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As more hospices hit Medicare cap, legislation calls for a moratorium

Hospices disagree and call for other solutions

Legislation introduced by Oklahoma lawmakers U.S. Sen. James Inhofe and U.S. Rep. John Sullivan calls for a three-year moratorium on efforts by the Centers for Medicare & Medicaid Services (CMS) to collect overpayments for hospice patient care.

While experts throughout the hospice industry agree that the Medicare hospice cap needs to be re-evaluated, there is disagreement about the need for a moratorium.

"A moratorium has the potential for unforeseen consequences," says **Jonathan Keyserling**, JD, vice president of public policy and counsel for the National Hospice and Palliative Care Organization (NHPCO) in Alexandria, VA. "We have to be cognizant of the federal budget process, and while the cap is a crude tool to contain expenses, it does provide some control," he says.

A moratorium would remove all controls and potentially place hospice organizations that do admit primarily long-stay patients at greater financial risk, he adds.

Another risk of a moratorium is the reduction of payments to hospice organizations across the board, says **Greg Wood**, LBSW, executive director of the Hospice of North Central Oklahoma in Ponca City and president of the Oklahoma Hospice Association. A moratorium might save money for some of the hospices that owe CMS now, but in the long run, CMS might reduce hospice payments in order to control costs and manage the budget, he says.

Wood questions the data that lawmakers Inhofe and Sullivan used as proof that Oklahoma hospices were in trouble. "The statement that 40% of Oklahoma hospices have hit the cap is not accurate," he says. There are 157 hospices in Oklahoma, with 99 of them handled by one Medicare intermediary and 58 handled by another, he explains. Forty percent of the 99 hospices have hit the cap, but there are no data released about the other 58 hospices, he says.

Based on feedback from association membership and leadership, the Oklahoma association does not support the moratorium, says Wood. The cap is not new, he points out. "It is described in the Conditions of Participation to which we all agree," Wood says.

In 1982, CMS began paying hospices a flat fee for care of hospice patients but designated a cap on the total amount that a hospice can be reimbursed for a patient's care. "It is an aggregate payment level, so we look at all patients admitted and multiply the cap level by total number of payments to get the total reimbursement for that year," says Wood. The cap was $21,410 per patient in 2007, he points out.

In 1998, limits on the number of days that a patient could receive hospice care were removed, which increased access to hospice for terminally ill patients with diseases other than cancer, says Wood. "Although a hospice may care for some patients longer than six months, most hospices care for a wide range of patients and the patients who are in hospice care for less time will bring the average number of days and the reimbursement level down below the cap level," he points out.

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Smaller providers benefit from a moratorium

One of the supporters of the moratorium is **Lois Armstrong**, president and chief operating officer of Sojourn Care in Tulsa, OK, and one of the organizers of the National Alliance for Hospice Access (NAHA), an advocacy group committed to study and revision of the hospice cap.

"This issue became important to my partner and I when our hospice hit the Medicare cap in 2005," she says. "We received a demand letter for $2 million 18 months after we provided care for patients who did meet Medicare admission criteria," she says.

Armstrong and her business partner organized NAHA to pull together hospice organizations that might not be part of larger organizations and might feel the effects of the cap more dramatically, she explains. "If you are part of a larger organization or part of a chain, you can afford to pay money back to Medicare, but smaller, independent hospices have already spent the money on patient care and don't have the financial resources to meet the demand for repayment," she explains.

A key component of NAHA's advocacy effort is the moratorium that would stop the calculation of any 2006, 2007, or 2008 cap overpayment that has not yet been calculated, and stop collection of any cap overpayment that already has been calculated but not collected by CMS, says Armstrong. Review of the hospice cap and any changes to the cap might take two to three years, and independent providers cannot survive that length of time if they do not have a moratorium in place, she adds.

Four trends identified

The percentage of hospices that have exceeded the cap has grown from 1% to 6.8% in the past five years, admits Wood. Medicare fiscal intermediaries have reported four distinct trends that contribute to a hospice reaching the cap, he says. Reasons range from premature admission to hospice, to long lengths of stay and lack of administrative processes to handle discharges and financial monitoring. However, there are several ways that hospice managers can reduce their hospice's risk of

reaching the cap, Wood adds. **(See article, below right, for more information.)**

The federal cap on hospice payments is an issue that needs to be reviewed in the context of all issues affecting hospice payments, Keyserling says. "The NHPCO has submitted a proposal that looks at all four levels of hospice care and adjusts geographical reimbursement rates," he says.

