THE CANCER LETTER

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In the Cancer Centers

Rosen Moves to City of Hope

By Paul Goldberg

Steven Rosen is leaving his job as director of Northwestern University Robert H. Lurie Cancer Center to become the center director, provost, and chief scientific officer at City of Hope National Medical Center.

The move is interesting in part because, after 25 years in the top job at Northwestern, Rosen is the second longest-serving director of a cancer center in the U.S. (Rosen's friend Max Wicha, who became director of the University of Michigan Cancer Center 27 years ago, is the first.)

The change is all the more noteworthy because the role Rosen is taking at City of Hope will require him to be a part of a management team, where he would run the scientific and academic functions, but would report to that institution's president and designated next CEO, Robert Stone.

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Conversation with The Cancer Letter

Rosen's New Role is Part of an Evolution Of Administrative Structure at City of Hope

Robert Stone, president and incoming CEO of City of Hope, described the evolution of the novel leadership structure at his institution.

While most directors of cancer centers have to fulfill a multitude of very different roles, City of Hope has redistributed these roles, creating the role of provost and chief scientific officer to shape and direct the scientific and educational activities at the institution.

The role encompasses all units of City of Hope: the Comprehensive Cancer Center, the Beckman Research Institute of City of Hope, a National Medical Center, a Medical Foundation, a graduate school for biological sciences, and nationwide philanthropy.

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In Brief

Kun Named Clinical Director at St. Jude

LARRY KUN was named clinical director and executive vice president of **St. Jude Children's Research Hospital**.

He will oversee clinical operations, clinical effectiveness practices and patient care quality programs for the hospital. Kun has served as chair of the St. Jude Department of Radiological Sciences and will remain in that position.

Kun joined St. Jude in 1984 to establish a department to treat cancer with radiation therapy and to initiate the multidisciplinary brain tumor program.

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Rosen's Job Represents Rethinking Of Role of Cancer Center Director

(Continued from page 1)

Rosen's first day at City of Hope will be March 1, 2014.

The position represents a reconfiguration of the cancer center model that often requires the director to be a scientist, a scientific administrator, a healthcare executive, a strategist, and a fundraiser.

Though some directors report to deans or the boards of directors, the City of Hope schema is unique, because its power-sharing structure formally delineates the responsibilities.

"The world is becoming so complex, that for us, the way we navigate this complexity is to not try to rely on one individual to have all of the answers on every subject," Stone said to The Cancer Letter. "It's to build the leadership community where people bring different skills and understand what they know and don't know."

A conversation with Stone appears on p. 1.

"I think that in the future things are going to be so complicated and so challenging that leadership teams will evolve, and City of Hope is moving in that direction now," said Michael Friedman, the institution's retiring CEO. "Having truly gifted business leaders, truly gifted strategists, truly gifted scientists, clinicians, and so forth, is going to be necessary, and the sheer quantity of leadership will need to be greater."

Rosen said he liked the team at City of Hope.

"I liked the people, and I thought I would fit in the team, and we would work effectively together," he said to The Cancer Letter. "We would have a collective power, and the resources are so significant to recruit stars in the field."

City of Hope was awarded more than $79.7 million in research grants during 2012 and received $224.6 million in revenues from patented technologies.

The redefinition of the traditional authorities of a center director wasn't a problem, Rosen said.

"I've been doing this for 25 years, I am comfortable with all the nuances, I've been an advisor to over a dozen cancer centers, I've seen places that have thrived, places that have suffered in different leadership structures," Rosen said. "I feel I understand what's necessary to put together a team to do important work.

"The goal is to establish an environment where everyone feels nurtured and wants to be there to advance the mission."

Initially, Rosen will serve as director of the City of Hope cancer center, but at some point, he may recruit a replacement who would report to him.

"I will first have to settle in," he said. "I have to learn a great deal about the institution, and once I feel comfortable, we would make collective decisions about whether it's best for me to stay in the position or recruit someone else."

Rosen first came to Northwestern as a college student in 1969, and with the exception of a fellowship at NCI, has been there since.

He said he started to look for other opportunities after the most recent round of the cancer center grant review by NCI, where the center was rated "outstanding" and Rosen's leadership "exceptional."

