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HOME INFUSION THERAPY MANAGEMENT™

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American Health Consultants® is A Medical Economics Company

OPAT and CoPAT: It's all about getting paid for a good practice

Secondary insurance still the only means for Medicare patients at home

"We've been able to take outpatient antibiotic therapy [OPAT] and community-based parenteral anti-infective therapy [CoPAT] to the point where we have as many people on intravenous therapy outside the hospital as we do inside the hospital," says **Alan D. Tice**, MD, a 20-year veteran in the war against infectious diseases. His Tacoma, WA-based practice, Infections Limited, is an outpatient infectious disease unit providing community services for people with serious infections, treating them at home rather than just hospitalizing them.

The practice of administering parenteral anti-infective therapy in the home and in other community settings has grown rapidly over the past 20 years. In the United States, CoPAT is a multibillion-dollar-a-year industry. It is estimated that more than 250,000 Americans are treated with CoPAT each year, and the growth rate for this practice is estimated to exceed 10% a year.[1] But receiving reimbursement for OPAT and CoPAT — especially from Medicare — can be difficult.

"Medicare regulations were developed in the mid-1960s, before people had any concept we could be treated with IV antibiotic therapy on an outpatient basis," says Tice. "Medicare has been very inflexible, claiming that this was a home care benefit and was never intended to be covered in the '60s, so we won't pay for it at all."

Outdated policies

IV antibiotics administered in the home, with the exception of those that require durable medical equipment, are not currently covered by Medicare. And the huge potential Medicare savings associated with a new ambulatory IV benefit underscores the present outdated Medicare coverage policies for outpatient antibiotic therapy.

The program pays for inpatient care but excludes equally effective, less costly outpatient alternatives. This situation not only ignores the wide acceptance of outpatient IV therapy by the medical community and private health plans, but also illustrates the need for a change in Medicare's benefit structure, which fails to take advantage of cost-effective medical advances. Medicare's blanket prohibition of outpatient self-administered drugs is also inconsistent with recent congressional efforts to provide more care options to Medicare beneficiaries and slow the increase in Medicare expenditures.[2]

Fees add up

Ironically, the benefit for OPAT and CoPAT is provided if the therapy is applied in doctors' offices. "If you have a drug you can give once a day and it's fairly convenient for a person to go to a doctor's office, get an intravenous drug, go home, and go back the next day, then you're OK," says Tice. "We're able to bill for it. The reimbursement is not good, and there are many practices in which doctors feel they can't afford to provide these benefits to Medicare patients. But we have a sufficient volume, and I'm able to do so by charging the cost of the drug in addition to charging for the room fee and the physician visit."

However, travelling to a doctor's office on a daily basis is just not feasible for some patients, especially those who require two or more infusions per day. For Medicare patients, having supplemental insurance is currently their only key to obtaining reimbursement.

Kathy Pinson, one of Tice's Medicare patients, says, "If I had to rely totally upon Medicare paying my bills, without having a secondary insurance, I would have to drive an hour to an hour and a half every single day to the clinic here to get treatment."

Monitoring the care of patients receiving CoPAT includes attention to venous access, monitoring by means of specific laboratory tests, and emphasizing the importance of administering the first dose in a supervised setting. Anti-infective selection and administration issues involving CoPAT include observations that once-daily drug administration is convenient.[2] Medicare requires a physician be present to oversee the therapy.

"It's a fairly big hurdle, but we just hate to see people confined to the hospital because of monetary and regulatory issues," Tice says. "It's not easy; and the way things are going with Medicare, it may be increasingly difficult. Hopefully, some of the focus on health care by the potential presidential candidates will loosen things up a little bit and the government will provide more services to Medicare patients rather than having them confined to a hospital or going to a nursing home to get their medications instead of being treated at home."

As far as his non-Medicare patients are concerned, Tice says there has been a general appreciation of the cost savings of OPAT and CoPAT therapy by most private payers.

"The individual states vary on individual welfare payments," he says. "Sometimes, you just can't afford to provide that through your office or home care company. As far as private insurers are concerned, they will usually try to get people out of the hospital as soon as possible because of the cost savings. A usual day in the hospital is about $1,000 for an insurance company. A home care agency will get $150 to $250 per day for the same treatment in an otherwise healthy person."

Outpatients rule

Private payers, not satisfied with avoiding the higher costs of hospitalization, have begun ratcheting down the benefits for outpatient therapy, which Tice sees as a real threat to the quality of outpatient care — especially given the inherent problems of measuring outcomes and quality assurance in the nonhospital setting.