Per diem reimbursements vary according to geographical location, Wood says. A hospice providing services in an urban area might receive a higher per diem than a hospice operating in a different part of the state, he explains. "Even though per diem rates vary, the cap is the same for all hospices," Wood says. This variation means that providers receiving the higher per diem are more likely to reach the cap sooner than providers receiving the lower per diem, he explains. "Solutions to this problem would be the same per diem for all hospice organizations or a cap that is based on geographical differences," Wood says.

In addition to adjusting reimbursement rates or the cap itself, Wood also would like to see some long-term changes in the hospice Medicare program to ensure that potential problems within hospices are identified before they reach a crisis stage. "We should have more surveyors and more frequent surveys for hospice," he says. Hospices are not surveyed frequently, with some undergoing surveys every 10 years, and we've had an explosion of new hospice organizations, he says. The rapid growth of hospice means that surveyors don't get back to resurvey organizations in a timely manner, he says. "Home health agencies are surveyed every 36 months, and hospice should have the same oversight," he says. "This will require hospice managers to stay up-to-date on financial reports, monitoring quality of care, and documentation requirements."

Even without surveys, hospices should consider Additional Documentation Requests (ADR) from CMS as red flags to carefully review practices and processes, suggests Wood. The key is to address small problems before they become big problems, he adds.

Because many patients see hospice as a source of palliative care, many hospice owners and managers would like CMS to consider funding palliative care services separately, says Wood. "You may have a multiple sclerosis patient who would benefit from palliative care, but they might not be considered terminal for years," he says. "If CMS offered a palliative care benefit, we could still care for these patients and keep hospice care for terminally ill patients."

The hospice cap is a looming issue that needs to be addressed now, says Keyserling. The percentage of the total population of Medicare decedents who die of noncancer-related causes is 70%, and the percentage of Medicare decedents in hospice care that die of noncancer-related causes is 54%, Keyserling says. "As hospice moves toward the 70% of noncancer-related deaths, there will be longer stays and an increase in the number of hospices reaching the cap if no changes are made," he says. ■

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Trends help hospice managers avoid the cap

Four key items contribute to financial woes

Every hospice is different with varying populations to serve, but an analysis of the reasons that 40% of the 99 hospices in Oklahoma served by Palmetto Government Benefit Administrators (GBA), a Medicare fiscal intermediary, hit the hospice cap shows four predominant reasons, says **Greg Wood**, LBSW, executive director of the Hospice of North Central Oklahoma in Ponca City and president of the Oklahoma Hospice Association:

- **Premature admission to hospice.**

Even if a patient has a terminal illness, there is a period of time that other health care services, such as home health, can meet the patient's needs, says Wood. Just because a physician signs an order that the patient has a terminal illness, hospice may not be the only option or even the best option, he points out.

"In some cases, a physician may state that a patient is terminally ill to qualify them for admission to hospice when the physician is an owner or financially tied to the hospice organization," says Wood. While this is not the case for many physicians and patients, it does raise the issue of enforcement and places the burden on the Centers for Medicare & Medicaid Services (CMS) to enforce the rules, he adds.

• **Long length of stay.**

A hospice often will have patients who live longer than others, so it is important that care is taken to ensure a mix of patients that will keep the aggregate number of days of care below the cap, Wood says. Achieving this mix requires careful review of the patient's needs upon admission and at any recertification point, he adds.

A hospice's patient base should reflect the community, says **Jonathan Keyserling**, JD, vice president of public policy and counsel for the National Hospice and Palliative Care Organization (NHPCO) "There should not be a disproportionate number of short-stay, mid-stay, or long-stay patients," he explains. "Hospice providers may need to redouble their efforts to attract short-stay patients."

• **Inadequate discharge planning process.**

Even patients with terminal illnesses may reach a point during their illness that they don't require hospice services, Wood says. Unfortunately, many hospices don't have discharge planning processes in place to make sure that these patients are referred to home health or other services if their disease is in remission or if the decline in their health has stopped, he says.

