THE PROMISE AND PITFALLS OF BIOSIMILARS

Dermatologists laud potential cost savings, urge measures to protect patients

14 Quality Measures
26 Employee Appearance
30 Sunshine Act
36 Academy News
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I always look forward to June — that month when the days become their longest.

It may be my penchant to want to cram too much into each and every day that makes this so appealing. So nice to see the daylight when leaving the office after a late-running clinic. Walks after dinner become possible even on the country roads near my home. And then there are the countless weddings that always seem to be plentiful during this month. Don’t know about in your world, but there’s been a rash of diamond rings flashing amongst those I know. Diamonds clearly are thought of by many as the most perfect stone.

How about the biologics? Are the versions that we have the most perfect? To some of my patients, these medications have been life-changing. The coming of the biosimilars is going to rock the pharmaceutical world — the potential for equal efficacy at a lower cost would certainly be a big help to patients. So the question becomes, will the biosimilars offer patients a similar therapeutic outcome? How thoroughly will they be tested to ensure safety to our patients? How effective will they be? Will they behave like real diamonds, or will they be more like cubic zirconia? I know that you’ll want to read our piece on these upcoming medications. The future is practically here.

New regulations are hitting us from all sides of late; just take a look at our piece on the new Sunshine Act rules. Transparency will reign in medicine with this new legislation in place. As our colleague Stephen Webster says, the importance of ethical standards in medicine is not a new concept. It was first written about by Thomas Percival in 1803. Perfect this legislation is not, and the fear is that it will be easy for the public to misunderstand this information. But perfect or not, it is here. Our patients will be able to learn about our potential conflicts if they choose to check. With potential penalties of up to one million dollars, you need to be aware of this regulation.

I also want to call your attention to our piece on the details of the revised HIPAA regulations. So many new rules have come down the pike in the past few years, and so it is hard to believe that we are already seeing revised versions. However, the new rules have been issued, and it is imperative that we all be savvy about complying.

Two of our other columns deal with the types of vexing issues we all wrangle with in our practices: when to use the 25 modifier and what to do to prevent the dreaded call that there was no biopsy specimen in the bottle when it reached the path lab. Both pieces get down to specifics on how to handle these situations. In both cases there are several good suggestions to implement. I trust that you’ll agree.

Hope that your summer is beginning uneventfully. I’ll have a few days of R and R to visit with my family and take in the sparkling sea. Hope that your schedule includes something equally lovely.

Enjoy your reading.

ABBY S. VAN VOORHEES, MD, PHYSICIAN EDITOR
“If biosimilars give us safe and effective treatment in the same way that biologics are working today, we want to see them on the market in a way that patients can afford them.”

COVER STORY
THE PROMISE AND PITFALLS OF BIOSIMILARS
Dermatologists laud potential cost savings, urge measures to protect patients
BY JAN BOWERS

LOOKING THE PART
Setting the standard for the face of your practice
BY JOHN CARRUTHERS

DOLLARS OR DONUTS?
Sunshine Act requirements bring new scrutiny to physicians’ relationships with pharmaceutical companies
BY RUTH CAROL

depts

FROM THE EDITOR

CRACKING THE CODE
To 25 or not? Part one.

ROUNDS
Tanning bed rules, more.

ACTA ERUDITORUM
Skin-shedding mouse offers potential wound-healing insights.

LEGALLY SPEAKING
Dealing with a lost tissue specimen.

TECHNICALLY SPEAKING
Reporting quality measures related to HIT and EHR use

IN PRACTICE
HIPAA: Change is coming.

FROM THE PRESIDENT

ACADEMY UPDATE
Shade Structure Program grant winners chosen, more.

ACCOLADES

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To 25 or not? Part one

An established patient comes in complaining of a steadily enlarging, friable papulonodule on the nose. You obtain a history pertaining to the growth, query the patient concerning previous sun exposure, examine and palpate the lesion, discuss your presumptive diagnosis of a basal cell carcinoma, recommend a biopsy, obtain informed consent, do the biopsy, and instruct the patient on aftercare. You did a significant amount of evaluation and management (E/M) service. In addition to the 11100 biopsy charge, is it appropriate to additionally bill for a 99212 or 99213 established patient visit with an appended 25 modifier?

The CPT tackles the identification of a separate E/M service delivered on the day of a procedure by providing a 25 modifier to be appended to the appropriate E/M code. The modifier is defined by the CPT as: “Significant, Separately Identifiable Evaluation and Management Service by the Same Physician or Other Qualified Health Care Professional on the Same Day of the Procedure or Other Service.” It is appropriate to use the modifier to distinguish billing for E/M services beyond those included in the valuation of minor surgical procedures.

There are several questions to answer in deciding whether a 25 modifier is appropriate to the service provided. These are delineated below and will be explained individually.

- What is the insurer’s payment policy regarding modifier 25?
- Is the patient a new or established patient?
- Was a minor surgical procedure (one with a zero- or 10-day global surgical package) done?
- Was an E/M service done that is beyond that included in the procedure code valuation?
- Did you appropriately document the separate E/M service?

Medicare contractors recognize and pay in full for services appropriately billed with a 25 modifier. However, some private insurance carriers do not follow CPT guidelines or may have specific billing or reimbursement peculiarities that you must recognize in order to be reimbursed fairly. Specifically, some insurers insist upon paper billing with supporting chart documentation to be submitted when billing with a 25 modifier. Others may require that a 25 modifier be appended to new patient visits. There have also been attempts at reducing the reimbursement for a procedure when an E/M service is concomitantly billed. It is therefore imperative that you or a reliable designee review individual insurers’ policies and procedures dealing with modifiers to determine how billing should be done and whether you are likely to be paid for E/M services with 25 modifier use. Additionally, careful tracking of the insurer’s payment explanations of benefits may uncover sudden shifts in 25 reimbursement patterns.

Medicare policy specifies that a 25 modifier should not be appended to new patient visits, as these codes are excluded from restrictions based on the global surgical package. In such instances, when billing Medicare, bill the procedure code and an appropriate new patient visit code (99201-99205) without any modifier. (Dermatologists who use them should be aware that infusion and injection (96401-96477) and photodynamic therapy (96567) codes are not surgical codes, and a 25 modifier is needed when billing a new patient visit along with these codes.) As mentioned, some private insurers may have different policies.

A significant E/M service may qualify for billing with an E/M code along with a 25 modifier only when a minor surgical procedure with a zero- or 10-day global period is done on the same day. One must therefore know the global surgical periods for surgical series codes. The chart below summarizes the dermatology-pertinent global periods.