"I think the opportunities and needs are really there to keep people in the community, at home, [and] back at work if there is leadership on the part of nurses, physicians, [and] pharmacists, as well. What we find when we ask people after their course of therapy whether they would prefer to be hospitalized for another course of IV therapy or to be treated at home, 99% of them say they prefer to be treated as outpatients. And these are people who have been hospitalized and then treated as outpatients, so they know both sides of the fence. We've also found that about half the people who are employed can go back to work before they complete their courses of therapy. The majority of children are able to go back to school, too, and learn while they're being treated," Tice says.

Tice and his fellow physicians have started a network to try and assure the quality of care for outpatient antibiotic therapy. They now have over 4,000 patients in their database from 20 different sites around the country. The goal is developing a useful standard to help people understand issues,

such as what's a safe complication rate and what's not, and what are the outcomes of therapy.

According to Tice, the greatest needs for infection control and quality assurance are in the community, not the hospital.

"As medical care evolves, you'll see more and more people who used to be required to be in the hospital for treatment being treated at home. Increasingly, we're faced with the need for a support system for these people — for quality control and safety measures to be certain things go well with them. But it's difficult to do. There's a clear cost savings of $500 or more dollars per day for their insurance companies to get people out of the hospital, but there are risks there, as well," he says. "We have educational materials and are trying to evolve a network of centers that is going to be helpful in measuring the quality of care to create benchmarks. We've also been involved in writing guidelines for CoPAT."

Guidelines outlined

OPAT and CoPAT have proven to be clinically effective treatments. A series of studies from 1991-95 looked at 137 patients, most of whom were hospitalized for a short time and then received OPAT with ceftriaxone in combination with other antibiotics. The clinical success rates ranged from 88% to 100%. A statistical analysis of 30 patients involved revealed 380 hospital days were saved.

Tice says the Infectious Disease Society of America (IDSA; www.idsociety.org) has taken a leadership role in trying to outline the responsibilities of home care companies that are attending to patients in their homes and in developing standards for monitoring patients to be certain they don't develop toxic problems or toxicity from the drugs they are receiving in order to assure a positive outcome.

The IDSA guidelines for patient selection says the following items should be observed in determining which patients should receive CoPAT:

- **The patient's medical care needs do not require hospitalization and do not exceed resources available at the proposed site of care.**
- **The patient or caregiver is capable of safely and effectively delivering parenteral anti-infectives and compliant with recommended treatment and, after discussion of the benefits, risks (including informed consent when appropriate), and economic considerations (such as insurance issues), willing and able to participate in the proposed therapy.**
- **Lines of communication between the patient, caregiver, physician, and other health care personnel are sufficient for monitoring therapy.**
- **The home/outpatient environment is safe and adequate to support care.**[1]

The appropriateness of CoPAT for drug- or alcohol-using patients should be carefully evaluated before therapy is initiated. If a patient was actively abusing parenteral drugs immediately before the acute presentation, administration of IV antibiotics in a supervised setting is recommended. Tice cautions that plans for quality assurance and outcomes monitoring should be incorporated into CoPAT programs. He also believes that an experienced physician director or advisor for any CoPAT delivery organization is important for the success of the program. The venous access site and device generally need to be carefully examined every three to four days by a nurse or physician for evidence of local tenderness, phlebitis, infiltration, erythema, or other sign of local infection.

Traditionally, patients or their caregivers have infused anti-infective drugs by the gravity-infusion method. A variety of alternative methods, including elastomeric infusion devices, syringe pumps, programmable infusion devices or direct IV bolus injection techniques, have been used increasingly to circumvent several potential barriers to using CoPAT.[1]

New Medicare proposal

For appropriate candidates, ambulatory IV antibiotic therapy is safe, effective, and less expensive than inpatient hospital care, Tice says. Private insurers and Medicare HMOs have promoted home care for stable patients requiring IV antibiotic therapy, he adds. Also, he says, a proposed Medicare benefit for ambulatory IV antibiotic therapy can reduce Medicare expenditures while providing good clinical outcomes.

Hospitals would continue to benefit since under the Medicare diagnosis-related group system they receive a fixed amount per case, regardless of how long the patient is hospitalized, Tice says. Medicare fee-for-service coverage of ambulatory therapy could also result in substantial cost savings, he adds.

Furthermore, he muses, the new benefit would be fully self-financing. As Congress and the president continue to consider Medicare program changes that will reduce expenditures and

expand beneficiaries' care options, an ambulatory IV antibiotic benefit that meets both goals should receive serious consideration, Tice believes.[2]

References

1. Williams D, Rehm S, et al. Practice guidelines for community-based parenteral anti-infective therapy. *Clin Infect Dis* 1997; 25:787-801.

2. Tice A, Poretz D, et al. Medicare coverage of outpatient ambulatory intravenous antibiotic therapy: A program that pays for itself. *Clin Infect Dis* 1998; 27:1,415-1,421. ■

Colds and flu reduce nation's blood supply

A relentless cold and flu season, two weeks of holiday-reduced blood donation, and curtailment of blood drives due to fear of Y2K problems have plunged the nation's blood supplies to critically low levels, according to Washington, DC-based America's Blood Centers (ABC), whose nonprofit community blood centers collect almost half (47%) of the U.S. blood supply.