"I had a conversation with one hospice provider who told me that his hospice didn't believe in discharging Medicare beneficiaries because they've earned the benefit," Wood recounts. "I don't advocate abandoning patients, but if they can be well served by other providers, discharge them to those providers and readmit them to hospice when appropriate."

• **Lack of knowledge regarding cap and financial performance.**

Hospice managers must monitor their reimbursement levels to determine how close they are to reaching the cap, says Keyserling. "Providers should be monitoring their financial data on a monthly basis," he recommends.

If you do see that you are close to the cap or exceeding it at any point, be prepared to set aside some funds to be available for future repayment, suggests Wood. This will ensure that the hospice will not be harmed financially by a demand from CMS, he adds.

Another basic problem is the lack of knowledge about the cap itself, says Wood. "A hospice provider once admitted to being in business for 10 years and not knowing that there was a cap on Medicare payments," he says. "Although it is only one little paragraph in the conditions of participation, it was also one of the first things I was taught when I was hired to run a hospice." ■

Don't put up roadblocks when callers want info

Correctly handled calls can bring 30% of admits

"I just have a few questions." "I'm calling to get some information." "I don't need an appointment now. I'm just making a call for a family member."

How many times have the receptionists or customer service people in your hospice heard these statements? How many of these inquiries or information-only calls do they turn into new clients?

"Every hospice is missing opportunities for new referrals if these information-only calls are not properly handled," says **Polly Rehnwall**, president of Polly Rehnwall Inc., a consulting firm in Salt Lake City. When addressed correctly, inquiry calls can represent as high a percentage of admissions as referrals from professional sources, she says.

Not all hospice organizations know how to handle these calls, admits Rehnwall. "My firm offers a 'mystery caller service' to make calls to different hospices to see how the person answering the phone handles the request for information only," she says. "Often we hear the hospice representative say that a doctor's order is needed, the patient must have a terminal illness, and that a brochure can be mailed." None of these responses will help turn a call into an admission, she points out.

When her hospice began treating all calls as potential admissions, there was a significant increase in admissions and referrals, says **Terri McEntee**, RN, BSN, CHPN, associate director for referral services at Delaware Hospice in Wilmington. "All calls, emergency and information only, are handled the same way by our referral center staff," she explains. Obviously, emergency or professional referrals require a visit by a nurse, but information callers also are offered a visit by a hospice staff member, McEntee says. "We explain that we can easily schedule an information visit at the callers' convenience."

The hospice staff member answering the phones should say, "I'll be happy to give you some help. Tell me why you are calling," suggests Rehnwall. "Then listen patiently in order to build trust." Rather than putting up barriers such as doctor's orders, the staff member can open the door to setting up a visit, she points out.

Information-only visits, as opposed to clinical visits, are scheduled, explains McEntee. Staff members who make the visits don't have to be clinicians, points out McEntee. In fact, a nonclinician often makes the family more comfortable, she adds. Often the caller has very general questions about the services or medical equipment that hospice provides, but some may have specific clinical questions, McEntee says. "If the staff member making the visit cannot answer a question, he or she calls the supervisor and gets the answer before leaving the home," she says.

"Traditional health care people don't always have the attributes needed for a service representative or customer service staff position," Rehnwall says. "Many health care employees are used to following a rule book and working within a highly regulated industry. I've found that people with real estate, sales representative, or even wedding planner experience have made excellent service representatives." The key to finding the right person is to look for someone who is "infinitely curious," she says.

Gather info, paperwork during visit

Paperwork completed during the visit should include information sheets with patient's name, insurance, place of employment, contact information, family member information, and any other information you might normally collect, says Rehnwall.

"Leave all signed paperwork with the family, and explain that this will make the admission process simpler when they are ready," she says.

In addition to information about hospice services, be sure the service representative can talk about all services that might help the caller and the family, suggests Rehnwall. "Meals on Wheels or home health care might be more appropriate services for the family at the time of the visit," she points out. "Your goal is to help the initial caller care for someone in the family, even if it means pointing them to another provider because it is the right thing to do."

Don't be afraid to refer someone to another provider because you already have earned their trust by listening and offering them resources, says Rehnwall. "When the family reaches the point at which hospice is right for the patient, you'll be remembered," she says.

