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Pharmaceutical companies must find new ways to market products

Gifts, CME sponsorships may draw fraud and abuse investigations

For years, professional medical societies have warned their members that accepting the free meals, trips, and other gifts offered by pharmaceutical sales personnel can compromise physician-patient relationships and should be avoided.

Now the industry's marketing efforts also have drawn the attention of federal regulators, who warn that these activities may run afoul of federal anti-kickback laws.

In a compliance guidance draft for pharmaceutical companies issued on Sept. 30, the Department of Health and Human Services' (HHS) Inspector General **Janet Rehnquist** detailed several marketing practices that could draw investigations, fines, and other penalties from federal regulators.

Key among the areas of promised scrutiny are gifts and other incentives offered to health care professionals.

"Pharmaceutical manufacturers and their agents may have a variety of remunerative relationships with physicians and others who order or prescribe their products," the guidance states. "As these relationships may implicate the anti-kickback statute, they should be examined carefully."

Specifically mentioned in the guidance:

• **Switching arrangements** — Although payments offered by pharmaceutical companies to pharmacies, pharmacy benefit managers (PBMs), physicians, or other prescribers each time a patient switches from a competing product to the manufacturer's product are features of some managed care arrangements, these arrangements violate federal fraud and abuse statutes if the products are reimbursable under Medicare, the guidance explains.

• **Consulting and advisory payments** — Engaging physicians and other health care professionals to act as consultants, advisors, or researchers in connection with marketing and research activities could be questioned if appropriate safeguards are not in place.

"Pharmaceutical manufacturers should ensure that they [and their sales agents] compensate health care professionals only for providing actual, reasonable, and necessary services and that the arrangements are not merely token arrangements created to disguise otherwise improper payments," the guidance states.

Payments must also be "fair-market value" for the services rendered, it continued, and manufacturers must document how they determine the amount paid for such services.

• **Other remuneration** — Arrangements that, directly or indirectly, offer benefits to physicians or others in a position to make or influence referrals also may implicate the kickback statute, officials warned. Such benefits include:

— entertainment, recreation, travel, meals, or other incentives in association with information or marketing presentations;

— sponsorship or other financing related to third-party educational conferences and meetings attended or taught by physicians;

— scholarships and educational funds;

— grants for research and education;

— gifts, gratuities, and other business courtesies.

"These practices raise a particular risk where they involve parties in a position to prescribe or order the manufacturer's products or to influence such prescriptions or orders," the guidance states. "These parties include physicians and other health care professionals, as well as PBMs, hospital systems, and the like."

Research backs up conflict

The Chicago-based American Medical Association (AMA) has had guidelines covering ethical interaction between pharmaceutical companies and physicians since 1990, but has recently launched an aggressive educational campaign aimed at raising physician awareness of the problem, says AMA chair **J. Edward Hill**, MD.

"The American Medical Association has long been concerned about inappropriate pharmaceutical marketing practices that jeopardize the trust of patients and the credibility of the medical profession," he adds.

Such concerns have been heightened in recent years by studies that document how marketing incentives have influenced physician behavior.

A meta-analysis of 29 different research studies published in the *Journal of the American Medical Association* (*JAMA*) found that physician interactions with pharmaceutical representatives were generally endorsed, began in medical school, and continued at a rate of about four times per month.[1]

Furthermore, according to the studies examined, meetings with pharmaceutical representatives were associated with requests by physicians for adding the drugs to the hospital formulary and changes in prescribing practice.

Drug company-sponsored continuing medical education (CME) preferentially highlighted the sponsor's drug(s) compared with other CME

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Editor: **Cathi Harris**.
Vice President/Group Publisher: **Brenda Mooney**, (404) 262-5403, (brenda.mooney@ahcpub.com).
Editorial Group Head: **Lee Landenberger**, (404) 262-5483, (lee.landenberger@ahcpub.com).
Managing Editor: **Alison Allen**, (404) 262-5431, (alison.allen@ahcpub.com).
Production Editor: **Nancy McCreary**.

Editorial Questions

Questions or comments?
Call **Alison Allen** at (404) 262-5431.

PhRMA Voluntary Code on Marketing Practices

These points summarize the Pharmaceutical Research and Marketing Association (PhRMA) voluntary code on interactions with health care professionals. The full document is available on the association's web site at www.phrma.org.

