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Electronic standards on the horizon for coding and submitting claims

HCFA publishes proposed regulations, analyzes comments

Despite its own problems dealing with the Y2K dilemma, the Department of Health and Human Services, with significant help from the Health Care Financing Administration, is set to streamline the health care industry by implementing electronic standards for coding and submitting electronic health claims.

With the comment period closed since July, HCFA now is prepared to finalize the regulations, according to a HCFA spokesman.

"We're in the process of analyzing the comments," says the spokesman. "As soon as we analyze them and can respond to the comments, we will issue a final regulation, which will align how providers will implement the regulations as well as set a deadline."

It's likely the deadline will be two years after the effective date of the final regulation, so home infusion providers may have close to three years before the regulations are mandatory.

"It would be several months [before final regulations are posted] because it takes that long to go through the comments and there is a lot of national interest in these," notes the HCFA spokesman. "The nature of the comments also dictates how fast we can issue the final regulation."

Potential hang-ups

Bruce Rodman, chair of the Home Infusion EDI Coalition (HIEC) and reimbursement section manager for Abbott Park, IL-based Abbott Home Infusion Services, recently addressed HCFA regarding concerns the coalition had about simplification of the regulation.

"I am commenting with intent of improving the final rules in such a way that it becomes possible for home infusion providers and payers to achieve administrative simplicity for our insurance-related transactions," Rodman told HCFA. "If our needs are not incorporated into the final rules, it will not be possible for our home infusion industry to achieve the objectives."

Rodman notes that the home infusion industry is critical to the implementation of any standards because of its already burdensome insurance administrative process.

"Home infusion is estimated to be a $4 to $5 billion industry in the United States," according to Rodman. "Historically, home infusion providers have been burdened with what is widely recognized as the most difficult and least efficient insurance administrative process in health care. Home infusion insurance claims are also very expensive for insurers to process."

Such problems arise because of the lack of common standards for home infusion claims, notes Rodman, as well as the fact that most home infusion claims are submitted on paper. Submitting claims also is burdensome because of the lack of a national standard for coding home infusion services. As a result, Rodman points out that home infusion providers must custom-code claims for nearly every insurer.

Recommended revisions

While in favor of the proposed rules as a whole, HIEC's suggestions to HCFA included specific recommendations in the following areas:

1. Electronic format.

HCFA recommended the adoption of NCPDP Telecommunication Claim Version 3.2 or equivalent NCPDP Batch Standard Version 1.0 for "retail drug" health care claim and equivalent encounter transactions, to which the HIEC responded, in part:

"Home infusion providers need to submit claims by only a single electronic format to obtain maximum administrative efficiency. This format should be the X12 claim standard. The NCPDP Version 3.2 and Version 1.0 standards will not support a home infusion claim because the transaction does not support compounded drug claims and it also does not support claims for the supplies, pumps and clinical pharmacy services of a home infusion provider. The X12 standard supports claiming of all services of a home infusion provider. "

2. Placement of codes.

In its proposed regulation, HCFA stated: "Administrative functions necessary to process and facilitate claims by health insurers can be achieved by using 'administrative' codes placed in fields other than those used for medical diagnosis and procedure codes or by attaching a modifier to a medical code."

HIEC's response noted: "To suggest codes needed to charge for administrative functions, such as the administering of a health care service, are to be placed in fields other than those used for medical diagnosis and procedure codes, or by attaching a modifier to a medical code, is simply ludicrous if this means a provider cannot bill a charge for all of its services."

Rodman notes that home infusion claims are often submitted to private insurers for per-diem services under terms of a contract between the provider and payer, and the only way to encode such a charge is through assigning a procedure code.

"At a minimum, the final rule should be revised to guarantee that a health care provider is not prohibited from submitting a claim which codes and charges for all of its services, including administration of the health service expressed as a per diem charge, as well as administration of drug therapy," notes Rodman.

3. Coding standards.

While the HIEC developed and maintains a national coding system for home infusion products and services, any new electronic submission standards could prove to undermine its work. With this in mind, Rodman has recommended that HCFA include the HIEC Home Infusion Services National Coding System in the standards.