Creating a successful program to turn inquiries into referrals requires a shift in organizational culture, admits Rehnwall. At first, hospice managers assume that most of their admissions are due to referrals from other providers because they don't get consumer calls, she points out. "In fact, some of my hospice clients have discovered that 30% of their calls come from family members, not doctors or hospitals," Rehnwall says.

The number of calls coming from family members or friends makes it important to move away from the strictly clinical focus of scheduling patients for admission to hospice, says Rehnwall. "Hospices need to return to their social roots, using chaplains, social workers, volunteers, and nonclinicians who can take on some responsibilities for giving information and support to people who ask for help," she suggests. "Nursing case managers don't have to do it all."

Make sure all staff members throughout the

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hospice understand the switch to service representatives and giving all callers the same level of service, says Rehnwall. Because you never know who will answer a phone, have a question asked of them in the community, or meet a friend of a patient at the patient's home, all staff members need to know that simple information-only requests can matter significantly to the hospice, she says. "You have to approach every inquiry with the thought that this inquiry is an admission until proven otherwise," Rehnwall says. ■

Prepare to reduce risk, consequences of RAC audit

Demonstration project expands to hospice

With more than $370 million in overpayments identified in fiscal year 2007 by auditors in the Recovery Audit Contractors (RAC) demonstration project, the Centers for Medicare & Medicaid Services (CMS) has determined the project a success and is making plans to expand the program beyond the three states in the demonstration project.

Hospice and home health managers have not had to worry about a RAC audit during the three-year demonstration project because the two types of organizations were excluded to simplify the administrative process for the project. This will change, however, as the program expands, says **Peter Ashkenaz**, CMS spokesman.

"We expect the RAC program to include home health and hospice organizations as it expands," he says. Although home health won't likely be included in the first part of the program expansion, it will be added as the four regional RACs are named and get their programs up and running, he says.

Expansion of the RAC program from the demonstration states of California, Texas, and Florida to all states will begin in late spring as the regional contractors are named, says Ashkenaz. The program will expand gradually until 2010 when the program is fully implemented, he says. **(For the proposed timeline and changes, see p. 55.**)

No one realized how intrusive this comprehensive oversight would be for providers, says **Michael Manthei**, Esq., partner with Holland & Knight, a Boston-based law firm. Organizations that have undergone RAC audits have had to re-task administrative staff, approve overtime, or hire part-time staff to help gather files and information for the initial audit or for the appeals, he explains.

"CMS plans to ease some of the administrative burden as it makes the program permanent, but . . . agencies should build contingencies into their budgets to address potential expenses of RAC," suggests Manthei. "Make sure you are able to respond to an auditor's demands and handle appeals in a timely manner, and that may mean expense for additional staff."

The program will affect all suppliers and providers because CMS is driven by fiscal concerns, and leaving any group out of the program potentially could leave unrecovered funds, he says.

Contractors paid a percentage of funds

One of health care providers' main concerns about the RAC program is the method that is used to determine payment to the RAC firms, says **Robert W. Markette Jr.**, partner, Gilliland and Markette, an Indianapolis-based law firm.

"Contractors are paid a percentage of the funds they recover," he explains. This means that auditors are likely to apply narrow interpretations of standards and requirements to claims in order to find reasons to improve the amount of funds recovered, he says. An auditor is looking for problems as opposed to just verifying accuracy of claims, he says. "If there are two possible interpretations of a standard with one interpretation leading to recovered funds and the other interpretation not leading to recovered funds, the auditor is more likely to choose the first interpretation," he explains.

Although there is an appeals process in place, the burden of proving the legitimacy of the initial claim falls to the agency, points out Markette. There is a narrow time frame for appeals, so be sure that someone in the agency is responsible for overseeing the process, he suggests. If you decide not to appeal the decision, you can negotiate a repayment plan, but act quickly, he warns.

"If you do not negotiate a repayment plan, CMS will deduct what is owed from future reimbursements," he explains. "Many . . . agencies cannot survive if 100% of their Medicare payments are held for any length of time."

There are certain trends identified in the demonstration project that can help agencies avoid negative RAC findings, says Manthei:

• **Make sure coding is accurate.**

"The biggest problem in the claims that RAC auditors found was upcoding," says Manthei. "Make sure that your coding staff is well trained, and send them to continuing education courses to stay on top of changes in codes." Also, make sure your coding policies and procedures are clear and consistent, and review them regularly to ensure that they reflect changes, he adds.

