# Volume 53 | Number 1 | Winter 2011 | www.opma.org **Ohio Podiatric Medical Association** Tournal

### OHIO PODIATRIC MEDICAL **ASSOCIATION**

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At right: Exchanging the OPMA Gavel at the HOD with the Oath of Office being administered by outgoing President Dr. Thomas Kunkel to 2011 OPMA President Dr. Alan J. Block.

**President's Message** 

### **Getting Your Dues Worth**

by Alan J. Block, DPM, MS



2011 OPMA President

WHAT DO I GET FOR MY DUES IN THE **OPMA/APMA?** If your only answer is a discount to seminars – or worse, you're really not sure – you probably need a refresher.

Three years ago I was privileged enough to go to the APMA

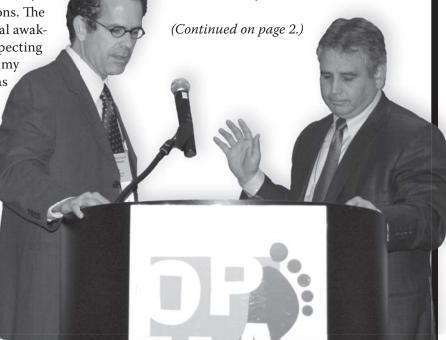
House of Delegates in Washington, D.C. with our OPMA contingent. Until this point, I was on the other end of the political spectrum. I was a speaker on the

educational side. I spoke, was wined and dined, and went to receptions. The APMA was a real awakening – even expecting me to purchase my own coffee! I was quickly awakened to the business of podiatry and what political action truly entailed. I left that meeting awakened to the political first time.

implications for This fight is not about podiatry...it's about money and politics.

We continue to face a 23.1 percent reduction of Medicare fees for services rendered by the end of 2011 if the SGR is not fixed. It has been projected that 46 percent of physicians would stop practicing medicine. More patients and fewer physicians is a certain recipe for disaster. The solution is to become proactive in a system that has always been reactive.

Let's break it down by the numbers. Number one on the agenda is Title XIX, the inclusion of podiatry in the Medicaid program. The implications of exclusion from the Medicaid program as optional service providers are enormous, with incredible financial ramifications to the state. A recent article in The Columbus Dispatch discusses that Medicaid covered one in three births in Ohio, 70 percent of children's hospital visits and 70 percent of nursing home care. Medicaid is 40 percent of Ohio's budget. This formula is repeated throughout the 50 states. In 2014, under the banner of na-



### **President's Message**

(Continued from page 1.)

tional health care, all people eligible will be covered under Medicaid. This will add an additional 32 million to the Medicaid roster.

The story of the coach's son is apropos here. Being the better athlete doesn't always equate to playing time. With diabetes increasing at a blinding speed, one in three people will be afflicted by 2050. Include a projection of diabetes costing \$334 billion dollars a year by 2034, podiatric physicians are no longer optional – we are indispensible. When podiatry can demonstrate its superiority, born out by the Thompson-Reuters study, in the treatment of the foot and ankle, then it becomes fiscally irresponsible and dangerous to exclude the very profession that has been identified as the best in class.

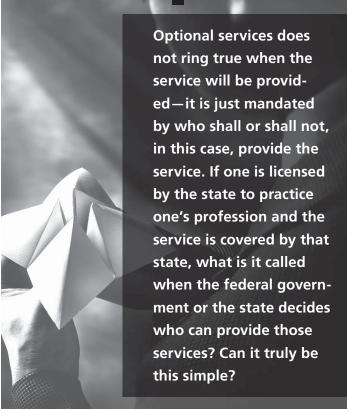
In yet another study by Health Services Research, lead author Frank Sloan, Ph.D., and colleagues at Duke University, they looked at six years of Medicare claims data on nearly 190,000 diabetic patients with foot problems. The study included approximately 118,000 patients diagnosed as stage one; about 32,000 in stage two; 31,000 in stage three; and 55,000 in stage four (some participants experienced more than one stage). People with diabetic foot problems can lower their risk of leg amputation by relying on a coordinated care approach that includes a podiatrist.