4. National review process.

HCFA recommends there be a "national process established for reviewing and approving codes that are needed by any public or private health insurer." Codes are currently maintained by HCFA and other groups through an Alpha-Numeric Editorial Panel, which meets three times per year in meetings not open to the public.

HIEC responded to the proposal by stating that health care providers, as well as any other interested parties, must be included in the process of reviewing and approving codes.

HCFA also had proposed that temporary codes be established as needed for use by all health insurers.

Rodman told HCFA: "We object to the proposed process for establishing temporary codes because it provides HCFA with sole decision-making authority over establishing these codes. While we have respect for HCFA's area of expertise in administration of government health insurance programs, we believe HCFA is not qualified to make decisions on coding used for the trading partner relationship between health care providers and non-government insurers."

HIEC made several other technical suggestions to the proposed regulations. You can obtain a copy of Rodman's presentation to HCFA on behalf of HIEC by e-mailing him at **Bruce.Rodman@abbott.com.**

HCFA also has introduced a proposed rule that would require every health care provider to acquire an alphanumeric identifier for use when filing claims for reimbursement by public and private insurance programs. HCFA contends that the currently required multiple provider numbers slow the payment process, increase costs, and result in a lack of coordination. The proposed rules are two of the administration's simplification steps provided for in the Health Insurance Portability and Accountability Act of 1996.

Under the proposed ID number rule, all health care providers would apply for an eight-digit identifier to use when processing electronic claims. The identifier would remain with the provider, even if it moves or changes specialties. ■

Is an alternate-site infusion suite for you?

The experts tell you how to decide

Simply opening an alternate-site infusion suite isn't all that difficult if you are a home infusion provider, but opening a successful suite is another story. And the first step in making sure your business venture is a success is to do your homework.

Steven Taglianetti, president of alternate-site therapy for Baton Rouge, LA-based Amedysis, says there are six questions you must answer prior to opening a site:

1. Where will your referrals come from?

The bottom line is to make money. If there aren't enough referral sources in your area willing to send patients to your suite, then opening one isn't an option.

Marcia Wise, RN, past president of the National Association of Vascular Access Nurses (NAVAN) and director of clinical support for Catheter Innovations of Salt Lake City, has helped many providers open infusion suites. She agrees that referral sources are critical.

"Interview your current referral base," she says. "What typically happens in home infusion is, if you are seeing 100 patients a month, a third of those may end up becoming ambulatory patients. You may gain some new referrals, but for home infusion it's often more just trading for a more cost-effective place of treatment."

However, she does note that there is the possibility of adding new referrals if you know where to look.

"There may be patients who are not being referred to home care," says Wise. "Blood transfusions are tough to do in the home, and financially they're not cost-effective. But if local oncologists send patients to short-term stay or hospital outpatient, they can then send them to your infusion center."

2. Is there physician support?

Obviously, having physicians who believe in alternate-site infusion therapy goes hand-in-hand with referrals. Taglianetti notes that not all physicians are comfortable with such a setting.

"Some will only support a center that you manage within their office," he says. "We find that infectious disease doctors and surgeons are most willing" to use alternate infusion suites, Taglianetti adds.

3. Is there managed care support?

If you're currently involved in managed care contracts, you will have to approach the MCO to see what, if any, agreement you can reach. For many providers, this is a major sticking point.

"Most companies have problems dealing with managed care because they are cutting deals that are not profitable," says Taglianetti. "We'll walk away from managed care business that will not be profitable. It has to benefit the payer, the provider, and certainly the patient."

Wise agrees that pricing is a critical issue that often presents problems for providers.

"People have a hard time understanding how to price their services," she says. "But if I'm a home infusion provider with an MCO contract, I should be able to go to the MCO and offer a discount on patients that can come to the suite."

By offering a discount, you may find your referrals picking up as a result.

"We have gone in and said, 'We have a $100-a-day contract with you, but if a patient is a candidate for the ambulatory infusion center, we'll do it for $85 a day.' The MCO then funnels patients to that lower-cost setting to save money," according to Wise.

4. Is there payer support?

Look at your entire list of payer sources and touch base with each to address reimbursement issues. Don't leave such a critical area to chance.

