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Special Report: Protecting Patients at Any Cost

Is cash a coercive element in a patient's decision to volunteer for clinical trials?

Ensure risk levels do not determine monetary value

Would you participate in a medical research project that required you to periodically give blood, undergo invasive diagnostic screenings and tests, and spend significant parts of each week at a local hospital undergoing these procedures? What if the results of the research project would provide no benefit to you, but could one day lead to a cure for a fatal disease?

What if researchers offered to pay you $50? Or $500?

What amount of compensation is needed to encourage people to participate in research projects? Does compensation for participation violate the principles of informed consent by "coercing" someone to participate when they would ordinarily refuse?

These are questions that many ethics committees and institutional review boards (IRBs) are struggling with as pressure from the private sector mounts to recruit more and more people to participate in medical research projects. Pharmaceutical companies, in particular, are eager to get their drugs through required clinical trials — and they have the financial capital to recruit as many people as they need.

"Concern has been expressed that the offer of money could compromise the voluntariness of someone's decision, in essence influencing them to do

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Special Report: Protecting Patients at Any Cost

something contrary to their interests or values," explains **Christine Grady**, RN, PhD, a researcher in the department of clinical bioethics at the National Institutes of Health in Bethesda, MD.

Grady recently published a paper examining this topic in the spring issue of the *American Journal of Bioethics*.[1]

She concludes that money is just one of many factors that might influence a person's decision to participate in a research project. Other factors might include the availability of a medical procedure or product not otherwise available or the chance to receive free medical care.

As long as the amount of money offered is not excessive, the payment can be seen as just compensation for the time and contribution that subjects made and an indication of respect for the subject, she says.

The question is, at what point does simple compensation end and coercion begin?

"IRBs or their institutions should establish guidelines for determining when and how much should be offered to participants in a study," Grady tells *Medical Ethics Advisor.* "Guidelines would provide a rationale for payment, and preferably a formula or a basis for calculations. This way, decisions would be standardized within an institution (and thus fair), and IRBs have some framework for their particular decisions."

Decisions made on case-by-case basis

Many institutions that sponsor research, particularly those who receive federal grants, do have guidelines on payments made to research participants. These guidelines are published, along with other requirements investigators must meet, in the respective institution's research guidelines and on their web sites.[2,3]

However, establishing a standard formula for paying participants would be difficult, says **Ada Sue Selwitz**, director of the office of research integrity (ORI) at the University of Kentucky in Lexington. The ORI oversees all research conducted at the university and supervises three medical IRBs and one nonmedical, scientific IRB.

"IRBs have to look at a number of variables in trying to decide, first of all, is it appropriate to pay subjects and, if so, how much is appropriate

and when is it too much?" she says.

For example, if the study group is primarily people living in a third-world country, even a small-dollar amount of cash compensation could be coercive. Yet, a similar amount of money would not be a significant incentive to a study group drawn mostly from middle-class people living in this country, she says.

"That is the first criterion you look at: What is the study population? And in that context, is the proposed amount appropriate," she explains.

The IRB at the University of Nebraska Medical Center in Omaha tries to focus its compensation on reimbursing participants for the time they must spend participating in the various parts of the research, says **Ernest Prentice**, PhD, vice chancellor for academic affairs and IRB co-chair.

The amount might vary from study to study, based on what was asked of the people involved.

"We base our compensation levels on what would be a reasonable hourly rate for the time spent in preparation for, participation in, and recovery from a particular research intervention," he explains.

For example, if a participant must undergo a bronchoalveolar lavage, he or she would have to come to the hospital, undergo anesthesia, undergo the procedure, recover from the procedure at the hospital, and most likely be accompanied home by a companion, he says. "They probably wouldn't recover from the anesthesia for a couple of hours. They probably would have a sore throat and maybe a little bit of fever. Clearly, it is inconvenient."