- **General Interaction:** Interaction should focus on informing the health care professional about scientific and educational information and supporting scientific medical research and education to maximize patient benefits.
- **Entertainment:** Interaction should not include entertainment. Interaction should occur at a venue conducive to providing scientific or educational information. Specifically, this means no dine and dash, no entertainment, and no recreational events (for example, sporting events or spa visits).
- **Continuing Education:** Companies can provide support to the conference sponsor but should not fund individual participants. That means, a company should not pay an individual's tuition, but could provide support to the event sponsor. That sponsor may in turn provide grants to individuals to participate or to reduce the overall registration fees for all attendees.
- **Consultants:** Legitimate consulting or advisory arrangements are appropriate but token consulting arrangements should not be used to justify payments to health care professionals. Characteristics of legitimate consulting arrangements include the retention of professionals based on their expertise, not as a reward or inducement for prescribing, and retaining no more consultants than needed for the specific program. For example, it would be inappropriate to retain 10,000 physicians for a program that requires no more than 1,000, or to select them as a reward for high prescribing.
- **Educational and Health Care Practice-Related Items:** Educational and practice-related items may be provided to health care professionals, but should be for the health care benefit of patients and of less than substantial value ($100 or less). Items for the personal benefit of the health care professional should not be offered or distributed. In short, nothing should be offered or provided that would interfere with the independence of the health care professional's prescribing practices.

Source: Pharmaceutical Research and Marketing Association, Washington, DC.

programs. And attending sponsored CME events and accepting funding for travel or lodging for educational symposia were associated with increased prescription rates of the sponsor's medication. Attending presentations given by pharmaceutical representative speakers also was associated with nonrational prescribing, the *JAMA* author found.

Despite such evidence, many health care professionals have become accustomed to the perks that drug companies offer and find it hard to turn away such offers, says **Catherine Marco**, MD, chair of the ethics committee of the American College of Emergency Physicians (ACEP), based in Irving, TX, which developed its own guidelines on physician acceptance of gifts from industry.

"Organizations are becoming more proactive in helping their members make decisions about these kinds of things, and that was the basic goal of the ACEP policy, to give them guidelines about how to make decisions, what might be OK to take and what other things are probably not," she explains.

A few years ago, it was common for pharmaceutical companies to pay for physicians to go on trips, she says. That practice has now become much less common, but has not disappeared.

"I still know some people locally who routinely go on golf outings, to dinners, with pharmaceutical reps," she says. "Clearly, that kind of thing, to me, is unethical, because it is basically bribery. There are lots of ways to sugarcoat it. Everybody says it doesn't influence their [clinical decision making], but research clearly shows that that is not the case and it does influence prescribing practices."

CME sponsorship

CME sponsorships continue to be a complicated ethical area for physicians and the drug industry, says Marco.

"CME is very common, and a lot of people feel that is acceptable. But there are different types of educational support that drug companies give," she notes.

Unrestricted educational grants, in which the company gives financial support for an educational offering without the inclusion of advertising associated with their products, is not problematic, Marco says.

But many companies sponsor conferences at which they promote a speaker who also has a financial arrangement with the company.

SOURCES

- **Catherine A. Marco**, MD, Associate Professor Emergency Medicine, St. Vincent Mercy Medical Center, 2213 Cherry St., Toledo, OH 43608-2691.
- **J. Edward Hill**, MD, American Medical Association, 515 N. State St., Chicago, IL 60610.
- **Pharmaceutical Research and Marketing Association**, 1100 Fifteenth St., Washington, DC 20005.

"For example, the company supports the speaker with large honorariums and pays all the expenses and that kind of thing," she says. "That speaker is clearly going to be motivated to promote the product in his or her talk. That's when it becomes more questionable."

Trade organization guidelines lauded

Shortly before HHS issued its document, the Pharmaceutical Research and Manufacturers Association of America (PhRMA), a trade organization based in Washington, DC, representing the nation's pharmaceutical research and biotechnology companies, issued its own guidelines on appropriate marketing practices, the Code on Interactions with Health Care Professionals.

Their voluntary code took effect on July 1.

"The new code makes it crystal clear that the interactions of company sales representatives and health care professionals are to benefit patients and enhance the practice of medicine," says PhRMA president **Alan F. Holmer**. "It explicitly spells out that that all interactions should be focused on informing health care professionals about products, providing scientific and educational information, and providing supporting medical research and education."

The code specifies the circumstances in which company officials can offer physicians and other health care professionals a meal (in connection with sales or promotional presentations, but no entertainment or recreational events); provide token compensation for advisory or consulting services (the stipend should not be used to justify compensation for travel, lodging and other expenses); and offer gifts (value not to exceed $100 and must be primarily used to benefit patients).

The HHS document advises that these guidelines should help companies determine whether their practices are appropriate, although compliance with the code does not ensure that questionable marketing practices won't be investigated.

The draft guidance is open for public comment for 60 days, at which time the HHS might make revisions before issuing the final guidance.

The AMA in cooperation with other medical societies is carefully reviewing the guidance and will submit its own comments to the inspector general, says Hill.

The goal is to eliminate undue influences and conflict of interest while still allowing pharmaceutical companies to offer needed support for medical education and scientific research.

"We will have to wait and see what kind of impact it will have," Marco adds. "The problem is the pharmaceutical industry is such a huge economic industry and finances are such a huge part of that industry that I think the drug companies are motivated to do whatever marketing it takes to sell their product."