"People who are sick with a cold or the flu cannot donate blood until they have been healthy for a week," says ABC president **Celso Bianco**, MD. The Centers for Disease Control and Prevention in Atlanta recently announced that 19 states were experiencing high flu incidence, including Arizona, California, New York, New Jersey, Pennsylvania, and Virginia.

"We already are seeing blood centers ask hospitals to postpone nonemergency room surgeries. The blood supply is extremely fragile, and we are providing blood on an as-needed basis in many states. This is critical," Bianco says.

Replenishing the supply

ABC serves the majority of hospitals in the flu-affected states, including ABC's largest blood center, United Blood Services, based in Phoenix, which alone collects about 8% of the U.S. blood supply. United Blood Services serves hospitals in 18 states, and has launched critical appeals for blood in 14 of those states. About one-third of the rest of ABC's 72 members also have critically low inventories of all blood types, especially O-negative, which can be given to any patient. California and Florida have been hit hard by shortages, as have parts of the South and Northeast.

Many blood center officials have cited Y2K as another reason for low donations. Corporate blood drives are blood centers' largest source of blood donations. "Blood drives were cancelled or delayed before the new year because corporations were preparing for any Y2K problems that may have erupted. We are in the process of rescheduling these drives, but the blood supply is fragile. It needs constant monitoring and replenishment," Bianco says. "We urge anyone who is healthy, 17 years or older, and weighs at least 110 pounds to call their local blood center. It takes only one hour to donate blood, and each blood donation could save three lives."

One blood donation (about a pint) can be separated into three components (red blood cells, platelets, and plasma). Red blood cells carry oxygen through the blood and are given mostly to trauma, heart surgery, and transplant patients. Red blood cells can be used up to 42 days from the day of donation. Platelets are given primarily to cancer patients undergoing chemotherapy, which destroys the body's blood cells. They must be used within five days. Plasma also helps blood to clot and can be used within a year if frozen.

How to donate

Prospective donors can call (888) 256-6388 (BLOOD-88) for the blood center location nearest them. The phone system reads the caller's area code and provides a list of the nearest blood donation centers. Donors must bring photo identification and Social Security information with them to their donation appointments.

Pre-Blood Donation Tips

- Get a good night's sleep.
- Eat breakfast.
- Drink plenty of fluids several hours before donating blood.
- Relax.

Post-Blood Donation Tips

- Drink juice or something with sugar to raise blood sugar levels.
- Eat a hearty meal.
- Do not drink any alcoholic beverages for five hours.
- Do not smoke for one hour.

For further information, contact Melissa McMillan, America's Blood Centers, (202) 393-5725, ext. 21. ■

Bayer Corp. responds: Update on Prolastin

In response to concerns voiced by representatives of National Home Infusion Association (NHIA) about the new method of distribution for the infusion drug Prolastin, *Home Infusion Therapy Management* contacted Bayer Corp. to request clarification of its position about NHIA's questions and concerns about Bayer Direct, the company's new marketing arm, and received the following statement:

Bayer Corp. has been providing patients with medications they need for over 50 years. Bayer is pleased to announce the continuation of that tradition with the introduction of a new program designed to give patients direct, fair, easy, and reliable access to two important life-saving pharmaceutical products, Prolastin and Gamimune, that patients rely on in treating such serious illnesses as emphysema, liver and lung diseases, and pediatric HIV infection. This new program is called Bayer Direct.

Prior to the introduction of the Bayer Direct program, Prolastin and Gamimune were distributed to the public exclusively through various providers in the distribution channel. We implemented the Bayer Direct program in direct response to complaints we received from Prolastin and Gamimune patients and patient advocacy groups about serious inequities in the way some providers in the distribution channel were distributing and pricing these products. Prolastin and Gamimune are often in short supply because the amount of each product Bayer can produce is limited by the availability of human plasma (which itself is often in short supply).

These shortages have made it difficult for patients to obtain reliable access to Prolastin and Gamimune on fair terms from certain providers in the distribution channel. Those problems were compounded when patients traveled or moved and needed to find a new source for their prescriptions. In fact, some entities in the distribution channel tried to take advantage of the shortages by imposing huge price increases. Bayer Direct was designed to eliminate these problems by giving patients direct access to Prolastin and Gamimune when, where and how patients need them.

Why is the Bayer Direct program necessary?

Bayer traditionally has distributed Prolastin and Gamimune through intermediary channels of distribution such as distributors (which sell pharmaceuticals to retail pharmacies) and home health care agencies (which provide pharmaceuticals to patients). Patients were unable to avoid the middleman by making purchases directly from Bayer.

