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FDA to audit Y2K-testing results for manufacturers of critical devices

Official downplays prospects of device seizures

The federal Food and Drug Administration (FDA) in Rockville, MD, may be using a contractor to review manufacturers' year 2000 (Y2K) test results, but don't expect it to begin seizing problematic medical devices.

On May 25, 1999, the FDA's acting deputy commissioner for policy testified that the FDA plans to hire a contractor to conduct an on-site review of manufacturers' test results supporting their compliance certifications for a sample of critical devices. This was a reversal of earlier statements made by the FDA, stating it didn't have the resources to conduct such reviews.

A few weeks later, **Kevin Thurm**, deputy secretary of the Department of Health and Human Services in Washington, DC, told members of the Senate Special Committee on the Year 2000 Technology Problem that the FDA might "issue public warnings or suggest voluntary recalls" of devices that the agency believes will malfunction on Jan. 1, 2000, and might even seize dangerous devices in "extreme cases."

The threshold for a seizure is high, however, says **Tom Shope**, special assistant to the director of the office of science and technology at the FDA. "[Thurm] was enumerating the list of authorities that FDA has to operate under. If there is a device that presents an unreasonable risk to public health, the FDA can seize it. [But] we don't know of many products that by virtue of the Y2K problem will present that kind of risk to patients." More likely, the FDA would encourage the manufacturer to do a voluntary recall, he adds.

Through the audits, the FDA is attempting to develop some additional assurance that the manufacturers are following the kind of procedures that would indicate that they have assessed the devices correctly, Shope says. The audits are a voluntary activity with the manufacturer; the FDA will publicize overall results of the audits, but company-by-company results will remain confidential.

In addition to the audits, the FDA has published a list of potentially high-risk computer-controlled medical devices that have the potential

for the most serious consequences for the patient should they fail because of date-related problems. **(See list, at right.)**

If the FDA finds products that have Y2K-compliance problems, it plans to take action, Shope says. "We would expect the manufacturer to take the appropriate steps to notify customers, and if needed, the FDA would certainly publicize the issue as well."

The possible recall or even seizure of medical devices puts additional pressure on the vendors and hospitals that haven't completed a significant amount of compliance testing, says **David Hall**, senior consultant at ACS Technology Solutions in Oak Brook, IL.

Some have no idea if they have problems

"I'm still finding medical centers and some equipment vendors that haven't done much to figure out whether they have a [Y2K] problem," he says. If the FDA announces a problem with a certain medical device, they are under the gun to make sure the one they have works.

At this time, however, the FDA says it has found no indications that the manufacturers haven't done a good job of assessing their products, Shope says. "We don't know of any verifiable incidences that manufacturers have not identified problem products appropriately."

(Editor's note: The FDA offers a Federal Year 2000 Biomedical Equipment Clearinghouse database that provides the general public, government agencies, and the health care and research communities information on the Y2K-compliance status of biomedical equipment. The database can be found on the Internet at www.fda.gov/cdrh/yr2000/year2000.html.

For more Y2K-compliance information, the General Accounting Office in Washington, DC, also recommends that providers check manufacturers' Web sites, although the quality of the data varies significantly from site to site.) ■

FDA releases list of high-risk medical devices

Inclusion depends on assessment of patient risk

To more sharply focus its efforts on the possible impact of the year 2000 (Y2K) date problem on medical devices, the federal Food and Drug Administration (FDA) in Rockville, MD, has developed a list of types of computer-controlled, potentially high-risk medical devices that have the potential for the most serious consequences for patients should they fail because of date-related problems. **(For more information about the FDA's Y2K activities, see cover story.)**

Inclusion of a type of device on this list does not mean that all devices of this type have a date-related problem (are Y2K-noncompliant) or, if they are Y2K-noncompliant, that they necessarily pose a significant risk to patients.

Rather, this list includes those types of devices that could pose a risk to patients if the date-related failure affects the function or operation of the device. The FDA will use this list to identify those devices (and manufacturers) that would present the most serious risks to patients if they experienced a Y2K-related failure. This will help the agency focus attention on the devices that could present the highest levels of risk.

These potentially high-risk devices are those that are:

- used in the direct treatment of a patient where device failure could compromise the treatment or could injure the patient;
- used in the monitoring of vital patient parameters and contain data that are immediately necessary for effective treatment;
- necessary to support or sustain life during treatment or patient care.

The list does not include diagnostic devices which failures would not result in immediate

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harm to the patient, even though the diagnostic information they provide might be unavailable or incorrect. However, a few diagnostic devices have been included, if the results of calculations or other information processing by the device would not be readily apparent to the user, and a Y2K failure of the device could reasonably lead to serious adverse health consequences before being detected by the user.

This list should not be considered definitive of all high-risk devices. It may change as the FDA receives comments on the types of devices included in the list.

Device list

Where the generic device type has been classified by FDA, the list includes the section number in Title 21 of the Code of Federal Regulations where the device type is described. For those devices cleared for market through the Premarket Approval application process or which have not yet been classified, no classification regulation number is given.

Classified devices

(Classification regulation number followed by classification name)