"I thought it was an opportune time for transition," he said. "There wasn't a natural next position for me here at Northwestern and opportunities started to become available."

Northwestern officials said a national search for Rosen's successor would begin shortly.

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Conversation with The Cancer Letter

Robert Stone: "It Takes a Team" To Run a Major Cancer Center

(Continued from page 1)

Earlier this week, City of Hope announced the recruitment of Steven Rosen, director of Northwestern University Lurie Cancer Center, to serve as the provost and chief scientific officer.

Stone spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *I don't know of another cancer center that has this structure. How would you describe the box diagram of authority at City of Hope? How will the institution function?*

Robert Stone: We have an institution-wide executive leadership team, of which Steve Rosen would be an integral part as the provost and chief scientific officer. All the academic and research aspects of our organization will flow through Steve.

PG: *And then you?*

RS: And Steve will report to me.

PG: *And the cancer center director?*

RS: Interestingly, it will work as Steve determines it should work. I told Steve when we recruited him that he would have the discretion to organize it under him as he thinks best.

It would be up to Steve whether the most effective structure is for him to be the cancer center director, whether he should be the cancer center director for a period of time and then recruit a new cancer center director who would report to him, or whether he quickly recruits a new cancer center director.

PG: *He would be doing more than oncology, right?*

RS: The provost position is a significant role for us. The cancer center is a major part of the role. We also have an important focus in diabetes research and basic science. We have a graduate school for biological sciences. All of these areas ultimately report to Steve.

We are also in the process of negotiating a relationship with the Providence Health System of Southern California that relates to their five hospitals in Southern California.

An important component of that relationship will be expansion of our research, so Steve would be involved there. It's a significant job that touches every part of our organization.

PG: *Cancer center directors—let's just focus on one part of his position—have to be good at many, many things. They have to be scientists, administrators, executives of massive health systems, fundraisers, strategists, and nuts-and-bolts implementation people. Is there anything I missed?*

RS: I think that covers it.

PG: *Can one person be expected to be good at all that?*

RS: I think it takes a team. No matter how you structure the leadership positions for our science and academics, it takes a team to be able to handle all the demands, much like it takes a team or a leadership community to handle all of the aspects of the organization as a whole.

Steve would tell you that he does not have any illusions of doing this job alone. He will be a leader of leaders. He intends to rely on good people who are here and good people that he will recruit.

PG: *This power-sharing probably exists in most centers. But in this case, it's actually formal that there is a team, and that the team includes the CEO who is a lawyer by education.*

RS: City of Hope is a complex organization that exists in an increasingly complex environment. It takes members of a leadership team that have different skills. Let me give you an example. The Southern California marketplace will change perhaps dramatically as a result of health reform. Funding will become tougher. Reimbursement for clinical care will become less. There will be, I fear, the threat of decreased access for patients who would benefit from our care.

And Steve, with all of the experience he has, would do well in navigating that environment, but his focus should be on creating the most impactful research environment at City of Hope. We also have an executive officer of our medical foundation named Harlan Levine, who is a physician by training. Harlan came to us from WellPoint, where he was executive vice president of comprehensive health solutions.

Harlan is incredibly talented, yet he is not a cancer center expert.

The power we have in our executive team is combining the skills and experiences of Harlan Levine with Steve Rosen. I think it allows us to serve our mission and make an impact far greater than either of those two people can do alone.

And those are just two people. You add to that mix people like Marty Sargent, who is our chief operating officer, and Alexandra Levine, who is our chief medical officer, just to name two.

You start to understand that the whole is greater than the sum of the parts.

PG: *How did the idea of power-sharing evolve?*

RS: City of Hope, because it's an independent

organization that has different component parts to it, has always had a tendency towards collaborative leadership.

What I described is not wholly unique to what our history has been. We've always had a cancer center director who has the authority that's required by the NCI. That will not change.

But the notion of taking different pieces and skills and putting them together isn't new to us. We've just taken what for us is the next logical step and formalized it.

PG: *Was it the board that came up with this idea? Was it you? Was it Michael Friedman [the retiring CEO and cancer center director]?*

RS: The board obviously appointed me and made the decision that I should succeed Michael. But the notion of leadership community is something that I utilized when I became president about 18 months ago.

It actually started formulating when I was chief executive of our medical foundation before that, and this is just a logical extension.