• **Document medical necessity.**

Areas that have gotten RAC attention include physician orders for hospice care and medical necessity for a wide range of services including home health, says **Beth Kresse**, RHIA, CCS, manager of coding, quality review, and education for Care Communications, a Chicago-based health information management and revenue enhancement consulting company. "They are looking for physician orders and a justified diagnosis that meets medical necessity for the services," she adds.

Even if you have physician orders that indicate medical necessity for hospice care, if you have a patient who requires care for a longer period than is normal for the original diagnosis or for your region, be sure to document carefully, experts suggest.

Manthei says, "Documentation is critical for all claims, but especially if your physician orders something that makes the claim an outlier." In these cases, you should include as much documentation as possible to support the reasons for the physician order, even more than might normally be included, he adds.

You can't assume that a physician's order automatically will be considered proof of medical necessity, he adds.

Also, make sure your physicians' orders are in the appropriate charts, suggests Markette. "I've had cases of clients who were audited, and the physicians' orders were not in the files," he says. Even if your agency has paperwork that travels through different offices or departments, make sure that someone is verifying that all documents are in the files when claims are made, he says.

Also, be sure that you have a system to track the location of documentation so that you can find it quickly, he adds. "An auditor that can't find a physician's order in one file will assume that this is a mistake you make across the board and will include more claims in the audit," he says.

Another way to reduce your risk of a RAC audit is to carefully monitor or audit your own claims, says Markette. "An internal audit should be conducted on at least a quarterly basis," he says.

Need More Information?

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Examine clinical documentation, make sure signatures are present, make sure that medical necessity and verification of homebound status are clearly documented, and double-check coding, he recommends.

"If you find mistakes that are being made, you can take steps to correct the mistakes and prevent future mistakes through staff education," he says. "Self-audits can be time-consuming and add to staff expense, but the investment in self-audits is less than the bill CMS might hand an agency after a RAC audit." ■

Full implementation of RAC program in 2010

Changes will alleviate administrative headaches

The Recovery Audit Contractors (RAC) demonstration program began in March 2005 ran until March 2008. The RAC program will be a permanent program and expanded nationwide by no later than Jan. 1, 2010.

The Centers for Medicare and Medicaid Services (CMS) expects to meet the following timeline:

• In the spring of 2008, CMS will announce the names of the companies chosen to be the permanent RACs for the four regions.

• In the spring/summer of 2008, CMS and the new RACs will conduct extensive provider outreach. CMS will work with provider associations to help facilitate outreach.

Based on feedback from RACs and providers, CMS has made the following improvements to the RAC program:

- The look-back period has been changed from four years to three years in the permanent program.
- In the demonstration, CMS did not give a maximum look-back date. In the permanent program, the RACs will not be able to look for any improper payments on claims paid before Oct. 1, 2007.
- In the demonstration, RACs were not allowed to review claims during the current fiscal year, but they will be allowed to review claims during the current fiscal year in the permanent program.
- Certified coders were not mandatory in the demonstration. In the permanent program, each RAC must have certified coders.
- There was an optional medical record limit set by the individual RAC in the demonstration. The permanent program will have mandatory limits set by CMS.
- During the demonstration, discussion with the medical director regarding claim denials if requested by providers was optional. In the permanent program, it is mandatory.
- The demonstration called for limited reporting by the RACs on the problem areas they had identified. Frequent problem area reporting is mandatory in the permanent program.
- During the demonstration, the RACs only had to pay back the contingency fee if they lost at the first level of appeal. This has been changed to all levels of appeal for the permanent program.
- The RACs did not offer a web-based application that allows providers to customize addresses and contact information or see the status of cases during the demonstration. In the permanent program each RAC must have this web-based application by Jan. 1, 2010.
- During the demonstration, an external validation process was optional, and it varied by state. The external validation process is mandatory for the permanent program, and it is a uniform process.

Source:

Centers for Medicare & Medicaid Services CMS RAC Status Document FY 2007 — Status Report on the Use of Recovery Audit Contractors (RACs) In the Medicare Program. February 2008. Accessed at www.cms.hhs.gov/RAC/Downloads/2007%20RAC%20Status%20Document%20vs1.pdf. ■

Nurses learn to 'speak the language of ethics'

Program helps nurses add to ethics discussions

Some of the language of ethics doesn't come naturally to nurses, according to a nurse-ethicist. But an initiative by Indianapolis-based Clarian Health aims to make ethics training and discussion second nature to the 5,000 nurses working there.