- 862.1345 glucose test system
- 862.2140 centrifugal chemistry analyzer for clinical use
- 862.2150 continuous flow sequential multiple chemistry analyzer for clinical use
- 862.2160 discrete photometric chemistry analyzer for clinical use
- 862.2170 micro chemistry analyzer for clinical use
- 868.1150 indwelling blood carbon dioxide partial pressure (PCO_2) analyzer
- 868.1200 indwelling blood oxygen partial pressure (Po_2) analyzer
- 868.1730 oxygen-uptake computer
- 868.2375 breathing frequency monitor
- 868.2450 lung water monitor
- 868.5160 gas machine for anesthesia or analgesia
- 868.5330 breathing gas mixer
- 868.5400 electroanesthesia apparatus
- 868.5440 portable oxygen generator
- 868.5470 hyperbaric chamber
- 868.5610 membrane lung (for long-term pulmonary support)
- 868.5830 autotransfusion apparatus
- 868.5880 anesthetic vaporizer
- 868.5895 continuous ventilator
- 868.5925 powered emergency ventilator
- 868.5935 external negative pressure ventilator
- 868.5955 intermittent mandatory ventilation attachment
- 870.1025 arrhythmia detector and alarm
- 870.1750 external programmable pacemaker pulse generator
- 870.3535 intra-aortic balloon and control system
- 870.3545 ventricular bypass (assist) device
- 870.3600 external pacemaker pulse generator
- 870.3610 implantable pacemaker pulse generator
- 870.3700 pacemaker programmers
- 870.4220 cardiopulmonary bypass heart-lung machine console
- 870.4320 cardiopulmonary bypass pulsatile flow generator
- 870.4330 cardiopulmonary bypass on-line blood gas monitor
- 870.4360 nonroller-type cardiopulmonary bypass blood pump
- 870.4370 roller type cardiopulmonary bypass blood pump
- 870.4380 cardiopulmonary bypass pump speed control
- 870.5225 external counter-pulsating device
- 870.5300 dc-defibrillator low energy (including paddles)
- 876.5270 implanted electrical urinary continence device
- 876.5630 peritoneal dialysis system and accessories
- 876.5820 hemodialysis systems and accessories
- 876.5860 high permeability hemodialysis system
- 876.5870 sorbent hemoperfusion system
- 876.5880 isolated kidney perfusion and transport system and accessories
- 880.5130 infant radiant warmer
- 880.5400 neonatal incubator
- 880.5410 neonatal transport incubator
- 880.5725 infusion pump
- 882.5820 implanted cerebellar stimulator
- 882.5830 implanted diaphragmatic/phrenic nerve stimulator
- 882.5840 implanted intracerebral/subcortical stimulator for pain relief
- 882.5850 implanted spinal cord stimulator for bladder evacuation
- 882.5860 implanted neuromuscular stimulator
- 882.5870 implanted peripheral nerve stimulator for pain relief
- 882.5880 implanted spinal cord stimulator for pain relief
- 884.1700 hysteroscopic insufflator

• 884.1730 laparoscopic insufflator
• 884.2660 fetal ultrasonic monitor and accessories

The following device classifications include radiation treatment planning systems that are accessories to these device types:

• 892.5050 medical charged-particle radiation therapy system
• 892.5300 medical neutron radiation therapy system
• 892.5700 remote controlled radionuclide-applicator system
• 892.5750 radionuclide radiation therapy system
• 892.5900 X-ray radiation therapy system

The following include post-medical device amendments Class III devices and devices not yet classified:

• ventilator, high frequency
• cardioconverter, implantable
• defibrillator, automatic implantable cardioverter
• defibrillator, implantable, dual chamber
• pulse-generator, dual chamber, implantable
• pulse-generator, program module
• pulse-generator, single chamber, sensor driven, implantable
• pulse-generator, single chamber
• system, pacing, temporary, acute, internal atrial defibrillation
• automated blood cell and plasma separator for therapeutic purposes
• lipoprotein, low density, removal
• separator for therapeutic purposes, membrane automated blood cell/plasma
• pump, drug administration, closed loop
• pump, infusion, implanted, programmable
• kit, test, alpha-fetoprotein for neural tube defects
• stimulator, cortical, implanted (for pain)
• stimulator, electrical, implanted, for parkinsonian tremor
• stimulator, sacral nerve, implanted
• stimulator, spinal-cord, totally implanted for pain relief
• stimulator, subcortical, implanted for epilepsy
• device, thermal ablation, endometrial ■

'Frontier medicine' comes into a new age

Technology upgrades productive for rural providers

When the Minnesota Rural Health Co-op thought about initiating a telemedicine project, it knew that its 42-rural-member organizations were not as sophisticated technologically as many urban providers. The Willmar-based Co-op just didn't realize how much.

"As we investigated telemedicine, we discovered that as late as 1994 and 1995, one of our communities did not have touch-tone dialing. It had rotary dialing," says **Sharon Ericson**, project director at the Minnesota Rural Health Co-op. Another member was not aware of a platform difference between Macintosh and IBM machines.

"In some ways, rural health gets to be like frontier medicine," Ericson says. "We don't have all the equipment that more urban environments do." To communicate to members, the Co-op had to rely on members' postal mail and an occasional fax.

Ericson and the Co-op realized that the communication and information sharing between the Co-op's 17 hospitals and 25 medical clinics across 12 rural counties needed to be vastly improved. They decided to install remote systems management software for communication with all its members. The CONNECT:Remote system from Sterling Commerce in Atlanta runs on a Windows NT network.

"The decision was related to wanting our members to be able to continue to be in the business they are in," Ericson says. "That would require having a PC network."

Implementing the plan

Another problem the Co-op encountered in investigating members' technological capabilities was that most of the information systems in the individual organizations were either proprietary or didn't have the level of sophistication to make them function beyond a proprietary method.

"For example, even if one of our hospitals was sending a UB92 electronically, it couldn't give [the Co-op] a copy," Ericson says. "We did an ER study to get some baseline data on urgent care vs. emergency room use. Several of our facilities could not tell us without doing a hand examination of the records what presented itself in a 12-month period in the emergency room."

Also, most Co-op members were so small that they didn't have their own information management staff. "Everyone [in these organizations] is

pushed in terms of work flow. People are doing lots of jobs. They might have multiple functions instead of individual functions."

When the Co-op made its decision to go to the network, Ericson knew that the upgrade would have to presented to members in a certain way. This presentation included emphasizing these points:

❒ **The upgrade would give them information they need on a just-in-time basis.**

"For example, they could download information about making referrals for networks to use when they need it," Ericson explains. "They certainly don't want to have to search the office for the piece of paper that someone stuffed in a drawer."

❒ **The upgrade could happen quickly.**

The Co-op had to send someone who could upgrade the system and train the users without taking a lot of time away from the users' jobs, she says.

