a UB-92 or 1500 that tells the story of the services rendered to a patient. In exchange, the third-party payer sends a string of numbers back with the results of what was submitted. This string of numbers provides detailed information about payment, partial payment, outlier payments, denial or suspended claims status. While this information is filled with potential compliance and reimbursement concerns only a sampling is presented here.

Managing the 72-hour rule. The diagnosis related groups' (DRGs) 72-hour rule simply states that all diagnostic outpatient services (including clinical diagnostic laboratory tests) that fall within 72 hours of an inpatient visit must be merged with the inpatient bill, regardless of the reason for the visit. This applies to outpatient services provided to a beneficiary by the admitting hospital or by an entity wholly owned or operated — sole owner or operator — by the hospital (or by another entity under arrangements with the hospital). [1]

Outpatient services cannot be billed separately unless they are therapeutic in nature, and they are not related to the inpatient admission as defined by the principal diagnosis.

Despite this directive, providers either inadvertently continue to be paid for outpatient services in violation of the 72-hour rule or continue to receive denials from the Fiscal Intermediary (FI). In order to retain the integrity of their revenue process and make sure they are being paid correctly, facilities should regularly query their payment data file.

Hospitals should utilize Section 415.6 of the Medicare Hospital Provider Manual to develop a query to analyze their payment data files by:

- Trending payment data for outpatient/inpatient claim overlaps that occurred within 72 hours of the inpatient claim. Even if the claim was denied, the FI still stores the fact that the denial occurred.
- Tracking provider numbers that would fall under the wholly owned and operated scenario. These provider numbers were not included in the original Department of Justice settlement and continue to be a source of compliance risk.
- Tracking and trending reason denial code CO-60, "Outpatient/Inpatient Claim Overlap".
- Closing the loop on this process to ensure accurate payments in a compliant manner.

APC issues. Ambulatory Payment Classifications (APCs) make up a complicated payment system, but also incorporate a rich supply of detailed APC coding information. Hospitals can glean much of this information through their own payment data. Several areas have raised the potential for compliance problems and lower-than-appropriate reimbursement.

Unlisted specific procedure codes. These non-specific procedure codes represent unusual, variable or new services that are typically packaged into or paid as the lowest rated APC for the category. The biggest problem in using these codes is that most often, the code doesn't represent the service rendered. It can be a target for review. [2]

These codes are very vague and very easy to use incorrectly. At several hospitals, I uncovered the frequent use of code 94799 — unlisted pulmonary service or procedure — for pulmonary rehab, which is not covered by Medicare. It's really an unlisted procedure code for respiratory therapy. This issue is on the radar screen of the FI and/or Office of Inspector General (OIG) staff. In such cases the hospital should have coded the individual respiratory treatments that were provided to the patient.

Outlier payments. Within a hospital's payment data is a record of all its outlier activity for each claim. Hospitals should conduct queries of their payment data to see in which instances outlier payment are occurring. And if so, whether the claim was coded and billed correctly. This is a targeted area for the OIG Work Plan 2002.

I often see hospitals' incorrect use of CPT and HCPCS codes that results in a claim generating an outlier payment when it should have produced a regular payment.

One example involved a hospital that billed $46,932.80 in total charges for insertion of a pacemaker procedure. While that may not sound out of line, there were two fundamental

problems with the claim: (1) rather than putting the correct code on the bill for the actual pacemaker charge, the hospital inserted a nonspecific code 33999 — unlisted procedure, cardiac surgery; and (2) there was no C code on the bill for the pacemaker device which had a charge of $36,500.

The low payment for the nonspecific code (33999) of $91.57 coupled with the lack of C code for the pacemaker device caused the claim to receive an outlier payment of $11,943.12 in addition to the APC payment totals of *only* $177.92. The total payment for the claim was $12,121.04.

If the claim had the correct CPT code for the insertion of pacemaker procedure (33213) and the C code for the pacemaker device (C1785) then the Medicare payments would have been $2,776.03 and $10,297.00 respectively. Thus the total claim would have been correctly paid at $13,159.38, which is in excess of the previous payment and would have eliminated the potential red flag associated with the high outlier payment for a non-specific procedure.

Correct modifier usage. Incorrect modifier usage will trigger overpayments and underpayments. Since the hospital's payment data contains the history of modifier usage, this is the first place hospitals should look to find solutions for this issue.