Find out what will change for your reimbursement staff before treating the first patient in the ambulatory setting.

5. What will your setting be?

Taglianetti says you need to consider whether you will focus on a rural or urban setting.

"Some rural physicians will support a center because they know there is a real issue where you don't have hospital coverage," he says.

Your present service area will dictate how much you are able to benefit from opening a suite, according to Wise.

"A nurse can see 10 patients a day in an ambulatory infusion center and maybe four a day in a rural home care setting or in big urban centers where traffic makes it difficult," says Wise. By doing away with travel time, you're increasing each nurse's productivity.

However, the flip side of the coin is that you'll need to consider how much space your office will need. This will depend not only on the number of patients who come into the suite each day, but also on the duration of their therapy.

"If you're going to be primarily doing blood transfusions and chemotherapy infusions that are going to take four to six hours, that is going to be more difficult than if you do a lot of antibiotics that come in and out in 30 or 40 minutes," she says.

6. Can you handle the billing?

"The billing is complex, but anyone can learn it," says Taglianetti. "But you need a billing center that bills properly for an alternate-site center." **(For a comprehensive look at billing issues with ambulatory infusion suites, see *Home Infusion Therapy Management*, July 1998, p. 77.)** ■

Complete the transition with safety sharps

Don't let your first step to needle safety be your last

Amid the current trend toward greater safety, it's clear that more and more providers are implementing the use of safety needle devices. In fact, it could be just a matter of time before such devices become mandatory.

Robert Orenstein, DO, director of HIV / AIDS at the Hunter Holmes McGuire Veterans Affairs Medical Center in Richmond, VA, says most providers are only halfway to where they should be. While many have begun using needleless tubing systems, which is a major step in the right direction, they've yet to replace needles and other hollow-bore devices.

"Needleless systems for IV therapy have reduced injuries in nurses close to 90%, which is where most injuries were occurring," says Orenstein. "However, they were lower-risk injuries."

The more dangerous (albeit less frequent) problem lies elsewhere.

"The problems tend to be with the devices that are going directly into the patient to draw blood or insert an IV," he says. "Those are the higher-risk needlestick injuries where there is direct contact with blood, and those are the injuries we have not done a very good job of preventing."

The trend toward safety seems to have thus far fallen short of where it should be, he says.

"If you look nationally at what devices people are using, most have switched to the needleless IV systems, but they have not switched to the devices that will protect people from the high-risk injuries," adds Orenstein. "This certainly gives people a false sense of security."

Lynda Arnold, RN, an activist for needlestick prevention through the National Campaign for Healthcare Worker Safety, says the problem may be that the safety emphasis has been placed on the least dangerous area.

"The biggest mistake people make is trying to identify which devices are causing the most frequent needlestick injuries, and that is the wrong approach," she says. "The devices causing the highest frequency of needlesticks are probably getting the most use and may not pose the biggest danger." **(See related story, p. 125.)**

Arnold recommends identifying the biggest risk first, which typically are hollow-bore, blood-filled needles.

"Don't look at frequency first, because while you may be taking care of the most prevalent problem, you're not taking care of the biggest risk," she says.

Orenstein points out that the move to safety appears to be coming in the form of a two-step process. Phase one was the move to needleless tubing.

"In the first stage, everyone looked at where the greatest number of needlesticks was occurring rather than at the highest risk," he notes. "The original objective was to reduce the frequency of needlesticks, hoping that if you reduced the total

number of needlesticks you would reduce the risk of transmission of bloodborne diseases. But there is not much data showing a reduction because it is such an infrequent event to start with. There aren't that many health care workers who are getting infected by needles at work."

In Orenstein's opinion, a move to safer hollow-bore, blood-filled devices will have a greater impact on reducing the incidence of transmitted bloodborne diseases.

"Preventing blood exposure would certainly have a larger impact on disease transmissions," he says. ■

Make the right move to needle safety

Six-step checklist to finding the perfect device

If you're not sure how to go about selecting the safety device that best suits your needs, here's a checklist that will help you make the right choice.