The Co-op first wrote the grant to get the money for the project in 1995. Some grant money helped members purchase newer, basic systems, which included Windows 95 and 16MB of memory. "Our rationale for buying the systems for members was that it was so critical for people to have the information," Ericson says.

Member communities were upgraded at various stages. "Given our lack of resources, that's been a good thing," she says.

Members remain at various levels of use, as well. Some remain resistant to the technology, but the Co-op has a sufficient core of members who are actively using the system to communicate and get access to information. "[The member participation] makes it a functional system," Ericson says. "We just have to try to convince the others that this is the right thing to do."

Keeping in touch

Since hooking up most members on-line, the Co-op's copying bill has dropped from an average of $1,000 per month to $100, while the postage use has dropped from $300 to $75 per month.

The Co-op now is able to put administration manuals and their updates sent by health plans on the network where members can click on a topic and access that information at will. The network also provides information about providers and their participating health plans.

"We had made an Excel worksheet that outlines what specialty services are available when and what physician is in what network. But no one could ever find that piece of paper when they needed to make a referral," Ericson says. "Instead, we published it on the system and then connected it to different specialties. If members need a gastroenterology referral, they click on gastroenterology and it takes them to that part of the worksheet." The Co-op updates the worksheet weekly for members.

The Co-op also uses the network to publish information about the cooperative. This information includes:

❒ minutes and agendas of functional member meetings;

❒ information about contracts with health plans, as well as any information the health plans send to the Co-op, such as monthly performance results;

❒ information about quality improvement efforts;

❒ information about each of the members.

"We use the system to reduce the amount of travel time of the members participating in a quality improvement team. They can do some of the work from their desks," Ericson says. The information about fellow members is helpful, as well. "Some of them don't know each other well," she says. "It shows what the others are doing and gives them a place to brag about their programs."

Although most members are not connected at the clinical level to the Internet, they do communicate with the Co-op and other members through system e-mail. "A strength of the system is problem solving through e-mail," Ericson says. "[For example], a clinic manager in one of the communities may have a specific operational issue. She is able to e-mail all the other clinical managers and say, 'I'm having this trouble; is anyone else? If you are, how are you solving that problem?'"

Member communities are not yet transferring patient information. They are, however, using a common referral form so that one day the information from the forms may be placed into a database so the Co-op can look at the referrals across the communities.

Ericson recently realized how well the system was working. The Co-op experienced a month-long system failure related to phone company problems that resulted from moving the server to another location. "The volume of phone calls from people who couldn't get access to information increased exponentially without the system," she says. "From our vantage point, it's an absolute necessary tool to do this kind of process across this kind of distance." ■

Q & A Corner

Who's minding the compliance store?

By **Allan P. DeKaye**, MBA, FHFMA
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Q. Much has been made about the need for providers to develop compliance plans to ensure they meet federal regulations and guard against claims of fraud. Are these plans serving their purpose?

A. Everyone has a compliance plan or is talking about developing one. But is it genuine compliance or paper compliance? Even though providers put safeguards in place, is anyone minding the store? I think that's the key question.

Take the example of the discharge vs. transfer issue — one of the federal government's focuses for fraud under the False Claims Act. The hospital recording the discharge, not the transferring hospital, gets the DRG payment. If someone in the transferring hospital didn't know to enter "transfer to other facility" in the discharge column on the UB92 and recorded it as a discharge instead, then that hospital gets the benefit of the DRG. The benefit would be considerably higher than a per diem type of rate, which is usually assigned to a transfer.

The reason for the error can be a careless mistake, a transposition, or a miss on the keyboard. In a Windows-based system, a flip of the wrist can result in the mouse selecting the wrong answer.

It might not be fraud, but the government will tell us what it thinks. It will take the hard line — all these mistakes must be fraud. The onus is on the hospital to prove that they were good corporate citizens.

Q. Don't compliance plans help guard against some of these mistakes?

A. They don't help if hospitals are not data-defensive. Some don't even look at their own data; they just submit them. They are not taking a step back and seeing if they have any problems. I'm a firm believer that you need to measure and monitor your denials by payer, by reason, and determine whether these are refutable.

What can happen is hospitals will develop a compliance plan and not follow through. Reports say that they are spending a lot of money on plans but no one knows if the plans are working. Even the government isn't sure it will attribute a reported drop in the incidence of fraud to compliance planning. Everyone just has to do some measuring of data.

Q. What specifically should be measured?

A. Discharge vs. transfer is high on the government's list. Hospitals might want to start screening the top 10 diagnoses. Wouldn't it make sense if they have a compliance plan that talks about doing proactive studies on the diagnoses? Facilities don't necessarily have to do it immediately.

Maybe they can decide to do a study on transfers in the third quarter. Then they can figure out a methodology and audit the data. If they don't study all the diagnoses, maybe they can study a sample.

Quality assurance committees will sometimes have meeting notes or discharge planning groups. That information can be used, too.

Q. What are red flags for possible problems?

A. If you are the discharging hospital, and you submit your claim and it doesn't get paid because of a blocking admission somewhere else, then you know the problem was someone else's. The other facility entered discharge instead of transfer information. But if the business office gets a call from the second hospital saying that your facility is blocking its case, the office will have to do a debit/credit adjustment. Any time hospitals have those kinds of Medicare debit/credit adjustments they should see a red flag warning that tells them to look at transfers and see if other information should be in the discharge columns.

Q. What other compliance issues should concern providers?

A. "Readmit, same day" is going to become a quality issue that the government is going to start banging the door down about. A facility discharges

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DRG CODING ADVISOR®

CPT panel endorses E/M code revisions

Group promises simplification

The Current Procedural Terminology (CPT) Editorial Panel of the American Medical Association has submitted its long-expected recommendations to the Health Care Financing Administration (HCFA) for revising its documentation guidelines for evaluation and management (E/M) codes. The E/M codes are used to report physician visits, consultations, and similar services.

The June 2 recommendations came about after many providers complained last year that HCFA's previous E/M proposal was too complicated and confusing.