Also cited in the study, those with diabetes-related foot ulcers can reduce their risk of amputation by 31 percent.

Diabetes leads to poor circulation and damaged nerves, which make foot injuries more likely. When injuries occur, diabetes slows the healing process. That is why 30 percent of people with diabetes over age 40 have diabetes-related foot problems. If you have diabetes, your lifetime risk of developing a foot ulcer is 15 percent or more. About a quarter of diabetic foot ulcers refuse to heal and eventually require amputation. It stands to reason if the patient's issue is addressed in an efficient manner by an experienced professional as quickly as possible, the patient can be treated and cured at a great savings both economically and physically.

This arena is a political one. While frustration at the local podiatry level continues to boil on the political front, citizens are aware of the price of health care. With health care premiums that continue to rise, one is left to ponder how far the increases can go? Additionally, our aging population means more people with more health concerns. The result is that health care costs are the fastest growing part of the federal budget.

Optional services does not ring true when the service will be provided—it is just mandated by who shall or shall not, in this case, provide the service. If one is licensed by the state to prac-

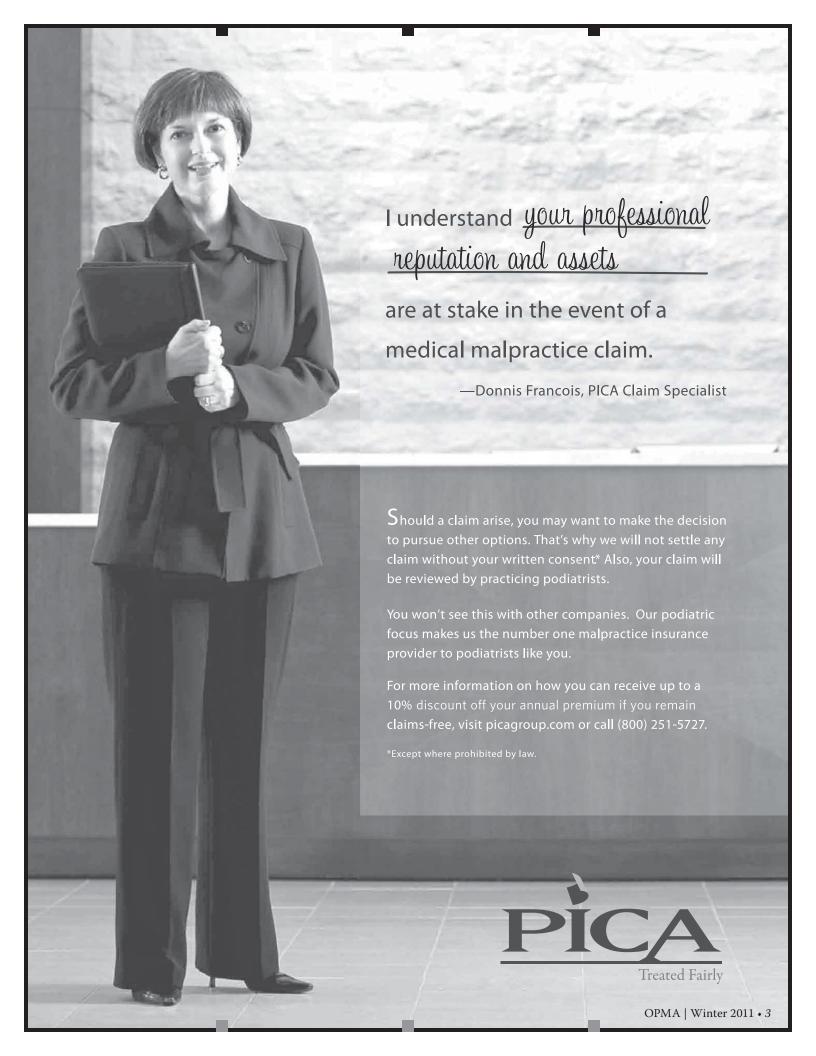


tice one's profession and the service is covered by that state, what is it called when the federal government or the state decides who can provide those services? Can it truly be this simple?