1. Reduce the highest risk first.

Lynda Arnold, RN, an activist for needlestick prevention through the National Campaign for Healthcare Worker Safety, says your first step should be to find out where your nurses and patients are at the most risk.

"Identify the biggest risks first, and then work down from there," she says. "The biggest challenge is to identify which types of devices meet the high-risk category, particularly, which are the hollow-bore blood-filled needles? Identify the risk first, then the frequency."

2. Consider everyone at risk.

Your nurses obviously will be at risk, particularly when doing insertions in the home. But it would be an oversight only to consider nurse safety, Arnold says. In fact, standard tubing, cannulas, and catheters present risks to a wide range of individuals.

"Patients themselves see the need for safety devices in the home," says Arnold. "Accidents happen in the home that we think would never happen in a hospital because in the hospital most variables are controlled and there aren't dogs jumping on the bed. You also want to protect family members and caregivers from exposure to blood. You also have to think of all the people involved in the disposal. What happens to the worker who is responsible for the collection of the device, or the child who comes in contact with a device that was not properly disposed of?"

It was through such careful consideration that Deaconess Home Medical Equipment and Infusion in Evansville, IN, opted for needleless tubing as its first move into safety devices. When looking at the potential risk to patients and caregivers as well as nurses, needleless tubing was the obvious choice.

"When I tell patients we don't use needles in the home, their faces light up," says **Ann Williams**, RN, CRNI, an infusion nurse with Deaconess.

3. Prevent major change.

Once you have identified the device that poses the greatest risk to staff and patients, look for a substitute safety device that won't require a major overhaul in technique.

"Select a device that uses little or no user action training or retraining," says Arnold. "You want to find a device that is comparable to the device you are currently using so the only difference is the safety mechanism."

Arnold recommends finding a "passive" device.

"Most devices require some user action to activate the safety mechanism, but you want as passive a device as possible," she says. "But you may have to go with a product that requires activation, so don't wait for a totally passive device."

One way to evaluate devices is to get first-hand information from other providers and manufacturers.

"Talk to other providers, see if they have switched and which ones they liked," says **Robyn Lit**, project officer for Plymouth Meeting, MA-based research agency ECRI. "Also talk to manufacturers and have them in to trial devices."

By doing such research, Williams was able to rule out some complex needleless tubing systems that were reported to have too many pieces. She also settled originally on the Clave system because it didn't give nurses the opportunity to use needles and forced them to use the safety feature.

"Some of the products didn't make the nurses go needleless, and I was against that," says Williams. "If you're going to switch, go all or none. As a nurse, if you are in a hurry and you have a choice you are going to stick the needle in there."

4. Don't swap risks, eliminate them.

"Make sure the [new] device does not present an additional risk where there was no risk before,"

says Arnold. "For example, make sure the safety feature doesn't allow more exposure to blood than the previous device. Even though that's not as dangerous as a puncture, you don't want to introduce a new risk, in this case more blood exposure."

Orenstein agrees that some devices simply replace one risk with another.

"With a device that is more difficult or more cumbersome to use, nurses may have to stick the patient three times instead of once, so that exposes them to three times the risk of getting the needlestick, not to mention the patient who is getting stuck more times."

Risk isn't the only factor to consider. You also have to make sure patient outcomes don't suffer. An increased infection or phlebitis rate means you'll soon be shopping once again.

"You want the therapy to finish with a positive outcome with the least amount of complications anticipated or occurring as possible," says **Debbie Benvenuto**, CRNI, nurse educator for IV therapy with the Intravenous Nurses Society in Cambridge, MA.

Williams points out that she looked at infection studies available from manufacturers on each product she considered.

5. Provide proper training.

"Once the evaluation and selection of the device is complete, there needs to be a commitment to education and inservicing on the part of the manufacturer for that particular device," says Arnold. "Make sure the manufacturer is going to stand by the product and provide the level of education necessary. This is a long-term commitment." Talk with the manufacturer about what kind of commitment you can expect, and ask other users of the device to confirm the manufacturer's commitment.

Orenstein agrees that ongoing training is critical in making sure your safety devices are being used properly.