Reference

1. Wazana A. Physicians and the pharmaceutical industry: Is a gift ever just a gift? *JAMA* 2000; 283(3):373-380.

For more information

• A copy of the draft compliance guidance for pharmaceutical companies is available on the web site of the Department of Health and Human Services' Office of the Inspector General at: www.oig.hhs.gov/index.html. ■

Chaplains natural fit in organ donation process

Balanced, objective role key to informed decisions

The list of people awaiting solid organ transplants grows, and more hospitals are turning to interdisciplinary teams of medical professionals, social workers, organ procurement experts, and family support personnel who are trained to work with families of potential organ donors to ensure that opportunities for donations are not missed. Research has shown that such efforts increase consents for organ donation.

As professionals trained to counsel families facing or coping with the death of a loved one, hospital chaplains often are considered a natural fit for these teams. But exactly what role they should play has not been determined.

At some facilities, chaplains serve as the designated requester, the person responsible for approaching the family about donation. In almost every situation, chaplains will be asked to help families make a decision and cope with the outcome in some way.

"In our protocol, only the most experienced chaplains serve as participants in the donation process," says **Alexander Tartaglia**, DMin, associate professor and chair of the department of pastoral care at Medical College of Virginia Hospitals and the School of Allied Health at Virginia Commonwealth University in Richmond. "While it is impossible to remain completely value neutral in these circumstances, our chaplains are trained to respect individual needs, beliefs, and values of families."

Virginia Commonwealth has developed a standardized protocol that governs the process of requesting organ donation and counseling the parties involved. Chaplains have designated roles in this process.

The primary obligation of a chaplain, in any critical or end-of-life situation, is to offer emotional and spiritual support for families, Tartaglia explains. Chaplains must be able to exercise openness, flexibility, and patience, showing respect for family and cultural variances, and helping the medical staff to do the same.

"In the event of a neurologically devastated patient who is a potential organ donor, there are some responsibilities that take on added importance," Tartaglia adds. "Facilitating communication is key. In our program, we work hard to assess family understanding of the process as well as their comprehension of the grave prognosis, testing, and the concept of brain death."

Chaplains can monitor family's understanding

Although medical information is explained by the clinical staff, family members' ability to comprehend and process the information is compromised. Listening to families talk among themselves or to the questions they ask in the absence of the other staff enables the chaplain to monitor the family's understanding, he says.

"Chaplains role includes facilitating family discussions on value clarifications, end-of-life decision making, and organ donation," Tartaglia states. "And, unless the family initiates this, discussion about donation should be reserved until after the brain death declaration has occurred, and the organ procurement organization has completed the initial approach for donation."

Although the practice at many hospitals, chaplains should not be the designated requesters — the primary person responsible for asking a family member to consider organ donation, Tartaglia feels.

"The chaplain first meets and engages the families for the purpose of offering emotional and spiritual support," he says. "To shift roles and become a designated requester is morally problematic."

The change in focus can confuse and frighten families and chaplains have a responsibility to remain neutral and serve the family's preferences.

"We would not want to risk influencing their decision based upon our care for them," Tartaglia says. "Second, we believe chaplains should not be placed in a conflict-of-interest situation whereby securing consent could become an agenda."

Key Elements of the Virginia Commonwealth Organ Donation Protocol

- Request for the organs takes place in a private setting. Possibly a conference room in or near the ICU, but not in a public waiting area.
- The request is made as a joint effort between the organ procurement organization (OPO) coordinator and a designated hospital staff person, in VCU's case the chaplain. While both individuals are present at the request, only the OPO representative initiates the discussion. The role of the chaplain is to continue to function as a supportive presence and witness to the consent process.
- The declaration of death is separated from the decision to donate. It is most important that the declaration of death and understanding of death by the family occur before any mention of donation takes place. In addition, the physician who declares the death and informs of the family of it is not a participant in the donation request. This helps to dispel, as much as possible, any appearance of a conflict of interest on the part of the physician.
- The provision of a consistent family support mechanism (the chaplain) is required. An organ donation committee has been established. This committee reports to the hospital critical care committee and oversees and monitors the hospital donation process. ■

But different approaches may better serve different families, and saying that one particular person or another is never appropriate is problematic, argues the **Rev. Kevin Massey**, BCC, a hospital chaplain at Advocate Illinois Masonic Medical Center in Chicago.

"I don't think there is any specific discipline that ought to have the main spot in doing it, whether it should always be the doctor or always the organ bank representative," Massey says. "I can think of times when the nature of the support I've given the family would make it appropriate that I make the initial approach, but it varies by case. I can also think of times that I wouldn't have wanted to be the requester."

In Illinois, state law requires that a trained representative from the local organ procurement organization, the Gift of Hope, make the initial request, he notes. But barring such regulation, he recommends that teams canvass among themselves to determine which person is best to make the approach to that specific family.