Lucia Wocial, RN, CCNS, PhD, nurse ethicist at Clarian's Charles Warren Fairbanks Center for Medical Ethics, says, "All nurses will encounter ethical issues, and as a new nurse, you develop experience on a continuum from novice to expert. You become more aware of ethical issues as you gain more experience, and by centering our ethics training around the units where they work, their ethics training develops along with their experience."

Predictably, nurses that deal with death are creating the most demand for the unit-based ethics discussions. "When you're facing the issues of patients dying, the nurses who are exposed to dying patients for hours a day have a higher need for ethics conversations," Wocial says.

The Fairbanks nursing ethics program focuses particular attention on the system's intensive care units, where severe illness and high-tech medical care often raise important ethical questions for hospital staff, patients, and families. Through staff education, consultation support, and research, Clarian's nurses will have support in managing ethical conflict and emotional distress that can result from carrying out a plan of care that sometimes contradicts their beliefs about what is in the best interest of the patient.

Nurses confront ethical dilemmas, too

Wocial says while "nurses don't drive the bus" when it comes to treatment decisions, they often are the people patients and families have the most frequent contact with. They often get asked difficult questions while carrying out prescribed treatment.

"Doctors are in charge, and one of the challenges I've seen as nursing has come into its own is that nurses talk about nurse ethics in an adversarial way [to physician ethics], and that's counterintuitive," Wocial explains. "We need to introduce nurses as an interdisciplinary team

member. The initial grant from the Methodist Health Foundation to begin the program in nursing ethics is consistent with Clarian's desire to bring nurses to the ethics table as equal partners. The most recent $5.4 million gift from the Richard M. Fairbanks Foundation will support this program and others at the Fairbanks Center."

Nurses don't establish plans of care, she continues, "but we have input and an ethical perspective; as a nurse, you have a completely different relationship with patients than physicians do, so you have a different perspective that can be extremely valuable."

For example, a do-not-resuscitate (DNR) order is a physician's order, so a nurse can't have "the DNR talk" with families to actually establish the order, Wocial says. However, nurses are in a good position to talk with the family about what to do when the patient can't speak for himself and generally prepare the family to talk with the doctor about the DNR order. "And when you help teach nurses to speak the language of ethics, they can make more of a contribution to the health care team," she adds.

Discussions on individual units

The nursing ethics program at Clarian centers around unit-based discussions; the nurse ethicist and other faculty from the Fairbanks Center go to individual nursing units to conduct conversations in ethics. The topic of the conversation is driven by those who come to the conversation, typically a patient situation happening on the unit, or a type of situation often encountered. The goal of the conversation is to provide a morally safe space for participants to discuss their concerns and identify strategies for managing their distress or resolving ethical problems.

"The unit-based discussions can give them real-time opportunities to learn to speak about ethics in an effective way, to harness emotions they feel about ethical issues, and channel it into a constructive approach to the issue," Wocial suggests. Each unit-based session is an hour long. Early this year, Wocial, who has been on the job since July 2007, already had 80 such sessions scheduled.

"What we know is that nurses who participate in the discussions go back and participate on a different level with their patients at the bedside," she says. "They take the skills and thinking that we role model during the discussions, and they take that back to the bedside."

The discussions aren't just changing how nurses interact with their patients, Wocial adds. "We're starting to see how it affects how nurses communicate with physicians," she says.

"They are thinking more about what's happening, rather than just reacting to the situation. It's very easy to just react to something you hear about, but when you step back and think about it and sort it through, you can see that there's an ethical decision being made there, when before you might have been so busy that you didn't recognize it. And that's what we're encouraging nurses to do." This step is important, she says, because as a profession, nurses make up the largest proportion of members on Clarian's hospital ethics committee. ■

Drug delivery system targets liver cancer

For years, researchers have been working to develop systems to avert the systemic toxicities that chemotherapy produces when treating cancer patients. Limiting dosages means more patients are lost to disease.