"You have a fair amount of turnover in most health care institutions, so you may have people who come from elsewhere that are not familiar with the devices," he says. "You might introduce a needleless system and in a year and a half many of your nurses have changed, so you need an ongoing system of education for everybody coming."

"The inservice program from the manufacturer regarding proper use should be used," says Benvenuto. "A person becomes dangerous to themselves if they think they know all the peculiarities of a device and they really don't."

Looking for safety device information?

Here are resources to help refine your search

In addition to sales representatives, peers, and manufacturers, the following resources can provide helpful safety device information:

- The International Healthcare Worker Safety Resource and Research Center compiles data on safety devices. Telephone: (804) 924-5159.
- There is an infusion therapy e-mail list available that allows providers to solicit and exchange information. To subscribe, send an e-mail message to majordomo@ohsu.edu with the words "subscribe venous" with no quotes in the body and no subject.
- ECRI has published two reports on safety devices and an evaluation protocol in its August-September 1994 issue. For more information, call ECRI at (610) 825-6000.
- Lynda Arnold's National Campaign for Healthcare Worker Safety can be reached by calling (800) 936-7370, or by visiting its Web site at www.healthcaresafety.com. ■

6. Evaluate acceptance.

Orenstein says the move to a safety device isn't complete until you've measured acceptance.

"Do pilot studies to make sure the device is accepted," he says. "Initially people think they are using a safer device, then realize they are often more difficult to use than conventional devices."

A pilot study can be as simple as making sure your nurses are comfortable with the device before you make any purchase. What feels right during a demonstration may not be quite as easy to use in the field.

If a device required even a slight change in technique on the part of your staff, it will take some time to find out if they are adapting to the new device or giving up in frustration. Only careful follow-up will provide answers.

Constant follow-up and evaluation also will allow you to stay abreast of what's on the market and move to more efficient devices as they become available. After nearly two years using the Clave needleless system, Deaconess recently switched to the Ultrasite.

"It has a positive-pressure-effect feature when you take the syringe off," says Williams. "With the Clave we had a number of our midlines that were having clotting-off problems, and we had to declot them."

While Clave also has a new product with a similar positive-pressure feature, the Ultrasite proved less expensive. So by staying on top of problems and what was currently available, Deaconess not only moved to an updated product but also saved money in the process. ■

For a cleaner clean room, try technology training

New CD-ROM provides policies, procedures

You sink a fortune into your pharmacy clean room, but it's only meaningful if pharmacists and technicians consistently follow strict mixing guidelines. With a training program on CD-ROM called *Good Compounding Practices* from Cognitive Design Associates (CDA), an Upper Saddle River, NJ-based health care consulting firm, you can make sure your pharmacy is operating according to well-founded policies and procedures and ensure that pharmacists and technicians are on the same page.

Chances are that somewhere, somehow, you're doing things that hinder the effectiveness of your clean room, no matter how hard you try, according to **Kate Douglass**, president of CDA. Douglass notes that it doesn't take much to undermine the effectiveness of your investments.

"We have seen people storing product in the clean room," she says. "That increases particulate count, and it doesn't matter that you just spent $120,000 on the clean room. People spend a lot of money on high-tech clean rooms, but all that is lost if they don't know how to operate the facility and they're not organizing their work flow properly."

Douglass says it's not just oversights such as storing product that can undermine your best efforts to keep your clean room clean. Pharmacists who walk in and out of a clean room dozens of times a day, or keep on the scrubs that they just went out to lunch in, are making simple yet costly mistakes when it comes to keeping particulate matter at a minimum.

And then there's professional discretion when mixing.

"There isn't any room for professional discretion when it comes to aseptic compounding," says Douglass. "There's certainly room for professional discretion when interacting with physicians and patients, but in aseptic compounding there just is not a lot of room for professional discretion."

The problem is that there is no single standard for pharmacists to follow. And that's where CDA and its CD-ROM, *Good Compounding Practices*, come into play.

"There is no one standard that says this is the way you need to compound," says Douglass. "We took information from acknowledged sources such as ASHP [American Society of Health-System Pharmacists], NABP [National Association of the Boards of Pharmacy], USP [US Pharmacopoeia], and the FDA [Food and Drug Administration], identified commonalties, and applied them to what is reasonable in the business setting, resulting in *Good Compounding Practices*."