"I would speak against there being any absolutes other than that person should feel comfortable and informed enough to do the initial requesting," he adds.

In the Virginia hospital protocol, the chaplain introduces the organ procurement organization coordinator to the family and remains during the initial request, but does not actually make the request, Tartaglia says.

"The role of the chaplain is to continue to function as a supportive presence and a witness to the consent process," he says.

Chaplains definitely should not tell families what choice to make, Tartaglia agrees. In times of crisis, many families will turn to clergy for advice on the right thing to do.

"In this situation, it is appropriate to assist the family in exploring the previously expressed wishes of the patient as well as their own beliefs and values to arrive and an answer that is congruent with who they are," he says.

Families' concerns

The main role of the chaplain should be as a support for the family, to ensure that they are given the space to experience grief and to make an informed decision, agrees Massey.

"Whenever anyone is a candidate for organ donation, the death has almost always been unexpected, the sudden death of a loved one," he explains. "I see both a professional and a personal responsibility to advocate for the family to be given the space to make whatever decisions are appropriate to them."

Families frequently wonder whether their religious tradition approves of organ donation. Even though most major religions do support organ donation, Massey says he is careful not to speak as a religious authority.

"When someone asks the question, 'Do you know if my religion approves of organ donation?' I will say what I know to be true, but I will also offer to put them in touch with an authority from their own religious tradition because I don't want to speak for them," he says. "I also don't want them to feel that their religion's beliefs obligate them to donate. It remains a personal decision. If you choose to do that, then your religious community will support you, but if you also choose not to because of whatever reasons are important to you, they will support that decision as well."

Families often have problems understanding the clinical information presented to them and need help coming to terms with the reality of their loved one's prognosis, adds **Ken Faulkner**, MA, MDiv, assistant professor of clinical ethics at School of Allied Health of Virginia Commonwealth University.

"One of the biggest challenges is helping families understand the concept of brain death," he says.

In most situations, only patients who have lost almost all brain function (all motor and reflex responses), but whose breathing, heartbeat and respiration continue, although mechanically maintained, are eligible to be organ donors.

Because patients on ventilators seem to continue to breathe and have a heartbeat, family members often have difficulty accepting that these patients will never recover or awaken.

"The chaplain pays particular attention to how families receive and comprehend information.

SOURCES

- **Ken Faulkner**, MA, MDiv, Assistant Professor of Clinical Ethics, Program of Patient Counseling, School of Allied Health, Virginia Commonwealth University, Richmond.
- **Alexander Tartaglia**, DMin, Associate Professor and Chair, Department of Pastoral Care, Program of Patient Counseling, Medical College of Virginia Hospitals, Virginia Commonwealth University, Richmond.
- **Rev. Kevin Massey**, BCC, Advocate Illinois Masonic Medical Center, 836 W. Wellington Ave., Chicago, IL 60657.

They may need to facilitate further communication between the family and medical staff," he says.

Families also have concerns about funerals, for example, whether they will be able to have an open casket. And as in other end-of-life situations, the chaplain can help families find spiritual comfort through prayer and other rituals that assist them in saying good-bye.

"We have had a number of situations where families have initiated discussion of donation and felt strongly that they wanted to do that," he says. "Then, in some instances, when explored, it has been determined that the patient is not a suitable donor. Families then experience a second loss that needs to be addressed."

Above all, it is important that the chaplain enable the family to have enough space to make an informed decision. Often, this means having the initial discussion in a private place and allowing the family or family member time alone to consider the decision.

"Time is often an issue," says Massey. "But I will advocate inside the health care team for the family to have some time alone. We will say to them, 'We've given you some information but we'd like to get you some space and privacy to be together as a family and talk about this.'"

The family then approaches the health care team with additional questions or when they have made a decision.

The chaplains also are a resource for the staff as well as the family involved, says Tartaglia. In some cases, the chaplain may be more familiar with the donation process and the hospital's protocol than the health care professionals involved in the patient's care.

"One role of the chaplain can be to educate new staff in a collaborative manner," he says. "This is particularly true in a teaching hospital with turnover of medical staff." ■

Alzheimer's patients EOL care often misdirected

Cancer care model doesn't address some needs

The patient **Jan Daugherty** was visiting at an Arizona long-term care facility was very near the end of his life. Barely able to move and unable to speak, he communicated only with his eyes, which brightened when she gave him a drink of water. Later during the visit, she was able to feed him three glasses of juice and two cups of ice cream.

"Hospice personnel had advised the staff that if he had difficulty swallowing, they didn't have to feed him. And he did have problems swallowing the day before, but he didn't the next day," says Daugherty, special projects manager with the Phoenix-based Desert Southwest chapter of the Alzheimer's Association.