How can we help? First we must dispel the assumption that a podiatrist's expertise is a forgone conclusion. In fact, because a podiatrist's perspective includes a vast knowledge of the treatment of the lower extremities, podiatrists have a tendency to lose sight that the public is not aware of all our capabilities. Educating the public is key to our success. We must educate the public from classrooms to club meetings to grand rounds. Knowledge is power and education is our weapon. Our legislatures are misinformed when, on a political front, they believe we are paid up to \$50,000 to amputate a foot and/or a leg.

If we arm our legislators to the facts of studies, such as the Thompson-Reuter study, and if we explain in financial terms that better treatment means better quality of lives with fewer amputations at a substantial savings, we have made an ally. We will become allied not only with politicians but also with the public. With diabetes on the rise the need for our specialized services will zenith.

The OPMA/APMA is our voice. They answer to each and every one of us. Grassroots educational efforts will serve to strengthen our foundation on all levels. The opportunity for Title XIX is stronger than ever. A new legislative body with a health care agenda is the right set of circumstances to explain the impending diabetic epidemic and our role as podiatrists in staving that tide.



# From The Desk of the Executive Director A Passion for Podiatry

by Jimelle Rumberg, PhD, CAE

It's pleasant when you spend



time with acquaintances and get to know them on a more personal level.

When I serve a different president annually, sometimes the travel time affords an opportunity to learn about family and personal experiences that I wouldn't have known otherwise. On my last academy visit traveling with Dr. Kunkel, he made a comment about my passion and commitment to podiatry and that I wasn't even a podiatrist. Actually I had never thought about that fact, always being fiercely loyal to any association for which I've worked. But podiatry is different. I told him this story.

Whether you know it or not, your professional medical expertise touched my life forever when I was only seven years old. My paternal grandmother, who was a Type II diabetic, lost one leg due to diabetic ulcer complications in 1960.

I can remember this event vividly because my aunts and uncles wept openly about the fact that their mother was losing her leg. At the tender age of seven, I can remember

thinking how horrible that would be to lose a leg. She was a very loving grandmother of 24 grandchildren who had immigrated to America at age 15, became a U.S. citizen, and whose feminine dignity wasn't marred by losing a leg at 67 years old. I can remember climbing up in her hospital bed at her home, seeing her trapeze, and her showing me her above-the-knee amputation. She taught me to crochet while convalescing. You see, I had been totally disregarded by several of my maternal great aunts for being left-handed, but my Grandmother Farris, who raised 10 children, realized that she could teach me if I sat opposite of her and mirrored her stitches. I can still remember her sweet smile, her accent and her singing while we crocheted. Today, I realize how her strength and determination have played such an important role in my life. Sadly, after a few months, ulcerations appeared on the other leg and she was scheduled for surgery. She passed away on May 5, 1961 after suffering a massive coronary the evening before her admission to the hospital. At seven, I lost my mentor, my hero and someone who knew that my left handedness didn't matter.

My grandmother was a statistic. Rest assured, that when I go to the legislature, I relay her story in diabetes legislation testimony. My passion to save others and optional services for podiatry draws strength from my personal experience.

### DO YOU HAVE A PASSION FOR SERVING?

A passion for "*Optional* Services"? Not likely. You realize that life is **not** optional, dying to a treatable disease like diabetes is **not** optional and **cutting basic health benefits in Medicaid is NO option at all.** 

#### DID YOU KNOW . . .

- Over 3,000 lower extremity amputations are performed each year in Ohio.
- The direct cost of an amputation associated with a diabetic foot is estimated to be between \$30,000 and \$60,000.
- APMA found that the direct cost of major limb amputations are approximately \$70,400 per limb.
- Treatment for a foot ulceration cost approximately \$20,500.
- In 2007, more than one million adults in Ohio were estimated to have diabetes; 830,000 were diagnosed. In 2005, diabetes was the sixth leading cause of death in Ohio.