"The major upside is the mechanical, bookkeeping approach of the old guidelines has been largely eliminated," says **Catherine Fischer**, a reimbursement policy advisor with Marshfield (WI) Clinic.

"The new proposed guidelines are much less rigid, more broad and fluid, than the 1995 and 1997 versions," she says. "This is a vast evolutionary improvement over many physicians' complaint that they often felt forced to do a lot of things they normally would not do, or need to do, simply to justify to an auditor why they charged for a certain level of service."

The potentially bad news, especially to HCFA, is that the new approach also makes it easier to justify a higher level of service — and higher bills. As such, the question now becomes: At a time when the Clinton administration is trying to restructure the Medicare program and reduce future health care spending, is it politically willing to accept a revised E/M coding system that could result in higher claims?

"This gets down to a basic issue of whether you design a coding system which can be easily used and gives the majority of honest docs some regulatory breathing room; or, do you go for a rigid approach whose main purpose is trying to prevent a few greedy providers from padding their claims?" says Fischer.

The basic changes in E/M policy recommended by the Editorial Panel include:

- Emphasize clinical communication as the primary role of the medical record and the need for confidentiality.
- Make requested revisions to the history, examination, and medical decision making guidelines components.
- Revise body system examination elements in the draft guidelines in response to specialty and other requests.
- Identify ways to reduce the role of "counting" of examination elements by emphasizing the importance of the actual CPT definitions and of using all pertinent information in the medical record that bears on the level of E/M code.

After another period of reviews, pilot tests, and refinements expected to last at least until the end of this year, HCFA is expected to propose replacing both the 1995 and 1997 E/M guidelines currently in use with the final revised version.

The following analysis provides a detailed account of how E/M codes should be approached and documented under the CPT Editorial Panel's June 2 proposal.

• Reviewing the level of service provided.

The level of service is intended to reflect the work involved in providing the service. Under the proposal, all of the key components (i.e., history, examination, and medical decision making)

must meet or exceed the stated requirements to qualify for a particular level of E/M service for the following new or initial patient categories/subcategories: office, new patient; hospital observation services; initial hospital care; office consultations; initial inpatient consultations; confirmatory consultations; emergency department services; comprehensive nursing facility assessments; domiciliary care, new patient; and home, new patient.

Two key components (i.e., history, examination, and medical decision making) must meet or exceed the stated requirements to qualify for a particular level of E/M service for the following established or follow-up patient categories/subcategories: office, established patient; subsequent hospital care; follow-up inpatient consultations; subsequent nursing facility care; domiciliary care, established patient; and home, established patient.

• **History.**

The extent of the medical history depends on the physician's clinical judgment and the nature of the presenting problem(s) or the reason for the encounter.

If the physician is unable to obtain a sufficient history from the patient or other source within a clinically appropriate time frame, the record should describe the patient's medical condition or other circumstance that precludes obtaining a sufficient history. These may include:

• urgent/emergent condition(s);
• patient's inability to communicate;
• patient is at a very high level of risk, where immediate action is necessary;
• lack of interpreter;
• no medical record available;
• no family/significant other or legal guardian available in person or by telephone

Documenting the circumstances related to the inability to obtain a sufficient history will be considered the same as a comprehensive history for code selection purposes. However, this is only permitted for new patients, emergency department visits, initial hospital care codes, or patients new to the consulting physician.

CPT describes four types of history:

• problem focused;
• expanded problem focused;
• detailed;
• comprehensive.

Each type of history is made up, to varying degrees, of the following components:

• chief complaint or reason for the encounter;
• history of the present illness (HPI);
• review of systems (ROS);
• past, family, and/or social history (PFSH);

Any record format for documenting any component of the history (i.e., chief complaint/reason for encounter; history of present illness; review of systems; past, family, and/or social history) is acceptable, including, but not limited to, preprinted history forms completed by the patient, other informant, and/or ancillary staff, with documentation of review by the physician or other health care professional. (There must be a dated notation confirming, or supplementing as necessary, information recorded by others, including, but not limited to, preprinted history forms.)

Components may be identified separately, or they may be combined, for example, in the HPI. A single item of history should be considered either part of the HPI or the ROS but not both.

— **Chief complaint and/or reason for encounter:** This can include items such as referral by another physician, lab test performance, specific complaints, or physician directed return for follow-up. It must be easily inferred if not explicitly documented.

— **History of present illness:** The HPI may include positive and clinically pertinent negative statements describing different aspects of the presenting problem(s) (e.g., location, quality, severity, duration, timing, context, modifying factors, associated signs and symptoms, and related functional status descriptors).

HPI is documented as follows:

Brief HPI — statements about:

1. one to three items about the present illness(es)/presenting problem(s), OR

2. one or two present illness(es)/presenting problem(s), or chronic or clinically pertinent inactive conditions, in any combination.

Extended HPI — statements about:

1. at least four items about the present illness(es)/presenting problem(s), OR

2. at least three present illnesses/presenting problems, or chronic or clinically pertinent inactive conditions, in any combination.

— **Review of systems:** A review of systems obtained during an earlier encounter does not need to be re-recorded. Any new review of systems information should be documented, or alternatively document the lack of change (e.g., no change) from previous ROS with notation of date or location of previous ROS.

Review of systems is documented as follows:

Brief ROS — positive and / or negative responses for one to four systems.

Extended ROS — positive and / or negative responses for at least five systems.

For CPT coding purposes, the following systems are identified:

- constitutional symptoms (e.g., fever, weight loss);
- eyes;
- ears, nose, mouth, throat;
- cardiovascular;
- respiratory;
- gastrointestinal;
- genitourinary;
- musculoskeletal;
- integumentary (skin and / or breast);
- neurological;
- psychiatric;
- endocrine;
- hematologic / lymphatic.

— **Past, Family, and/or Social History (Allergic/ Immunologic):** PFSH is documented as follows:

Brief PFSH — at least one item from any PFSH area.