The patient was at the end of his life — he died five days after her visit — and did not really need a nutritional meal. Still, he could enjoy the sensation of eating — the coolness of ice cream in his throat and the interaction with another person that sharing a meal can bring.

His case illustrates the problems that many patients with advanced dementia face in getting appropriate care at the end of life, Daugherty says. People in the advanced stages of Alzheimer's disease may live for years. Unable to speak or walk unassisted, they are completely dependent on others for care. Yet their caregivers — both family members and health care professionals — frequently don't understand what these patients need and want and what they are still capable of.

Four demonstration projects to explore options

The Desert Southwest chapter recently initiated a study of palliative care for dementia patients — with four demonstration projects to explore different treatment options in long-term care, assisted living, and hospice settings.

"Especially with hospice, what the nurses and other members of the team tend to know is cancer care, which is really great, except that dying from dementia is not anything like dying from cancer," Daugherty says.

For example, many cancer patients lose their appetite and don't want to eat. But dementia patients often indicate they still feel hunger and thirst right up until the last days of life.

"Clearly, they gain some pleasure from it, or they would not keep doing it," she adds. "That is one of the last enjoyable things that they have."

And cancer patients may not want to move or be in different positions because it is painful for them. But patients with advanced dementia do not have the same physical challenges and may want to get out of bed and sit in a nearby armchair or be turned toward a window.

"You have to really look for and pay attention to

nonverbal clues with these patients," Daugherty says. "In some ways, they can be the easiest patients to care for because they don't make any noise. In other ways, it can be very challenging because we have to anticipate every need that they have."

In educating caregivers, Daugherty advises them to think about the person as if they were a newborn baby, unable to talk or move by himself, yet still needing to be cared for.

"That is kind of where we are, developmentally, with this population," she notes. "They are like an infant in terms of where they are neurologically, their ability to communicate — they are often turning back to primitive resources."

Paying attention to nonverbal clues such as grimaces or moans that indicate discomfort or a brightening of the eyes that shows pleasure can guide caregivers in providing stimulation.

"Music can be extremely important, for example," she says. "We have even had some aphasic patients begin to sing with us when we sing to them. So we know that interaction is still important to them."

Use of technology controversial

Too few skilled nursing facilities are even using the hospice approach of less technology and more patient-caregiver interaction in caring for dementia patients at the end of life, adds **Stephen Post**, PhD, professor of biomedical ethics and associate director of educational programs at the Center for Biomedical Ethics at Case Western Reserve University in Cleveland. Post is also the author of *The Moral Challenge of Alzheimer's Disease: Ethical Issues from Diagnosis to Dying,* published by Johns Hopkins University Press in 2000.

"While hospice teams have made inroads into the culture of long-term care, there is still a good deal of resistance," he says.

For example, most hospices don't recommend the use of percutaneous endoscopic gastrostomies (PEGs) in patients with advanced dementia. PEGs involve the use of artificial feeding tubes that are placed in the abdomen of patients who are unable to eat or have difficulty swallowing.

"The Alzheimer's Association, as well as several recent scientific studies over the last four years, have indicated that assisted oral feeding is a better option in all respects to the use of a feeding PEG," Post says.

Feeding PEGs does not require major surgery, but they do require that the patient be transferred out of his or her current setting to the hospital for tube placement, which often upsets and disorients the person.

PEGs are preferred by some nursing homes because of the perception that they require less staff time.

"Feeding tubes are not easy; they do have complications," he explains. "Feeding PEGs create a lot of aspiration pneumonias, they lead to diarrhea, and they create a problem with the use of restraints because the person — not having insight into what the little tube is for — try to pull them out, wind up in restraint, which can lead to increasing bedsores, decubiti, etc."

Assisted oral feeding, which may take longer, is much better for patients and leads to fewer complications.

Patients with advanced dementia are going to suffer intractable weight loss whether they are on assisted oral feeding or on feeding PEGs, though many caregivers erroneously believe that use of feeding tubes helps keep a patient's weight up, and this indicates that the person is healthier.

"Weight loss is simply part of the progression of the disease and will occur regardless," Post says.

Many administrators erroneously believe that state surveyors will monitor dementia patients for signs of weight loss or gain, but most surveyors now understand that weight loss is normal in that population, he adds.

Many gastrointestinal specialists and surgeons do not favor the use of PEGs in this population, but face pressure to perform the procedures from the referring medical directors and from department chairs concerned about losing revenue by turning such surgeries away, Post says.

"If that one situation [the overuse of feeding PEGs in dementia patients] could be changed it would make a lot of difference," he says.

Another issue is the use of antibiotics, which most hospice programs do not support in the case of patients with advanced dementia.

Patients at the advanced stage of dementia may get several infections, particularly chest infections. Given antibiotics, they frequently will clear the infection only to quickly get another infection that is resistant to the initial drug. Most hospice programs use other methods to treat the symptoms of chest infections.