<table>
<thead>
<tr>
<th>GLOBAL PERIOD</th>
<th>PROCEDURE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Zero days</td>
<td>Skin biopsy (11100), shaving of epidermal/dermal lesions (11300-11313), Mohs</td>
</tr>
<tr>
<td>10 days</td>
<td>Dermatology-specific surgical codes except those above and below</td>
</tr>
<tr>
<td>90 days</td>
<td>Flaps (adjacent tissue rearrangement) and grafts</td>
</tr>
</tbody>
</table>

A detailed listing of global surgical periods for all surgical codes may be accessed on the CMS website at www.cms.gov/apps/
Once on the above Web page you must select appropriate search criteria:

- Under Type of Information, click on Payment Policy Indicators.
- Under Select HCPS Criteria, select a single, a list, or a range of codes.
- Under Policy Indicators, type in the single, multiple, or range of CPT codes.
- Under Modifier, select Global OR Physicians Professional Service.
- Submit your request and you will see a listing of codes, their short descriptions, and the global periods.

The global periods are most commonly listed as: 000, 010, 090, or ZZZ. ZZZ refers to an add-on code (such as additional biopsy, 11101). The primary service code (in this case, 11100) will have the global period numerically specified. Keep in mind that some individual payers may not follow the Medicare global periods guidelines and/or may specify different global periods.

Next, you must determine whether a significant service beyond that included in the procedure valuation has been done. Both minor and major surgical procedures contain a component of cognitive, evaluation and management services. The exact amount of E/M service incorporated in a surgical code varies by code. In general, a surgical code valuation includes at least the following components:

- An assessment of the lesion or problem area.
- An explanation of the procedure.
- Informed consent.
- Postoperative care instructions.

Lastly, if a service is not adequately documented, then there is no proof that it has actually been done. Lack of adequate chart documentation is a major reason for payment denials following chart audits.

Keep in mind that although dermatologists are recognized as the highest legitimate billers of E/M visits along with surgical procedures, routine, indiscriminate use of the 25 modifier will cast you as a statistical outlier. That is the surest way to an audit.

In Part 2 of “To 25 or Not?” next month, I will discuss specific tactics and scenarios for determining appropriate uses of the 25 modifier. dw
FDA proposes stricter regulations on indoor tanning devices

STRONGLY RECOMMENDS MINORS AVOID TANNING BEDS

The U.S. Food and Drug Administration (FDA) proposed stricter regulation of tanning devices and issued a strong recommendation against the use of tanning beds by minors under the age of 18 on May 6, Melanoma Monday®. The American Academy of Dermatology Association (AADA) announced that it supports the reclassification of indoor tanning devices and placing additional restrictions on indoor tanning, and is pleased that the FDA has taken this important first step.

The FDA announced that it is proposing to raise the classification for sunlamps and tanning beds from Class I, the category for items that have minimal potential to cause harm to individuals, such as adhesive bandages and tongue depressors, to Class II, which would institute stricter regulations to protect public health. The proposed change follows an Advisory Panel hearing convened by the FDA in 2010 to examine the current classification and regulations of tanning beds. Representatives from the AADA, leading dermatologists, and researchers testified before the panel highlighting the risks associated with indoor tanning and the need to protect the public from these dangers.

Comments on the proposed rule are due to the FDA on Aug. 7, after which the FDA will review all submissions and issue a final rule. The AADA will provide comments in support of the proposed regulations prior to the deadline, and will continue to communicate to the FDA the need for stricter regulations on the use and sale of indoor tanning devices.

More information, including how the FDA’s proposed order would affect the labeling requirements on tanning beds if it is implemented, is available at www.aad.org/members/aada-advocacy/regulatory-affairs/drugs-and-devices/drugs-and-devices.

– AMANDA GRIMM

Reporting to avoid value-based payment modifier begins in 2013

Penalty assessed in 2015 for groups of 100 or more

Physicians in groups of 100 or more eligible professionals (EPS) who submit claims to Medicare under a single tax identification number will be subject to the value-based payment modifier in 2015, based on their performance in 2013. These groups will need to self-nominate (from July through mid-October 2013) and choose one of three group reporting methods through the Physician Quality Reporting System (PQRS): the Web-interface group reporting option, a registry, or requesting that CMS calculate the group’s performance on quality measures from administrative claims. Doing so will allow groups to avoid a negative 1 percent value modifier adjustment to 2015 payment under the physician fee schedule.

If physicians within a medical practice group need or prefer to participate in PQRS as individuals, such as through the AAD’s PQRS registry for reporting the dermatology measures, the group would still need an authorized group representative to commit the group, as a whole (via a CMS-hosted registration process), to having CMS calculate a quality score from administrative (claims-based) quality measures. It is important to note that this administrative claims reporting requirement is only necessary if a physician in a group practice of 100 or more EPS still wants to report quality measures as an individual for the PQRS payment incentive in 2013. All physicians who submit claims to Medicare will be subject to the value-based payment modifier by 2017.

– ALISON SHIPPY
Dermatologists focus on truth in advertising

STATE NEWS ROUNDUP

AS THE PRACTICE OF MEDICINE EXPANDS to include more non-physician clinicians, members of the American Academy of Dermatology Association (AADA) and their state dermatology societies are pushing for more effective truth in advertising legislation. The Academy has strongly supported this type of legislation to protect patients against misleading advertising and to make it easy to identify a practice or hospital employee’s education, qualifications, and licensure at a glance. The AADA position statement on the matter reads, in part, “America’s patients deserve to know the licensure and qualifications of their health care providers. The AADA believes those who regulate and deliver medical care have an obligation to inform the public of the qualifications and limitations of their care prior to beginning treatment.”

Legislation related to truth in advertising is active in a number of states (see the map above); the bills address the issue in a variety of ways:

- In Florida, SB 612 would prohibit medical professionals who do not hold an MD or a DO degree from using either “doctor” or “Dr.” as a title in medical settings.
- Nevada SB 211 would require that all advertisements for health services also include the type of professional license and applicable board certification that the advertised professional holds. Further, all health care professionals would be required to wear a name tag that identifies their license type during patient encounters.
- In Arizona, dermatologists opposed SB 1045, a truth in advertising bill that did not set a definition for the term “board-certified.” Had the bill been enacted, it would have allowed physicians to advertise as “board-certified” with certification from any organization offering its endorsement, not solely the American Board of Medical Specialties or the American Osteopathic Association. The AADA did not support the bill, rather requesting that the bill be amended with language rectifying the problem that had been created in conjunction with the AMA and with other specialty societies. The bill eventually failed to advance.

To review the details of legislation in the other highlighted states on the map above, visit www.aad.org/members/aada-advocacy/state-affairs/pending-state-legislation. For more information on becoming involved, visit the AADA’s Truth in Advertising Advocacy Toolkit, at www.aad.org/members/aada-advocacy/state-affairs/advocacy-toolkit/truth-in-advertising. - JOHN CARRUTHERS
Q&A

DR. VAN VOORHEES: Let’s start by defining autotomy. Since most of us are far from our biology days, please remind us what it means. In what part of the body is it generally seen? Which animals have been known to demonstrate this ability?

