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* Per Skaane, Andriy I. Bandos, et.al. 2014 271:3, 655-663

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ON THE COVER:
Julie Brahmer, MD, MSc, medical oncologist and director of the Thoracic Oncology Program at the Sidney Kimmel Cancer Center at Johns Hopkins Bayview
As summer ends and we kick into gear with hectic fall routines, we tackle weightier medical topics in this issue like the oft-promised ‘cure’ for cancer. After decades of fits and starts in developing better detection and treatment of cancer, the U.S. has launched a ‘Cancer Moonshot’ to accelerate research efforts, including more targeted therapies.

In our cover story (p.10), we speak with three physicians who deal with some of the most intractable cancers, including lung and liver cancer, about advances in cytostatic approaches to block tumor growth rather than the cytotoxic ones used in chemotherapy. One of our interviewees co-chairs a molecular tumor board that is actively helping them connect with appropriate clinical trials and setting up care appointments. That kind of care coordination continues to be missing too often in healthcare, and may be as critical to treatment success as the therapies themselves.

I especially hope you’ll take a moment to read the touching story of Hopkins’-based Lillie Shockney’s efforts to improve life for terminal metastatic breast cancer patients. She created a program that allows these women to write cards to their children for future significant milestones, such as their birthdays, marriages and the birth of their first child. It’s a departure from our usual clinical case format that’s well worth your time, and I hope you’ll consider the implications for your own medical practice.

We also look at the burgeoning field of telemedicine (p.18), which has overcome initial barriers on the reimbursement, credentialing and provider/patient reluctance fronts to become widespread in everything from the ICU to psychiatry. It can help reduce costs, increase access for patients in more rural or underserved areas, and reduce the impact of shortages in some specialties like psychiatry. It can also make running a quality ICU affordable despite fluctuations in the census.

The dramatic increase in the availability of medical cannabis throughout much of the U.S. is about to spread to Maryland. As we went to press, the first licenses for growers and processors have been announced. At the federal level, not much has changed. Cannabis is still illegal, and few physicians have registered for the Maryland program. This issue’s Compliance article (p.17) helps you understand how to comply with the laws while helping appropriate patients.

Finally, many physicians have found themselves contemplating a sale of their medical practice. Our Solutions article (p.8) helps you understand the three most common valuation methods for assessing medical practices – market, income, and asset-based – so you can make a more informed decision.

These next couple of months deliver some of the best weather our Chesapeake Bay region has to offer. Our Bay (p.22) showcases a bit of our region’s beauty. For many of us, it’s a time of spiritual renewal. To that end…

To Life!

Jacquie Cohen Roth
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As the administrative director of the Johns Hopkins Breast Center for nearly two decades and the director of Johns Hopkins Cancer Survivorship Programs for our cancer center, I made a conscious decision to incorporate patients with metastatic cancers into our survivorship programs, and not exclude them, as commonly happens. Some patients live for years with their disease, while others may succumb to their cancer after a short period. My specialty is metastatic breast cancer from a clinical and research perspective, focusing on preserving quality of life.

Each woman has life goals that need to be discussed. Their most common concern is leaving their children behind; they fear there will be no one to instill their values, express the love only a mother can show, and most of all, be remembered by their children.

One way to fulfill their hopes for their children and themselves is to provide a selection of cards that are sent by a ‘keeper of the cards’ after their death. These cards can convey their thoughts for their children’s milestones – birthdays, communion, bar mitzvah, getting their driver’s license, graduating from high school and college, marriage, and their first child. The hand-written words in these cards help ensure that they will always be remembered and will allow them to express their wisdom and love.

A few summers ago, I received a call from a 24-year-old woman whom I had never met. “Anna” told me that I took care of her mother 14 years ago, when she was just 10 years old herself. Her mother died of stage 4 breast cancer that year, and was in and out of the hospital a lot during the last few months of her life. Anna had overheard her mother tell her Aunt Sarah that, “Lillie said to do this and Lillie said to do that,” but she never understood who Lillie was until her mother passed away and Aunt Sarah became the keeper of her cards. Then, with each milestone of her life, she received a card from her mom.

Anna said she loved seeing her mother’s handwriting and words of wisdom, hope for her future, and motherly compassion. She told me that when she got married a few weeks before our call, her aunt had placed her bridal veil on her head and handed her a card from her mom. The edges of the envelope were yellowed after 14 years. She opened it, saw a beautiful card, and her mother’s handwriting inside.

She read to me what her mother had written to her: “I know you would have chosen wisely someone you deserve to spend the rest of your life with. Marital advice: Don’t ever go to bed angry with one another. Whatever it is can be talked through. When your dad lifts your veil and kisses your right cheek, you will feel me kiss your left.”