"If the antibiotics are absolutely palliative, as in the case of someone with a urinary tract infection, they may be used but in general the effectiveness of antibiotics diminishes with use in this

SOURCES

- **Stephen Post**, PhD, Center for Biomedical Ethics, Case Western Reserve University School of Medicine, 10900 Euclid Ave., Cleveland, OH 44106-4976.
- **Jan Daugherty**, Alzheimer's Association, Desert Southwest Chapter, 1028 E. McDowell Road, Phoenix, AZ 85005.

population, and they verge on futile, anyway," Post says.

Hospice benefit too limited

Many patients with Alzheimer's also never get hospice care because the Medicare benefit is limited to six months, another way care is structured to meet the needs of patients with end-stage cancer, but not the needs of those with dementia.

Patients may be in the advanced stage of Alzheimer's anywhere between one and about three years, says Daugherty. It is difficult for physicians to know when these patients are close to death, particularly within six months.

"There are people who die and you least expect it. They are in the late middle stage, when they are still able to walk around, then they get a fever, take to their bed and die within a few days," she explains. "Then there are patients who can't talk, are barely eating, and they just keep going and going. They'll get an infection and get better."

Only 10%-15% of the census at most hospices represent patients with dementia, says Post. About 5%-10% of people with Alzheimer's are cared for at home by relatives, and most are admitted to long-term care.

"There has been some improvement at the federal level with the hospice benefit," he adds. "Physicians can make the diagnosis of six months or fewer, and, if the patient lives longer, which frequently patients with Alzheimer's will do, they can recertify them for an additional six months, and sometimes a third time."

The national Alzheimer's Association has defined the third stage of Alzheimer's as terminal, which has helped patients get more of the palliative care they need, he says. "You can't define mild Alzheimer's as terminal, you can't even define moderate Alzheimer's as terminal. People can live in those states for years and years. But the advanced stage is a time of severe decline and decreased function, and relatively imminent death."

There still are some financial disincentives to getting appropriate palliative care for patients with dementia — reimbursement rates that favor use of higher technologies such as feeding tubes as opposed to simpler caregiver activities such as assisted oral feeding, says Post. But these are slowly being resolved.

It's more important for caregivers to be educated about treatments and options that are appropriate for these patients, adds Daugherty.

The Arizona demonstration projects are beginning to yield some data, with evidence that patient outcomes are improved in patients who have received interventions recommended by the Alzheimer's Association.

Once there are appropriate protocols for caring for these patients at the end of life, and providers are more knowledgeable about what these patients need, then health care professionals can advocate for changes in reimbursement and coverage policies that reflect appropriate care, she says.

"By and large, this is a group of people that we just warehouse right now," she says. "There are policy implications, but we need to develop models of care that work, and then work on policy."

Suggested reading

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Is more treatment better or a cause for concern?

Pediatric prescriptions on the rise

The nation's spending on prescription drugs for children and young adults has soared 85% over the past five years, with spending in some categories of pediatric prescriptions jumping more than 600%, according to a report released by the pharmaceutical benefits manager Medco Health Solutions Inc., located in Franklin Lakes, NJ, and a subsidiary of the pharmaceutical giant Merck Inc.

According to the report, which reviewed the prescription drug use of a half million people younger than 19, pediatric patients are taking more — and more expensive — prescription medications for longer periods of time.

For patients younger than 19, the one-year rise in prescription spending per patient, a figure known as "drug trend," was 28%, compared to 23% in the 35-49 age group and less than 10% in the 65 and older age group.

"Increased diagnosis rates and new medicines are two key areas contributing to the higher cost and increased utilization of prescription drugs, providing more effective treatment and significantly improving the quality of life for America's children," **Robert Epstein**, MD, Medco's chief medical officer said in a statement released with the report. "Parents and pediatricians have become much more active in recognizing illness in children and pursuing treatment."

But newer drugs and therapies are more expensive. "Of particular concern now are the so-called orphan drugs, drugs that are the only ones on the market for a particular condition, that are very effective, but treat a condition that affects a small percentage of children, but are also very expensive," says **Richard Walls**, MD, FAAP, a pediatrician in La Jolla, CA, and a member of the Elk Grove Village, IL-based American Academy of Pediatrics Committee on Drugs.

Medco Health, which manages the pharmacy benefit for large companies and health plans, surveys its clients each year about prescription drug utilization and spending. Their findings were released on Sept. 24 in the *Medco Health Solutions 2002 Drug Trend Report*.