Yet modifiers are a sticky wicket for hospitals especially when their systems don't edit out incorrect usage. Some errors are more obvious than others. Many hospitals use modifier–50, bilateral procedures, in places where by definition, you don't have these types of bilateral body sites. I also frequently see hospitals attaching modifier–91 — repeat clinical diagnostic lab test — for services other than laboratory services. There are also many cases where the hospital payment data will have a denial for incorrect or missing modifier (CO-4).

Upon investigating this issue, it turns out the modifier code was placed on the billing record not by a coder, but by a business office staff person. This online claims adjudication occurs once the claim has been filed by the hospital and suspended by the FI. The changes are actually made in the FI system and not on the hospital's data.

Analysis of the provider's payment data is the only way to ensure that there are no breakdowns in the revenue cycle regarding accurate modifier coding.

Denial trending. With APCs, hospitals are filing much detailed, service level information. Denials will occur at both a claims level and at the service level.

The payment data file provides the hospital with a wealth of information that the third-party payer already knows. For hospitals that don't see the detailed payment information, a service level denial will not be identified since the payment is posted at the claim level. They are getting that high level information that incorporates submitted charges, co-payment, deductible, and payment. However, the service level denials that exist within the body of a claim will not appear until the patient complains about the additional amount owed that was not anticipated. This results in a public relations issue and a potential compliance issue because the partially denied claims are not identified through routine posting of payments.

An example of a service level denial occurs when requested information was not provided or is insufficient. For that, hospitals will receive denial reason code CO-17. Using a modified barium swallow as an illustration, facilities need to remember that sometimes more than one set of information is required when Medicare requests documentation. In this case, a modified barium swallow involves both radiology and speech pathology data and hospitals will need to provide both pieces of documentation — a radiology report and a speech pathology note.

I recommend that hospitals query their payment data file and trend denials by reason code and dollar volume.

Advanced Beneficiary Notices

It is important for hospitals to regularly review their payment data to see if the FI accurately classified any ABN-related claims. Hospitals look at one of two things when they submit a claim that triggered an ABN Medicare denial:

- the patient disagreed with the hospital's decision and wants it to submit the claim to the FI for approval or denial. After reviewing the claim, the FI will likely ask to see the medical record and will determine whether the procedure is medically necessary. The result of that determination will be found in the payment data with one of the following codes if it was denied: COB-22 "Denied Based on Diagnosis" or PR-46 "Non-covered Services."
- when the hospital knows a service is not covered but needs that denial from the FI to file the claim with a third-party payer.

Claims must have an ICD-9 code attached for the procedure to evidence medical necessity. Facilities should query payment data files for all COB-22 or PR-46 denial reasons to determine if the provider initiated the request or if the FI denied based on incomplete claims information submitted.

This is not only a compliance issue, but also a lost revenue concern. One hospital had service-level denials (not claims-level) over a one-month period that amounted to $11,974. $5,000 of that amount could be tied to code CO-B22. That means that approximately 45 percent of its service level denials were attached to this ABN issue. Without analysis and intervention, this can grow to substantial losses. If you have a good compliance plan, you will also secure your revenue.

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[1] Medicare Hospital Provider Manual Section 415.6, Federal Register February 11, 1998.

[2] Medicare Hospital Provider Manual Section 440.

purchases leading to additional discounts, dialysis supplies might be sent at a reduced charge to "induce" other purchases, and the federal healthcare programs might not share appropriately in the discounts.

The OIG determined that these "bundled" discounts may allow customers to cost-shift among reimbursement systems, distort the true cost of items, lead to overutilization, and make it difficult for federal programs to determine proper reimbursement levels. Because there is potential abuse in supplying goods at a reduced charge in order to induce the purchase of other goods under the federal healthcare program, OIG could potentially impose administrative sanctions. Whether an actual violation exists would require a review of the parties' intent, which is beyond the scope of this opinion. ■

OIG Advisory Opinion 02-11, August 7, 2002, ¶150,191

Governmental initiatives may increase private-party plaintiff suits for fraud

by Raio G. Krishnayya, J.D.

In July, the U.S. Attorney's Office for the District of New Jersey announced a settlement in the Medicare fraud case against Hackensack University Medical Center. The settlement requires Hackensack to pay $4.2 million for false pneumonia upcoding in exchange for the government's promise to refrain from seeking triple damages and other penalties. Also, under the agreement, Hackensack must have paid the $4.2 million within 10 days of the settlement date.