Anna told me, “Miss Lillie, I swear I felt my mother’s kiss. I have always felt her presence through these cards she left for me. Thank you for enabling my mom to always be in my life.”

I told Anna that if she planned to have a family, she also would receive cards when she becomes pregnant the first time and when her baby is born, and would also receive a cassette tape of her mother reading children’s stories so that her child would know his or her grandmother’s voice.

I have organized this card program for a long time as one way to support patients approaching their end of life. We need to help patients fulfill their goals rather than just saying, “I am sorry you will miss the milestones of your children’s lives. I hope you are not forgotten.”

Dying in pain can be effectively prevented with early palliative care. When you talk with your metastatic cancer patients, consider asking them what they are most worried about. Also consider holding a card drive where people donate cards for your patients. These cards are a powerful way to help patients maintain their family connections and feel confident they will impact their children’s lives for decades to come. That gives them one less thing to worry about as they prepare for death.

Donated Cards Allow Metastatic Cancer Patients to Convey Love Beyond Death

By Lillie Shockney, RN, BS, MAS

Lillie Shockney, RN, BS, MAS, is university-distinguished service professor of Breast Cancer; administrative director, the Johns Hopkins Breast Center; director, Cancer Survivorship Programs at the Sidney Kimmel Cancer Center at Johns Hopkins; and professor, JHU School of Medicine, Departments of Surgery and Oncology. She can be reached at shockli@jhmi.edu.
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How to Value Your Medical Practice

BY MARK NORRIS

There are typically three approaches considered when valuing a physician practice – market, income and asset-based. In theory, these are very similar to the approaches that a real estate appraiser uses when appraising. Within each approach, there are multiple valuation methods. The following summarizes the more common methods used.

**Market Approach**

Within the market approach, the valuation method that is typically considered is the guideline transaction approach. Under this method, sales transactions of comparable physician practices are obtained from databases. Various financial data is analyzed, including balance sheet data, profit and loss data, profitability ratios (such as percentage of net income), earnings before taxes (EBT), and earnings before income taxes, interest, depreciation, and amortization (EBITDA) as a percentage of revenue. This data is compared to the subject practice.

In addition, various sales price multiples are developed by dividing the sales prices of the transactions by their respective revenue, EBITDA, EBT and net income. These multiples are then used to develop a value for the subject practice.

The critical issue when using this valuation method is whether the practices included in the sales transactions are truly comparable. Issues regarding comparability might include:
- Geographic area
- Contracts with insurance companies
- Competition
- Type of practice
- Physical condition of office and fixed assets
- Number and type of providers

**Income Approach**

Within the income approach, the valuation methods typically utilized include the capitalization of earnings and the discounted cash flow methods. The capitalization of earnings method focuses on the past financial performance of the practice. In the capitalization of earnings method, five years of historical financial statements are typically reviewed. Adjustments are made to “normalize” any unusual and non-recurring transactions. One of the most important adjustments is the normalization of physician’s compensation to a market rate. Basically, the market rate of compensation should represent what would have to be paid to a non-owner physician to provide the same services the owner physician performs.

Making these adjustments produces normalized profit and loss statements for each of the years reviewed. The valuation analysts then must determine whether to average all the years’ normalized net income, average just some of the years, or utilize only one year. The overall goal is to develop a net benefit stream that represents the best estimate of what the practice will generate in the future. This after-tax benefit stream is divided by a capitalization rate to produce the value of the practice.

**Asset-Based Approach**

In the asset-based approach, the valuation method generally used is the adjusted net asset value method. In this technique, the assets and liabilities of the practice are adjusted to fair market value. The adjusted liabilities are subtracted from the adjusted assets to produce the adjusted net asset value for the practice.

Most physician practices maintain their financials on a cash basis. Therefore, the most common adjustment made when using this method is to record accounts receivables (after insurance adjustments), and an income tax liability applicable to the accounts receivables. In addition, the fixed assets are adjusted to fair market value based on an appraisal prepared by a machinery and equipment appraiser.

Most of the medical practices we appraise today are valued using this method because we are unable to identify comparable sales transactions in the market approach, and the practice is not profitable after normalizing owner physician compensation.
Most of the medical practices we appraise today are valued using [the asset-based] method because we are unable to identify comparable sales transactions in the market approach.