Extended PFSH — at least one item from at least two of the three PFSH areas.

Past history — describes the patient's past experiences or lack thereof with illnesses, operations, injuries, and treatments, some examples of which are:

- listing and / or review of current medication(s);
- allergies (food, drug, and / or environmental);
- operations;
- injuries / trauma;
- past illnesses and / or hospitalizations;
- pregnancy history;
- growth history;
- development history;
- immunization history;
- behavioral history;
- functional status history.

Other relevant past history — e.g., sexual history, gynecologic history, mother's history, newborns, birth history, school history, treatment / medication compliance.

Family history — a review of medical events in the patient's family, including diseases which may be hereditary or place the patient at risk, some examples of which are:

- cardiovascular disease (stroke, myocardial infarction or other cardiovascular illness);
- cancer;
- drug abuse;
- domestic violence and / or child abuse;
- metabolic / lipid disorders;
- hereditary disorders.

Social history — describes age-appropriate past and current activities. Some examples include:

- marital status;
- tobacco, alcohol, or drug use / abuse;
- employment status;
- occupational history;
- education;
- housing and / or source of drinking water;
- financial status;
- exercise patterns;
- diet history;
- travel history.

Other relevant social factors — a review of past, family, and / or social history obtained during an earlier encounter does not need to be re-recorded. Any new PFSH information should be documented, or "no change" from previous PFSH, with notation of date or location of previous PFSH, should be alternatively documented.

• Selecting the type of history.

All of the applicable history categories must be met for a given level of history, except that:

— Two of the three applicable history categories are sufficient for newborn infants.

— Two of the three applicable history categories are also sufficient for those levels of E / M services requiring a detailed or comprehensive interval history (e.g., 99231-99233, 99261-99263, 99301-99302, 99311-99313, 99331-99333, 99347-99350).

The chief complaint and / or the reason for the encounter is required for all codes except those that require only an interval history (e.g., subsequent inpatient hospital services).

Types of history:

Problem focused — brief one to three items about the present illness(es) / presenting problem(s) or one or two present illness(es) / presenting problem(s), or chronic or clinically pertinent inactive conditions, in any combination.

Expanded problem focused — brief one to three items about the present illness(es) / presenting problem(s) or one or two present illness(es) / presenting problem(s), or chronic or clinically pertinent inactive conditions, in any combination.

Brief problem focused — positive and / or negative responses for one to four systems.

Detailed extended — at least four items about the present illness(es) / presenting problem(s) or

at least three present illnesses / presenting problems, or chronic or clinically pertinent inactive conditions, in any combination.

Detailed brief — positive and / or negative responses for one to four systems.

Brief — at least one item from any of the three PFSH areas.

Comprehensive extended (HPI) — at least four items about the present illness(es) / presenting problem(s) or at least three present illnesses / presenting problems, or chronic or clinically pertinent inactive conditions, in any combination.

Comprehensive extended (ROS) — positive and / or negative responses for at least five systems.

Extended — at least one item from at least two of the three PFSH areas.

• **Examinations.**

CPT describes four types of examinations:

— problem focused;

— expanded problem focused;

— detailed;

— comprehensive.

These examinations may be a general multisystem examination, the examination of a single body area or organ system, or any combination thereof. Any examination may be performed by any physician regardless of specialty. Actual content of the examination is selected by the examining physician in accordance with the needs of the patient.

The extent of the examination performed is dependent on clinical judgment and on the nature of the presenting problem(s). The levels of E / M services recognize four types of examinations, defined as follows:

Problem focused examination — a limited examination of the affected body area(s) or organ system, which typically includes one to five exam items.

Expanded problem focused examination — a limited examination of the affected body area(s) or organ system and other clinically relevant or related body area(s) or organ system(s), which typically includes six to 11 exam items.

Detailed examination — an extended examination of the affected body area(s) and other clinically relevant or related body area(s) or organ system(s), which typically includes 12 to 17 exam items.

Comprehensive examination — a general multisystem examination or a complete examination of a single organ system and other clinically relevant body area(s) or organ system(s). **Note:** The comprehensive examination performed as part of the preventive medicine evaluation and management service is multisystem, but its extent is based on age and pertinent risk factors. It typically includes 18 or more exam items (within the constraints imposed by the urgency of the patient's mental status and / or clinical condition).

Any type of record format is acceptable, including, for example, simple checklists to indicate that an item has been performed.

If a checklist or template includes descriptors of distinct elements but also includes an indicator that the entire group was normal or negative, a notation to indicate all indicated elements were examined suffices. In this approach, elements not actually performed should be crossed out or otherwise indicated.

A brief statement or notation indicating "negative" or "normal" is sufficient to document normal findings.

Specific abnormal and clinically relevant negative findings should be documented. A notation of "abnormal" without elaboration is insufficient. For subsequent visits, a notation of "unchanged" in a previously abnormal finding is adequate.

• **Simplified documentation.**

Simplified documentation of a single body area and / or organ system is acceptable and is equivalent to performance of a single examination item. The exception is head, eyes, ear, nose, and throat, where organ systems are grouped collectively. For example, examination of the head, eyes, ear, nose, and throat will be equivalent to three examinations, as this includes several organ systems.

• **Medical decision making.**

CPT describes four levels of medical decision making. For purposes of documentation, three levels are considered:

— low complexity (encompasses straightforward complexity);

— moderate complexity;

— high complexity.

Medical decision making refers to the complexity of establishing a diagnosis and / or selecting a management option as reflected by:

— the scope of the presenting problem(s), number of diagnoses considered, and / or risk of complications, morbidity or mortality;

— diagnostic procedures / tests ordered and / or the amount of data to be obtained or reviewed;

— management options considered.

(Editor's note: A full version of the report can be found on the Internet at: www.ama-assn.org/emupdate/mso292.doc.) ■

(Continued from page 134)

a patient and then readmits him — what was it thinking? Medical records notations — especially to indicate what happened — are very important. If the same hospital is readmitting the patient, it will have to be more than mechanically careful on whether it creates a new admission. I can't advise on whether the best policy is to reinstate the account or open a new one. Hospitals have to look at their bylaws and state regulations.