According to 2009 data, approximately 6.1 percent of those eligible for Medicaid have been diagnosed with diabetes. Of these, nearly 64 percent are women. Ohio's present and future diabetes statistics may include your family, neighbors, friends, or patients. Diabetic statistics don't discriminate. No one chooses to be a diabetic. Diabetes is not optional, and neither should be treatment choices.

#### CAN YOU SHARE THE MESSAGE . . .

In 2007, more than
one million Ohio adults
were estimated to have
diabetes.

Will you join me in advancing this mission when I call for action legislatively?

You can relay powerful messages of patients, service and care. I'll be asking for help soon and I hope that you are just as passionate for podiatry.



The OPMA *Journal* is published 4 times per year. The advertising dead-line is mid-month preceding publication

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Alan J. Block, DPM, MS

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#### EDITORIAL DISCLAIMER

The OPMA Journal is provided to Association members and Industry Affiliates of the profession as a part of our communications to inform/ update our members on podiatric issues and events. The contents of OPMA Journal are intended for general information purposes only and should not be read as specific legal, financial, or business advice regarding specific issues or factual events. We urge you consult your legal, financial, and professional advisors with any specific questions you may have.

# AROUND OHIO Ohio Podiatrist Named Director of Hospital Wound Care Center

Ara Kallibjian, director of Parma Community General Hospital's Division of Podiatry, has been named medical director of the hospital's Wound Center. The wound center was opened in 2009. It treats non-healing wounds and ulcers. Dr. Kallibjian, a podiatrist and graduate of the Ohio College of Podiatric Medicine, is board-certified in foot



Dr. Ara Kallibjian

and ankle surgery by the American Board of Podiatric Surgery. He specializes in wound treatment.

| Source: PM News. |

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### WHO WILL DO IT?

### **A True Tale**

nce upon a time, there were four podiatric physicians: Dr. Everybody, Dr. Somebody, Dr. Anybody and Dr. Nobody. They were involved, back in the day, in getting podiatric physicians H&P privileges as well as admitting privileges in Ohio's hospitals. Dr. Everybody was asked to contribute. Dr. Everybody was sure Dr. Somebody would do it. Dr. Anybody could have done it, but Dr. Nobody did. Dr. Somebody got angry because it was Dr. Everybody's job. Dr. **Everybody realized that Dr.** Anybody could do it, but Dr. Nobody realized that Dr. Everybody would

it. So, Dr. Everybody blamed Dr. Somebody, when Dr. Nobody did what Dr. Anybody could have done.

To ensure that the job does get done, please send your contribution today to OPPAC, a non-profit, non-politically aligned organization run for Ohio's doctors of podiatric medicine for the betterment of Ohio's DPMs.

Make personal checks to OPPAC and mail to: OPPAC, 1960 Bethel Road, Suite 140, Columbus, OH 43220-1815.

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May we suggest a monthly
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the Association that
made podistrists' hospital
privileges in Ohio what
they are today. OPPAC is
waiting to hear from you!

#### **MEMBER NEWS UPDATES**

### **House of Delegates**

THE 2010 HOUSE OF DEL-EGATES met on December 4, 2010 at Embassy Suites in Dublin.

### **CAC Report**

Cigna Medicare transition date is June 18, 2011. No other information is available at this time. Watch cignamedicare.com web site for updates. PQRI payments have gone out.

ICD10 will be implemented October 2013. ICD9 codes 13,000 codes. ICD10 codes 70,000 codes.

The next CAC meeting is April 12, 2011.