CDA's *Good Compounding Practices* can give a home infusion pharmacy guidelines for a streamlined process and helps fill in the gaps for areas that may have been overlooked.

extenCare, an Elkridge, MD, pharmacy that provides mixing services for a number of clients ranging from hospitals to long-term care facilities, has been using the CD-ROM for about a month.

Stacy Reid, CRNI, OCN, clinical operations director for extenCare, says anyone who works in the clean room has to come through the program.

"All of our personnel have been trained in the process control procedures we use to control our final product, and this CD-ROM is adjunct to that," she says. "It's a way to test employees and see if they have learned and retained the training."

Reid points out that there are several benefits of the CD-ROM:

1. It starts with basic principles and provides a solid foundation of knowledge in the review portion. Before tackling advanced issues, the review begins with fundamental principles such as why a clean room is used, how it operates, what contamination means, and the differences between various types of contamination.

Douglass notes that even though such information is basic, it's still critical.

"We strongly urge people to go back to the basics," she says. "Go back to good gowning and

gloving, go back to using masks, go back to what works. Look at your own processes and procedures internally, tighten them up, and make them consistent."

2. *Good Compounding Practices* allows staff to proceed at their own pace.

"The computer-assisted series allows a learner who is advanced to go through and complete the requirements quickly," says Douglass. "The software incorporates elements such as hypertext where an advanced-level word that a novice learner might not know is explained when the learner clicks on the word and the definition appears."

3. Because the policies and procedures are laid out in a specific manner, it's easy for pharmacists and technicians to use the same exact policies and procedures, thereby removing the potential for confusion that arises from professional discretion.

"Professional discretion allows you to make TPN [total parenteral nutrition] a certain way and another pharmacist to make TPN another way," says Reid. "With *Good Compounding Practices*, everything is done the same way all the time."

As a result, when Reid looks in her clean room, she can see who is doing what by looking at where they are. The color of tub the pharmacist is using and the way the label is tilted on top of his or her hood tell Reid exactly where the pharmacist is in the mixing process because these elements are predetermined in the procedures. According to Reid, this allows staff to get into a very quick routine.

Using the CD-ROM as a study tool isn't enough, though. Once the review is complete, staff must pass a test on the material. Reid says the testing module is beneficial because it provides her with an objective method of measuring progress.

"This has assisted me by providing a concrete tool to tell someone, 'You are not where you need to be at this point, and we need to extend your orientation,'" she says. "Instead of subjective things people often use, this is a black-and-white way to assess someone's competency."

But Reid has access to more than just a final pass/fail grade. Because the test allows people to progress at their own pace, Reid can see what areas any particular staff person had difficulty with.

"The program tells you how many times they had to try to get the right answer, so you can tell when they are struggling with a concept or technique," she says. "We put that in a person's file, and if they didn't do well, they have to go back to the drawing board."

Douglass adds that the convenience of providing training on a CD-ROM is another benefit.

"It's not only a way to document training, but staff can do training during downtime between job activities or take it home," she says. "They can do it on a PC anywhere." ■

Network shopping? Consider your goals

One size does not fit all providers

Have you been looking into joining a network? Are you already in a network, but wondering if there is a better option for you? If you answered yes to either question, you're not alone.

According to **Tom McNulty**, PharmD, president of Health Integration Strategies, a Pasadena, CA-based data processing and home care consulting firm, there is no perfect network for all home infusion providers. In the second part of a two-part series on networks, *Home Infusion Therapy Management* takes a look at the various network models that exist and the benefits and disadvantages of each.

"It's an individual choice," says McNulty. "It depends on the individual provider, what their goals are in their marketing, and what their particular market is experiencing."

Networks vary from small, provider-based networks to regional and national provider-based networks, as well as integrated health systems and independent non-provider-based networks. While the choices are numerous and complex, McNulty says each type of network has its own benefits and disadvantages.

Possibly the fastest-growing trend is that of integrated health systems, which McNulty defines as a health system that is either hospital-based or physician group/hospital-based.