Researchers also reviewed current pediatric drug trend data and compared them to data obtained for pediatric prescriptions for the last five years. The comparison revealed significant increases in both cost and utilization:

- Younger patients are taking 34% more medication than they were five years ago, based on days of therapy.
- More than half of the increase in drug spending for children was due to an increase in the cost of drugs, including price inflation, and the introduction of new and more effective therapies.
- Spending on proton pump inhibitors to treat heartburn and other gastrointestinal disorders in children, a class of drugs whose use was virtually nonexistent in that age group five years ago, has increased by 660%.
- An increase in pediatric asthma diagnosis and treatment and the introduction of new allergy medications has contributed to a 211% rise in spending.
- Spending on therapies for attention-deficit-hyperactivity disorder increased by 122% over the past four years.
- Spending on antibiotics increased by 42%; however, recent studies have shown that physician prescribing in this category is on the decline.

The three primary drivers of the spending increases were treatments for asthma, allergy, and anti-infectives, closely followed by neurological/psychological treatments and dermatologics.

For some classes of drugs, new medicines drove increases in spending up by more than 600% since 1997.

Though the findings primarily indicate improved treatment options for childhood illnesses, they are cause for concern because increased medication prices and spending threaten to send costs out of reach for many, says Epstein.

"While we should certainly take advantage of the tremendous advances in modern medicine, we must realize that fiscal innovation and therapeutic practicality are the most effective tools in managing the rising costs of prescription drug care."

By and large, the increased number of prescriptions and increased spending represent the greater number of options available to treat childhood illnesses, says Walls.

The past few years have seen more clinical trials of medications in younger patients. Pediatricians now have good data upon which to base decisions about use of prescription medications in children.

In particular, long-acting antihistamines now are being studied in children as young as 2; previously,

COMING IN FUTURE MONTHS

- Iowa officials drop case against Planned Parenthood
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- Defining death
- Lack of consent in research trials

SOURCES

- **Medco Health Solutions**, 100 Parsons Pond Drive, Franklin Lakes, NJ 07417-9991. Web site: www.-medcohealth.com.
- **Richard Walls**, MD, 7300 Girard Ave., #106, La Jolla, CA 92037.

the youngest children studied were 12, he says.

There are now many treatment modalities to address cough and cold problems in younger children.

For the past few years, there has also been a push in the pediatric medical community to more aggressively diagnose and treat asthma in children, which is reflected in the report of higher numbers of prescribed asthma medications, Walls explains.

"For many years, there were no nationally accepted diagnostic criteria for asthma in children, so it was difficult to do studies comparing different populations," he says.

But with the development of standardized criteria, pediatricians have made an effort to accurately diagnose asthma and initiate treatment at an earlier stage — before children begin to need hospitalization for exacerbations of the illness.

The trend is reflected in the Medco study, which found significant increases in prescriptions for asthma medications, but also found reductions in the number of pediatric hospital visits due to the illness.

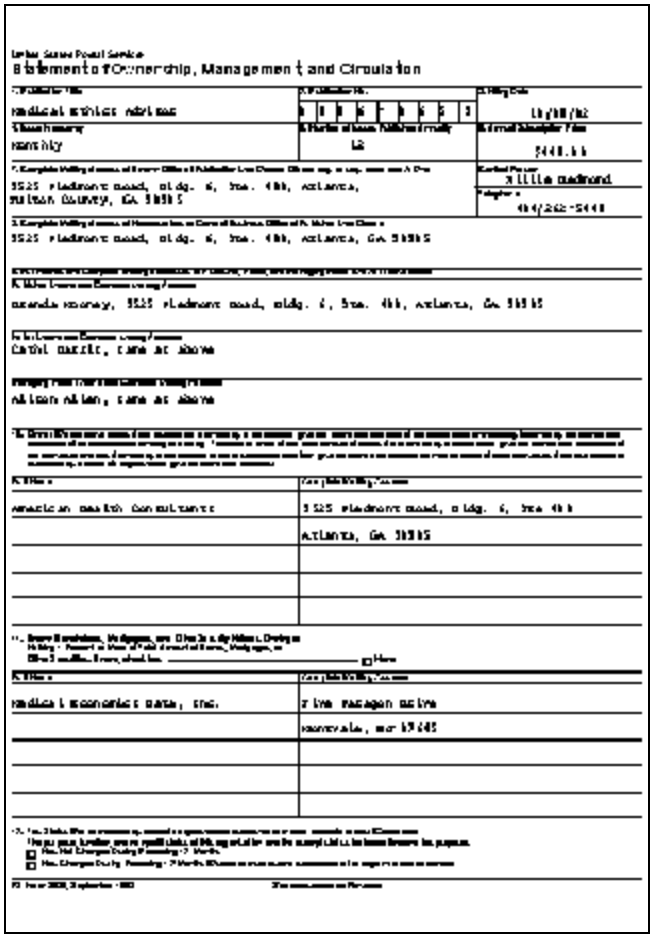
Another factor that is likely influencing the trend, is the availability of newer classes of antidepressants, particularly SSRIs (selective serotonin reuptake inhibitors), that can be used to treat adolescent and childhood depression, he adds.