Submitted by
Paul Lieberman DPM
CAC representative
OPMA Trustee



The 2011 APMA HOD Delegation (left to right): Dr. Angelo Petrolla; Dr. Paul Lieberman, Chairman of the Delegation; Dr. Mark Gould; Dr. Bruce Saferin, Alternate; Dr. Alan Block, Alternate; Dr. Kevin Schroeder; Dr. Thomas Kunkel; and Dr. Bruce Blank.



The 2011 Executive Committee: Dr. Marc Greenberg, Second Vice President; Dr. Angelo Petrolla, Secretary-Treasurer; Dr. Alan J. Block, President; Dr. David Hintz, First Vice President; and Dr. Thomas Kunkel, Immediate Past President.

do

## Congratulations to the 2011—25 Year Members

Gregory A. Black, DPM
Michael D. Cardinal, DPM
Diana G. Karnavas, DPM
M. Elaine Krosse, DPM
Lee Pearlman, DPM
John M. Rootring, DPM
David F. Schwein, DPM
Brad R. Wenstrup, DPM
Peter A. Wiggin, DPM

### Welcome New Members — 2010 – 2011 Fiscal Year

Dr. Said Atway	Αź
Dr. David Baer	A(
Dr. Darrell BallingerR	13
Dr. Michael F. BowenR	13
Dr. Michael Boyer	A(
Dr. Jessica Brent	ΑŹ
Dr. Elizabeth Ann Brown R	13
Dr. Keith Robert Crandall R	13
Dr. Nicole Lynn CuppR	13
Dr. Brian Thomas Damitz R	13
Dr. Maninder Deswal R	12
Dr. Michelle Dunbar	Α:

Dr. Carli J. EidelR13
Dr. Ryan S. Ellsworth R13
Dr. Samuel FeinbergA1
Dr. Stephen Frania AC
Dr. Brian Larry Freeman R13
Dr. Jamie LeAnn HallR13
Dr. Bryan James HallR13
Dr. Samantha Yvonne Harris. R13
Dr. Julian McNees Lambert R13
Dr. Ryan LawrenceR33
Dr. Scott LittrellA1
Dr. Angie MedureR13
Dr. Sonya Michelle Morse R13
Dr. Amy Elizabeth Mosowick R13
Dr. Adam Myers AC

Dr. Tiffany Orlando-WeberFC Dr. Mathew Painting	Dr. Sarah Beth Newey R13
Dr. John David PetersonR13 Dr. Mark Elliott PetreR13 Dr. Alexis Nicole PrebihiloR13 Dr. Jacquelyn QuercioliA1 Dr. Roodabeh SamimiA1 Dr. Jessica M. SciulliR13 Dr. Kimberly SmithA1 Dr. Steven SzamesAC	Dr. Tiffany Orlando-Weber FC
Dr. Mark Elliott Petre	Dr. Mathew PaintingA1
Dr. Alexis Nicole PrebihiloR13 Dr. Jacquelyn QuercioliA1 Dr. Roodabeh SamimiA1 Dr. Jessica M. SciulliR13 Dr. Kimberly SmithA1 Dr. Steven SzamesAC	Dr. John David Peterson R13
Dr. Jacquelyn QuercioliA1 Dr. Roodabeh SamimiA1 Dr. Jessica M. SciulliR13 Dr. Kimberly SmithA1 Dr. Steven SzamesAC	Dr. Mark Elliott PetreR13
Dr. Roodabeh Samimi	Dr. Alexis Nicole Prebihilo R13
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Dr. Kimberly SmithA1 Dr. Steven SzamesAC	Dr. Roodabeh SamimiA1
Dr. Steven Szames AC	Dr. Jessica M. SciulliR13
	Dr. Kimberly SmithA1
Dr. Mathew Testrake R33	Dr. Steven Szames AC
DI. WIGHTON TCSHARE	Dr. Mathew TestrakeR33
Dr. Corey E. ValentineR13	Dr. Corey E. Valentine R13
Dr. Kulo Wiro A1	Dr. Kyle WireA1
	DI. Nyle WileAl