DR. SEIFERT: Autotomy is the self-inflicted or externally induced loss of an appendage without death or drastic decline in fitness. Basically it means if an animal is attacked it can release a body part, usually an appendage. This is usually a self-defense mechanism to avoid predation. The classic example would be something like a gecko, which can autotomize its tail in response to a predator attacking — if a bird or rodent tries to grab hold of the gecko by the tail, the gecko’s tail will break off. The gecko moves in one direction, the tail is left wriggling, and that distracts the predator, allowing the gecko to escape. Autotomy in vertebrates is usually associated with geckos and skinks. It’s also seen in some invertebrates, including crustaceans like lobsters and crabs that lose their claws, and in other vertebrates, including several species of lizards and salamanders as well as several species of rodents that can autotomize their tails and, as we show in our paper, sometimes even their skin.

DR. VAN VOORHEES: What is the difference between “true autotomy” and “false autotomy”?

DR. SEIFERT: Autotomy is quite rare in rodents; it’s been documented in 34 species. Of those documented cases in mammals, you see two versions, true and false autotomy. In one case, an animal will grab on to the tail and the entire tail sheath will slide off the tail and leave behind the vertebrae and connective tissue associated with it; later on the animal usually chews off the tail. That’s referred to as false autotomy because the tail itself isn’t breaking at some sort of break plane. True autotomy refers to those few rodent species where when something grabs the tail or bites it, it actually breaks along pre-defined break plans in between the vertebrae.
DR. VAN VOORHEES: What prompted you to look at these two species of African spiny mice?

DR. SEIFERT: There are really two reasons. Firstly, when I began my post-doctoral work in regeneration I was working with species of salamanders that are well-known for their powers of limb regeneration and I had just become interested in skin and wound repair. So I started developing a model in the axolotl [a Mexican salamander] for full-thickness excisional wounds. Right after I began that work, I had the opportunity to accompany my wife, who is an ecologist, to Kenya for her field work, and before we left one of her colleagues who knew I was interested in regeneration told me about these species of rodents over there that, when mammalogists trapped them, released portions of their skin or shed it, as they described it to me. I laughed when I heard that because it sounded like a terrible adaptation for a mammal in Africa to lose part of its skin — a behavior like that could result in all sorts of problems: infection, water loss, blood loss, etc.

I figured I would spend some time trying to trap these animals and first document whether or not they tore their skin easily or lost pieces of it. And that’s exactly what I experienced trapping some of these spiny mice in the wild; they’re very difficult to handle, especially when they’re stressed, and I saw everything from small tears to very large tears — in our paper we show an animal that lost 50 percent of its back skin. Once I figured out that it was actually happening, I thought it would make an interesting project to investigate how they repaired these kind of injuries. You might predict an animal with this kind of adaptation to have some compensation with respect to its ability to heal wounds.

DR. VAN VOORHEES: Tell us about your study. What were you able to document about these mice?

DR. SEIFERT: First, from a behavioral standpoint we were able to document that the mice have skin that readily tears and that this can cause pieces to come completely off their bodies, either when captured and they’re stressed or from holding them together in a cage if they fight. And those are usually deep wounds, full thickness; the skin may be removed or there may be just a little tear which will then heal. Secondly, we made some mechanical measurements and what we found is that their skin is incredibly weak so it tears under very low amounts of tension. That was a way for us to mechanistically show, compared to lab mouse skin, how much weaker it was. We found that it took 70 times more energy to break a piece of lab mouse skin compared to the skin of these animals.

DR. VAN VOORHEES: In addition to the mechanical properties, were you able to identify structural properties in the mouse skin that allowed for this tearing?

DR. SEIFERT: We compared the histological and cellular structure of their skin to lab mouse skin. We found that it was pretty similar in terms of the basic organization of the skin. But the percentage of the dermis that was occupied by adnexa, which are the hair follicles and glands, was greater in the spiny mice, mainly because they have these large spiny hairs. We hypothesized that this might have something to do with the structural weakness. We also found that their skin was rather oily; we’re not sure exactly how, or if, this contributes to healing, but it seems to be associated with weaker skin in other rodents.

DR. VAN VOORHEES: Once injured, what allows these tears to heal? Is it a form of regeneration or fibrosis? Does wound contracture play a role? Do these wounds heal quickly? What proof were you able to identify for this process?

DR. SEIFERT: On the healing and regeneration front, we found that when we made large circular wounds on their backs, 1.5 cm in diameter, first they would contract those wounds to a very high degree, which is common in loose-skinned mammals, so about 95 percent of the original wound area would contract. But then in the center of that wound we found that they were capable of regenerating hair follicles, all throughout the wound area, and when we looked at the dermis during repair it looked as if the fibrotic response was muted. We observed production of collagen 3 and a much slower onset of collagen type 1 production, which is sort of the opposite of what you see in a normal scarring wound where you see aggressive production of type 1 collagen that’s deposited along with collagen 3. Lastly, building on some work that was done in the ’50s, we turned to the ear, where contraction doesn’t occur, and made 4 mm hole punches through their ears. That was extremely exciting because we found that when we removed contraction from the equation, they were able to regenerate almost all of the missing tissue, which includes not only the skin and hair follicles, but also the cartilage which runs down the center.

DR. VAN VOORHEES: So you’re saying that there’s a component of both regeneration and of more traditional fibrosis and contraction occurring in most places on these mice, maybe in different percentages in different locations?
DR. SEIFERT: Yes, and that hair follicles, glands, and cartilage are regenerating. From a clinical perspective those are some of the most exciting aspects of the finding. I think the general assumption is that to regenerate these structures you have to go about employing different, unique molecular pathways or that the process might be completely different in some way. Of course, that may very well be true in some situations. However, what we’ve showed is that all the same wound repair processes are occurring — inflammation, fibrosis, contraction, etc., but either the timing or the relative composition of what’s being produced differs. And when fibrosis is controlled in some way it’s almost as if you liberate a regenerative capacity that’s already there, it just isn’t occurring because the fibrotic response is so strong that scarring ablates any structure that was there and prevents its regeneration.

DR. VAN VOORHEES: What are possible implications of this work for human wounds?

DR. SEIFERT: I think this type of basic science helps us understand the mechanisms that are responsible for how wounds either heal with a scar or regenerate. I think first and foremost it will provide us comparative information about how scarring and regeneration in an adult mammalian model of wound healing are different and the relevant aspects of the processes involved, the timing, etc. It may be that as we continue to investigate we can test some of the outstanding hypotheses about why regeneration doesn’t occur in mammals, such as the role of the immune system, the proposed tradeoff between adaptive and innate immunity with adaptive immunity favoring scarring. We’ll be able to test that in these animals. Also the role of inflammation, how either pro-inflammatory or anti-inflammatory molecules might be signaling and controlling fibrosis. Lastly, I think we’ll be able to take a look at the composition of the extracellular matrix and what role the environment within the wound bed is playing that either stimulates regeneration or stimulates scarring. It will serve as a model to test hypotheses and understand basic mechanisms of mammalian regeneration.