PG: *It would seem that a structure like this would work only when people know what they don't know. Where does your knowledge stop?*

RS: It's a fair question. There are things that I must bring to the leadership team. Knowledge of the marketplace and how to best position City of Hope; how to build the type of culture that we've been talking about, a culture that continues our 100 yearlong dedication to serving humanity while still evolving to meet the current environment; and the ability to identify and recruit leaders who know what they don't know and work well with others. I can bring that to this community—the commitment to putting the mission first.

I am not going to be the one who defines the best scientific direction to make the greatest impact. It's why I am fortunate to recruit and hire people like Dr. Rosen. And, I know, one of the attractions of the position to Steve is my knowing what I don't know and my ability to say to him: "You have the authority to set the scientific direction. Your charge is to help us deliver on our mission."

PG: *When did you join City of Hope?*

RS: 1996. I joined as a junior member of the legal department and became general counsel of the medical center in 2000. I then became the entire organization's general counsel in 2003.

PG: *Did you ever think you would become the CEO?*

RS: It was never in my career path. I came to COH back then because I saw it as an opportunity to make a difference. The successive responsibilities over the years have always been in pursuit of making an impact. When I started, the best way for me to do this was through the law.

As both the institution changed and the environment changed, several years ago, the best way for me to make the highest impact was to move into the strategy area, so I became chief strategy officer.

PG: *That was Michael's idea?*

RS: It was. I've had the benefit of working with Michael since he got here. To the extent I have accomplished anything here, much of it is due to Michael putting me in the position to contribute.

He appointed me as general counsel and then as chief strategy officer. Then when we formed the medical foundation and the skillset needed there was to bring people together to a common goal, he named me chief executive. And then 18 months ago, he created the position of president and appointed me to deliver on the strategic plan.

PG: *So what you are really saying is that Michael is the architect of this idea of group leadership, or power-sharing, or whatever you want to call it.*

RS: Again, it's embedded in our history. Architect is probably a word we never thought to use in this context. But it absolutely is something that has evolved under his leadership over the past decade.

PG: *I guess I know many cancer centers that are run by lawyers, but that's de facto. What's unique here is that it's formally so.*

RS: First. I am a recovering lawyer. I have great admiration for the profession, but I haven't practiced law in a number of years. So I look at the skills I bring as knowing the marketplace, the commitment to focus on culture and keep alive what's been so special about us, and to recruit leaders like Steve Rosen.

If you look at the strength of the leadership team that we've assembled, the issue of what my educational background was long ago isn't relevant. What will be relevant is how I will pull together the leadership and what the vision and direction is that we set into the future.

PG: *What does the future look like?*

RS: The future for City of Hope is incredibly bright, but the environment will add a level of complexity that will take the strength of the leaders to navigate.

I think we are really well positioned because of the ability to build on the strengths we have now, the ability

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to focus on making an impact, investing in the people that work here now and recruiting new people, and the ability to partner out in the community so patients and their families will continue to have our level of care available to them.

I don't know of many cancer centers that are looking out over the next five years and saying that to deliver on our commitment to our community, we are prepared to internally invest more than $100 million in our science and care in order to accelerate the pace of meaningful discoveries that extend both quality and length of life. We are fortunate enough to be in that position.

Quality of Care

ASCO Publishes "Top Five" Ways to Improve Cancer Care

The American Society of Clinical Oncology published its second list of five opportunities to improve the quality and value of cancer care in the Journal of Clinical Oncology.

The list was part of the Choosing Wisely campaign, sponsored by the ABIM Foundation, to encourage conversations between physicians and patients aimed at curbing the use of certain tests and procedures that are not supported by clinical research, according to an ASCO statement.

One of the first nine medical societies to join the campaign, ASCO issued its first list in April 2012.

"As physicians, we have a fundamental responsibility to provide high-quality, high-value cancer care for all of our patients," said Lowell Schnipper, lead author of the JCO article and chair of ASCO's Value of Cancer Care Task Force. "That means eliminating screening and imaging tests where the risk of harm outweighs the benefits, and making sure that every choice of treatment reflects the best available evidence.

"By providing evidence-based care, we not only help our patients live better with cancer, we also assure they are getting high-quality care that will deliver the greatest possible benefit for the cost."