Key Take-Aways in Practice Valuation
The key points to keep in mind when valuing a practice are:

- Due to negative pressure on reimbursement rates, most physician practices are not profitable after normalizing physician compensation.
- Even if the income or market approach produces a value for the practice over and above the adjusted net asset value, the valuation analyst must consider whether this value contains personal goodwill. Any personal goodwill applicable to the owner physician will reduce the practice’s sale value, chiefly because there is a significant risk that patients will not continue coming to the practice when the current owner physician has exited.

The healthcare industry is filled with significant uncertainty today. Unfortunately, uncertainty produces risk, and risk has an inverse relationship to value. As a result, physicians should maintain realistic expectations when preparing to value and sell their practices. Using a professional valuation service can help them get a fair appraisal. CP

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The U.S. has announced a ‘Cancer Moonshot’ to accelerate research efforts, including more targeted therapies. Experts discuss the current state of these therapies for lung and liver cancer, and how molecular and multidisciplinary tumor boards can help.

Unleashing Targeted Therapies Against Resistant Cancers

Dr. Julie Brahmer, director of the Thoracic Oncology Program at the Sidney Kimmel Cancer Center at Johns Hopkins Bayview, is developing new immunotherapy approaches for lung cancer.
Immune Checkpoint Discovery Offers Hope for Lung Cancer

Lung cancer is the leading cause of cancer-related mortality throughout the world, with over 80% of these carcinomas classified as non-small-cell lung cancer (NSCLC). Chemotherapy has provided the majority of patients with only modest improvements in longevity, even when bevacizumab, an angiogenesis inhibitor, is added to their treatment regimen.

Julie R. Brahmer, MD, MSc, medical oncologist, director of the Thoracic Oncology Program and associate professor of Oncology at the Sidney Kimmel Cancer Center at Johns Hopkins Bayview, has helped lead the charge for developing more effective immunotherapy treatments for NSCLC.

She explains, “Early immunology-based therapies, including vaccine therapies, were largely ineffective. However, once researchers discovered that tumors take advantage of multiple immune system ‘checkpoints’ to diminish the anticancer immune response, immunological approaches have become more successful.”

Dr. Brahmer adds, “The first such pathway was described by Jim Allison, PhD, chair of...
Cancer uses multiple checkpoints and we’re developing more and more antibodies to attack them.

– JULIE BRAHMER, MD, MSC

Immunology at the University of Texas MD Anderson Cancer Center, who developed an antibody to block an immune checkpoint known as CTLA-4, the path in melanoma.”

The system, says Dr. Brahmer, provides a kind of “handshake” or connection between the programmed death receptors on immune cells (PD-1) and their sister receptors on tumor cells, called PD-L1. Checkpoint inhibitors block that handshake, alerting immune cells to target cancer cells for destruction.

“Two ligands bind to the PD-1 receptor on T cells and cause it to become exhausted and not work,” she notes. “The immunotherapy is an antibody that binds to the PD-1 receptor on the T cell, or on the ligand of the cancer cell, allowing the T cell to remain active. While the cancer response is less in lung cancer than in melanoma, this is the first time there’s been a response, so it’s significant. These therapies are now being approved in bladder, lymphoma and other cancers that have traditionally had few options.”

CHECKPOINT INHIBITOR DRUGS

The ‘checkpoint inhibitor’ drugs that are furthest in clinical development are nivolumab and pembrolizumab, which inhibit PD-1 directly, and atezolizumab and durvalumab, which block PD-L1.

“I was involved in the first clinical trials that used immunotherapy for cancers beyond melanoma and kidney cancers,” says Dr. Brahmer. “These earlier studies led to large international Phase III trials of nivolumab for metastatic lung cancer. We’re now working on biomarkers and learning to identify which patients will most likely respond to these treatments. We test the ligand with a biopsy of the cancer, and if PD-L1 staining is high (i.e., a significant portion of the cancer expresses the ligand), there’s a 40 to 50% likelihood the patient will respond to immunotherapy.”

Dr. Brahmer was the lead author of a clinical trial reported July 9, 2015, in the New England Journal of Medicine comparing survival rates among patients with advanced squamous-cell NSCLC who received docetaxel vs. nivolumab. Approximately 20% receiving nivolumab responded to the drug, compared with 8.8% who took docetaxel.

At the end of one year, 42% of the nivolumab group were alive, compared with only 24% of those taking docetaxel. Nivolumab was FDA-approved in March 2015 for use in patients with metastatic squamous cell NSCLC whose disease progressed despite chemotherapy.

In October 2015, nivolumab received FDA approval for use in patients with metastatic non-squamous-cell NSCLC whose disease progressed despite chemotherapy. Researchers are exploring whether combining these drugs with chemotherapy, targeted therapy or other immunotherapies can provide additional benefit.