DR. VAN VOORHEES: It will also be very interesting to look at the role that having the spiny hairs plays in the dermis for wounds. Certainly there are differing wound properties for humans as well in hair-bearing vs. non hair-bearing locations.

DR. SEIFERT: That’s exactly correct. I’ve had several people when I’ve given talks about this ask me about the role of those hair follicles, and you can see in the paper how much bigger they are. It’s possible that stem cells of those hairs may have a larger population which contribute not only to re-epithelialization but to the creation of new follicles, and that’s something I suspect researchers will be interested in following up.

DR. VAN VOORHEES: How does this connect to what you’ve seen in salamanders? Where might it lead?

DR. SEIFERT: We use salamanders as a model for skin regeneration as well. (See “Skin Regeneration in Adult Axolotls: A Blueprint for Scar-Free Healing in Vertebrates.” PLoS ONE 7(4): e32875. doi:10.1371/journal.pone.0032875.) One of the things the wound healing field lacks is an adult model of skin regeneration. In the early ’90s a popular basic science model was the fetal model for scar-free healing. People would do in-utero surgeries on all sorts of mammals, sheep, mice, rats, etc., and showed that the fetal animals had the capacity to regenerate skin after wounding compared to the adults, which would scar. The problem is that the animals were fetal — so we don’t have an adult model for what skin regeneration would look like.

I started using the axolotl and adopted a wound healing model that people used in mammals, these full-thickness excisional wounds, and showed that these salamanders, over the course of 80 days or so, were capable of regenerating all the different layers of the skin, including the muscle beneath. I was excited about that because these animals are tetrapods, they live on land the same way that mammals do; their physiology might be different, but we were able to compare similar wounds and the composition and timing of the extracellular matrix and production. I’m excited about using this model as well because I think that, in conjunction with some of the spiny mouse work, it will give us insight into common pathways and events that are used during skin regeneration and allow us to ask questions about how fibrosis is regulated. Using this knowledge, we may be able to develop new therapies or products to treat human wounds; at least, that is my hope. dw
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Dealing with a lost tissue specimen

Upon entering his office at 8 a.m., Bryan hears his telephone ring. It is Annette, a dermatologist who is Bryan’s client. She is tense and obviously worried.

Bryan: Good morning, Annette! I haven’t heard from you in a while. Is everything going well?

Annette: No, Bryan. I really need your help. I just received a call from the pathology lab I use. They told me there was no biopsy specimen in the bottle I sent them! What should I do?

Bryan: Let’s take it from the top. First, when you performed the biopsy did you or your assistant look into the bottle to make sure the specimen was actually there? If it was a small specimen, it could have gotten stuck on your equipment or on a gauze pad.

Annette: Absolutely. My nurse always looks into the bottle and makes sure the specimen is in there before he puts the cap on the bottle.

Bryan: What happens to the bottle after the specimen is placed in it? How does it get to the lab?

Annette: A courier from the lab picks up our pathology specimens and takes them to the lab.

Bryan: Does the courier sign anything to confirm that he picked up the specimens?

Annette: No. Why should I bother having him sign? This lab has never lost a specimen of mine.
Bryan: Effective immediately, you absolutely should have the courier sign when he or she picks up your specimens. My other dermatology clients have couriers sign or initial a log that simply lists the names of each patient and the number of specimens being sent. The courier looks at each of the specimen bottles and confirms that there is something inside. It only takes a few moments. If a bottle appears empty, the courier notifies the doctor before leaving the physician’s office. Once the courier signs the log book and takes the specimens, the responsibility for the subsequent transportation and handling of the specimens is the pathology laboratory’s.

Annette: What if the courier won’t sign a log book?

Bryan: Find another lab.

Annette: What should I tell the patient?

Bryan: The truth. Not only is it required by the rules of the Board of Medicine in most states, but it is ethically and pragmatically the right thing to do. Isn’t that what you would want if you were the patient? Besides, how else would you explain to the patient that you have no report? You may want to offer to re-biopsy the lesion without charging so that the patient will be less annoyed. That’s up to you.

Annette: Do I need to contact my malpractice carrier?

Bryan: Although the patient may take no further action, you have a duty to promptly notify your insurance company of any potential legal action. If you do not contact them in a timely fashion your malpractice insurer may have grounds to deny coverage. Although other attorneys have advised their clients to wait until they receive a notice of intent, there is little or no downside to communicating with the insurance company at this point.

Annette: Won’t that increase my insurance rate? I am currently “claims free” and have their lowest rate.

Bryan: Although there are exceptions, most malpractice companies will not increase your rate unless you actually report a claim. Simply notifying them of a possible claim will not usually increase your rate.

Annette: I’ll certainly follow your advice. If I change my procedure now and have the laboratory courier sign for pathology specimens, won’t that be admitting that I did something wrong?

Bryan: Although the adoption of measures or new procedures that address a situation after the fact may be introduced as evidence for certain very specific purposes, most states have rules of evidence that do not allow these measures to be introduced as evidence of negligence. State laws recognize that if this was not the case, dangerous situations would be allowed to persist until pending litigation was resolved.

You should go ahead and make the necessary change to your procedure to prevent a similar situation from occurring in the future. One last bit of advice: should you hear anything from the patient, please contact me immediately.

Annette: Absolutely, Bryan. Have a great day!

KEY POINTS

• The courier from the laboratory should sign for specimens. If he/she is not willing to do so, find another pathology laboratory.
• Tell the patient the truth. It is ethically, pragmatically, and legally the correct thing to do.
• In the event of an adverse incident, notify your insurance company in a timely fashion so that they do not have grounds to deny your coverage.
• Subsequent remedial measures are usually not admissible in court as evidence of negligence.

If you have any suggestions for topics to be discussed in this column, please e-mail them to me at loberc@gmail.com. See the February 2013 issue of Dermatology World for disclaimers.

DW
The Centers for Medicare and Medicaid Services (CMS) use quality measures for quality improvement, public reporting, and pay-for-reporting programs. CMS defines “quality measures” as:

tools that help us measure or quantify health care processes, outcomes, patient perceptions, and organizational structure and/or systems that are associated with the ability to provide high-quality health care and/or that relate to one or more quality goals for health care. These goals include: effective, safe, efficient, patient-centered, equitable, and timely care.