The researchers should come up with an amount that compensates that person for the time they must spend involved in the research from beginning to end — in this instance, the time spent going to the hospital, undergoing the procedures, recovering from the procedures, plus compensating the person who is needed to accompany them.

"We usually use the reasonable hourly rate figure of around $10 per hour," he says. "Obviously, if the person is a CEO making $300, this is not his or her normal hourly compensation, but we aren't going to go there. This is a reasonable compensation for the time spent."

The focus, he says, is really to eliminate any disincentives to research participation rather than really "compensating" them for the service, he says. "We don't want anyone to assume financial liabilities for taking part."

The IRB would like to move toward having a set compensation amount for every procedure that a research study might perform, Prentice adds. "We would like to have more standard, definitive guidelines in place. And, we are trying to work on what would be a reasonable dollar

CME questions

13. Participants involved in high-risk research projects should be given more compensation than those involved in research that involves no risk or is low-risk.
    A. True
    B. False
14. Factors that should be considered when determining the amount of payment given to participants in research project include:
    A. The characteristics of the population being studied (age, low income level, normal access to health care, etc.).
    B. The amount of time involved in participating and the effort required by the participant.
    C. Whether the subject successfully completed the study.
    D. A and B.
    E. none of the above
15. Physicians who prescribe opioids like OxyContin for management of chronic pain:
    A. Have an obligation to monitor patients for signs of inappropriate use.
    B. Should advocate for balanced policies that preserve access for legitimate uses while preventing diversion for abuse.
    C. Should follow established practice guidelines for use of opioid derivatives.
    D. All of the above
16. Ethicists have raised the following concerns about U.S. policy allowing patents on life forms:
    A. Issuing patents will restrict scientific progress by impeding the free flow of communication between researchers.
    B. The benefits of research will only be available to an elite segment of the population.
    C. Patents on life forms are inherently unjust because they are creations of nature, not of man.
    D. All of the above
    E. None of the above

amount for performance of a whole series of procedures — from bronchoscopy with lavage all the way to a skin biopsy."

One benchmark that should not be used to determine the level of compensation, both Prentice and Selwitz say, is the level of risk involved.

"The level of payment must never be based on the level of risk," says Prentice. "You do not elevate the amount of compensation you deem acceptable."

In the past, some IRBs considered this an acceptable way of compensating participants, but this is now thought to be clearly coercive, Selwitz says.

"Some used to say, in approving a protocol, if it is really risky you get, say, $1,000," she says. "If there is less risk involved, $50. I don't think anyone is doing that anymore."

You don't want payment to be the reason that people agree to participate in, and remain in, a very risky study, she explains. "If it is a high-risk study and there is no potential benefit to the participants — no chance of a medical benefit — then the IRB is going to look very closely at the dollar amount."

Both Selwitz and Prentice also recommend that IRBs require payments to subjects to be prorated, if the project involves multiple appointments or tasks over days or weeks.

"The payment schedule can make a difference in whether the payment is coercive or not," says Selwitz. "We don't allow there to be a lump sum at the end of the project, conditional upon the person completing the project. They must feel free to withdraw at any time."

The University of Kentucky IRBs require that subjects be paid for each portion of the project they complete, whether they remain in the study to the end or not.

Prentice encourages investigators to pay subjects a selected portion at each visit, and that the amount be tied to the amount of time involved.

"Say you have five visits. The first visit is pretty extensive, so you pay the person $50," he says. "The second visit involves significantly less time so you pay the person $25."

Under no circumstances, he says, should there be a bonus for completing the project — such as a payment schedule that lists the last visit as worth twice as much as the previous visits, he says.

A major controversy in payment of research subjects has been the question over whether children should be given compensation for participation in research, or whether their parents should receive compensation.

"What happens when the person you are enrolling is a child?" asks Selwitz. "That is a different issue. "If you offer cash compensation to the parents, you can run into situations where the parent says, 'My child will participate whether he wants to or not.' Because the parent wants or needs the money."