DIFFERENT SIDE EFFECTS THAN CHEMO

Dr. Brahmer notes that immunotherapies produce different side effects than chemotherapy, and cautions physicians to be on alert. “Patients don’t lose their hair, but they can develop autoimmune diseases and symptoms that you don’t usually see in cancer survivors. Hypothyroidism is the most common effect. While these therapies are usually easy to tolerate, if a patient presents with fatigue, you have to consider it could be a rare endocrine/autoimmune disorder.”

She adds, “We’re partnering with endocrinologists, rheumatologists and other specialists in the community to help monitor these issues in cancer patients, and we’re educating primary care and emergency physicians, encouraging them to call us with any questions.”

FUTURE USE IN EARLY STAGE CANCER

“Currently, only 20 to 40% of our patients respond to chemotherapy, and it typically doesn’t last more than six months,” Dr. Brahmer explains. “The average life expectancy is eight to 12 months with treatment, and three to six months without. If we can detect the disease early, there’s a small chance we can cure it. In the future, we hope to administer immunotherapies to patients without having them first undergo chemotherapy.”

MAINTAINING HOPE

Despite the poor prognosis for many lung cancer patients to date, it’s important that physicians refer them for specialized care to maximize their chances for survival. Dr. Brahmer remarks, “These patients can live for years with targeted therapies. I just saw a patient who’s survived with metastatic lung cancer for over three years. Just because someone has metastatic lung cancer no longer means they shouldn’t have hope. They should be referred to an oncologist to discuss their treatment options. We’re there to support primary care physicians as part of the team.”

“Checkpoint inhibitors are now being applied to almost every cancer,” she concludes. “It’s another arrow in our quiver that we can use. Cancer uses
multiple checkpoints and we’re developing more and more antibodies to attack them. Typically, one in 10 drugs may be a blockbuster, but in these drugs, we saw results right away. We’re now seeing rapid changes and results.”

Turning the Tide on Liver Carcinoma

For decades, the good news in treating liver and pancreatic carcinomas has been sparse, with incidence and death rates for both cancers bucking the decline seen in most other cancers. The American Cancer Society reports that the five-year survival rate for all liver cancers combined is only 15%.

Colon cancer that has metastasized to the liver is the most common cancer affecting this organ; hepatocellular cancer (HCC) is the most common primary liver carcinoma, typically related to viral hepatitis B or C infection, or cirrhosis. HCC is the fifth-most common cause of cancer death in men and the ninth-most common in women.

“The bad news is that, from 1980 to 2012, the incidence of pancreatic and liver cancer increased,” says Steven Cunningham, MD, FACS, director of Pancreatic and Hepatobiliary Surgery, Saint Agnes Hospital in Baltimore. “One glimmer of good news is that the incidence is decreasing among those under age 50, which may indicate we’re finally making headway.”

EARLIER DETECTION IS NEEDED

One complicating factor is that most HCC is still not detected until it has reached intermediate or advanced stages. Detection methods include alfa-fetoprotein (AFP), which increases in 70% of HCC patients. The mainstay of diagnosis is multiphasic CT and MRI. In fact, in a recent article in Journal of Cancer Therapy, “Early Hepatocellular Carcinoma (HCC): Diagnosing the Difficult Nodule,” Dr. Cunningham and colleagues reviewed the many diagnostic pitfalls associated with small lesions in high-risk patients. “It is therefore essential,” explains Cunningham, “to have not only the right scan, but the right radiologist, with expertise in advanced hepatobiliary imaging.

“The key is early detection,” he adds. “High-risk

Dr. Steven Cunningham, director of Pancreatic and Hepatobiliary Surgery, Saint Agnes Hospital, offers advanced treatments for liver carcinomas.
patients should undergo surveillance every six to 12 months to detect HCC early, when the chance of cure is higher.”

Similarly, colonoscopies beginning at age 50 and treatment of polyps are essential to reduce the incidence of colorectal liver metastases.

**TREATMENT OPTIONS**

Surgery remains the most common method of treatment, and many procedures can be performed laparoscopically. Dr. Cunningham notes, “The liver is one of the few organs that regenerates; up to 70-80% of the liver can be removed and the remainder will grow to replace it.”

For unresectable tumors, several other options exist. Radiation has an important but limited role, and chemotherapy is typically reserved for secondary liver cancer.