The Value of Cancer Care Task Force developed the following list, and each recommendation is based on a review of current clinical evidence conducted by the task force:

1. Don't administer anti-nausea drugs to patients starting on chemotherapy regimens that have low or moderate risk of causing nausea and vomiting.

Different chemotherapy treatments produce side effects of variable severity, including nausea and vomiting, and many medications have been developed to help control these side effects.

When successful, these medications can help patients avoid hospital visits, improve quality of life, and lead to fewer changes in the chemotherapy regimen.

In recent years, new drugs have been introduced to help manage the most severe and persistent cases of nausea and vomiting that result from certain chemotherapy regimens.

ASCO recommends the use of these drugs be reserved only for patients taking chemotherapy that has a high potential to produce severe and/or persistent nausea and vomiting, as they are very expensive and not without their own side effects.

For patients receiving chemotherapy that is less likely to cause nausea and vomiting, there are other effective anti-emetic drugs available at a lower cost.

2. Don't use combination chemotherapy instead of single-drug chemotherapy when treating an individual for metastatic breast cancer unless the patient needs urgent symptom relief.

While combination chemotherapy has been shown to slow tumor growth in patients with metastatic breast cancer, it has not been proven to improve survival over single-drug chemotherapy, and it often produces more frequent and severe side effects, worsening a patient's quality of life.

As a general rule, therefore, ASCO recommends giving chemotherapy drugs one at a time in sequence, which may improve a patient's quality of life and does not typically compromise overall survival.

Combination therapy may, however, be useful and worthwhile in situations where the cancer burden must be reduced quickly because it is causing significant symptoms (e.g., pain and discomfort) or is immediately life threatening.

3. Avoid using advanced imaging technologies—positron emission tomography, CT and radionuclide bone scans—to monitor for a cancer recurrence in patients who have finished initial treatment and have no signs or symptoms of cancer.

Evidence shows that using PET or PET-CT to monitor for cancer recurrence in asymptomatic patients who have completed cancer treatment and have no signs of disease does not improve outcomes or survival.

These expensive tools can often lead to false positive results, which can cause a patient to have additional unnecessary or invasive procedures or treatments or be exposed to additional radiation.

4. Don't perform PSA testing for prostate

cancer screening in men with no symptoms of the disease when they are expected to live less than 10 years.

Men with medical conditions or other chronic diseases that may limit their life expectancy to less than 10 years are unlikely to benefit from PSA screening.

Studies have shown that in this population, PSA screening does not reduce the risk of dying from prostate cancer or of any cause.

Furthermore, such testing could lead to unnecessary harm, including complications from unnecessary biopsy or treatment for cancers that may be slow-growing and not ultimately life threatening.

For men with a life expectancy of greater than 10 years, however, ASCO has previously recommended that physicians discuss with patients whether PSA testing for prostate cancer screening is appropriate.

5. Don't use a targeted therapy intended for use against a specific genetic abnormality unless a patient's tumor cells have a specific biomarker that predicts a favorable response to the targeted therapy.

Targeted therapy can significantly benefit people with cancer because it can target specific pathways that cancer cells use to grow and spread, while causing little or no harm to healthy cells.

Patients who are most likely to benefit from targeted therapy are those who have a specific biomarker in their tumor cells that indicates the presence or absence of a specific abnormality that makes the tumor cells susceptible to the targeted agent.

Compared to chemotherapy, the cost of targeted therapy is generally higher, as these treatments are newer, more expensive to produce, and under patent protection.