A BRIEF HISTORY OF QUALITY MEASURES

How did we get to a place where we’re reporting quality measures to CMS via registries and electronic claims? The history of quality measures in the United States dates back to 1917 when the American College of Surgeons established its Hospital Standardization Program (HSP). This program included a set of five standards known simply as “minimum standards,” which included some of today’s most common and accepted medical practices, such as keeping records that include history, physical exam, and lab results. The HSP eventually led to the formation of the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO), which was tasked with reviewing medical records to assess quality of care and developing statistics on readmissions and screening procedures as a measure of performance.

State oversight of physicians has been in effect ever since states started licensing physicians around the late 1800s. Federal oversight started in 1935 when the Social Security Act set minimum standards for maternal and children’s services. This oversight was expanded with the passage of the Social Security Act of 1965, which created the Medicare program, granting Americans over age 65 medical and hospital insurance. In order to participate in the program, providers had to meet certain...
“Conditions of Participation” — essentially a set of basic quality measures.

Quality reporting initiatives continued to evolve and be refined until, in short order, three new laws created the three Medicare-related programs I will discuss in the rest of this column:

- In 2006, the Tax Relief and Health Care Act established the voluntary Physician Quality Reporting System (PQRS), which provided for incentive payments to eligible professionals who satisfactorily report data on quality measures for covered professional services provided to Medicare beneficiaries.
- In 2008, the Medicare Improvements for Patients and Providers Act (MIPPA) authorized a combination of incentives and payment adjustments (deductions) to encourage eligible professionals to use electronic prescribing (eRx).
- Finally, in 2009, the Health Information Technology for Economic and Clinical Health (HITeCH) Act was passed. It provided for financial incentive for the meaningful use (MU) of electronic health records (EHR). Core Measure 10 of MU Stage 1 requires that providers seeking the incentives report on six clinical quality measures (CQMs).

All of these federal programs only apply if the eligible professional (EP) serves a specified level of Medicare or Medicaid patients. Thus, these programs are not applicable to dermatologists who only accept private insurance or who provide services not covered by insurance.

MEANINGFUL USE
What has to be done to meet the requirements?
For meaningful use Stage 1, effective through the end of 2013, in addition to reporting on 15 Core Objectives and five Menu Objectives, EPs need to report on a total of six CQMs. There are no minimum thresholds to meet for CQMs. EPs simply report the data exactly as it is calculated by their certified EHR.

At least three CQMs must be chosen from a group of core/required measures or alternate measures. Fortunately it is acceptable to have a zero in the denominator if the EP does not have an applicable population. Since none of these measures specifically relate to dermatology, an EP may enter zero for the denominator of these measures, effectively not reporting any of the core CQMs.

EPs are also required to select three CQMs from the list of 38 additional quality measures for Stage 1 that are relevant to the practice. These CQMs are related to diseases such as diabetes, heart failure, coronary artery disease, pneumonia, and cancer. Once again, it is acceptable to enter a zero in the denominator if these conditions are not related to a provider’s services.

There are new CQMs for 2014 that might apply to dermatologists such as:
- NQF 0022: Use of High-Risk Medications in the Elderly
- NQF 0419: Documentation of Current Medications in the Medical Record
- CMS507v1: Closing the referral loop: receipt of specialist report

It is necessary for each dermatologist to review the full list of CQMs when reporting each year. Beginning in 2014, EPs will need to report on nine of 64 CQMs covering at least three of the six National Quality Strategy domains. A list of 2014 CQMs and their domains is available at www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/EP MeasuresTable_Posting_CQMs.pdf.

How do you submit quality measures?
In order to submit CQMs, an EP must be using an EHR certified for meaningful use. The EHR system calculates the numerator, denominator, and exclusion for each of the CQMs. In general, the numerator represents the number of patients/items from the measured population who qualify for that measure. The denominator represents the entire number of unique patients in the measured population, and the exclusions indicate the number of the measured population which does not apply to that CQM.

Data on CQM performance is reported through attestation of relevant numerators and denominators on the CMS EHR incentives site. Beginning in 2014, all Medicare EPs beyond their first year of MU participation must submit aggregate CQMs to CMS electronically while Medicaid EPs must submit CQMs electronically to their state.

Eligible Professionals who meet MU may qualify for up to $44,000 (over five years) for the Medicare program run by CMS or $63,750 (over six years) for Medicaid program run by each state. Those who do not comply with MU by 2015 are subject to penalties of a 1 percent reduction in 2015 and a 2 percent reduction in 2016, increasing by 1 percent each year up to a 3 percent reduction in 2017, and up to minus 5 percent in 2019 if at least 75 percent of the total number of physicians nationwide does not attain MU. For each year, the EHR reporting period for the penalty is the calendar year two years prior to the payment adjustment period. So the penalty for not achieving MU in 2013 will be assessed in 2015, however CMS has allowed a one-time extension for those physicians beginning meaningful use in 2014. They will have until Oct. 1, 2014 to submit their attestation to avoid the 2015 penalty.

PQRS
What has to be done to meet the requirements?
There are four dermatology-appropriate measures for the 2013 PQRS program, none of which are related to the CQMs required for MU. These include:
- PQRS Measure #137/NQF 0650 – Melanoma: Continuity of Care – Recall System
- PQRS Measure #138 – Melanoma: Coordination of Care
- PQRS Measure #224/NQF 0562 – Melanoma: Overutilization of Imaging Studies in Melanoma
- PQRS Measure #265 – Biopsy Follow-Up

Descriptions of these four measures appear online at www.aad.org/qrs. Dermatologists can also file PQRS Measure #46/NQF 0097 – Medication Reconciliation and PQRS Measure #130/NQF 0419 – Documentation of Current Medications in the Medical Record.
How do you submit quality measures?

There are several methods by which to submit quality data to CMS. While eligible professionals may report to PQRS (1) on their Medicare Part B claims, or (2) through a qualified PQRS registry, or (3) via a qualified EHR product, or (4) through the Group Practice Reporting Option (GPRO), the four dermatology-appropriate measures can only be reported via registry. A registry is an electronic system built by an outside vendor that allows the provider to enter the information online. For example, the cost to report through the AAD Quality Reporting System is $249 per physician; this registry can be found on the AAD website.

Providers must report a minimum of three quality measures to earn an incentive; there is no payment advantage to reporting more than three. Although not eligible for any incentive, providers who report at least one measure for one patient in 2013 will avoid a 1.5 percent payment reduction in 2015. The penalty increases to 2 percent in 2016 and beyond. While with MU, EPs may report a 0 percent performance, for PQRS, the percent performance rate must be greater than zero for all reported measures.

EPs who report on PQRS can receive a 0.5 percent incentive in both 2013 and 2014. The PQRS incentives are phased out after 2014.

EPRESCRIBING (eRx)

What has to be done to meet the requirements?