**OPTIMAL DOSING OF CHEMO**

In 2014, Dr. Cunningham and colleagues published a paper in the *Journal of Clinical Oncology* titled, “Are We Systematically Under-Dosing Patients With Fluorouracil?” They hypothesized that traditional chemotherapy may occasionally under-dose patients. Since fluorouracil works by binding and inhibiting thymidylate synthase (TS), they tested tumors using a novel antibody that binds the inhibited TS, and found that these patients had incomplete binding of TS by fluorouracil, and likely a suboptimal drug effect.
Dr. Cunningham explains, “We can measure drug levels in the bloodstream, but this is the first time we’ve been able to measure the chemotherapy actually binding and inhibiting the tumor in humans. It may provide a future approach to improve personalized dosing in patients with colorectal liver metastases.”

NEWER THERAPEUTIC OPTIONS

Attempts to develop more targeted molecular therapies have had limited success, although studies with checkpoint inhibitors – the class of drugs discussed by Dr. Brahmer above – are underway for HCC patients as well. “Unfortunately, however, sorafenib – the only molecular therapy with a slight survival benefit for HCC patients – is not highly effective,” Dr. Cunningham notes.

He adds, “In addition to the standard tripod of surgery, chemotherapy, and radiation, other therapies include transarterial chemoembolization (TACE) and radioembolization (TARE). These are appropriate for advanced HCC, combined with sorafenib or ablation, or as a bridge to liver transplant.”

TACE uses a catheter to deliver chemotherapy directly to the liver tumor and then embolizes the tumor’s blood supply, minimizing systemic effects. TARE, which employs radiotherapy, has had reported tumor responses of between 25 and 80%.

“Fortunately, most of the blood supply to the tumor is through the hepatic artery,” Dr. Cunningham notes, “whereas most of the liver’s healthy cells are primarily supplied via the portal vein. We also perform thermal ablation with radiofrequency or microwave energy, and when tumors are near critical structures, a very new therapy – irreversible electroporation – is sometimes used, since it avoids some disadvantages of thermal ablation by preserving collagen architecture.”

NIHILISTIC ATTITUDE IMPEDES CARE

Dr. Cunningham believes that nihilism about hepatobiliary and pancreatic cancers works against clinical success. He says, “If a patient presents with pancreatic or liver cancer, he or she should be evaluated by a multi-disciplinary tumor board. Only a small portion of cancers that are treatable are actually being referred for treatment, and that’s a shame.”

He concludes, “I don’t want to give patients false hope, nor, however, do I want to deprive them of hope, because there is hope for all patients.”

Molecular Tumor Board Promotes Personalized Medicine

Molecular tumor boards are springing up around the country to analyze advanced and rare primary cancers that may respond to targeted therapies. The tumor board at the Inova Center for Personalized Health in northern Virginia is one local example.

Timothy Cannon, MD, a medical oncologist who is clinical director for the Molecular Tumor Board and Personalized Medicine Initiative, says, “Today, it costs only several thousand dollars to sequence a genome. However, doctors don’t always know how to use that information.”

He adds, “Many patients are in search of treatments that more effectively target the cancer and have fewer side effects. We analyze sequencing panels that look at anywhere from 50 to several hundred genes known to play a role in the development and/or propagation of cancer when mutated.”

The Inova Schar Cancer Institute contracts with N-of-One, a molecular decision support company based in Cambridge, Mass. “Their database can provide information when there’s a mutation in the tumor gene we aren’t familiar with,” notes Dr. Cannon. “They also give us loads of additional, constantly updated information on more common mutations.”

Presently, DNA sequencing is most useful for...
people whose cancer has progressed despite standard treatment. "While DNA is the most accessible, we’re also performing analysis of RNA at this time. We plan to use of the burgeoning field of proteomics (the large-scale analysis of proteins) and phosphorprotein analysis to more accurately determine which mutations are driving the cancer," Dr. Cannon explains.

RNA sequencing can have better sensitivity and dynamic range than DNA microarray, detecting splicing variants and mutations, but has a higher cost and large files that require more sophisticated analytic tools.

**TUMOR BOARD ALSO COORDINATES CARE**

Dr. Cannon states, "To the best of my knowledge, our tumor board is the only one in the country that invites the patient to join us. They really like participating. We are also unusual in that we do all the legwork to help them manage the logistics in obtaining targeted therapy. For example, we don’t just recommend a clinical trial and give them a phone number – we actually find out if they are eligible, if the trial is enrolling, and set up an appointment. This addresses one of the greatest frustrations I had in private practice – the lack of coordinated care.

"Patients need someone to navigate for them," he continues. "Most of them have no idea how to identify an appropriate clinical trial, and no one center has trials for all the possible mutations."

He emphasizes that tumor board patients remain under the care of their own provider, and return to their oncologist’s office once they have completed a clinical trial.