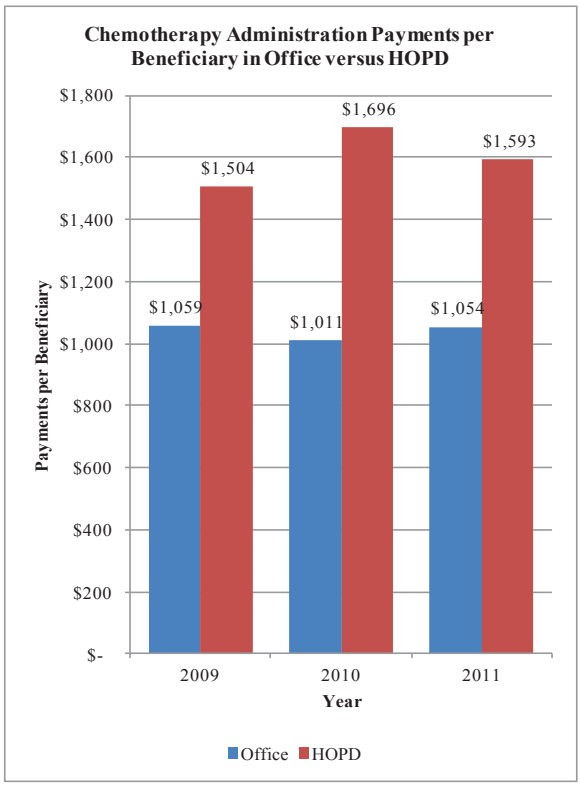
In addition, like all anti-cancer therapies, there are risks to using targeted agents when there is no evidence to support their use because of the potential for serious side effects or reduced efficacy compared with other treatment options.

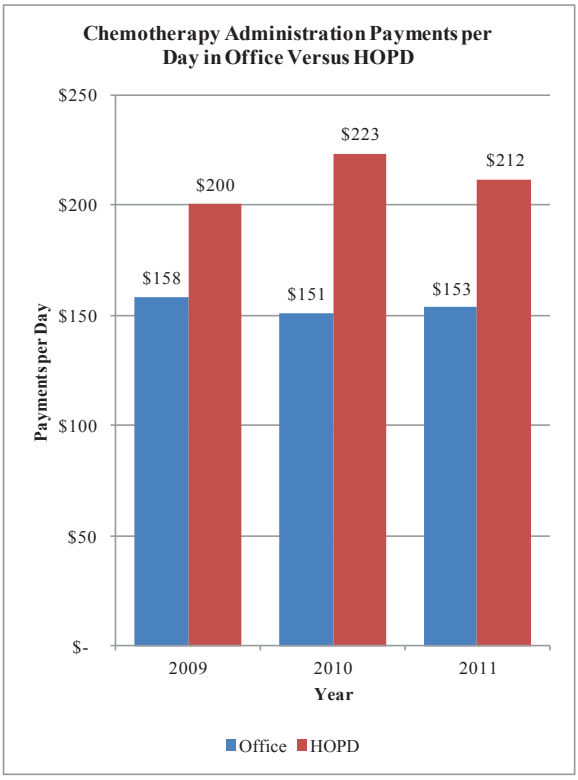
"All medical professionals should be accountable for both their patients' well-being as well as their wise stewardship of health resources," said ASCO President Clifford Hudis. "High-value care not only benefits patients, but also reduces societal health care costs which should be a concern for everyone.

"At ASCO, we want to ensure that oncology providers have the skills and tools needed to assess the benefits of tests and treatments and to discuss options with their patients," Hudis said. "These goals are not in conflict: the best care for patients is the best approach for society."

To help members assess care in their practices based on ASCO's Top Five lists, measures based on the five recommendations are offered as test measures in ASCO's Quality Oncology Practice Initiative, a national program that helps practices assess and improve the quality of care they deliver through retrospective medical record abstraction and performance analysis, according to ASCO.

A team of clinicians and quality measurement experts are reviewing the Top Five test performance based on more than 14,000 records (160 practices) and further refining the measures for future implementation.





Differences in Actual Chemotherapy Administration Reimbursement, from the Moran Company report "Cost Differences in Cancer Care Across Settings."

Cost of Care

Medicare Patients Charged More In Outpatient Care Settings

Patients receiving chemotherapy in hospital outpatient departments face up to 47 percent higher costs compared to patients treated in physician community cancer clinics, according to a report prepared by The Moran Company and released by The US Oncology Network and the Community Oncology Alliance.

Titled "Cost Differences in Cancer Care Across Settings," the report analyzes Centers for Medicare and Medicaid Services data from 2009 to 2011.

The report focuses on payment rate differentials between cancer clinics and hospitals due to differences in the utilization of drugs and services, as well as methodologies employed by Medicare to set payment rates.

Key findings in the report include:

• On a per beneficiary basis, hospital outpatient chemotherapy spending was approximately 25 to 47 percent higher than physician clinic chemotherapy spending.