There were a number of problems associated with this method of distribution. Some providers in the distribution channel capitalized on the high demand for, and short supply of, Prolastin and Gamimune to raise their prices unfairly. Many patients whose health depended upon their access to these drugs were forced to pay exorbitant prices. Indeed, Bayer has received reports of certain entities in the distribution channel forcing patients to pay as much as $14,000 a month for Prolastin — thousands of dollars more than the price charged by others in the distribution channel. Patients who were unable to afford these steep prices were forced to go without these life-saving drugs.

Patients also complained that, in addition to the problems caused by exorbitant and inconsistent pricing, the shortages of Prolastin and Gamimune created significant confusion and uncertainty among patients about their ability to obtain further supplies. Individual providers in the distribution channel used their own allocation systems to allocate Prolastin and Gamimune. Many patients felt that they had no way of knowing when, how, where, or even whether they would be able to get needed dosages.

Moreover, some entities in the distribution channel refused to allow patients to transfer their allocations of Prolastin or Gamimune to new providers when patients relocated or wanted to switch health care companies for some other reason. Patients complained to Bayer about their fears that, if they chose to switch doctors or pharmacies or to move across the country for that matter, they would lose their access to Prolastin and Gamimune. Indeed, even some patients who stayed with the same supplier were unable to count on receiving a steady supply of these products since many suppliers had no system in place for distributing the drugs in an orderly fashion. Patients and patient advocacy groups asked that Bayer do something about these inequities. Bayer responded with Bayer Direct.

How does Bayer Direct work?

In November 1999, Bayer introduced the Bayer Direct program to address the problems patients were facing in obtaining Prolastin and Gamimune. Bayer Direct allows patients to obtain the Prolastin and Gamimune they need when and where they need it by shipping these products directly to patients (or to whomever patients designate).

Bayer Direct is open to all patients. Any patient whose health depends upon Prolastin or Gamimune can receive these products through Bayer Direct regardless of the pharmacy they use or the state where they live. Patients can sign up through the mail, via the Internet, over the phone or through their physician. Bayer's representatives are on hand at all times to help patients and physicians complete enrollment forms,

obtain the patients' insurance information, and schedule any nursing visits that may be needed for administration of the products.

How does Bayer Direct help patients?

First, Bayer Direct protects patients from the practices of certain providers in the distribution channel who, in the past, have used product shortages as an excuse to institute dramatic price increases. Now, patients are guaranteed the benefit of being able to buy directly from Bayer.

Second, Bayer Direct eliminates patients' uncertainty and confusion about when, where and how they can continue obtaining new supplies of Prolastin and Gamimune. Bayer Direct operates on a clear and fair set of ground rules for the allocation of Prolastin and Gamimune. For instance, with regard to distributions of Prolastin, during enrollment each patient is given, in sequential order, a patient identification number. When Bayer assembles a sufficient amount of Prolastin to ship a patient a 28-day supply of the product, it ships a 28-day supply to that patient, beginning with Patient No. 1 and continuing until the supply of product is exhausted. When new supplies become available, the next patient in line will receive his or her shipment. These ground rules give patients certainty about when and how they can expect to receive their needed dosages in times of shortage.

Third, Bayer Direct guarantees that patients will not have to give up their ability to obtain Prolastin or Gamimune if they choose to change doctors or move to a new neighborhood. Patients who sign up for Bayer Direct will be able to get the Prolastin and Gamimune they need shipped directly to them at whatever location they choose. Moreover, in conjunction with Express Scripts, the nation's largest independent pharmacy benefit manager, Bayer Direct will also arrange for those patients who need infusions of Prolastin or Gamimune to receive treatment at a location of their choice. For more information about Bayer Direct, please call toll-free, (800) 305-7881, or visit our Web site at www.bayerdirect.com. ■

OIG evaluates infusion reimbursements

An Office of Inspector General (OIG) 1999 report unveils the Medicare home infusion industry, including its reimbursement trends, coverage, company characteristics, and physician financial arrangements. The report found that:

• **While Medicare patients appear to be only 10% to 15% of the total market, Medicare payments for home infusion therapy are rising rapidly.**

• **Some carriers cover only the drugs and conditions specified in the Health Care Financing Administration (HCFA) *Medicare Carrier's Manual,* while others cover a wide variety of unspecified drugs and conditions.**

• **Physician ownership or other financial involvement with home infusion therapy companies is common.** The report recommends that HCFA monitor spending to better identify trends, provide more specific coverage guidelines, and gather information on physician ownership of or compensation by those companies, and report fraud and abuse to OIG.