The 2011 OPMA Board of Trustee (front row, left to right): Dr. Marc Greenberg, Dr. Angelo Petrolla, Dr. Alan Block, Dr. David Hintz, Dr. Thomas Kunkel. Back row (left to right): Dr. Jack Buchan, Dr. Karen Kellogg, Dr. Bruce Saferin, Dr. Brian Ash, Dr. Sam Feinberg, Dr. Paul Lieberman, Dr. Mark Gould, Dr. Kevin Schroeder, and Dr. Peter Wiggin.

#### Above right:

The OPPAC Cornhole Champions for 2010— Dr. Thomas Kunkel (at left) and Dr. Paul Lieberman.

#### Below right:

Dr. Thomas Kunkel receiving the Thomas J. Myer Award from Dr. Alan Block.



### coding News

### 2011 Changes to the CPT Debridement Codes

by Paul Kinberg, DPM APMA Chair, Coding Committee

If anything is consistent in medicine, it's change. And there are plenty of changes coming for the new year. In 2011, the debridement codes in Current Physician Terminology are changing. Please note, while there are other changes, this article pertains to debridement codes.

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#### **Codes Out and In**

Codes 11040 and 11041 will be deleted as of January 1, 2011. **11040** (Debridement; skin, partial thickness) had a non-facility relative value unit (RVU) of 1.19; **11041** (Debridement; skin, full thickness) had a non-facility RVU of 1.36.

Why am I telling you about the RVUs? You will see if you keep reading.

The two deleted codes (11040 and 11041) will be cross referenced to the active wound-care codes 97597 and 97598:

• Code 97597 (Removal of devitalized tissue from wound(s), selective debridement, without anesthesia (e.g., high pressure waterjet with/without suction, sharp selective debridement with scissors, scalpel and forceps), with or without topical application(s), wound assessment, and instruction(s) for ongoing care,

may in-

clude use

of a

whirlpool, per session; total wound(s) surface area less than or equal to 20 square centimeters) and

• Code 97598 (greater than 20 square centimeters).

Code 97597 has a non-facility RVU of 1.71 and 97598 a non-facility RVU of 2.12. You will not be losing anything by use of these codes. This means that effective January 1, 2011, for any wound debridement that does not include the subcutaneous tissue you would either bill 97597 or 97598.

#### There's More...

There are other changes found in the debridement code section. The verbiage for the remaining debridement codes will now be based on size:

- **CPT 11042** (Debridement, subcutaneous tissue (includes epidermis and dermis, if performed) *first 20 square centimeters or less*);
- **CPT 11043** (Debridement, muscle and/or fascia (includes epidermis, dermis, and subcutaneous tissue, if performed) *first*20 square

centimeters or less); and

• **CPT 11044** (Debridement, bone (includes epidermis, dermis, subcutaneous tissue, muscle and/or fascia, if performed) – *first 20 square centimeters or less*).

### Out-Of-Sequence Codes

There are new CPT debridement codes for "each additional 20 square centimeters, or part thereof" that will be list separately in addition to code for primary procedure and that will appear "out-of-sequence." These new codes will immediately follow the primary code and will be used in conjunction with that code. Out-of-sequence codes are nothing new for CPT. It may take a little to get use to using these codes based on wound size with the addon codes.

- **CPT 11045** (each *additional* 20 square centimeters, or part thereof) should be listed separately *in addition to code* **11042**.
- **CPT 11046** (each *additional* 20 square centimeters, or part thereof) is to be used *in addition to* **11043**; and
  - CPT 11047 (each

additional 20 square centimeters, or part thereof) will be used in addition to 11044.

These add-on codes can be used multiple times based on the overall size of the wound.

As with the other CPT add-on active wound code, these new codes will be based on the overall size of all wounds combined, not on each individual wound. It means now, more than ever, measurements of wounds will a mandatory part of any wound documentation.