• If all physician clinic chemotherapy administration services had been paid using hospital outpatient department payment rates over the 2009 to 2011 period, Medicare would have paid 19 to 38 percent more for these services.

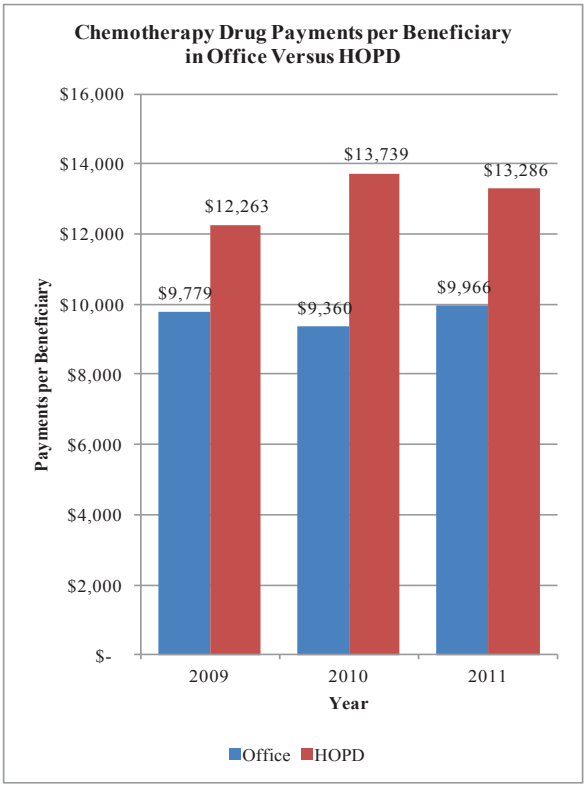
• Chemotherapy days per beneficiary were about nine to 12 percent higher in the hospital outpatient department than the physician clinic setting across the 2009 to 2011 period.

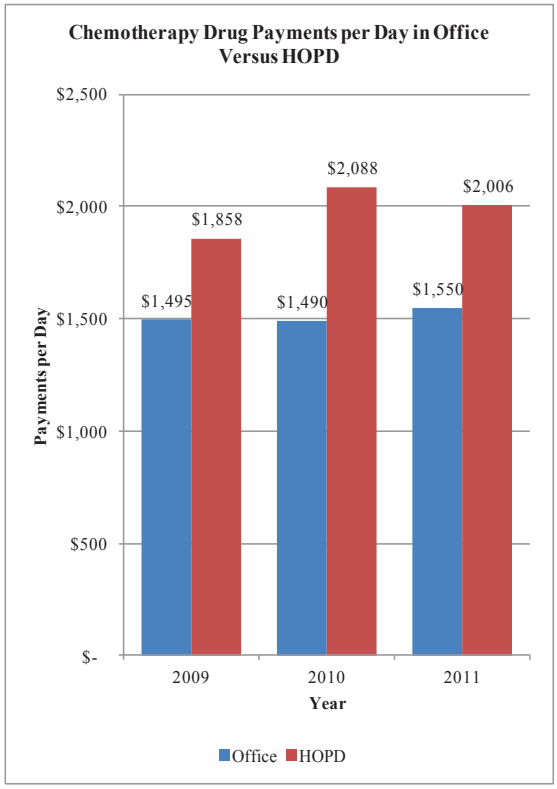
"Medicare data again confirms that outpatient cancer care in hospital outpatient departments costs significantly more than the same care in community cancer clinics," said Barry Brooks, chairman of the contracting subcommittee for The US Oncology Network. "Medicare policies create perverse incentives for hospitals to acquire community practices and bill Medicare at a higher rate.

"Unfortunately for patients fighting cancer and for taxpayers, cancer care will cost more than it should until current government policies favoring hospital-based care are ended," Brooks said.

The latest Moran Company report builds upon a June report that found 87 percent of cancer care occurred successfully in cost-effective community oncology practices.

By 2011, Medicare beneficiaries received nearly a third of their outpatient chemotherapy services in the





Differences in Actual Chemotherapy Drug Reimbursements. *Source: Moran Company*

hospital outpatient setting, according to a statement from The US Oncology Network.