Should you pay the children directly? Even a small amount of money could be coercive to a child, she says. "Many IRBs have chosen not to offer compensation for children involved in research at all."

Instead of cash, some investigators offer the child a small coupon to a toy store or small gift certificates, she says. "Sometimes an IRB will be OK with that and sometimes they won't."

The University of Nebraska IRB does not compensate children at all, but will make cash reimbursements to parents for their time in taking the child to and from the medical center, says Prentice.

"We are not going to hand $10 to a child. Anything, whether it is money, pizza, gift certificates. We are very concerned about that," he adds.

Cash compensation pros and cons

Some IRBs, deciding that cash is inherently coercive, will allow compensation only in other forms, says Selwitz.

"Some IRBs allow payments, but not cash payments," she explains. "Particularly with vulnerable populations like children, or with [college] students. Some IRBs feel that students are already in a coercive situation. So, if you give them a free pizza or gift certificate, as opposed to $20, is that less coercive? Some IRBs say yes and some do not."

Prentice agrees with Grady that there are issues other than compensation for participation that have more potential to be coercive. And IRBs have to be sure to be aware of these, as well.

"You have to look at why people participate in research," he says. "The first reason is usually to get a particular drug or procedure that they feel may offer them some hope, but they may not

have access to outside a research trial. Second, they may not have health insurance and may see the research as a way to get free medical care."

The second issue, in particular, has the potential to be very coercive and the IRB must be extremely careful to look at the planned study population and how investigators intend to recruit participants.

"We ask for a rather detailed description of the target population," he says. "In terms of demographics, we want to know what the age range is, the gender, ethnic minority status, where they are going to recruit subjects from, and how they are going to recruit them," he says.

It is important that poor people and minorities, who traditionally have less access to health care, are included in research efforts. But, it is important to ensure that these populations are not targeted because they will be less likely to refuse, or less likely, once enrolled, to leave the project.

"If the investigators say, we're going down to the Last Chance Clinic in north Omaha, which has a high percentage of poor African-American people, and that's where we're going to get our people, that is a red flag to us. We need to have balance. You have balance access to the benefits of research participation without coercing people into a project and accepting risk that they would not ordinarily do so. It is a hard balance to achieve."

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Will patent law, not science, guide research?

Argument shifts from 'if' to 'under what conditions'

With the Bush administration's decision to allow limited federal funding of stem cell research, scientists and bioethicists have expressed renewed concerns about the impact of "life patents" — patents on biological materials — on scientific research.

Even though stem cells can be found and extracted from every human embryo, the Wisconsin Alumni Research Foundation (WARF) has a patent on the process used to extract the cells, as well as patents on the stem cell lines it has derived. It turns out, no one in the United States — using federal funds or not — can do research on embryonic stem cells without the foundation's permission.

"We are no longer arguing about whether or not we can patent life, patent genes, and stem cell lines, but we are arguing about what the conditions of use can be," says **Stephen E. Lammers**, PhD, the Helen H.P. Manson Professor of the English Bible at Lafayette College in Easton, PA.

A 1981 Supreme Court decision, *Diamond v. Chakrabarty*, changed U.S. policy to allow patent protection of materials that occur in nature, as long as applicants can show that their "invention" is "unique, nonobvious, and useful." As a result, U.S. researchers have obtained patents on genetically modified plants and animals, and on specific genes, DNA, and processes by which these things are studied.

With the mapping of the human genome last year, the number of applications for patent protection on sections of human DNA exploded. Biotech companies that discovered genetic mutations linked to diseases sought patent protection for the affected genes. Researchers able to isolate specific genes applied for patents on the specific DNA sequence. Universities formed separate, private corporations to pursue investment capital and commercial opportunities for

academic research findings.

The result, claims Lammers, is that scientific research principles are being compromised by the need to protect corporate investments.

"Instead of the usual scientific practices of free and open communication, we have the practices of corporations and patents and intellectual property, restrictions on use, and restrictions on the exchange of information," he says.