While such settlements are not unique to the healthcare compliance arena, this settlement arises in the wake of a recent U.S. Court of Appeals for the Sixth Circuit decision, *In re: Columbia/HCA Corp. Billing Practices Litigation.* At the heart of the Hackensack agreement was the voluntary disclosure of the false upcoding, which is represented by Acting U.S. Attorney, Ralph J. Marra Jr.'s statement, "[a] voluntary settlement is in the best interests of the Medical Center and the United States. The Medicare program receives reimbursement it is owed, and a well-regarded medical center avoids potentially harsher sanctions. This is the kind of corporate behavior we want to encourage." However, under the *Columbia/HCA* case, this kind of behavior may not be encouraged.

Selective waiver denied. In the *Columbia/HCA* case, Columbia/HCA faced numerous suits based on fraudulent reimbursements from private part insurers. See *Selective waiver agreement, no protection from private plaintiffs*, CCH Healthcare Compliance Letter, Vol. 5, Issue 13, July 8, 2002. The case arose after a massive investigation by the Department of Justice (DOJ) into federal healthcare fraud in the mid-1990s. The case against the government ended with a settlement agreement, similar to the Hackensack case, requiring Columbia/HCA to waive protections under the attorney-client and work-product privileges and voluntarily disclose all incidents of false or fraudulent reimbursements. In exchange, the agreement provided that although Columbia/HCA had waived protections under those privileges as to the DOJ's case, those privileges would be protected as to subsequent claims by private party-plaintiffs.

At the conclusion of the DOJ's case, the foreseeable occurred; numerous private insurers filed suit against Columbia/HCA in June 2000. The major issue in that case was whether the "selective waiver" provision of the agreement with the government actually allowed the attorney-client and work-product privileges to be asserted as to the private parties. In June, the Sixth Circuit handed down its ruling ordering Columbia/HCA to turn over the same materials disclosed to the DOJ. In holding that the selective waiver did not apply, the Sixth Circuit asserted that selective waiver provides defendants with unfair advantages and also results in a government-imposed obstacle to ferreting out fraud by private parties. The *Columbia/HCA* case left open the question, what is the incentive to voluntarily disclose incidences of fraud?

Pros and cons. Cases like *Columbia/HCA* and Hackensack University Medical Center demonstrate that voluntary disclosure to the government is encouraged for a number of reasons. In terms of benefits for the provider, disclosure can avoid costly and long, drawn out litigation that could detrimentally impact the reputation of the provider. In addition, most agreements do not impose a requirement that the provider admit to wrongdoing. Although agreement to make monetary reparations arising from allegations of fraud seems like an admission of wrong doing, as a legal matter there is no imposition of guilt, which may save other provider relationships, such as with creditors and third-party contractors. In addition, the government will often promise to not seek harsher penalties. However, the *Columbia/HCA* case has given providers a very good reason not to make voluntary disclosures — fear of making private-party lawsuits easier to win.

Global implications. In a related matter, several weeks ago President Bush signed into law H.R. 3763, or the "Sarbanes-Oxley Act of 2002." The general purpose of the bill, according to the President, is to send a message to "every dishonest corporate leader: you will be exposed and punished; the era of low standards and false profits is over; no boardroom in America is above or beyond the law." A few of the specific provisions of this law include:

- strengthen the independence of auditing firms,
- increase corporate responsibility, and
- increase corporate financial disclosures.

In a time where public trust in the corporate structure of America is at an all time low and in light of legislative mandates such as the Sarbanes-Oxley Act, the choice of voluntary disclosure is really no choice at all. On the one hand, a provider that forces a case to trial may face harsher penalties for opting to remain silent. On the other hand, the provider who makes the disclosure, while privy to leniency from government prosecutors, may open the gates for potentially crippling private-party suits — suits that could sound the death knell for providers like Hackensack. A copy of the U.S. Attorney's Office press release can be found at http://www.njusao.org/files/ha0718_r.htm. A copy of the White House press release regarding the Sarbanes-Oxley Act can be found at http://www.whitehouse.gov/infocus/corporateresponsibility/. ■

CCH Chicago Bureau, Aug. 20, 2002

False Claims

Blue Cross of California and WellPoint health networks fined $9.25M

by Patrick J. Osborne

The Justice Department has announced that Blue Cross of California (BCC) and its parent company, WellPoint Health Networks, have agreed to pay the United States $9,250,000 to resolve allegations that BCC defrauded Medicare. BCC, which was under contract with the Centers for Medicare & Medicaid Services to process Medicare claims in California until December 2000 (Medicare Part A fiscal intermediary), is alleged to have knowingly falsified data regarding its performance of cost report audits for Medicare.