Infusion services at SNFs found wasteful

Another OIG final report says that infusion services provided in 22 skilled nursing facilities (SNFs) were often unnecessary, overpriced, and/or misclassified on SNF cost reports. As a result, the 22 SNFs were reimbursed unallowable costs totaling approximately $5.3 million ($4.8 million for services not medically necessary) out of $9 million claimed during 1995-98. The primary problem was the old retrospective reasonable cost-based reimbursement system, which was vulnerable to abusive billing schemes.

Currently, SNFs are paid under a prospective payment system (PPS). OIG recommended that HCFA consider the impact of improper payments for infusion therapy services before making any refinements or updates to the SNF prospective payment rates. OIG also recommended that HCFA identify and recover overpayments which were made to SNFs for unnecessary and overpriced infusion services prior to the adoption of PPS, and direct its contractors to perform medical reviews of selected SNF patients to ensure that patients are receiving appropriate levels of infusion therapy. HCFA generally agreed with OIG recommendations.

Parenteral nutrition benefits

Medicare beneficiaries with severe and permanent disease of the gastrointestinal tract who can receive the nutrients they need via parenteral nutrition are covered under Medicare's prosthetic device provision. In 1995, Medicare allowed $163 million in 1995 for parenteral nutrition solutions, not including pumps or supplies. Of this total, 89% were accounted for by just four procedure codes,

representing pre-mixed parenteral solutions with varying amounts of protein. An OIG report in October 1995 found that Medicare reimbursement for the four parenteral nutrition codes is an average of 45% higher than lower-paying Medicaid agencies, 78% higher than lower-paying Medicare risk-contract HMOs, and 11 times higher than some manufacturers' contract prices.

The report recommends that HCFA examine other payment methods that could lead to more cost-effective reimbursement for parenteral nutrition solutions. For example, the secretary of Health and Human Services or the Durable Medical Equipment Regional Carriers could use their "inherent reasonableness" authority to reduce reimbursement to more appropriate levels. HCFA could base its reimbursement on suppliers' acquisition costs or seek legislative authority to use competitive bidding to take advantage of its position of a high-volume purchaser of parenteral nutrition, the study stated. ■

'Your Bridge to Success:' NHIA Conference 2000

Program to include seminars, networking

The National Home Infusion Association's (NHIA) Ninth Annual Conference on May 17-20 in Cincinnati will be held in partnership with Expo 2000, a joint meeting of the National Community Pharmacists Association (NCPA), and the Chain Drug Marketing Association (CDMA). A primary networking and business opportunity for infusion specialists, the NHIA conference will feature 50 booths showcasing the full range of products and services used to support infusion therapy clinical services, operations, and management.

All NHIA Ninth Annual Conference programs are accredited for both pharmacy and nursing continuing education unless otherwise specified. For more information about NCPA and CDMA programming, including disease management and pharmacist care credentialing programs, call the NCPA at (800) 544-7447.

The programs include:

"The Executive Conference 2000 — Strategic Planning and Partnering." Developing critical success factors for home infusion therapy." Sponsored by Pharmaceutical Buyers, this conference provides an opportunity for home infusion owners, executives, and top-line managers to work together in a participatory format to discuss the most important factors in successful planning and management for infusion therapy. Karen Flores, PharmD, president of Health Management Associates (Woodside, CA) will present "Strategic Planning for the New Millennium." Lisa DiSalvo, strategic planning, Pharmaceutical Buyers, Boulder, CO, will facilitate. Cost: $100 for conference registrants; $125 to attend this program only.)

The clinical pre-conference program will include these content sessions:

• **Vascular Access Management: Strategies for Improved Patient Care.**

Offers an update on the latest issues in vascular access management, including research on device selection and strategies for preventing and managing catheter occlusions and other common catheter complications for home infusion therapy patients. Suzanne F. Herbst, RN, MA, is the speaker.

• **Clinical Outcomes Benchmarking.**

Part of the clinical pre-conference program, this segment will focus on clinical measurement efforts undertaken under the Joint Commission's ORYX initiative, preliminary findings, and their implications for home infusion practices. Discussion will include medication errors, adverse drug reactions, vascular access device complications and infections, primary bloodstream infections, and strategies for standardized reporting and efficient data collection. Barbara Rosenblum, BSN, MAOM, speaker.

• **Using Outcomes for Performance Improvement.**

Discussion by Tony Powers, PharmD, president, Medical Alternatives, of Memphis, TN, will include explanations of how to do a root-cause analysis use the data collected to show ways to reduce medication errors, vascular access device complications and infections, decrease hospitalizations, and improve patient care.

The general session on May 18 will feature:

• **Legislative/Regulatory Update.**

An update of the implementation of key components of the Balanced Budget Act of 1997, this program will cover various Medicare Part B home care issues, such as inherent reasonableness, competitive and consolidated billing, and key community pharmacy issues affecting infusion therapy such as acquisition-cost legislation, Medicare prescription drug coverage, freedom of choice, and state clean claims legislation. Speakers are Lorrie Kline Kaplan, executive director, National Home Infusion Association, Alexandria, VA, and Alan K.