He points to the recent declaration by several prominent medical and scientific journals that they will scrutinize articles submitted to them for evidence that the authors have been restrained by corporate sponsors.[1]

The joint statement of principles was prompted by instances in which researchers were pressured to not disclose parts of research that had been privately sponsored or that they had been asked to alter conclusions or alter language to preserve patent potential.

"The scientific community has now started to become concerned about this," he adds.

Patent office tightens reins

The U.S. Patent Office has apparently also become concerned, says **John Kilyk Jr.**, JD, an intellectual property attorney specializing in biotechnology patents at the Chicago-based firm Leydig, Voit & Mayer.

"The patent office has clamped down in the last nine months to a year on people who are trying to patent gene sequences where they really don't know what the genes are useful for, but since they need to meet the utility requirement, they make up a use," he says. "The patent office has made it clear they will accept only practical, real-world utility."

Researchers are granted patents on cells, genes, and other life forms because they are seeking protection of the entity as a separate form, not as a part of a living being, he says.

"You are claiming the gene or DNA in a sequence as an isolated and purified entity, which doesn't exist in people," he explains.

However, in order to get patent protection, applicants must demonstrate that their "version" of the DNA, gene or process is new, nonobvious, and, most importantly, useful. Until the FDA issued new guidelines earlier this year, applications for gene patents were claiming the genes were useful in research applications, such as probes to find other genes or molecules.

"A lay person might read that and think those sound like pretty good applications, but a person in the business would recognize that they are just stock diagnostic and research applications," he continues.

Kilyk's firm has recently seen an increase in the number of biotech patent applications being rejected, indicating increasing concern that "nonuseful" patents can impede the inventive process that patents are meant to protect.

Issues of justice

A great deal of attention has been given to the potential of genetic research to yield incredible therapies to cure disease and treat injury, says Lammers. But, with most of the genes and processes under patent protection, who will be the beneficiaries of such discoveries?

"This is going to provide a set of technologies, available for the foreseeable future to only the very wealthy," he explains.

The more attention and money and resources that are devoted to pursuing this technology, the less emphasis there is on providing a basic level of health care to the entire population, he adds.

Celebrities testify before Congress about the enormous potential of genetic research, and that is where much of the government support appears to be headed, he says.

"How much money is going to be spent on this research, and what benefits will society receive in terms of overall reduced morbidity and mortality?" he adds. "Now we don't have money for poor people's health problems, for public health, and we have working people who cannot afford health insurance. There is something weird going on."

Negotiations precede research

What patents are and what patents do is frequently misunderstood by both the public at large and those in the scientific community, Kilyk believes.

Patents allow the holder to prohibit others from doing whatever is claimed in the patent

for 20 years, he says.

If a researcher discovers the location of a gene or discovers a potential use for the gene, he or she can apply for a patent to ensure that other researchers must get permission before researching the same gene, he explains. However, if the gene has already been discovered and that information has been made public, it cannot be patented.

In the current environment, a researcher may want to apply for patent protection in order to safely preserve their right to conduct research in that area. For example, if a researcher discovers or isolates a particular gene and does not seek a patent or publicly disclose the discovery, someone else can patent that DNA sequence and then prohibit the original researcher from continuing.

And, notes Kilyk, biotech patent applicants must be careful that their patent does not overlap another patent.

"If one group has a patent on a whole class of genes and I later find out that one of those genes is particularly special, and I convince the patent office that it is separately patentable because none of the other genes have these same properties — I can get a patent on that," Kilyk explains. "I can stop any person, including the organization with the patent on the entire class of genes, from conducting research on that gene. But that organization with the broad patent can prevent me from using the specific gene because they claimed the whole class."

At that point, both parties must come to the table and work out an agreement that is acceptable, he says. "Generally, people are not interested in preventing someone from using a certain invention just for the sake of preventing it. It is just part of an overall business strategy. Usually capitalism prevails and either the party is using the object or process that they have patented or is licensing others to do so to make money."