Now, Delcath Systems (New York City) has reached Phase III trials with its technology that facilitates ultra-high dose delivery of chemotherapy directly to the liver to treat liver cancer.

The Delcath System (DS) uses a minimally invasive procedure combined with a catheter technology to isolate the blood flow from the liver, which allows for the infusion of a bolus dose of chemotherapy while preventing systemic toxicities. The procedure is being tested at the U.S. National Cancer Institute in a Phase III trial for metastatic melanoma to the liver from ocular and cutaneous origin. Delcath also has a Phase II trial for metastatic neuroendocrine tumors and adenocarcinomas to the liver, as well as primary liver cancer.

Impressive, durable tumor responses

Both trials are using a 3 mg/kg dose of melphalan directly to the liver, and both are showing impressive and durable tumor responses, according to the company. Previous testing used a variety of drug agents, including doxorubicin and 5FU. Data generated from the Phase III pivotal trial will serve as the basis for seeking final

approval from the Food and Drug Association under a Special Protocol Assessment.

"We all know that systemic chemotherapy poisons the whole body," **Richard Taney**, president/CEO of Delcath, says. "The DS is regional cancer treatment. It isolates an organ of the body and treats it with chemotherapy and then goes one step beyond by filtering the blood and returning it to the liver."

The main component of the DS is a 16 Fr double-balloon catheter inserted via the femoral vein and positioned within the retrohepatic inferior vena cava to isolate the hepatic venous outflow. Two independently inflated low-pressure occlusion balloons are positioned to block the inferior vena cava above and below the hepatic venous outflow. When the balloons are inflated, isolating the venous outflow, fenestrations on the catheter allow the hepatic venous blood to exit through the catheter into an extracorporeal blood circuit.

Blood that exits from the proximal end of the catheter is pumped through two carbon filters before returning to the systemic circulation through the internal jugular vein.

Treatment given every four weeks

Patients in the trials usually receive the treatment at four-week intervals, and up to 10 treatments have been administered to a patient. "We can administer chemotherapeutics over 30 minutes, and then we capture the blood exiting the liver — heavily doused with chemotherapeutics — run it through a filtration systems like a heart bypass, then return the cleansed blood," Taney said. "The process is over in an hour. The pump is turned off, catheters are withdrawn. This can be administered once every 21 days. It's a repeatable therapy."

So far in the Phase III trial, researchers are reporting 30% to 100% reduction in tumor volume and 50% response in patients. "Our target patients have at least 20 tumors — a heavy tumor load — which would typically be treated by surgical resection," Taney said. "We are the only technology out there that can bathe the entire organ in chemotherapeutics. A patient receiving chemotherapy systemically would typically get 0.4 mg/kg of body weight. We can deliver a targeted regionalized does of 3 mg/kg.

"We're not simply stabilizing the disease, we are seeing dramatic reduction in tumor size if not complete responses," he added. "The gold standard in liver cancer is to cut it out. Ninety percent of cases are nonresectable. We can reduce tumor load and make nonresectable cases resectable."

While the company doesn't claim to be curing cancer with its DS, Taney said that, unlike surgically isolated hepatic perfusion (IHP) which can be performed only once, this procedure (percutaneous hepatic perfusion) can be administered repeatedly over an extended period, thus improving its life-saving potential.

"When people die of melanoma, they are dying of metastatic disease," he said. "But usually when it goes to the liver, it's a death sentence. We had a patient who had over 50% replacement of her liver with tumors. We cured her liver cancer, but she died 42 months later of brain cancer."

Delcath has filed the DS as a Class III medical device, not a 510(k) because there is no predecessor device. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, general and special controls alone are insufficient to assure the safety and effectiveness of these kinds of devices. Therefore, DS will require the more stringent pre-market approval application route.

Taney added that Delcath also has an investigational new drug application in the works because, even though they are working with FDA-approved chemotherapeutics, the dosages are extremely high.

The DS is Delcath's only product, and Taney points out that its potential applications for other diseases are broad. "Basically, any drugs that have failed because of high systemic toxicity may be a candidate for DS," he said.

Cost estimated at $5,000 each

If approved, the DS may be marketed independently, Delcath estimating that the DS kits would cost $5,000 apiece and that his company could garner $15 million if it could penetrate even just 1% of the potential market. Global sales could multiply that number by 10.