Parver, Esq., president, National Alliance for Infusion Therapy, Washington, DC.

• **Nursing and Pharmacy Collaboration in Alternate Care Settings.**

Presents a contrast between traditional nursing and pharmacy roles with an updated, cross-functional model using specific steps and opportunities for collaboration. Presenters are Eric S. Kastango, RPh, president, Clinical IQ, LLC, Madison, NJ, and Kate Douglass, C,CNS, MS, CRNI, AOCN, vice president of clinical services, Coram Healthcare Corp., Whippany, NY.

• **Operational Benchmarking: Reaping the Benefits.**

Kenneth Lawson, PhD, associate professor, Pharmacy Practice and Administration Division, University of Texas College of Pharmacy, Austin, TX, and Rad Dillon, RPh, National Pharmacy Manager, Apria Healthcare, Louisville, KY, will present the key indicators for measuring operational performance in infusion therapy, using emerging benchmarks for these indicators.

• **Building Successful Managed Care Relationships.**

Judy Lewis, RN, infusion manager, Health Home, Phoenix, will discuss keys to managed care partnerships, major pitfalls to avoid when dealing with managed care payers, educating payers about using infusion services, ensuring appropriate coverage and reimbursement, managing and resolving conflicts when they occur, and contractual strategies for preventing coverage and payment conflicts.

• **Clinical Competency for Home Infusion Providers.**

Donald J. Filibeck, PharmD, regional pharmacy manager, Apria Healthcare, Columbus, OH, will discuss Joint Commission clinical competency requirements and how to implement a clinical competency evaluation program in a cost-and time-restricted environment. This talk will include current Joint Commission standards related to clinical competency evaluation and documentation for pharmacy and home health nursing providers, selecting the right competencies to evaluate at initial hire and on an ongoing basis, implementing appropriate policies and procedures, and strategies for developing clinical competency programs that are cost-effective and contribute to improved patient outcomes.

• **Electronic Claiming and Standardized Coding for Home Infusion: An Update.**

This program will also provide an update on the Home Infusion EDI Coalition, its per diem codes and federal mandates under the Health Insurance Portability and Accessibility Act, and the role of the National Council for Prescription Drug Programs.

• **Recognition and Reimbursement for Infusion Professional Services.**

Grant Brown, PharmD, executive vice president, Franchise Operations, Option Care Inc., Bannockburn, IL, will speak on trends and factors in gaining explicit recognition of and reimbursement for professional services. He will also address current strategies for related service sectors.

To attend NHIA's ninth annual conference, contact NHIA, 205 Dangerfield Road, Alexandria, VA 22314. Telephone: (703) 549-3740. Fax: (703) 683-1464. ■

New Safety IV catheter meets NIOSH and OSHA directives

B. Braun Medical's new Introcan Safety IV product has a safety clip covering the needletip that activates automatically when the needle bevel exits the catheter hub. The manufacturer says the product could eliminate nearly 50,000 of the most dangerous accidental needlestick injuries faced by health care workers each year — those from hollow-bore IV needles that could be filled with blood containing infectious agents like HIV or hepatitis B and C.

Dan Rice, vice president of marketing at B. Braun, says, "The key to designing safety devices is engineering a product that requires no change in technique, something that nurses and doctors do not have to think twice about. When health care workers use the Introcan product, safety is automatic." Rice adds that several prestigious teaching hospitals and medical centers have already converted to the Introcan Safety IV product.

Health care workers sustain between 600,000 and 800,000 accidental needlestick each year in the United States. According to a 1997 study, injuries from IV catheter stylets rank first in the "blood-filled needles" category, those that have a high risk of carrying bloodborne pathogens, despite the fact

that they comprise only 6% of the total number of injuries.

On Nov. 22, 1999, the Center for Disease Control and Prevention's National Institute for Occupational Health and Safety issued a safety alert urging hospitals to adopt needlestick-safety devices. Two weeks earlier, the Occupational Safety and Health Administration issued a directive that emphasized the "use of effective engineering controls, to include safer medical devices." The Senate (S.1140) and House (H.R. 1899) introduced the Health Care Worker Needlestick Prevention Act during 1999. In addition, four states (California, Tennessee, Maryland, and Texas) have enacted legislation on needlestick prevention and health care worker protection. Sixteen more states introduced bills in 1999. ▼

ECRI topics for 2000 telephone seminar series

The Emergency Care Research Institute (ECRI) topics for interactive telephone seminars to be held during 2000 include "Revisiting the Reuse of Single-Use Products" on May 17, 2000; "Don't Get Stuck with a Poor Needlestick-Prevention Policy" on July 19, 2000; and "Protecting the Privacy, Confidentiality, and Security of Electronic Medical Records" on Oct. 18, 2000.