Electronic prescribing is the electronic transmission of prescription or prescription-related information directly or through an intermediary such as an eRx network. To earn an incentive, a solo EP must report at least 25 prescribing events for which the denominator is eligible during 2013. In other words, prescribe electronically for 25 unique patient visits and report the G-code G8553. To avoid a penalty, the EP must submit at least 10 electronic prescriptions and report the G-code via claims during the first six months of 2013, or apply for an exemption. Group practices have higher thresholds based on group size. To be eligible to participate, office visit codes (E/M) need to represent at least 10 percent of the EP’s total Medicare Part B Physician Fee Schedule charges.

There are several hardship exemptions that prevent providers from being penalized for non-participation in eRx. However, it is already past the January 2013 deadline to request a hardship exemption to avoid the 2013 eRx payment adjustment. The deadline to apply for an exemption for 2014 is June 30, 2013. Exemptions include:

- Inability to electronically prescribe due to state or federal law, or local law or regulation;
- The eligible professional prescribes fewer than 100 prescriptions during a six-month payment adjustment reporting period;
- The eligible professional practices in a rural area without sufficient high-speed Internet access; and/or
- The eligible professional practices in an area without sufficient available pharmacies for electronic prescribing.


How do you submit the eRx measure?

To participate in the eRx incentive program, an EP must have and routinely use an eRx system, and report on its adoption and use. No sign-up or registration is required. The eRx system may be either a “stand-alone” system (a system designed for eRx only) or a qualified EHR system. To report on the adoption and use of eRx, the EP either (1) submits G8553 on Medicare part B claims, or (2) attests to a qualified registry, or (3) attests to CMS via a qualified EHR system, or (4) attests to a qualified data submission vendor. (G8553 indicates that at least one prescription created during the encounter was generated and transmitted electronically using a qualified eRx system.)

The 2013 eRx incentive payment is .5 percent, payable in 2014; this is the last year for which there is an incentive payment. If an EP does not report their use of eRx, Medicare will impose a penalty of 1.5 percent in 2013, and 2.0 percent in 2014 and 2015. The eRx incentive program ends after 2014. EPs who file for (or demonstrate intent to participate by registering in) the meaningful use incentive under the Medicare program are not eligible for the eRx incentive but are exempt from the penalty automatically (as e-prescribing is a core measure of MU). EPs earning the Medicaid MU incentive are eligible to also receive the eRx incentive. If you apply for both the eRx and meaningful use incentive, CMS will automatically give you the meaningful use incentive as that is paid out first. It is also most likely in your best interest to receive the meaningful use incentive as opposed to the eRx incentive since the eRx incentive dropped to 0.5 percent in 2015. You should calculate these figures out based on your Medicare Part B allowed charges to determine which incentive is greater for your practice.

CONCLUSION

I think the medical community all agree that providing the highest quality health care in a safe, efficient, patient-centered, timely manner is a worthwhile goal. As Ed Koch, former mayor of New York, used to say, “How am I doing?” Using quality measures allows providers to see where they are now and to implement strategies and workflows for improvement over time. Providers should also benefit from reduced prescription errors, increased patient satisfaction, and avoidance of unnecessary phone calls for prescription clarifications through the use of eRx. And as the incentives to implement quality measures are phased out, providers will be penalized at increasing rates on top of other reimbursement reductions. It makes sense to study the quality measures relevant to dermatologists and consider how you could change your workflow to be able to comply with and report on these measures.
It’s Time to Upgrade Your Website

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As dermatology practices deal with all of the new regulatory changes in healthcare—including meaningful use, e-prescribing, the Physician Quality Reporting System (PQRS), ICD-10, and health care reform—it can be surprising to learn that even the regulatory programs that were established several years ago continue to evolve and can change significantly. One such program undergoing noteworthy change is the Health Insurance Portability and Accountability Act (HIPAA). The Department of Health and Human Services (HHS) released a final rule that requires practices to comply with a variety of new HIPAA provisions by Sept. 23, 2013.

As a dermatologist, you are probably wondering what all of these new provisions mean for your practice. It will be the responsibility of your office staff to begin making all of the necessary updates to applicable HIPAA forms and prepare action items for all of the privacy and security requirements. The following FAQs should help your staff prepare for these changes by September.

WHAT HAS CHANGED WITH REGARD TO HIPAA?

The new provisions that HHS released in January 2013 address all of the required changes to HIPAA stemming from the Health Information Technology for Economic and Clinical Health Act (HITECH). This Act was passed by Congress in 2009 to not only provide regulations to safeguard electronic health information but also incentivize physicians to adopt electronic health records (EHR) through the meaningful use program. The main changes to HIPAA that dermatology practices need to be prepared for include:

- Updated notice of privacy practices form
- Expanded scope of business associate agreements
- Changes to breach notification requirements
- Required patient access to electronic medical records
- Protecting the privacy of self-pay patients’ medical records
- Marketing requirements
Changes in criminal and monetary penalties for violation of HIPAA

What are the steps I need to take in my practice to comply with these changes?

Step 1: Assign a compliance officer to be in charge of all the required changes if you have not previously done so.

Step 2: Have this compliance officer update your HIPAA policies and procedures manual to address the new changes by Sept. 23, 2013. You can use the Academy’s HIPAA manual as a starting point. If you have an EHR in your office, pay special attention to new policies that will need to be created for electronic protected health information including breach notification requirements, accounting of all disclosures, and the right of patients to access their own electronic medical record within 30 days of their request. Additionally, a new policy will need to be created to address a provision requiring providers to withhold disclosures of protected health information (PHI) to their insurer if a patient requests it and pays for the service completely out of pocket.

Step 3: Begin using your updated notice of privacy practice form for all patients either on or before Sept. 23, 2013. Post a new copy of this form in a visible location in your waiting room. Have all patients sign the updated form even if they are established patients.

Step 4: Have the compliance officer analyze all of your vendors to determine which should be classified as business associates under the revised definition, which includes vendors who have routine access to PHI such as an EHR vendor or server warehouse. Ensure you sign a new business associate agreement in advance of the Sept. 23, 2013 implementation date with each of these vendors as the new HIPAA regulations make business associates directly liable for compliance with the Privacy Rule.

Step 5: Train all clinical and non-clinical staff on the new policies and procedures. If you have an EHR in your office, ensure staff are aware of your breach notification requirements and policies addressing how to protect this information, including how to maintain strong passwords, protect wireless access, and other safeguards.

How should I comply with the provision requiring my practice to not disclose health information to the payer if the patient pays in full? I don’t want to create two separate medical charts for these types of instances.

A new provision in the HIPAA rule requires that practices not disclose a patient’s medical record to their insurer if the patient pays for the service completely out of pocket and requests this confidentiality. If you do not have an EHR in your practice, you will have to create a log or system that keeps track of these requests and ensure staff are trained to not inadvertently disclose the medical chart containing the confidential information to the insurer. If you have an EHR, speak with your vendor to determine how to flag the confidential information in the medical record and protect it from being disclosed to the insurer. You should also train your front desk staff in identifying patients who could potentially ask for this caveat (such as those who do not provide insurance information when making their appointment). Additionally, revise your financial policy form to include this information and always have your patients pay their full charge up front.