Blue Cross of California carried out watchdog services for the government with respect to Medicare fraud. BCC was responsible for, among other things, auditing cost reports submitted by hospitals and other Medicare providers to ensure that the providers were properly reporting their allowable costs and seeking accurate and appropriate reimbursements.

A former company auditor, Vipul Vaid, originally brought forth the allegations in a qui tam or whistleblower case under the provisions of the False Claims Act. The lawsuit alleges that BCC falsified audit activity dates entered into an audit tracking database in an effort to deceive the government into believing that the company had performed more audit work than it actually performed during the pertinent fiscal year. The performance of required audit work was one of the criteria used by the government to evaluate BCC's performance, and renew its contract, as a fiscal intermediary each year.

"This settlement demonstrates that the government will continue to aggressively pursue healthcare fraud not only by providers but also by intermediaries or other contractors who submit false or fraudulent information to Medicare," said Robert D. McCallum, Assistant Attorney General for the Justice Department's Civil Division.

The settlement resolves claims submitted between 1990 and November 30, 2000 for the covered conduct. The case was handled jointly by the United States Attorney's Office in Los Angeles and the Civil Division of the U.S. Department of Justice. The government received investigative assistance from the Office of the Inspector General of the U.S. Department of Health and Human Services (HHS) and the FBI. A copy of the DOJ News Release can be located at: http://www.usdoj.gov/opa/pr/2002/July/02_civ_435.htm. ■

CCH Chicago Bureau, July 29, 2002

Bioterrorism

Authorities anticipate smallpox vaccinations

by Judith A. Tichenor, J.D., LCSW

Recommendations for smallpox vaccinations of healthcare employees could be expanded as early as this fall once quantities of the vaccine become available, announced James Bentley, Senior Vice President, Strategic Policy Development, American Hospital Association (AHA), and the AHA's foremost expert on disaster readiness. Bentley made the pronouncement at the 38th Annual Conference for the American Society for Healthcare Human Resources Administration. Therefore, he added, compliance officers and human resource executives must develop strategies to manage the side effects and public health implications of the vaccination process.

First, some questions must be answered. Will just caregivers receive the vaccine? What about food service or maintenance personnel? Should the policy make vaccination mandatory or voluntary? If voluntary, what should management do with staff members who refuse?

These questions generate workplace safety and compliance issues, according to Bentley. Among them is the fact that a certain amount of hospital and healthcare facility employees are in a "contraindicated" status, meaning that for a variety of reasons, they cannot take the vaccine. For example, a staff member whose immune system is compromised by HIV or hepatitis C cannot be vaccinated for a communicable disease like smallpox without encountering the grave risks of complications, including infection. "The number of contraindicated individuals (working in healthcare settings) isn't small," Bentley stressed.

Also, while the risks for vaccine complications are low, smallpox vaccinations have been known to cause otherwise healthy individuals to develop severe symptoms and side effects, some of which can be fatal. These include allergic reactions and the development of a disease known as vaccina, which is the agent used in the vaccine to create the immunity to smallpox.

The fact that the vaccine involves a surface vaccination process also opens the door to employee privacy issues. Employees who comply with taking the vaccine may challenge those who did not, thus leaving the unvaccinated employee vulnerable to rumors of, for instance, HIV-positive status and thus, a loss of privacy.

Another matter for strategic planning is the cost issue. If the vaccination is voluntary, who will pay for it, the employer or the employee? Who pays for and administers the screening tests to check for contraindicated status?

There are added risks to the vaccine that the health community must take into consideration that may not have been prevalent up through 1972, when the last nationwide childhood vaccinations were administered in the United States. The primary concern revolves again around the fact that this is a surface vaccine. Everyone who comes into contact with a vaccinated individual is at risk of exposure to the disease, from patients in emergency rooms to healthcare professionals' family members and children. Again, those with compromised immune systems will be particularly at risk of contracting the disease from even indirect exposure to vaccinated healthcare employees. Bentley suggested that an eight-to-ten day quarantine of all vaccinated individuals might be re-

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quired, or at minimum, alternate assignments for a similar duration.