When pursuing patents on genes for biotech clients, his firm employs a "forward and backward" patenting technique, Kilyk says. "You can have various types of subject matter in claims defining the invention. When a university or company comes to us with a gene they have isolated, we try to not only protect the specific DNA sequence, but also ways of using it, ways of making it, variants — so that someone can't modify it a little and do the same thing, also the proteins that are coded by the gene, and the sequences that make up the protein."

In this way, if one part of the patent claim is later determined to be invalid, then other claims may hold up.

Some companies also try to "carve out" patents that are on the fringe of other companies' discoveries — a use for or a form of the discovery that is not included in the existing patent, he adds. "We see companies that make it a point to patent things that are not related to their own business, but are related to another company's business. Maybe the other company has a patent on some research that the original company wants to pursue. In that way, they can force the company to the negotiation table."

So, if a group wants to pursue research that is protected by a patent, they might already have protected other information that that patent-holder wants. "It's much easier to trade patents than to trade money."

Do patents protect or hinder progress?

Biomedical research would be drastically slowed if patents on life forms were disallowed, says Kilyk.

"People think that some of these things should be free to everyone," he says. "But you have to be really careful with that. If I develop a diagnostic test, genetic therapy, or a drug with great pharmaceutical potential, but there was no patent on it, would you be able to get the investors willing to put in the $100 to $200 million it would take to get that product through clinical trials and scale up production? As soon as you develop it, someone else can knock it off and start selling your discovery for a penny. No one would do the work. Unless you think the government should step in and do all of the work, nationalize it, what is the alternative?"

But, argues Lammers, scientific research produced medical advances before researchers could patent the life forms that were the core of their research, and researchers would be able to work around the lack of patents on basic biologic materials.

The results of genetic research — research involving genes that are common to all humans — should be preserved for the benefit of the

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entire population as much as possible, he says.

"It's not too late to change our minds. There is nothing to say that, although we've allowed this in the past, and though we will honor these patents, we will not allow this in the future," he says.

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OxyContin controversy may be 'giant step backward'

Drug will be harder to get for patients

Pain management specialists and advocates for chronic pain patients say they are worried by recent attempts at the state level to restrict availability of the tablet form of the popular painkiller, oxycodone, better known by its trade name, OxyContin.

Efforts by state law enforcement officials have made it difficult for pain patients to get the needed drug and medical professionals need to be more active in protecting legitimate access to the medication, experts warn.

"There have been reports that, even when appropriately prescribed by a licensed physician, patients are having difficulty in obtaining the medication," says **Michael Ashburn**, MD, MPH, president of the American Pain Society and a professor of anesthesiology at the University of Utah in Salt Lake City. "Some pharmacies are no longer carrying the medication — due to fears of robbery — and there have been efforts by policy-makers to restrict the availability of the drug."

Released by Purdue Pharma in 1996, OxyContin has become a popular pain relief medication for cancer patients and other chronic pain sufferers because it delivers a higher dose of oxycodone than Tylox and Percocet, and its controlled-released mechanism allows patients to take fewer tablets per day. But in recent years, state and federal law enforcement officials have documented dramatic increases in the illegal diversion and abuse of the drug.[1]

Several cities nationwide have reported armed robberies targeting pharmacies that stocked the medication. Additionally, more than 120 overdose deaths have been linked to OxyContin in the United States.[2]

Across the country, different cities and states are taking drastic actions to halt the spread of OxyContin abuse. In August, Vermont governor **Howard Dean** announced that physicians would have to get state approval in order to prescribe OxyContin to patients enrolled in Medicaid and other state-funded health programs. Previously, the governor asked that physicians find alternatives to prescribing the drug and asked pharmacies to stop stocking the medication.