Are small practices being audited? What can I do to mitigate this risk?

Small practices have been audited for HIPAA violations and paid steep fines for their non-compliance. The new rule sets forth a fines structure where practices would pay, based on the degree of their willful neglect, up to $250,000 per violation and face imprisonment for up to 10 years. Your compliance officer should stay abreast of changes and train staff yearly on safeguarding PHI. Your practice should also perform self-audits to catch any potential problems and pay special attention to how your staff are interacting on social networking sites. As these sites have gained in popularity, HIPAA violations related to them have increased, as staff may not be aware that they should not be posting PHI.

What resources can I use to help me with these steps?

The Academy has developed a new HIPAA manual titled “A Guide to HIPAA and HITECH for Dermatology.” This manual contains a model business associate agreement, model notice of privacy practice form, breach notification requirements, and other guidelines, tools, and worksheets explaining all of the new HIPAA regulations. You can order the manual by calling the AAD’s Member Resource Center at (866) 503-SKIN (7546).

The Academy has also developed a series of educational recordings on HIPAA focused on the new regulations as well as the privacy and security requirements. These recordings are available at www.aad.org/webinars.

You can also visit the Academy’s HIPAA Web page at www.aad.org/hipaa to learn more about the new regulations and any upcoming changes. dw
THE PROMISE AND PITFALLS OF BIOSIMILARS
Dermatologists laud potential cost savings, urge measures to protect patients

BY JAN BOWERS, CONTRIBUTING WRITER

No one disputes the appeal of the best-case scenario for biosimilars: the marketing of a new class of agents, developed to mimic the biologic drugs used to treat psoriasis and other disorders, that achieve an equivalent safety and efficacy profile at a significantly lower cost to patients. But dermatologists who rely on biologics to treat selected patients with moderate to severe psoriasis have voiced concern about the myriad questions that still surround biosimilars’ path to the market: Who will manufacture the biosimilars? What testing will the Food and Drug Administration require before deeming a biosimilar “interchangeable” with the reference drug? How much cheaper will the biosimilars actually be? Finally, will pharmacists be allowed to substitute a biosimilar for a reference drug without notifying the physician or patient? >>
Biologics now account for about one quarter of the $320 billion Americans spend annually on drugs, according to a report from research firm IMS Health, cited in the *New York Times* (“Biotech Firms, Billions at Risk, Lobby States to Limit Generics,” Jan. 28, 2013). Even with health insurance, out-of-pocket costs to patients can reach thousands of dollars. “I think the economic pressures to develop biosimilars are so large that they will happen,” said Alice B. Gottlieb, MD, PhD, professor of dermatology at Tufts University School of Medicine and chair of the department of dermatology at Tufts Medical Center. “Even a 10 to 20 percent saving will mean significant savings to our health care system. So I think it will happen; it’s only a question of when.”

Alluding to the difficulty of creating a drug equivalent to a large molecule biologic, Craig L. Leonardi, MD, associate clinical professor of dermatology at St. Louis University Medical School, remarked, “This is as complex as it gets; there might be some ramifications for health and safety, and there may not be. We won’t know until we try. But something has to be done, because the costs [of biologics] are mind-blowing.”

**FDA DRAFT GUIDELINES ISSUED**

A confluence of factors, in addition to the high cost of biologics, has given rise to the drive to create biosimilars. The Patient Protection and Affordable Care Act, signed into law in March 2010, created an abbreviated licensure pathway for biological products that are “demonstrated to be ‘biosimilar’ to or ‘interchangeable’ with an FDA-licensed biological product,” according to the FDA website. In the meantime, the “patent cliff” loomed for some of the leading biologics — the patent on Amgen’s Enbrel (etanercept), for example, was set to expire in 2012, though it has since been extended until 2028 (see sidebar).

Draft guidelines issued by the FDA in February 2012 address the agency’s “current thinking on scientific considerations in demonstrating biosimilarity to a reference product and quality considerations in demonstrating biosimilarity to a reference protein product.” In a February 2013 address to the Generic Pharmaceutical Manufacturers Association, Margaret A. Hamburg, MD, the FDA’s top official, said the agency is in the process of finalizing the guidelines and had just issued another draft guidance on how to study whether patients are at risk of having an unintended immune response to a biological product, and if they do, how to evaluate the impact of that response. She noted that the FDA has already received 14 Investigational New Drug applications for biosimilar development programs.

The draft guidelines state that the FDA will take a “totality-of-the-evidence” approach to reviewing applications for biosimilars, and that “the type and amount of analyses and testing that will be sufficient to demonstrate biosimilarity will be determined on a product-specific basis.”

**COMPLEX MANUFACTURING**

The expense of manufacturing a biosimilar may limit the savings that are realized once the new products reach the market, said Dr. Leonardi. “It’s not going to be dollars vs. thousands of dollars. The manufacturing facilities can’t take shortcuts in making these drugs, and it represents a huge investment in equipment, manpower, and the nature of the facilities. They’re very expensive to build, and the workers have to take multiple precautions to prevent contamination.”

A commentary entitled “Biopharmaceuticals and biosimilars in psoriasis: What the dermatologist needs to know,” co-authored by Dr. Leonardi and published in the *Journal of the American Academy of Dermatology* (2012;66(2):317-22), explains why the manufacture of

Most payers anticipate a biosimilar will come in between 10 and 20 percent less than the cost of the branded manufacturer.
biosimilars is so much more complex than the creation of generics for small molecule drugs. While small molecule drugs (compounds of low molecular weight) and their generic equivalents are based on medicinal chemistry and are chemically synthesized and purified, biologics are “biopolymers of organic molecules that are manufactured in living systems.” They can never be exactly replicated, and every step in the manufacturing process has the potential to change the characteristics of the biosimilars relative to the original biologic. In one plant Dr. Leonardi visited, he was told that “not every run is successful; about one out of every seven batches is contaminated and cannot be used.”

Even minute variations from the reference drug can have clinical implications, explained Mark G. Lebwohl, MD, professor and chair of the department of dermatology at Mount Sinai School of Medicine. “This is a huge molecule, so if it differs by even one little bit, it could make the efficacy worse, the safety worse — or it could make them better. But we won’t know until we have years of data and thousands of patients.”