"Integrated health systems are just getting rolling now and are starting to gain some steam," says McNulty.

However, even though all ancillary services such as home infusion are provided, the fact that such

systems are hospital-based doesn't necessarily mean they exclude stand-alone home infusion providers.

"It depends on what the health system's priorities are," notes McNulty. "Do they want to have their own home infusion program, or are they looking to subcontract? There are a lot of different structures in networks."

One example of network structure is a self-sustaining network, which is probably the easiest and quickest route.

"You may say, 'My payer wants a one-stop shop and I'm an infusion provider, so I am going to go down the street to my DME and nursing friends,'" says McNulty. "And you will take it upon yourself to run the network, consolidate the bills, authorize care, and coordinate everything."

A second option for a provider creating a network is the stand-alone method, in which the network will have its own budget, steering committee, management, and reporting systems.

Both the self-sustaining and stand-alone networks have their inherent benefits and disadvantages. The benefits include:

- **increased control over referrals;**
- **direct management of your relationship with the payer;**
- **direct accounting for financial success and days outstanding.**

Don't underestimate budget requirements

On the flip side of the coin are the risks, including:

- **Financial and time commitments associated with start-up.**

McNulty notes that a common mistake providers make is underestimating both time and budget requirements. He adds that it is important to remember that there is a six-month to 12-month sales cycle to sell a network to a payer, so for that time period it's unlikely you'll derive income from the network.

- **Potential for distraction from your primary business.**

"It is an in-depth business line that must be considered a new business line with all of the different components figured out," says McNulty.

"You have to decide on either central referrals or decentralized referral. Who does the authorizations? Who does the claims consolidations? Who does the payment disbursal? Who does any kind of reporting to the payers? Who handles the relationship with payers?" he asks.

- **Hidden costs such as phone systems and information systems.**
- **Handling existing provider payer contracts.**

"Does the new network contract supersede everything, and are you marketing against yourself or against one of your network providers?" asks McNulty. "Do you have your own dedicated staff to sell the network, or do you have your own staff sell the network? Is the contract exclusive or just one of many?"

McNulty points out that if the new network's contracts are exclusive, they supersede all previously existing contracts. But if the new contracts are not exclusive, does your sales staff sell just your home infusion business or the business of the entire new network?

If you're not interested in starting your own local or regional network, you can join an existing national provider, which offers several benefits over the local option:

- **You reduce your financial risk because there is no start-up cost or ongoing expense.**
- **It provides you with a new referral stream that you otherwise may be excluded from.**
- **It allows you to concentrate on your business rather than splitting time between home infusion and the network as a whole.**

However, McNulty adds that national providers have risks as well:

- **"You strengthen the competitor's position," he says.**

"The national provider becomes stronger because you are in the network, and if you're a quality provider, they don't sell that fact; they simply sell the fact that they can handle a larger capacity."

- **You have no control over referrals.**

"Depending on the referral process, you may receive only the worst cases from a contracted plan," according to McNulty. "If it is centralized referrals, you get what they give you, and unless you are the only person in that geographic region, they have no incentive to send you the best cases."

- **You sacrifice independence.**

"You lose payer visibility because you are just one of a network, so your name is lost."

- **Competition controls your livelihood.**

"Days outstanding and accounts receivable are controlled by a competitor," says McNulty. "The network may say, 'The payer hasn't paid us so we're not paying you,' and that can starve you for cash, which is no small issue." ■

NEWS BRIEFS

Expanded trial set for blood substitute

The Food and Drug Administration recently asked Evanston, IL-based Northfield Laboratories to expand the number of patients in Phase III clinical trials of PolyHeme, the company's blood substitute.

The FDA based its request on public concern over failures of competing products in Phase III trials. The protocol cleared earlier by the FDA included 240 elective surgery patients. The latest agreement, however, calls for a minimum of 600 patients to participate in the expanded study.

In the two years of the Phase III trial, PolyHeme has been infused in more than 100 patients without negative side effects, including infusions at a dose level of up to ten units. The company notes that the expansion of the Phase III trial will likely delay completion until late spring of next year.