Given the positive responses to date, Delcath has added a fourth arm to its Phase III trial targeting metastatic melanoma to treat patients who have recurrence of disease. Patients in that arm started treatment last June and, so far, have had 100% positive responses. ■

Erythropoietin and cancer death rates

Erythropoiesis-stimulating agents (ESAs) may increase the risk of death in cancer patients according to a new meta-analysis, which also suggests that the drugs are associated with a significant risk of venous thromboembolism (VTE).[1]

Researchers evaluated Phase 3 trials comparing ESAs (erythropoietin and darbepoetin) with placebo or standard care in the treatment of anemia among patients with cancer. The study included 51 trials with 13,611 patients that included survival information, and 38 clinical trials with 8,172 patients that included information on VTE.

Cancer patients who received ESAs had a higher rate of VTE (7.5% vs 4.9%, RR 1.57 7:95% CI, 1.31-1.87) and increased mortality risks (hazard ratio 1.10: 95% CI, 1.01-1.20). The risk of VTE has been previously reported, but this is the first report that raises the issue of increased mortality associated with use of the drugs. The authors cite eight recent studies that have shown increased rates of tumor progression or mortality with ESA use. These trials raise the concern that the ESAs directly affect tumors, a plausible theory since expression of erythropoietin and erythropoietin receptors has been demonstrated in a variety of human cancers and stimulation of these receptors has been shown to cause tumor effects including proliferation, antiapoptosis, and invasion.

The authors conclude that the ESA administration to patients with cancer is associated with increased VTE and mortality risks, and they raise concerns about the safety of ESA administration to patients with cancer.

Reference

1. Bennett CL, Silver SM, Djulbegovic B, et al. Venous thromboembolism and mortality associated with recombinant erythropoietin and Darbepoetin administration for the treatment of cancer-associated anemia. *JAMA* 2008; 299:914-924. ■

Free help for patients to track medications

If your patients are having difficulty remembering which prescriptions to take and when to take them, the Agency for Healthcare Research and Quality (AHRQ) now has an easy solution: a free online "pill card."

According to the AHRQ, using a "cheat sheet" such as the pill card reduces misunderstandings that can help improve patient adherence to provider's instructions. To view instructions on how to create a pill card for your patients, please go to www.ahrq.gov/qual/pillcard/pillcard.htm. ■

Signature requirements clarified by CMS

A recent change to signature requirements by the Centers for Medicare & Medicaid Services (CMS) clarifies what is acceptable for physicians' orders.

A handwritten or electronic signature is accepted, but stamp signatures are not acceptable. An exception to this requirement is that a "facsimile of original written or electronic signatures are acceptable for the certifications of terminal illness for hospice." A change to the requirement also specifies that "facsimile and hard copies of a physician's electronic signature must be in the patient's medical record for the certification of terminal illness for hospice."

To see a copy of the full transmittal, go to www.cms.hhs.gov and select "Regulations and Guidance" on the home page, then under the "Guidance" heading, select "Transmittals." Choose "2008 Transmittals" on the left navigational bar. Scroll down to "Transmittal R248PI," which was issued on March 28. ■

COMING IN FUTURE MONTHS

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NHPCO wins $250,000 grant to educate hospice workers

The National Hospice and Palliative Care Organization has received a grant of $250,000 from a court-approved fund benefiting nonprofit organizations in health care, the arts, education, and underserved populations, from Fujitsu Computer Products of America in Sunnyvale, CA.

In December 2006, Fujitsu reported a grant of more than $12 million in Fujitsu products and services to the U.S. hospice community. These grants of technology to 15 hospice providers and NHPCO were part of a $30 million independently managed and court-supervised technology grant program. NHPCO said it would use the grant to increase online and web-based educational opportunities for hospice professionals, support research and policy about quality hospice and palliative care, and expand public understanding of the benefits of end-of-life care.

The organization said that, in addition to receiving the grant, NHPCO is launching its expanded online educational portal for professionals that provides CE courses. Online modules will include clinical topics, management and leadership offerings, and sessions designed to increase capacity of the hospice interdisciplinary team.

NHPCO said additional support will also be available to ongoing research initiatives, its Quality Partners program, and Caring Connections, its consumer-focused initiative that provides information on hospice, advance care planning, and family caregiving. ■