Pamela Keating, ECRI's director for educational programs, says, "These seminars will focus on some of the most important topics of 2000. FDA is scrutinizing reuse, many states are passing legislation concerning needlestick-prevention devices, and those close to the issue believe that handling the Health Insurance Portability and Accountability Act may be even more of a challenge than preparing for Y2K."

ECRI's telephone seminars are similar to a call-in radio show. Participants listen to speakers on the topic then have a chance to call in during a question and answer period. All seminars are held from 1 p.m. to 2:15 p.m., EST. The registration fee, which includes participation for an entire site on one phone line, for each seminar is $199. However, ECRI is a nonprofit international health services research agency and a collaborating center of the World Health Organization.

ECRI provides information and technical assistance to the health care community to support safe and cost-effective patient care. The results of ECRI's research and experience are available through its publications, information systems, technical assistance, laboratory services, professional seminars, conferences, and fellowships. For more information on or to register for ECRI's Interactive Telephone Seminar Series for 2000, please contact ECRI at 5200 Butler Pike, Plymouth Meeting, PA 19462-1298. Telephone: (610) 825-6000, ext. 5888. Fax: (610) 834-1275. E-mail: info@ecri.org. ▼

Injex needle-free use for outpatient therapy

Rosch AG Medizintechnik, a partially owned subsidiary of Equidyne Corp., has signed a contract with Acanthos GmbH for outpatient cancer therapy using the Injex needle-free injection system, which allows treatment to be administered on an outpatient basis. The Injex needle-free injector, the company says, is a compact, uncomplicated device that delivers a painless injection through the skin in a fraction of a second, and eliminates needlestick and disposal problems. For more information contact Equidyne at (603) 880-6300. ▼

New hemodialysis access system

Creating and maintaining safe and effective vascular access is one of the most challenging and expensive components of dialysis. Dialysis-access placement, repair, and morbidity consumes over $7.5 billion worldwide each year. Vasca Inc. has submitted its 510(k) premarket notification with the Food and Drug Administration (FDA) for LifeSite Hemodialysis Access System. The FDA granted an expedited review status that is given when a device offers the potential for clinically meaningful benefit as compared to existing alternatives or when a new medical device promises to provide a revolutionary advance over currently available alternative modalities.

According to the manufacturer, the LifeSite System is the first major advance in dialysis treatment in nearly a decade and provides an alternative for vascular access in patients undergoing dialysis treatment. The device is implanted subcutaneously and can be accessed via a buttonhole technique by inserting a standard dialysis needle. The LifeSite System is designed to provide high flow rates, reduce the risk of infection, is unobtrusive, and can be used immediately

following implantation. For more information, call (978) 863-4400. ▼

Infu-Tech launches pain management on-line

Infu-Tech has signed an agreement with four leading pain management clinics in the Northeast to sell pain management products through the company's Web site, www.Smartmeds.com. Patients from those clinics will be able to obtain information and educational materials on pain management, and can communicate with Smartmeds.com's clinicians. They will also have the ability to follow their treatment schedules on Smartmeds' personal health calendar. The site will be used by physicians to order pain management medications and other pharmaceutical supplies, thereby reducing costs and increasing efficiencies.

Infu-Tech provides specialty pharmaceutical and medical services to patients in their homes, ambulatory infusion sites and in long-term care facilities. With more than 15 years of clinical experience and managed care relationships with enrollees of more than 70 HMO's, large employer groups, Medicare and Medicaid, Infu-Tech has earned a reputation for patient satisfaction and clinically proven success in delivering high levels of service to special need patients and is accredited by the Joint Commission on Accreditation of Health Care Organizations. ▼

Nasal spray reduces pediatric anxiety

A nasal spray that contains a drug similar to Valium reduced anxiety in children undergoing painful cancer treatments in a recent study of 43 cancer-stricken Swedish children. Researchers found that subjects given midazolam in a nasal spray prior to having a needle inserted into them for intravenous treatments were calmer and more comfortable than children given a placebo.

Although the drug was tested only on children with cancer, researchers said it could be used to ease anxiety in youngsters facing infusions and procedures for other medical problems. **Gustaf Ljungman**, MD, lead author of the study, says, "It's interesting for children who are very much afraid, where you otherwise would have to hold them down to carry through the procedure or immunization."