If they don't do quality assurance types of studies on the discharge/readmit issue, they are vulnerable to quality of care questions. The clue is in the data. To paraphrase a source from my book, *The Patient Accounts Management Handbook* (Aspen 1997), the hospital systems that survive will be the ones who have good data and can use it. (Sperry, Chapter 3.)

With more government resources going to fight health care fraud, more fraud investigators are looking at data, asking, "what is wrong with the picture?"

Q. Then what is the strength of the compliance plan?

A. Hospitals have to have a good compliance plan to show they are concerned about compliance. They also must show that they review it to find out when they made a mistake. But a compliance plan alone won't give you a veil of security that is impenetrable. That veil can be pierced. Providers need to put into practice what they preach.

[Editor's note: For more information, contact DEKAYE Consulting at (516) 678-2754, at adkcmpa@aol.com, or visit the company's Web site at www.dekaye.com.] ■

Switching to single-source EDI billing slashes costs

On-site database tracks entire life of claim

Just as too many cooks can spoil the broth, so can too many applications clog up the billing process. Catholic Healthcare West (CHW) in Carmarillo, CA, once struggled with this first hand.

"We had a number of systems that we used to bill electronically," says **Gigi Wallin**, director of business services at CHW. "The cost was excessive."

CHW's system was actually a combination of different independent software tools. Some terminals could only process Medicare claims; others processed only CHAMPUS claims. The incompatible formats of the machine-specific applications made it impossible to upload current data to the network or to access the data on line.

The system also "lost" an excessive number of claims each month. Some disappeared after payers rejected them. Payers claimed that others never arrived.

"We felt that the number of claims that the insurance companies were claiming that they weren't receiving was excessive, considering the fact that they were being electronically billed," Wallin says.

Like all providers, CHW couldn't afford the inefficiencies. Its billing office processes about 10,000 claims each month for inpatient and outpatient services provided at the 261-bed St. John's Regional Medical Center in Oxnard, the 180-bed St. John's Pleasant Valley Hospital in Camarillo, and a network of outpatient facilities.

It also serves a facility specializing in long-term care, a skilled nursing facility under contract with Medi-Cal (the Medicaid program in California), and three off-site therapy centers, each with different billing requirements. In addition, 60% of the claims processed by the 53-member office staff are billed to government payers, including Medicare, Medi-Cal, and CHAMPUS. Commercial payers, the largest of which is Blue Cross, account for the remaining 40% of claims billed.

Consolidating to a single source

In late 1997, CHW decided to try a single-source, electronic data interchange (EDI) solution. The application it chose, EDIMaster from EDIComm in Woodland Hills, CA, offered both EDI-enabling software and clearinghouse services. The system also included a data repository containing complete histories of claims data. This repository was placed on CHW's local area network (LAN), making it accessible to any of the provider's authorized staff.

"We took a multi-vendor situation that was not distributed on our LAN, and consolidated all these other systems into one vendor, residing on the LAN, and reduced our cost by about 60%," Wallin says.

Authorized staff throughout the health network can now submit traditional claims and encounter data, initiate claims status inquiries, receive and process electronic remittance advice, and perform automated secondary billing and patient eligibility verification on the system.

Overall, the new system captures more information electronically than the former one, which has allowed CHW to rearrange its work-flow patterns. The provider has cross-trained its billers to process any claim to any provider. The billers also can process the claims from their own desks, rather than going to a payer-specific terminal.

Once billers process the claims, the claims are checked for accuracy with payer-specific editing software within the system. "Billers like the editing portion because they can go in and edit their claims right away," Wallin says.

The system attaches an ancillary transaction file to each claim in the database. This file keeps an interactive on-line status of the claim, explains **Gene Reed**, chief operating officer of EDIComm.

When CHW daily transmits its processed and edited claims to the clearinghouse, the transaction files and database are automatically updated with information from payers about patient eligibility, claim status, and payment. By doing this daily, CHW has found that its electronically billed commercial payments arrive in 15 days — nine days less than with the former system.

Once the information from the payers has been received, the system provides CHW with daily reports of actual billings. In addition, if Medicare or Medi-Cal claims are rejected for any reason, an electronic notification arrives the following day along with suggested corrections. "The billers like to get a report showing their rejections and what they need to correct," Wallin says.

The results are in

Having all of the information about the life of claims available in one database allows staffs in billing offices to spend their time managing information as opposed to creating it, Reed says. Here are some of the results from consolidating to one system:

✔ CHW has significantly decreased the number of electronic claims that disappear after transmission. Using a tracking number supplied by the system, billers can verify transmission and receipt and determine whether claims were rejected or awaiting adjudication.

✔ In CHW's skilled nursing facility, the time necessary to build claims in compliance with the special requirements imposed by Medi-Cal has been reduced by two-thirds. Before the new system was installed, billing codes had to be manually converted for the UB92, copied on paper, then keyed into the system.

Today, billers can retrieve claims from the system, verify the information, and insert an accommodation code. The patient's name, Medi-Cal ID number, total charges, and total reimbursement are inserted automatically.

✔ Authorized personnel can retrieve archived UBs via any PC, review on screen, and print. Complete claims histories are similarly accessible by billing, collections, and customer service employees.

"We are able to retain UBs going back months, which we could not do on the [other] system, and reprint them at the desk," Wallin says. "That's a benefit of having it on the LAN — we can request a copy of the UB right then and there."

✔ The new system provides comprehensive views of billing activity that weren't available from its predecessor. "I can go in and pull reports and see everyone's production on a monthly basis, weekly basis, and daily basis in terms of the number of claims that got processed," she says. "We can design all kinds of reports for management purposes, based on employee, age of claims, and things of that nature. There's a lot of flexibility."

✔ CHW staff can now compile a risk-pool report of capitated claims sorted by insurance plan code. "We could not pull claims off the [old] system," Wallin says.