Other states have also removed OxyContin from their Medicaid formularies. And police in the small town of Pulaski, VA, recently announced that people who want to buy OxyContin at the town's six pharmacies will have to be fingerprinted to receive the drug.[3]

The result of these efforts is that patients who desperately need the medication are prevented from obtaining it, says Ashburn. Policy-makers need to be encouraged to reasonably regulate access to opioids like OxyContin, but efforts to essentially make the medication "illegal" need to be strongly resisted.

"Asking Medicaid not to cover the medication, and asking pharmacies not to stock it is a particularly egregious action, I feel," he says. "It denies access to a legitimate drug for an appropriate medical use."

Physicians reluctant to prescribe drug

In addition to state restrictions on coverage of OxyContin and pharmacies refusing to carry the medication, some physicians are becoming very

reluctant to prescribe it. Furthermore, patients are afraid to take the drug due to the increased scrutiny, says **Russell K. Portenoy**, MD, chairman of the department of pain medicine and palliative care at St. Luke-Roosevelt Hospital Center in New York City.

"Although we can't really quantify this, we sense that the country has taken a step back in being able to provide effective long-term opioid therapy to appropriately selected patients with chronic pain," Portenoy says. "The intense media attention on OxyContin appears to have reignited a climate of fear about the prescribing, dispensing, and taking of opioid drugs."

In 1996, the American Pain Society and the American Academy of Pain Medicine issued a consensus statement on the appropriate use of opioids to treat chronic pain. These guidelines were endorsed at the time by the U.S. Federation of Medical Boards, which then released guidelines similar to the consensus statement, says Ashburn.

Health policy-makers recognized that opioids had a legitimate medical use and established practice guidelines for clinicians to use, he adds. Now, although there's been no report of medical boards changing their policies, Ashburn is concerned that the medical community is not advocating more strongly for continued access.

Pain specialists in particular need to be sure that misinformation and misconceptions about OxyContin are corrected, and to ask policy-makers to develop regulations that protect pain patients' access to opioids, advises Ashburn.

As an example, Ashburn cites the Vermont governor's request that physicians try to prescribe medications other than OxyContin.

"There have been patients who have fairly good pain relief with OxyContin that have not experienced relief using other opioid compounds," he says. "There are patients who report better pain relief with one compound vs. another. As a pain physician, I want access to as many options as possible to allow me a better chance to meet the patient's needs. I need more options, not less."

Who should be responsible for misuse?

Both society and health care providers have a responsibility to make sure that drugs with addictive potential are not used inappropriately, say both Portenoy and Ashburn.

"There may be an increase in vigilance to make sure that physicians are appropriately prescribing these medications, and that is not all bad," Ashburn says. "But there is a fundamental difference between appropriate vigilance and inappropriate vigilance."

Possible new formula in the works

The Food and Drug Administration (FDA) formed an advisory panel to recommend what actions, if any, need to be taken to further regulate OxyContin. Purdue Pharma is responding to requests to develop a new formulation of the drug that will make it more difficult for the medication to be misused.

Portenoy, a member of the FDA panel, says it is likely they will examine possible enhancements to the labeling of OxyContin and increasing physician education about pain management and issues of chemical dependency.

At the same time, it is still essential that the drug continue to be available to patients who need it now, says Ashburn.

"Clearly, Purdue Pharma feels that they can move forward with research to make the product less likely to be diverted — clearly, that is something I support," he says. "But such development is very expensive and takes lots of time. Even if they had a product right now that they were ready to enter into clinical trials — and I don't think they do — it is likely to still be five to seven years before that product will be available. While they are developing a new product to roll out, we still must have access to the old one."

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Use care, common sense with impaired professionals

New standard targets identification and treatment

A new Joint Commission on Accreditation of Healthcare Organizations accreditation standard for 2001 now requires hospitals to implement a process to identify and treat impaired physicians — a process that is to be separate from the medical staff's disciplinary functions. The new requirement means that ethics committees will likely play an integral part in identifying those physicians.