As the time for the smallpox vaccine's release draws near, many standards and compliance questions continue to evolve. Bentley reminded conference attendees, an audience consisting of healthcare human resource managers and generalists, to be on the lookout for answers that the Center for Disease Control and state departments of public health will hopefully soon provide.

This year's ASHHRA conference was held in Atlanta, Georgia, from July 27 — July 31, 2002. ■

CCH Chicago Bureau, August 2002

Preparedness funding leaves trauma center problems unresolved

by Raio G. Krishnayya, J.D.

President Bush recently articulated that the war on terrorism would tap the resources of the scientific community in a challenging way. His comments reflect a government-wide push for healthcare providers to become bioterrorism prepared.

However, there may be a growing problem with a key component of the bioterrorism preparedness programs, internal strife between hospital administrators and staff physicians. In recent months, many providers have experienced problems in maintaining and operating their trauma centers due to the tug-of-war between operating budgets and increasing costs. While such strife is not a new problem, its resulting effect has a new twist because it could affect the efficiency for becoming prepared for a catastrophic event.

Operational setbacks. On July 4th, the *Washington Post* reported that the only Level One, medical trauma center in Las Vegas, the University of Nevada Medical Center (UMC), closed its doors after many of its surgeons resigned. The surgeons resigned in protest of the exorbitant cost of medical malpractice insurance. They asserted that the costs of malpractice insurance, coupled with high-damages lawsuits, have threatened their livelihoods. The local legal community responded by accusing the surgeons of waging a campaign of fear. Ten days later, the trauma center reopened after surgeons agreed to return under provisions of temporary employment contracts. During those ten days, the largest city in Nevada, along with parts of Utah and Arizona, were without facilities to handle a large-scale crisis like a bioterrorist attack.

A similar situation arose in Maryland, when in May a dispute between trauma surgeons and hospital administrators at Washington County Hospital forced the temporary closure of its trauma unit. The closure meant that seriously injured patients in Washington and Frederick Counties, as well as parts of West Virginia, would be sent to another facility. The closure even resulted in longer transport times for seriously injured patients from the Camp David area. The disputing surgeons argued that staff deficiencies were resulting in tenuous working conditions, thereby making execution of their duties difficult. Furthermore, the surgeons protested their "on-call" status, which resulted in lower wages rather than being "in-house", which would have allowed for salary increases.

Tug-of-war. Caught in the center of these fiscal disputes is the healthcare provider. On the one hand, providers operate trauma centers, and in many cases are taking affirmative steps to become bioterrorism prepared. On the other hand, the rising costs of healthcare coupled with the high-damages lawsuits and the potential for anti-fraud enforcement actions make it difficult to offer increased wages and incentives to physicians.

Despite great expenditures by the government to assist facilities in becoming prepared, these financial packages may not alleviate the problem that could truly inhibit an effective response to a bioterrorism event. Consider that in June, President Bush signed into law, a bioterrorism preparedness statute that allots $4.6 billion in spending for the nation's healthcare system to become bioterrorism prepared. The provisions of the law include:

- increased protection of the food and water supplies from biological attacks;
- increased stockpile of vaccines;
- a Health and Human Services (HHS) directive to create a national database of dangerous pathogens;
- the creation of an assistant secretary for public health and emergency preparedness position; and
- tighter controls on biological and chemical laboratory operations.

While this figure seems reassuring, there may be some doubt as to whether this money will resolve the types of conflicts illustrated in the UMC and Washington County Hospital examples. While these funds are designed to ramp up the resources of healthcare providers generally, neither of these funds includes provisions to specifically address the problems — tort reform and unfair wages — indicated by the two examples. Furthermore, the issue of enforcement leaves providers weary of providing too many or too generous incentives to their physicians for fear of violating Stark laws, antikickback laws and a myriad of other compliance regulations.

A copy of the President's remarks at Argonne National Laboratory is at http://www.whitehouse.gov/news/releases/2002/07/20020722-1.html. A copy of the *Washington Post* article is at http://208.58.30.127/TRAUMA%20WATCH/page2.html. A copy of the article related to the closing of Washington County Hospital is at http://www.wtopnews.com/news/newsdetail_print.cfm?NewsID=497831. A copy of the text of the bioterrorism preparedness law is at http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=107_cong_public_laws&docid=f:publ188.107.pdf. A copy of the HHS news releases is at http:www.hhs.gov/news/press/2002pres/20020710a.html and http:www.hhs.gov/news/press/2002pres/20020710.html. ■

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