**LIQUID BIOPSIES**

Researchers have discovered that tumors shed considerable amounts of DNA into the bloodstream, making it possible in some cases to identify mutations by drawing blood rather than performing a biopsy.

The FDA recently approved the first such test, developed by Roche, to detect mutations in genes that respond to Tarceva (erlotinib) as a treatment for first-line epidermal growth factor receptor (EGFR) metastatic NSCLC treatment, and advanced-stage pancreatic cancer treatment. Other liquid biopsy tests may not require FDA approval.

A recent study of over 15,000 liquid biopsies performed by Guardant Health, a Silicon Valley start-up, assessed mutations in 70 genes associated with various cancers, including lung, breast and colorectal. While certain mutations associated with tumor growth were confirmed upon biopsy over 90% of the time, about 15% of patients with a malignancy had no detectable mutations in their bloodstream.

Dr. Cannon comments, "Currently, our ability to detect a DNA mutation is far greater than our ability to treat it with a pill. This will improve each year, and should be vastly better within the next five years."
Experts project that serving patients under the Maryland medical cannabis law will begin in the spring or summer of 2017. Although physicians play a key role in the law, many physicians remain reluctant to participate. As of late July, only about 145 physicians had registered in the program. Common questions from physicians about their participation are addressed below.

Is cannabis illegal under federal law?
Because cannabis remains a Schedule I substance under the federal Controlled Substances Act (CSA), its possession, distribution and use are prohibited. The Schedule I status also carries a finding that the substance (1) has a high potential for abuse and (2) lacks any accepted medical use. There is no “medical necessity” exception under CSA enforcement, even where a person or organization is in compliance with state law.

Significantly for physicians, the CSA also prohibits the prescription of Schedule I substances. Physicians must be clear with patients that they cannot and will not prescribe medical cannabis.

The Department of Justice (DOJ), however, has stated a policy of deference to state and local enforcement in states that have a robust regulatory framework for medical cannabis.

If I certify medical cannabis in compliance with Maryland law, will I be subject to civil or criminal enforcement under the CSA?
No physicians have been prosecuted under the CSA for properly recommending or certifying medical cannabis to a patient. Also, an important federal appellate court held that physicians have a First Amendment right to discuss and recommend cannabis to a patient within a bona fide physician-patient relationship. There is no protection, however, for a physician prescribing cannabis or aiding-and-abetting or conspiring in its acquisition. For this reason, state medical cannabis laws employ a process of physician “recommendation” or “certification.” Accordingly, physicians who follow a proper process are not violating state or federal law.

Can the DEA revoke my registration for certifications?
Prior to 2002, the DEA sought to revoke some physician registrations. However, physicians’ First Amendment rights to recommend medical cannabis also protect against DEA de-registration.

Can I have an ownership interest in, or other associations with, medical cannabis businesses?
As recently as 2014, the DEA reportedly threatened physicians in Massachusetts with de-registration unless they severed ties with medical cannabis businesses. However, the Rohrabacher-Farr amendment of 2014, which prohibited the use of DOJ funds to prevent legal implementation of state medical cannabis laws, has made this more difficult. The laws of Maryland and most other states also have conflict-of-interest prohibitions that physicians must keep in mind.

Can I be kicked out of Medicare or Medicaid or terminated from a plan network?
A physician should not violate Medicare/Medicaid conditions of participation, which include compliance with state and federal laws, merely for proper cannabis certification. However, physicians should be careful about billing a federal program for a patient encounter involving even a discussion of medical cannabis. Physicians should keep apprised of insurer standards regarding medical cannabis, which will likely see significant development over the coming years.

Can I lose my medical staff appointment, clinical privileges or license for proper certifications?
This is highly unlikely so long as a physician is in compliance with state law and is engaging in First Amendment protected speech. Staff privileges and licensure carry due process protections.

However, physicians should be careful to comply with reasonable hospital rules. Physicians should further be careful to observe ethical duties and the standard of care, as with any other type of care. Physicians must also comply with the strict requirements of the Maryland law, e.g., bona fide patient relationship and annual evaluation. Physicians in several states have been subject to adverse licensure action for operating “marijuana mills,” failing to examine patients and failing to communicate the benefits and risks of cannabis. Communication and consent remain particularly difficult given the lack of data on medical cannabis, a fact that is in large part due to its Schedule I status.

COMPLIANCE TIPS
Because so much rides on effective compliance with state law – including federal and state enforcement, staff membership and clinical privileges, licensure, Medicare/Medicaid participation and network membership – physicians must establish an effective compliance program that includes proper policies and procedures, forms, documentation, and billing practices. CP

Joseph T. Kelley, III, is a principal at Offit Kurman Attorneys At Law. He can be reached at jkelley3@offitkurman.com.
While barriers to telemedicine still exist, more widespread reimbursement, less onerous credentialing requirements and greater patient and provider acceptance is fueling the growth of this practice.