### **Some Measured Tips**

Caution will need to be exercised when combining wounds based on depth. If the debridement is being performed at different depths, then different codes specifying those depths should be used. Remember to code to the depth of the debridement, not to the depth of the wound. It also means that the active wound care codes will be used for any type of debridement performed on partial and full thickness wounds and should not be combined with these debridement codes to determine an overall size.

Once these codes are put in place, each of the Medicare Administrative Car-

riers (MACs) will probably change their Local Coverage Determination (LCD) on Wound Care accordingly. However, if your LCD has limits on the overall use of the higher level debridement codes, those may not change. If your MAC previously prohibited use of the active wound care codes, then you should expect that to change. That change may not occur on January 1, 2011. You should watch Palmetto's announcements to see how Ohio will deal with these code changes.

### Learn More: 2011 Coding Seminar and EHR Exchange

The APMA Coding Resource Center (CRC) will have these new codes and their verbiage uploaded and updated in January. The new RVUs for both facility and non-facility usage will be available and can be found on the CRC.

To learn more about other new, changed and deleted codes, plan to attend the APMA 2011 Coding Seminar and EHR Exchange on February 25 in Columbus. This event, sponsored by OPMA, will have 6 CMEs of Cat II credit.

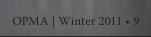
Details and registration brochure is at www.opma. org.

### A Consolidated Billing Caveat

One last important point: The active wound care CPT codes (97597 and 97598) fall under the section entitled, "Physical Medicine and Rehabilitation." All the codes in this section are subject to the consolidated billing (CB) requirements when furnished to a patient who is in a skilled nursing facility (SNF) resident regardless of where the service is provided. What this means is that these services are "bundled" into the Medicare Part A payment to the nursing facility if these services are provided,

for example, either in the SNF or your office setting. In order to get any type of payment for these services, you must look to the SNF for payment for these services. That means physicians will need to enter into an "arrangement" with that SNF to get payment when providing these active wound care services.

The debridement codes
(11042 – 11047) do not fall,
nor have they ever fallen,
under the CB rules of Medicare. Those codes
continue to
be billed to
Medicare
Part B.





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## MAKING STRIDES Baby Steps

### SGR Cuts Delayed until 2012

On December 15, President Obama signed the Medicare and Medicaid Extenders Act of 2010 (PDF) that delays, for one year, a 25 percent reduction in Medicare payments to physicians. The cut would have gone into effect Jan. 1, 2011.

The cost of delaying the SGR payment cut and extending the current rates for 12 months is estimated at \$14.9 billion. This expense will be paid for over a 10-year period by raising caps on how much individuals and families must return if they receive overpayments from health care affordability tax credits.

### 2011 Coding Updates Reminder from Palmetto

The 2011 Coding Update contains a wealth of information. This publication includes information on 2011 additions, deletions and changes for HCPCS, CDT and CPT codes and modifiers, proper use of modifiers and more.

http://www.palmettogba.com/palmetto/providers.nsf/ls/LMP3475?opendocument

#### REMINDER

### **Group Rating Enrollment Qualifying Businesses Should Respond Quickly**

Savings quotes and enrollment packets for CareWorks Consultants, Inc (CCI) Workers' Compensation Group Rating Program have been sent to newly qualifying applicants. Qualifying companies should return the forms immediately to CareWorks Consultants to ensure enrollment in our 2011-2012 group rating program. Our deadline for receipt of enrollment forms is February 23, 2011.

Companies currently enrolled in a Care-Works Consultants Group Rating Program do not have to re-apply and will not receive an enrollment packet. Renewal for the 2011-2012 group rating year is automatic as long as your company continues to meet the re-enrollment criteria.

If your company has not requested a nocost, no-obligation quote for the 2011-2012 group plan year, please contact CareWorks Consultants today at 1-800-837-3200 or apply on-line at www.careworks consultants.com/group ratingapplication.