In the future, CHW will have the ability to receive and process electronic remittance advice in any format from any payer having that capability. The system will automate the posting of payment information to patient accounts, provide for automated secondary billing, as well as report potential fraud and abuse violations. Also to be implemented in the future is an application with which CHW employees will be able to capture eligibility status, claim status, and other data directly from payers, such as Blue Cross.

The capability of EDI shows the importance of its implementation into billing functions, Wallin says. "I think that as an industry we used to think of EDI as a value-added type of thing. But now we've been moving into this century and realized it's a necessity, an added benefit, because anything that we can do to expedite out payments is a benefit." ■

Movement on privacy legislation stalls

HHS begins working on its own regulation

Major differences in bills introduced in the U.S. House and Senate prevented any significant movement toward the passage of patient confidentiality legislation as the August deadline approached, says **Kathleen Frawley**, JD, MS, RRA, vice president for legislative and public policy services for the American Hospital Information Management Association in Chicago.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 requires Congress to pass legislation governing electronic health information before Aug. 21, 1999. If Congress fails to act by that time, the responsibility for the regulation will pass to the secretary of Health and Human Services (HHS) in Washington, DC, with a final rule required by February 2000.

The Senate Committee on Health, Education, Labor and Pensions (HELP) has attempted at least four times to "mark up" federal records legislation. The "Health Information Confidentiality Act of 1999," which combined features of bills introduced by Sens. Patrick Leahy (D-VT) and Edward Kennedy (D-MA), Robert Bennett (R-UT) and Connie Mack (R-FL), Jim Jeffords (R-VT), and Christopher Dodd (D-CT), was comprehensive in scope and applied to medical records in both paper-based and electronic formats. On June 16, Jeffords (R-VT), committee chairman, again postponed a committee vote on the bill.

Lack of agreement slows bill

Serious disagreement on these issues was behind the lack of progress on moving a bill forward:

- whether federal legislation would preempt state laws that afford more privacy protection;
- whether an individual would be able to bring a lawsuit against a party that violated his or her confidentiality;
- how much access law enforcement should have to medical records;
- how much access parents or guardians should have to a minor's health records.

Democrats on the committee, led by Kennedy, refused to accept compromises that would have put a dollar cap on the damages for which individuals could sue for a violation of their privacy, as well as a provision to clarify state oversight of minors' privacy rights.

Frawley predicts the legislation markup won't happen until after the August recess, at the earliest. "Sen. Jeffords is hoping to have resolved these issues after Labor Day and to hold the markup," she notes. "But because of the four issues [of contention] that are key, it could reach a point that he is not able to move a bill forward."

The bickering continued during a July 15 hearing held by the House Commerce Committee's subcommittee on health. The focus of the hearing was to get public reaction on the latest medical record privacy bill, H.R. 2470, the "Bipartisan Medical Information Protection and Research Enhancement Act," introduced by Rep. Jim Greenwood (R-PA). Committee Democrats who attended the hearing were disturbed that other bills, introduced by Democrats, were not also to be discussed, according to *AHA* (American Hospital Association) *News*.

What might happen next

With Congress at a standoff, the staff at HHS began working on a regulation. "They know [the department] would have to introduce a notice of proposed rule making in the *Federal Register* this fall to allow time for the 90-day comment period required before a final rule can go into effect," Frawley says.

However, she notes, Congress missing its deadline does not necessarily take the medical privacy ball from its court. "[Congress] could extend the deadline by passing legislation giving itself more time, or the deadline could come and go and Congress could continue to do work on bills. The HHS secretary and the administration have urged Congress to enact legislation."

Another issue is that while most observers believe that HHS's authority under HIPAA is limited to electronic data, the department has sought a legal opinion regarding its authority to reach beyond electronic records and attempt to regulate all medical records in all forms, according to a report from the Joint Healthcare Information Technology Alliance (JHITA) in Washington, DC.

Some members of Congress may attempt to postpone, not only the HIPAA privacy regulations, but all of the HIPAA standards that are in process, JHITA says. ■

Clinton proposes more slicing and dicing

Plan offers to spend $7.5 billion on BBA relief

Providers looking to President Clinton for relief from cuts from the Balanced Budget Act (BBA) of 1997 might be disappointed in his reform plan. Under the plan, which requires Congressional approval, hospitals and health plans would be hit with payment cuts totaling more than $70 billion over 10 years. About $39 billion in cuts would come directly from hospital payments.

Dick Davidson, president of the American Hospital Association (AHA) in Chicago, says the plan "potentially exacerbates a major ailment, the devastation inflicted by the Balanced Budget Act."

The most publicized part of the plan involves a new prescription drug benefit that would be available to all Medicare beneficiaries. Here are some of the other proposals:

• **Inpatient care** — a freeze in the inpatient update from 2003 to 2009.

According to preliminary AHA analysis, this would total nearly $35 billion in cuts. For urban hospitals, the update would stick at marketbasket minus one percentage point. For rural hospitals, it would stay at marketbasket minus 0.5 percentage points in fiscal 2003 and increase by 0.1 percentage point each year until the same update applies for rural and urban hospitals.

• **Capital costs** — an extension through 2009 of a 2.1% reduction in payments for hospital capital costs, which amounts to about $2 billion.

• **Prospective payment system (PPS)-exempts** — an extension through 2009 in payment reductions to PPS-exempt hospitals, totaling $3 billion. This includes continuing a 15% reduction in payments for capital costs.

• **Related services** — reduced payments for ambulance, prosthetics and orthotics, hospice, ambulatory surgical centers, durable medical equipment, and laboratory services, to the amount of $4.7 billion over 10 years.

• **Fee for service** — savings of $25 billion by introducing competitive bidding into the fee-for-service program.

The plan would create a Medicare preferred provider option, and Medicare would contract with existing providers that meet yet-to-be defined quality and utilization standards. Beneficiaries would have lower cost sharing when visiting a Medicare PPO.