The Moran report is consistent with recent studies by Avalere and Milliman, which indicate that cancer center closures and consolidations result in higher cancer treatment costs to Medicare, seniors and taxpayers. Hospital-based cancer care costs Medicare approximately $6,500 more and seniors $650 more annually.

"The Community Oncology Alliance has been collecting data about cancer clinic closures and hospital acquisitions for several years, which has demonstrated alarming trends in the number of cancer centers that have been forced to close or consolidate," said COA Executive Director Ted Okon. "The data show why the site of cancer care matters to patients and payers.

"Care is drastically shifting towards the higher cost setting," Okon said. "We call on the Congress and the Administration to act immediately to reverse this trend before cancer care is unaffordable to seniors and Medicare."

The Moran Company's most recent report cites the difference in payment rates for chemotherapy services as attributed to differing policies adopted by CMS that set mechanisms by which payments to hospital outpatient departments and community cancer clinics are determined and updated.

The report said continuing disparities in the method of establishing payment rates for both settings are resulting in a widening payment gap that significantly favors hospital-based cancer care over care provided in physician-run community cancer clinics.

The Moran analysis finds this gap will continue to grow without any changes in Medicare policy by Congress.

"As community clinics struggle to keep their doors open, this report drives home the important role of community-based cancer care in providing cost-effective care to all patients fighting cancer," said Jeff Vacirca, chief executive of North Shore Hematology Oncology Associates on Long Island.

"As lawmakers look to future Medicare reforms, it is clear Congress must act immediately to put community cancer clinics in a sustainable position to maintain cancer care access for seniors," Vacirca said in a statement, on behalf of ION Solutions.

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In Brief

Kun Named Clinical Director At St. Jude Children's Hospital

(Continued from page 1)

Under his leadership, the department grew into the largest pediatric brain tumor research program in the country. Kun succeeds **Joseph Laver**, who has accepted a position at Stony Brook University Hospital in New York.

Until recently, Kun was chair of the NCI Pediatric Brain Tumor Consortium and has held leadership positions in the Pediatric Oncology Group, the Children's Oncology Group, the American Society for Radiation Oncology, the Society for Neuro-Oncology, and the American Board of Radiology. He is a founding member of the Alliance for Childhood Cancer.

Kun was awarded the Gold Medal from ASTRO, the Pediatric Oncology Award from the American Society of Clinical Oncology, the Janeway Medal from the American Radium Society, and the Pioneer Award from the Children's Brain Tumor Foundation.

PAULA RIEGER, chief executive officer of the **Oncology Nursing Society**, announced that she plans to retire May 16, 2014.

"It was a personal decision to step away from full-time employment to spend more time with her family," said a statement released by the society.

Under Rieger's seven-year tenure as CEO, ONS completed the development, testing, and validation of quality measures funded by the Breast Cancer Fund of the National Philathropic Trust through the ONS Foundation.

ONS achieved the CEO Gold Standard Seal in 2008 and has been reaccredited in subsequent years. In 2013, ONS won the Alfred P. Sloan Award for Excellence in Workplace Effectiveness and Flexibility.

"Paula as done a remarkable job of leading our organization for the past seven years," said ONS President **Mary Gullatte**. "Her loyalty, commitment, and dedication to ONS is greatly appreciated and will be truly missed."

THE OHIO STATE UNIVERSITY signed an agreement with **Microlin Bio Inc**. to license a portfolio of Ohio State's cancer discoveries, including nearly 100 issued and pending microRNA patents in prostate, ovarian, colon and lung cancers.

Additionally, Microlin has licensed a novel nucleic acid delivery technology to deliver these therapies to cancer cells, and Ohio State will have an equity position in Microlin. Microlin plans to build a development facility in Ohio.

These patents were developed by university researchers Carlo Croce and Robert Lee, and with collaborators from NCI and NIH. Croce first linked microRNAs to cancer over 10 years ago. MicroRNAs are now known to play a pivotal role in the growth and spread of many kinds of cancer.

Lee invented methods to deliver the microRNA to the target of interest with minimal degradation, prolonging stability of the molecules, which is an historical challenge in the field of microRNA therapy.

"Nanoparticles can improve the pharmacokinetic properties of oligonucleotides, including microRNAs, and help them get into the tumor and then into the target cell," says Lee. "My lab in the College of Pharmacy has designed proprietary formulations of lipid nanoparticles that can enhance the clinical performance of miR-based therapeutics by improving their delivery."