"The purpose of the process is assistance and rehabilitation, rather than discipline, to aid a physician in retaining or regaining optimal professional functioning, consistent with protection of patients," reads the revised language of standard MS 2.6 in the *Comprehensive Accreditation Manual for Hospitals.*

"If at any time during the diagnosis, treatment, or rehabilitation phase of the process it is determined that a physician is unable to safely perform the privileges he or she had been granted, the matter is forwarded to medical staff leadership for appropriate corrective action that includes strict adherence to any state or federally mandated reporting requirements."

The new standard recognizes that impaired physicians — defined as those with mental or emotional problems, alcohol and chemical dependencies, or chronic illnesses that affect their ability to function — are suffering from an illness that requires treatment. They are not clinicians who have willfully engaged in conduct that merits punishment, say experts in provider health issues.

Many state medical boards and professional societies already have separate programs for impaired medical providers that allow providers to receive confidential treatment and counseling and preserve their medical licenses and ability to practice. But hospitals have often lagged behind in recognizing the need to identify these providers and get help.

"Among impaired providers' peer groups and co-workers, the first reaction to a problem is frequently one of denial," says **Judith Anderson**, PhD, RN, CNS, a professor and chair of the department of acute and long-term nursing at the Medical College of Ohio in Toledo, who has worked on developing treatment and counseling initiatives for impaired nurses. "They tend to treat it as if it were a problem within the family. They might start making excuses for the person, covering up when they are late for work, or forget to do a task. In other cases, other physicians and nurses simply don't want to interfere in another person's personal business. They avoid acknowledging the problem until something forces them to do so."

Impaired providers often are caught in a cycle in which when confronted on the job, they immediately quit to avoid mandatory treatment or disciplinary actions, then seek work elsewhere.

"With addiction problems, over time, the person's ability to function deteriorates," says Anderson. "They start seeking jobs with less strict supervision, maybe working the night shift or taking a job as the sole RN at a nursing home. We see nurses who have held jobs six months in one place, seven months in another — a series of short-term positions. And because of the nursing shortage, they can almost always get hired somewhere."

Instead of getting treatment that would return them to functioning as productive and able providers, these professionals keep getting passed through the system until their impairment prevents them from being able to perform their duties or an incident involving theft or of patient safety intervenes, she says.

States focus on treatment

It's the acknowledgement of this pattern that has led many medical boards to develop alternative programs for dealing with impaired providers. Many states now allow providers who self-report impairment issues or who have been reported by colleagues to undergo a confidential, individualized treatment and counseling program. After successfully completing the program, the provider can retain his or her medical license without a period of suspension or other disciplinary action.

Minnesota was one of the first states to adopt such a program after the state legislature mandated it in 1994, says **Kent G. Harbison**, JD, an attorney specializing in health law litigation at the law firm Fredriksen & Byron in Minneapolis.

"Prior to that, all of the state licensing boards, when they were faced with a report of a physician or provider impairment, didn't have any choice but to run it through their standard disciplinary process," he says. "If the allegations were true, the professional faced punishment: suspension, fines, and even revocation of their medical licenses."

Members of the state Board of Medical Practice, which oversees physicians, pushed for the change as they realized the need to treat ill

physicians differently than those who "intentionally made an effort to violate some law or standard of practice," Harbison says.

Other professional licensing boards cooperated with the board of medical practice to develop the Health Professionals' Services Program (HPSP). A provider can either self-report to HPSP, be reported by a colleague or other person, or be referred to the program after a report to their state licensing board.

Once reported, the program works to establish a care plan with that individual, calling for the person to undergo a specified amount of counseling and treatment, submit to regular, random drug and/or alcohol screening, turn over his or her medical records to the program for supervision, and be supervised in the care plan for one to two years, says Harbison.

"In addition to designating a treating physician, the person must also designate a monitoring person — a supervisor or colleague who agrees to provide regular reports to HPSP about the person's progress," he adds. "In the workplace, that can be potentially awkward. The monitoring person has an obligation not to disclose the person's treatment information. But, as a practical matter, if it were an MD in a hospital or medical clinic, there would probably be a group of supervisory people who know about the program."