BY LINDA HARDER
The American Telemedicine Association defines telemedicine as “the use of medical information exchanged from one site to another via electronic communications to improve a patient’s clinical health status.” As an indication of the practice’s growing acceptance, in June 2016 the American Medical Association updated its ethics code, “Ethical Practice in Telemedicine,” to reflect the newer ways in which patients and physicians communicate.

In Maryland, telemedicine interaction is permitted in lieu of an in-person examination and to establish a patient-physician relationship. In Virginia, physicians can use telemedicine for “…diagnosing or treating a patient or consulting with other healthcare providers…”

While requirements vary, in most states today private insurers and Medicaid are reimbursing for telemedicine when it meets their criteria. Maryland, Virginia and D.C. all allow licensure reciprocity with neighboring states.

Burgeoning Telemedicine Services

Today, numerous hospitals and health centers offer telemedicine services. In Virginia, Inova offers telemedicine services that encompass telestroke, psychiatric, dermatology, pediatric, and ICU services in 25 locations. Johns Hopkins offers, among other services, a Care at Home program to Parkinson patients. The University of Maryland Medical System’s Greenebaum Cancer Center offers a teled program to affiliated community hospitals; the system also offers ICU telemedicine, high-risk pregnancy and psychiatric teleservices. Today there are even telemedicine fellowship programs, such as the one offered by the Department of Emergency Medicine at George Washington.

Telepsychiatry Helps Address Provider Shortage

Perhaps nowhere is telemedicine more needed to address barriers to accessing care than in psychiatry. From 1995 to 2013, the number of adult and child psychiatrists in the U.S. rose only 12%, while the number of physicians increased 45% and the U.S. population rose 37%. And the majority of psychiatrists are clustered in urban areas.

“Some 77% of counties report a shortage of psychiatrists,” states Ben Borja, MD, medical director of Crisis Services at Sheppard Pratt Health System in Baltimore. “Telepsychiatry is the field of the future, saving time for patients and providers. There are simply not enough psychiatrists, and too few psychiatrists are entering the field to replace those who are retiring. With the greying of the psychiatric workforce, we have to make more efficient use of our existing physicians.”

He adds, “The shortage is exacerbated by higher suicide rates, substance abuse and other issues in rural areas. Mental health is in dire need in those areas. We especially don’t have enough child psychiatrists.” Ocean City and the Eastern Shore of Maryland, for example, have only a handful of psychiatrists.
How It Works

About 10 psychiatrists at Sheppard Pratt participate in its telepsychiatry program. Using the latest videoconferencing equipment, they connect with social workers, therapists, mental health staff, nurses, patients, and their families on Maryland’s Eastern Shore to provide psychiatric evaluation and medication management services from Towson.

Telepsychiatry can also help working mothers and others who want to work part time or from home. One of Dr. Borja’s graduate residents, who is the mother of two young children, can provide telepsych services from home using a white screen and a secure line.

Thanks to Skype and mobile technology, people today are generally comfortable with using videos for intimate exchanges. Dr. Borja explains to patients that telemedicine is like Skype, which helps them understand the concept. “Of course, we purchase secure internet lines for HIPAA compliance. The quality of video transmission has also improved.”

Reducing Waits for ED Evals and Outpatient Appointments

A 2014 study by the University of South Carolina School of Medicine found that establishing a telepsychiatry program in the state reduced the average wait time for an ED psychiatric evaluation from four days to 10 hours. The program also decreased the frequency of hospital readmissions and involuntary commitments, and improved follow-up compliance participation in substance abuse rehabilitation. Further, costs were cut about $1,400 per consult, for a total of nearly $28 million in savings.

“Telepsych also significantly decreases the waiting time for outpatient appointments,” Dr. Borja explains. “Primary care physicians see the majority of mental health patients. If they need to refer to a psychiatrist, the appointment can take weeks. But if I have several hours set aside one day a week for video conferencing, I can see that patient far more quickly. Also, the patient often is more comfortable seeing me while with his primary care physician. Primary care physicians are great partners. They want us to use telepsychiatry as one way to make mental health more user friendly and available.”

Telepsych Challenges and Limitations

While telepsych has proved useful in the emergency department, the approach has some limitations. “We have to have a partnering clinic or emergency department. Also, telepsych cannot replace all face-to-face encounters, especially if the patient is psychotic,” acknowledges Dr. Borja. “For example, patients who are paranoid think they’re being watched, and a monitor exacerbates that perception.”