ANAND JILLELLA joined **Emory University** as a professor in the Division of Hematology and Medical Oncology and as associate director of community outreach in the Winship Cancer Institute.

Jillella served as the section chief of hematology/oncology and bone marrow transplantation at Georgia Regents University.

His primary clinical interest is bone marrow transplantation, with specific focus in leukemia, multiple myeloma, acute promyelocytic leukemia and other blood-related cancers.

He served as the acting director of the cancer clinical research unit and principal investigator of the Minority-Based Community Clinical Oncology Program supported by NCI and based at GRU.

FDA News

Gazyva Approved in CLL: FDA's First Approval Of A Breakthrough Therapy Drug

FDA approved Gazyva (obinutuzumab) for use in combination with chlorambucil to treat patients with previously untreated chronic lymphocytic leukemia.

Gazyva, also known as GA101, helps certain cells in the immune system attack cancer cells. Gazyva is intended to be used with chlorambucil.

Gazyva is the first drug with breakthrough therapy designation to receive FDA approval. FDA

had also granted Gazyva priority review as well as an orphan product designation.

"This approval reflects the promise of the Breakthrough Therapy Designation program, allowing us to work collaboratively with companies to expedite the development, review and availability of important new drugs," said Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA Center for Drug Evaluation and Research.

Gazyva's approval for CLL is based on a study of 356 participants in a randomized, open-label trial comparing Gazyva in combination with chlorambucil to chlorambucil alone in participants with previously untreated CLL. Participants receiving Gazyva in combination with chlorambucil demonstrated a significant improvement in progression free survival: an average of 23 months compared with 11.1 months with chlorambucil alone.

The most common side effects observed in participants receiving Gazyva in combination with chlorambucil were infusion-related reactions, neutropenia, thrombocytopenia, anemia, musculoskeletal pain, and fever.

Gazyva is being approved with a boxed warning regarding Hepatitis B virus reactivation and a rare disorder that damages the material that covers and protects nerves in the white matter of the brain, or progressive multifocal leukoencephalopathy. These are known risks with other monoclonal antibodies in this class and rare cases were identified in participants on other trials of Gazyva.

Gazyva is marketed by Genentech, a member of the Roche Group.

FDA requested that the manufacturer of the leukemia chemotherapy drug Iclusig (ponatinib) suspend marketing and sales of the drug, because of the risk of life-threatening blood clots and severe narrowing of blood vessels.

The agency recommends that patients currently taking Iclusig who are not responding to the drug should immediately discontinue treatment and discuss alternative treatment options with their health care professionals.

The manufacturer, Ariad Pharmaceuticals, has agreed to suspend marketing and sales of Iclusig while FDA evaluates the safety of the drug.

The agency also recommended that patients who are currently taking Iclusig and responding to the drug, and whose health care professionals determine that the potential benefits outweigh the risks, be treated under a single-patient Investigational New Drug application or expanded access registry program while FDA's safety investigation continues.

FDA plans to work with the manufacturer on a plan to quickly transition these patients to a program that will allow access under an IND or expanded access registry program, according to a statement from the agency.

"Health care professionals should not start treating new patients with Iclusig unless no other treatment options are available and all other available therapies have failed," said the FDA statement.

The agency's recent investigation of Iclusig revealed an increased frequency of blood clots and narrowing of blood vessels since the drug was approved in December 2012.

Currently, approximately 24 percent of patients in a phase II clinical trial, with a median treatment duration of 1.3 years, and approximately 48 percent of patients in the phase I clinical trial, with a median treatment duration 2.7 years, have experienced serious adverse vascular events, including fatal and life-threatening heart attack, stroke, loss of blood flow to the extremities resulting in tissue death, and severe narrowing of blood vessels in the extremities, heart, and brain requiring urgent surgical procedures to restore blood flow.

In some patients, fatal and serious adverse events have occurred as early as two weeks after beginning Iclusig therapy.

The clinical trials did not include a control group so it is not possible to determine the relationship of these adverse events to Iclusig, however the increasing rate and pattern of the events strongly suggests that many are drug-related, said the FDA statement. At this time, FDA cannot identify a safe dose level or exposure duration.