However, the FDA also has given Northfield the OK to infuse up to 20 units of PolyHeme in adults in Phase II trials being conducted among trauma patients. ▼

Results favorable for B-cell non-Hodgkin's lymphoma

Rituxan (rituximab), a drug co-developed by San Francisco-based Genentech, San Diego-based IDEC, F. Hoffmann-La Roche of Switzerland, and Zenyaku Kogyo of Japan has shown promise in battling combat relapsed or refractory low-grade or follicular CD20-positive B-cell non-Hodgkin's lymphoma. The FDA approved the drug for marketing in November 1997.

The trial, conducted at 31 U.S. sites, showed a 48% overall response rate in 166 intent-to-treat patients. Of these responses, 10 were complete and 70 were partial. And 56 of the 75 patients who did not achieve a complete or partial response reported a net decrease of measurable disease.

The projected median time to progression for responders was 13 months, with a median follow-up duration of 11.8 months. Side effects were mild, with fever and chills the most common events. Only 12% of patients had grade 3 toxicities, and 3% had grade 4 toxicities. Final study data will be re-analyzed after all the patients have relapsed.

Rituxan is given over a 22-day period in four infusions, typically in an outpatient setting. Special handling is not required of the therapy or patient. ▼

Virtual reality comes to IV training

HT Medical of Rockville, MD, recently introduced its CathSim Intravenous Training System to allow realistic practice of intravascular therapies prior to patient contact.

The PC-based CathSim system allows users to learn both cognitive and motor skills with intravenous catheterization. The system incorporates a robotic device that mimics the feel of the procedure. The system allows providers to feel the "pop" of the catheter needle going into the veins of simulated patients.

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CathSim, which costs $8,800, provides real patient variations, such as fragile, deep, and rolling veins, as well as patient preparation, pre- and post-procedure videos, and catheter insertion simulation. The latter includes stretching of the skin, the feel of the needle passing through the skin into the vein, flashback and threading of the catheter, optional side-view and transparency, and the patient expressing "pain."

HCFA recently signed a cooperative development agreement with HT Medical to incorporate features into CathSim to allow benchmarking of nurses' performance in placing intravenous catheters.

For more information, contact HT Medical at (301) 984-3796. ▼

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Needlesticks a thing of the painful past?

Researchers at Georgia Institute of Technology in Atlanta are building "microneedles," several hundred of which can be placed in a tiny chip and applied to the skin much like a transdermal patch. Penetrating only the top layer of skin, the needles are painless and could at first provide a single dose of a drug.

What's more, there is the potential for such microneedle-filled patches to be left on the skin and provide a continuous flow of medication using microprocessor technology. Researchers have already built needles that are just 150 microns long and that make holes about 1 micron in diameter. Additional development is focused on making the needles hollow, increasing the amount of drug they can deliver, and making the needles smaller so the punctures they produce will prevent the entry of infectious bacteria. ▼

Subcutaneous epoetin allows lower dose than IV

In a study recently published in the *New England Journal of Medicine*[1], patients on hemodialysis received an average weekly dose of epoetin that was 32% less than that for patients treated with IV epoetin.

The study was a randomized, unblinded trial conducted at 24 hemodialysis units at Veterans Affairs medical centers, and involved 208 patients receiving long-term hemodialysis and epoetin therapy with either subcutaneous or intravenous epoetin.

For purposes of the study, the epoetin dose was reduced until the hematocrit was below 30%, and then gradually increased to maintain the hematocrit level in the 30% to 33% range for 26 weeks.

Reference

1. Kaufman J, Reda D, Fye C, et al. Subcutaneous compared with intravenous epoetin in patients receiving hemodialysis. *N Engl J Med* 1998; 339:578-583. ■

Correction

In last month's news brief on the Home Care Consulting Partners national consortium on p. 119, an incorrect phone number was given. The correct phone numbers are (888) 570-HCCP or (847) 480-7030. ■

CE objectives

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

1. Identify the first step in deciding if an alternate-site infusion suite is for you.
2. Identify where your staff are most at risk of suffering a potentially dangerous needlestick and exposure to blood.
3. List the first two steps in selecting a safety device that will provide the greatest benefit.
4. Define an integrated health system. ■