The study was published in the January issue of the journal *Pediatrics*. Ljungman is a pediatric cancer specialist at Uppsala University Children's Hospital in Sweden. In the study, the spray or a placebo was given before a needle was inserted in an intravenous port, an opening left in cancer patients to avoid having to insert an IV each time doctors need to administer a drug. The main drawback to the spray seems to be that some children experience a burning sensation. The study also noted that midazolam only reduced the children's anxiety and not the pain associated with the treatment itself. ▼

New peripheral access system

SIMS Deltec Inc. has a new peripherally inserted central venous access system for delivery of chemotherapeutic drugs, antibiotics, pain medications, nutritional solutions, and other intravenous therapies. The P.A.S. PORT(R) Elite implantable access system is a small, low-profile portal designed for comfortable arm placement. The portal consists of a lightweight plastic exterior for patient comfort and a titanium interior floor for gouge-resistance and long-term durability. The system can be implanted in an outpatient procedure room, thereby eliminating inpatient and operating room charges. The new P.A.S. PORT(R) Elite system expands the peripheral product line available from Deltec, which includes the P.A.S. PORT(R) and P.A.S. PORT(R) T2 systems. For additional information, visit Deltec's Web site at www.deltec.com., or call Sandra Lochen Puckett,

COMING IN FUTURE MONTHS

- PPA effect: Elimination of venipuncture benefit fallout
- Sound off: The use of ultrasound in infusion therapy
- Outcomes: Designing a work model that works
- Unapproved drugs: A lawyer looks at declotting lines

product manager, at (651) 628-7185. ▼

Bioject and Serono team deliver needle-free therapy

Bioject Medical Technologies, Portland, OR-based developer and manufacturer of jet injection systems for needle-free drug delivery, and the Geneva -based Serono Laboratories, have agreed to deliver Serono's Saizen recombinant human growth hormone with a customized version of Bioject's Vitajet 3 needle-free delivery system. The exclusive licensing agreement begins when the drug receives FDA clearance.

Patients in clinical studies evaluating the bioequivalence of Saizen when delivered with the Bioject needle-free delivery system preferred the needle-free delivery system to traditional syringes. They also indicated that the needle-free device was less painful. The Bioject device will be adapted for use in the pediatric growth market, and will be sold under the Serono brand.

Bioject's president and CEO **Jim O'Shea** says, "Bioject is committed to improving patients' lives through strategic partnerships with pharmaceutical and biotechnology companies. We have made great progress over the last year in executing our strategy. Our partners now include AngioSense, Serono, and, in a preliminary agreement, another undisclosed major biotechnology company."

Serono Laboratories is the U.S. affiliate of Ares-Serono, S.A., a biotechnology company active in growth and metabolism products headquartered in Geneva. Bioject currently markets two FDA-cleared needle-free injection systems, the Biojector 2000 and the Vitajet 3 that have already received FDA approval, and is developing a third, the Iject. A copy of the package insert for Saizen somatropin (rDNA origin) for injection, is available from Serono's Product Information and Surveillance

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GWU: IPS decreasing HH access

Sixty-eight percent of all hospital discharge planners surveyed by George Washington University researchers reported increased difficulty in initially obtaining home health services for Medicare patients since the implementation of the interim payment system (IPS).

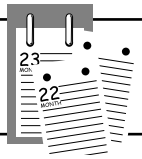
In addition, respondents to the GWU Center for Health Services Research & Policy survey show that only 22% of them reported no change in difficulty finding home health services for their Medicare patients.

The latest findings of the study were included in the second phase of the two-part study that is measuring the impact of payment changes mandated by the Balanced Budget Act of 1997.

Home health industry advocates said the results were further evidence that Medicare patients have decreased access to home health services for the sickest patients. The study's authors shared their opinion.

"There is compelling evidence of differential treatment of sicker beneficiaries in response to financial incentives of IPS that suggest problems with access to and quality of home care services for this population, the study concluded. "These findings raise significant policy questions that should be addressed in evaluating IPS and any other payment system that may be developed." ■

CALENDAR



• **Intravenous Nurses Society Annual Meeting** — May 8-11, Minneapolis. For more information, call (617) 441-3008.

• **Ninth Annual National Home Infusion Association (NHIA) Conference** — May 17-20, Fort Lauderdale, FL. For more information call (703) 549-3740. Fax: (703) 683-1484. E-mail: nhia@vais.net. **(See article, p. 31, for highlights of this year's conference.)**

• **NAVAN** Annual Conference — Sept. 6-9, San Diego. For more information, call (888) 57-NAVAN.

• **Medtrade 2000** — Oct. 3-6, Orange County Convention Center, Orlando, FL. For more information, call (770) 641-8181. ■

CE objectives

After reading the March issue of *Home Infusion Therapy Management*, CE participants will be able to:

1. Describe the benefits of community-based parenteral anti-infective therapy (CoPAT).
2. Discuss the benefits of needle-free hormone delivery.
3. Define optimal conditions for donating blood.
4. Cite three instances in which CoPAT should not be used. ■