The deadline to make a decision will approach quickly! Don't be left wondering what to do about your workers' compensation future! Call CareWorks Consultants at 1-800-837-3200 to discuss your potential savings and if they can match what you currently pay. We hope you choose CCI as your partner. We have a record of not only savings, but incredible service!

### CMS Wants Input on EHR User Registry

The CMS is taking public comments on a proposal to set up a registry of meaningful users of electronic health-record systems under the American Recovery and Reinvestment Act.

To be formally called the Medicare and Medicaid Electronic Health Record Incentive Program National Level Repository, the listing will include the names of participating physicians, other eligible providers, hospitals, critical-access facilities and Medicare Advantage organizations, as well as their National Provider Identifiers, business addresses, phone numbers, taxpayer identification numbers, CMS certification numbers and other information as specified by the CMS, according to a notice published in the Federal Register.

### Medicare Payments Reduced by One Percent in 2012

Eligible providers who do not successfully submit at least 10 unique e-prescriptions (eRx) during the first six months of 2011 may be subject to a one-percent penalty in their Medicare payments for 2012.

Reminder: Attend the 2011 APMA Coding Seminar and EHR Exchange in Columbus on February 25 to learn more about eRx and other EHR information. Registration details are online at www.opma.org.

### Prescription for Prevention Website Goes Live

The Ohio Department of Health has launched http:// www.healthyohioprogram. org/diseaseprevention/ dpoison/p4p.aspx as part of a comprehensive education and awareness campaign known as "Prescription for Prevention: Stop the Epidemic," to combat the epidemic of prescription drug overdose and abuse. The new site provides related statistics, 30 second public service announcements for television and radio, fact sheets on the epidemic, and other useful links and resources.

### Risks of Off-label Use and Promotion

The Food and Drug Administration (FDA) recognizes that a physician may use an FDA-approved drug or

device for any use the physician believes is medically appropriate, be aware that there are prohibitions and risks surrounding off-label uses and promotions.

The Food, Drug, and Cosmetic Act (FDCA) contains an explicit provision (known as the practice of medicine exception) that allows physicians to "prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitionerpatient relationship," however, the provision explicitly provides that the exception "shall not change any existing prohibition on the promotion of unapproved uses of legally marketed devices." Physician advertising is regulated by the FDA, Federal Trade Commission (FTC), and states. Advertising of off-label uses of a drug or device is prohibited, may be misleading and is potentially punishable under law.

In addition, while offlabel use may be common and, in some cases, may be the standard of care. it could be used against a physician in a malpractice case. A Tennessee Court of Appeals noted that "[s] everal jurisdictions, believing drug manufacturers to be uniquely knowledgeable about the proper use of their products, have held that a drug's labeling or its parallel PDR reference amounts to prima facie evidence of the standard of care as far as the use of that drug is concerned."

However, the court also noted that "a majority of

jurisdictions have determined that a prescription drug's labeling or parallel PDR reference is admissible to prove the standard of care, but only if the plaintiff also introduces other expert testimony regarding the standard of care."

Another issue is whether physicians must notify their patients that their prescribed treatment is offlabel. Informed consent is generally regulated by the states. While there is some disagreement about whether physicians should inform patients that a prescribed treatment or drug is offlabel, state laws generally limit the physician's duty to providing medical information However, the success of any action based on informed consent for failure to disclose that a treatment is off label will depend on the language of the relevant state law. Physicians may wish to disclose that a treatment is off-label as an extra measure of liability protec-

PICA has published an article on off-label use of medications and devices, so know that you get what you pay for by malpractice liability carriers. Members not insured by PICA should check with their malpractice carrier for any opinions on off-label use. As always, this information does not represent a legal opinion and APMA recommends that you seek the opinion of a health care attorney before making decisions that impact your practice.

| Source: APMA eNews 3,042 |



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