AHA is concerned about the competitive bidding proposal. "Giving government the ability to use the enormous economic power that Medicare has could disrupt health care in communities across the country, making the current market power of HMOs pale in comparison," Davidson says.

AHA also is not pleased with the plan for proposing to extend timelines of certain BBA provisions. To ensure that program growth does not "significantly increase" after most of the Medicare provisions of the BBA expire in 2003, the proposal includes out-year policies that protect against a return to unsustainable growth rates, but are more modest than those included in the BBA of 1997.

Even with these extended timelines, however, the proposal sets aside $7.5 billion over 10 years for BBA relief. The administration says it will work with Congress and outside groups to figure out how to best spend the money. One focus may be areas where access to services have been jeopardized.

Other relief efforts include:

• Postponing two years a policy to extend the inpatient transfer provision beyond 10 diagnosis related groups.

• Delaying "volume control" under the proposed outpatient prospective payment system (PPS). Also, the president suggested phasing in the PPS over three years.

• Reclassifying rural hospitals, making it easier for them to receive payments similar to neighboring urban facilities. ■

Clinton signs bill that limits Y2K lawsuits

On June 20, President Clinton signed legislation designed to limit liability for damages resulting from year 2000 (Y2K) computer failures.

Clinton had previously vowed to veto the "Y2K Act" because he said it extended beyond

the Y2K problem into broader tort reform issues, capping punitive damages in too many cases, and forcing too many class action suits into federal court.

A compromise on the bill was reached. The compromise includes a 90-day grace period for companies to fix Y2K-related problems before being sued, a cap on punitive damages for small businesses, and a guarantee that most business sued in Y2K cases will pay damages that only reflect their portion of the blame. In addition, the final bill includes language stipulating that hospitals sued for a Y2K-related event can, in turn, sue the device manufacturer. ▼

HIMSS executive director resigns in July

John A. Page, FHIMSS, resigned as executive director of the Healthcare Information and Management Systems (HIMSS) in Chicago in mid-July, according to HIMSS Chairman of the Board **Gary Kurtz**, FHIMSS.

"After more than eight years of leading the society," says Page, "I've decided to take some time off to spend with my family and devote more attention to a number of personal interests of mine." Under Page's direction, the society's membership has more than tripled.

The HIMSS staff will continue functioning under the guidance of R. Norris Orms, HIMSS director of operations, who has been appointed as the acting executive director, says Kurtz. ▼

McKesson HBOC loses CEO, other managers

Alleged "intentional deception" in accounting practices have cost the chairman and other executive managers their jobs at McKesson HBOC's Information Technology Business (ITB) unit, formerly known as HBO & Co., of Atlanta.

In a statement released June 21, 1999, McKesson HBOC announced that Charles W. McCall has been removed as chairman of the board and dismissed as an employee.

The following ITB officers were also dismissed: Albert Bergonzi, president and CEO; David Held, CFO and controller; Jay Lapine, senior vice president and general counsel; and Michael Smeraski, senior vice president and head of enterprise sales.

Others submit resignations

In addition, McKesson executives Mark A. Pulido, president and chief executive officer, and Richard H. Hawkins, executive vice president and chief financial officer, submitted their resignations. These two were said not to be involved in the "accounting improprieties" but were held responsible by the board for the fallout.

The improprieties at HBO required it to restate fiscal 1999 earnings, reversing $42 million in sales of software that were subject to "contingencies"

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and booked before they were final, according to the *Wall Street Journal*. Investors are filing several class action suits against the company.

When *Hospital Payment & Information Management* asked if the loss of the ITB management team would affect provider contracts with the company, a spokesperson did not comment. ▼

Not-for-profit hospitals' credit erosion accelerates

Not-for-profit hospitals' bond ratings continued to take a nose dive in the first six months of 1999 and did so at a quicker pace than last year, Moody's Investors Service said in July. The New York City rating company downgraded 35 not-for-profit hospitals and systems with more than $7.5 billion in debt in 1999's first two quarters.

This exceeds the 19 downgrades worth more than $3 billion in the first half of 1998. The decline is attributed to the Balanced Budget Act of 1997, increased managed care, losses from capitation, ongoing physician losses, and the growing size and complexity of debt-financed merger and acquisition activity. Moody's officials predicted further declines in credit quality for the next quarter and beyond. ▼

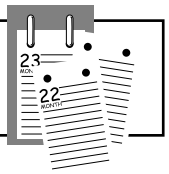
Compliance educational videotapes available

DEKAYE Consulting in Oceanside, NY, is offering providers a new three-videotape series, "Compliance and Awareness: Safeguarding Healthcare's Cash Flow Cycle from Fraud and Abuse."

Taped on location, this five-hour presentation provides managers, supervisors, and staff with real-life illustrations of the types of fraud and abuse that have made the national headlines. The series also discusses how compliance plans and programs need to go beyond "paper compliance" to effect meaningful procedures and reviews to safeguard a provider's assets — and its reputation.

Information and order forms for this set can be found on DEKAYE's Web site at: www.dekaye.com. Subscribers to DEKAYE's PAM LIST (Patient Accounts Management Listserv) will receive a $50 per set discount from the purchase price. ■

CALENDAR



• **The Elements of Best Practice**, the 71st national convention and exhibit of the American Health Information Management Association (AHIMA) in Chicago, will be held Oct. 2-7, 1999, in Anaheim, CA. For more information, call AHIMA at (312) 787-2672 or visit its Web site at www.ahima.org.

• **The 1999 Fall CIO Forum of the College of Healthcare Information Management Executives** in Ann Arbor, MI, will be held Oct. 12-15 in Palm Beach Gardens, FL. For more information, call (734) 665-0000 or visit the Web site at www.chime.org.

• **Quality Healthcare Information on the 'Net '99**, a conference offered by the Internet Healthcare Coalition (IHC) in Washington, DC, will be held Oct. 13, 1999, in New York City. For more information, visit IHC's Web site at www.ihc.net. ■