Provided the person completes all of the requirements satisfactorily, they retain all of the practicing privileges and the matter remains confidential.

An added benefit of Minnesota's plan, Harbison adds, is that medical colleagues, who are often under a mandated duty to report provider impairment, can report impaired professionals directly to HPSP and not the medical board.

Although the medical board might also refer this person for treatment, this way physicians and nurses can be sure their colleague's confidentiality and medical license is protected, he says.

One of the key fears keeping impaired providers from self-reporting and seeking treatment — and colleagues from reporting problems — is the fear that doing so will cost that person their livelihood, adds Anderson. It is unfortunate that more programs are not like Minnesota's, she says.

In Ohio, for example, providers are required to report directly to the state licensing boards, even though the state does have a similar provider assistance program.

"Our program used to be similar, but a change in state law requires that all reports be made directly to the board," says Anderson. Some other licensing boards also have different requirements about allowing an impaired provider to continue to practice after acknowledging an impairment, even if they receive treatment, she adds.

Some organizations, notably Public Citizen, have criticized provider assistance programs as too lenient, claiming that since they are sponsored by professional organizations, they focus too much on protecting the confidentiality and working privileges of the professional at the expense of compromising patient safety.

However, Harbison says, most of these treatment programs are difficult to complete and make every attempt to ensure the provider is able to safely practice. "Under HPSP, if the provider has a relapse, tests positive for drug or alcohol use, or commits a violation of the medical practice act

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while under supervision, they are taken out of the program and face disciplinary action."

Most programs also have fairly stringent eligibility requirements — not taking providers who have committed crimes related to their impairment, such as theft of drugs or prescription fraud, for example.

Providers who successfully complete treatment can become some of the best health care employees because they learn better ways of handling stress and often are more compassionate and able to identify with patients.

"There is often a public perception, and a feeling among nurses themselves, that a professional with a drug or alcohol problem is a morally bad person, or not strong," says Anderson. "However, managers have told me that they [nurses with problems] are often their best nurses. Studies have shown that, of nurses who report impairment issues, most of them were in the top quarter of their graduating class."

Even after treatment, providers who have had issues with chemical dependency or mental illness require support and an understanding work environment, continues Anderson.

She recommends forming support groups of health care providers who have had dependency issues because they can specifically address the pressures and complications that these professionals face — working near controlled substances, for example, or dealing with emotional trauma on the job. It's also important that the employee is honest about his or her problem. Since many hospitals are reluctant to hire professionals with histories of impairment, many may choose to keep this information confidential.

"I would advise the manager to pay attention to what that person is saying," she says. "If the person says, 'I had a problem with alcohol or drugs, but that's all over now,' or in some other way indicates he or she feels that this issue is in the past, that should be a red flag. They are still in denial, themselves. The process of addiction is ongoing. Someone who says he or she is in recovery or is a recovering alcoholic or addict is someone who has acknowledged the problem."

Hospitals and departments definitely need a plan, not just about how to identify people who might be impaired, but also how to work with people who have had issues in the past and continue to practice, she believes.

Medical and nursing schools and hospitals need to be doing more to head off impairment issues to begin with, adds Anderson.

"We need to begin the process early on, helping medical students and nursing students identify risk factors, such as family history, and educate them about substance abuse issues," she says. "And, we really need to look at how we treat our residents and our students in the workplace."

Medical residents and student nurses often are asked to work incredibly long hours, in very high-stress situations and are then given little opportunity to "debrief" or discuss their reactions to traumatic clinical situations or events.

Nurses and physicians who are treated for a real physical injury may become dependent on painkillers and other medications because they allow them to return to work early instead of taking the time to recover fully and because they feel that the drugs allow them to "cope" with long hours and little rest, she adds. ■