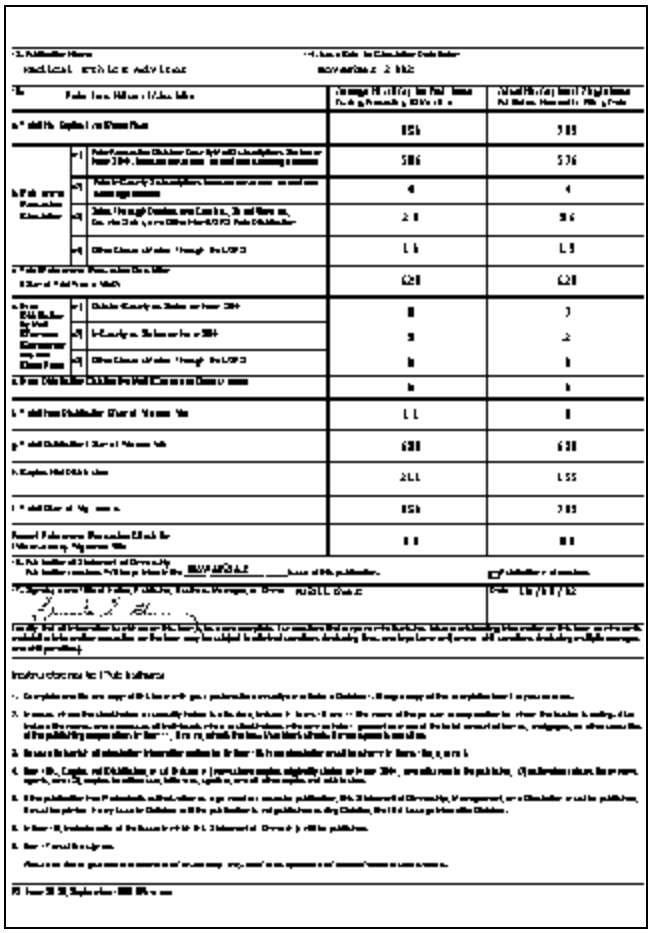
According to the Medco study, the use of antibiotics is still on the rise in pediatric patients, but both the researchers and Walls say this is likely beginning to decline.

"I predict in the next few years, you will see far fewer prescriptions for antibiotics in children," Walls says. "Especially with the availability of the longer-acting antihistamines and similar drugs."

To control spiraling costs, Medco is advising its clients to make better use of generic equivalents of medications and to implement software-based medical and prescribing programs to identify potential prescribing errors.

Clients using such software systems have reduced their drug costs by as much as three percent and cut hospital spending by up to 5%, says Epstein.


Statement of Ownership, Management and Circulation



Walls also recommends use of home delivery pharmacies and well-designed formularies of approved pharmaceuticals to limit spending.

In addition, smart rules to monitor appropriate prescribing patterns and health management programs to encourage treatment compliance would also help control costs.

Generic equivalents can be a good alternative, but in his experience, many generics are not truly the same medication as the original product and, often, they are not much lower in price.

"I have found that the generic manufacturers need to recoup costs for research and development, too — their [profit] margin is not as large as some people think," he notes.

Rising costs are definitely a concern, he admits. Families seen in his practice often pay more at the pharmacy for their drugs than they do for the office visit.

However, although Medco reported concern that spending by older people for their medications had not spiked as rapidly as that for younger patients, Walls emphasized that many young patients do not take the medications long-term, the way that the geriatric population often does.

CME *Questions*

CME subscribers: *Please save your monthly issues with the CME questions in order to take the two semester tests in June and December. A Scantron form will be inserted in those issues, but the questions will not be repeated.*

17. According to the article, chaplains at Advocate Illinois Masonic Medical Center:
A. Serve as initial requesters for organ donation.
B. Do not serve as initial requesters for organ donation.
C. Are not part of the organ donation process.
D. None of the above

18. What feeding procedure does the Alzheimer's Association not recommend for patients with advanced dementia?
A. Assisted oral feeding
B. Family feeding
C. Placement of a percutaneous endoscopic gastrostomy
D. All of the above

19. According to the article, what hospice coverage requirement is a barrier to palliative care for dementia patients?
A. Medicare's requirement of a prognosis of six months or less
B. Requirement that the patient not be able to ambulate without assistance.
C. The requirement that the patient demonstrate a certain cognitive level.
D. None of the above

20. The Pharmaceutical Research and Marketing Association defines an appropriate gift that may be offered to health care professionals:
A. Not worth more than $100.
B. Worth at least $100.
C. To be used primarily for patient benefit *and* as a value less than $100.
D. None of the above

"The pediatric approach is different in that when you put children on a medication, you expect to take them off that medication at some point," he notes. "It's different in geriatrics. When an older person starts a medication, they usually stay with it. You have some people who have 10 or 15 medications they are taking at once. That is definitely still cause for concern." ■