He notes, “Before the patient comes in, we work with screeners for safety. If the patient becomes acutely suicidal, there has to be a social worker at the clinic who can write an emergency petition, because the police can’t deliver the petition across state lines.”

Another limitation of telepsychiatry can be the lack of eye contact. According to Dr. Borja, it decreases the range of nonverbal cues that psychiatrists can obtain, so a solid patient relationship is useful.

Further, the geriatric population can be less receptive to telemedicine than younger populations. “It takes a little longer for them to warm up and they can be a bit threatened by the technology, but with patience, it can work.”

Finally, having skilled IT staff on both ends is important, especially since the camera is not stationary.

Improving Care in the ICU

A very different model for telemedicine can be found in the ICU at Western Maryland Health System (WMHS) in Cumberland, Md. After considering a Maryland telemedicine provider three years ago, the hospital selected a national group, Advanced ICU Care, based in St. Louis. The company, which started in 2006 with two tele-ICU clients, today partners with over 65 hospitals and hospital systems using a staff of over 140 clinicians in five operations centers.

Gerald Goldstein, MD, an anesthesiologist and CMO for WMHS, explains what drove the system’s search for tele-ICU services. “To staff our 18-bed ICU with in-house intensivists dedicated
to critical care 24/7 would require the equivalent of 5.5 specialists. We’re a Level III trauma center, and the closest major hospitals with critical care services are 55 to 70 miles away. As the sole player for many miles, we have to have a vibrant ICU service.”

The hospital used to staff its ICU with four pulmonary/critical care physicians, but the wide fluctuation in census from peak flu months to slower summer months, and the pulmonologists’ other commitments, made that approach less attractive over time.

**As Good as On-Site Care**

WMHS has been pleased with the tele-ICU program, which launched in January 2016. “Advanced ICU (AICU), which is based in St. Louis, can provide continuous coverage of our ICU,” states Dr. Goldstein. “Our AICU team includes one intensivist, two advanced practice professionals and two critical care nurses. Using Philips technology, AICU remotely monitors vital signs, EKG rhythm strips, pulmonary artery or central venous catheters, and more.”

He continues, “They can also view the entire patient chart, including lab and progress notes, X-rays, cardiology studies, etc. It’s as good as them being on site, except that they can’t examine the patient. However, even that capability is on the horizon, with a remote stethoscope likely to be available within a year or so.”

For example, If the intensivist at AICU notices an increase in the patient’s respiration rate and/or a decrease in their oxygen saturation, they can immediately camera into the room. “The camera can zoom in on medication pumps, the ventilator and bed; it can even see the endotracheal tube depth,” exclaims Dr. Goldstein.

In the event of a problem, the intensivist alerts the staff that they’ve virtually ‘entered’ the room and can communicate with the patient, family and/or staff via the two-way monitor and speaker.

How has this changed ICU practice? Dr. Goldstein observes, “We have a better early warning system now because this group is continually checking the status of all patients in their care. They can zoom in on the room or use the ASCOM phones to call the nurse. And because our nurses can also call them for advice, their satisfaction has increased.”

He continues, “While our reason for using this approach was to provide our patients with best practices in the ICU, not saving money, selling the program wasn’t hard because we wanted a 24/7 solution. While our critical care doctors are present during day hours, AICU is always present.”

**Credentialing and Costs**

The tele-ICU intensivists are credentialed by the hospital, have active Maryland DEA licenses, and are licensed to practice in the state. The company is accredited by the Joint Commission and the Society of Critical Care Medicine.

While the service is ‘free’ to ICU patients, WMHS pays a per-admission fee to AICU that is the same regardless of the patient’s length of stay. Dr. Goldstein states, “That’s consistent with our goals to always place our patients in the most appropriate level of care. Their incentive to move patients to the most appropriate care setting is aligned with our philosophy of value-based care.”

“They provide statistics on blood sugar, time on a ventilator, sepsis treatment, blood product utilization and many other metrics,” says Dr. Goldstein. “After only one quarter of data, we’ve already seen a decrease in our ICU length of stay, which is consistent with national trends.” Advanced ICU claims that its hospitals save an average of $1 million, have a 34% reduction in mortality and a 28% decrease in ICU length of stay.

Other telehealth initiatives at WMHS include having an off-site cardiologist read echocardiograms for higher-acuity infants and launching a part-time telespsych service, as well as a program that provides patients with COPD, heart failure and diabetes telemedical devices in their homes. These are funded by a $100,000 grant from CareFirst Blue Cross Blue Shield.

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