Reports that some of the leading manufacturers of biologics are said to be pursuing the development of biosimilars for their competitors’ drugs came as welcome news to the psoriasis experts. In a February meeting with analysts, Amgen Inc. said it expected biosimilars to be a multibillion-dollar opportunity for the company and announced plans to launch six biosimilars, beginning in 2017: four cancer drugs and two rivals to its own Enbrel (etanercept), AbbVie’s Humira (adalimumab) and Janssen’s Remicade (infliximab), according to Reuters.com (“Amgen biosimilar push takes aim at blockbusters,” Feb. 7, 2013). “I would like to see them manufactured by a company with experience in marketing biologics,” Dr. Gottlieb said. “I know they know how to do it and I know the FDA has looked at their manufacturing headquarters and has blessed them, so to speak. I do not want to use a biosimilar made in China or Venezuela.” Dr. Leonardi concurred, noting that “Amgen knows how to make biologic drugs. I don’t have to worry about melamine being introduced into the drug.”

**DERMATOLOGISTS CONFRONT TIERING**

Estimates of the likely cost of biosimilars vary. According to pharmaceutical industry newsletter FiercePharma (“How much cheaper will biosimilars be?,” March 2, 2012), biosimilars were initially expected to cost 30 percent to 40 percent less than the reference drug. However, “as the complexity of bringing biosimilars to market continues to be discussed, more recent data suggest that most payers anticipate a biosimilar will come in between 10 percent to 20 percent less than the cost of the branded manufacturer. In Europe, we know that biosimilars have often been just a 10 percent discount from the brand.”

If the cost savings are only modest, the introduction of biosimilars may not improve patient access to biologics to the degree that the health care community initially hoped. “You take a drug that costs $15,000 and you make it $12,000, that’s still out of reach of a lot of people,” Dr. Lebwohl said. Access to affordable care “is a huge issue for our patients,” said Leah McCormick Howard, director of government relations and advocacy for the National Psoriasis Foundation. “If biosimilars are going to give us safe and effective treatment in the same way that biologics are working today for our patient population, we absolutely want to see them on the market in a way that patients can afford them — but it’s not clear at this point what the savings will be.”

Even patients with health insurance can have difficulty obtaining biologics, as insurers place onerous restrictions on which patients can receive the drug and/

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### BILOGIC PATENT EXPIRATION DATES

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<th>MANUFACTURER</th>
<th>DRUG</th>
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<td>Humira (adalimumab)</td>
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<td>Janssen Biotech, Inc.</td>
<td>Remicade (infliximab)</td>
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<td>2022</td>
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<td>Amgen</td>
<td>Enbrel (etanercept)</td>
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*Information supplied by the manufacturers.*

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DERMATOLOGY WORLD // June 2013 23
or require higher co-pays, a process known as tiering. Dr. Lebwohl called the tiering of biologics by insurers “a problem across the country. You may know what’s going to be best for your patient, you may have a very clear, coherent reason why they should get drug A rather than drug B, but the insurance company has decided they’re going to determine who gets drug A vs. drug B, and they usually do it on the basis of cost.” Dr. Gordon said he’s experienced “tremendous pushback” from insurers.

“There’s the useful and the absurd. The main pushback is the amount of paperwork that’s put in front of us, and much of that is used to delay the prescriptions. It’s really an attempt to get doctors and patients to give up.” If cost savings related to biosimilars are only in the 20 to 25 percent range, “my concern is that we’re still going to have poor access for patients, and on top of it, have less information on the medicines we’re using for those patients who can get the medicine.”

And it’s not only drugs that are tiered. Physicians, too, are sometimes penalized by insurance companies for prescribing too many biologics and other costly drugs. “It’s euphemistically called ‘pay for performance,’” Dr. Gottlieb said. “Physician tiering uses claims databases and some quality measures, but it’s very much cost-driven. You are supposedly compared to your peers, but whether you’re in a tertiary care center is not taken into account, nor is your case mix or patient outcomes, because that’s not in the claims database.” The quality measures don’t address psoriasis, but rather, “do you write for Lotrisone, and do you have pregnancy on Accutane,” Dr. Gottlieb said. “I see the the most severe, recalcitrant psoriasis and psoriatic arthritis patients, and I’m compared to the doctor who, basically, gives topical steroids to the most severe of his psoriasis patients. So the irony is that the doctors who see the sickest patients are penalized, and that penalty is that all my patients — not just the psoriasis patients — pay a higher co-pay to see me. The result is that it’s very hard for a sick psoriasis patient to find good care in this state.”

THE POLITICS OF SUBSTITUTION

The issue of when and if a pharmacist can substitute a biosimilar for a branded product, once biosimilars are available, is drawing attention from drug companies, insurers, state regulators, physicians, and patient advocacy groups. In at least eight states, bills have been introduced that would expand substitution laws to include biosimilars but place restrictions on biosimilars that do not apply to generics, according to the New York Times article. For example, the laws would require that the FDA find a biosimilar “interchangeable” with the reference drug in order for the biosimilar to be substituted. To meet that standard, the FDA says, the manufacturer “must show that the proposed interchangeable product is expected to produce the same clinical result as the reference product in any given patient. When a product will be administered more than once to an individual, the manufacturer must also demonstrate that the risk in terms of safety or reduced effectiveness of alternating or switching between use of the proposed interchangeable product and the reference product is not greater than the risk of using the reference product without such alternation or switch.” Some of the bills place further restrictions on substitutions, requiring, for example, that the patient consent to the switch or that the pharmacist notify the physician. These additional requirements would put the state laws in conflict with the 2010 federal law, which states that once the standard of interchangeability is met, a pharmacist may substitute without consulting the physician.

In its Position Statement on Generic Therapeutic and Biosimilar Substitution, the AADA stipulates minimal thresholds that must be met before a biosimilar should be substituted for a reference drug. (The full position statement is available online at www.aad.org/Forms/Policies/ps.aspx.) One is that the biosimilar has a unique, nonproprietary name; another is that the prescribing physician provides explicit permission for substitution, and that both the physician and patient are notified if a substitution occurs. Dr. Gordon pointed out that with generic drugs, a pharmacy might substitute one generic one week and a different one the next — “whatever they got a better deal for that day. That’s not going to be the way you can do it with biosimilars. I don’t mean to be a naysayer on biosimilars. The problem is you need to do it right, and I think the fear of all of us who work in this area is that there’s a huge impulse to do things cheaply and not well. Doing this well and doing it right and actually saving some money would be great.”

Editor’s note: Dr. Gordon has served as a consultant to AbbVie (formerly Abbott), Amgen, and Centocor, the original innovator of Stelara. Dr. Gottlieb has served as consultant to AbbVie, Amgen, and Janssen. Dr. Lebwohl has served as consultant and investigator for Amgen and Centocor and a consultant to AbbVie. Dr. Leonardi has served as investigator, speaker, and advisory board member for Abbott and Amgen and as investigator and advisory board member for Centocor. dw
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For many patients, the first impression of a physician’s office helps determine the course and duration of their relationship with that practice. Their initial interactions with employees often set the tone for that visit and whether there will be a second, a third, and so on. So for dermatologists and practice managers, considering the topic of employee appearance is vital. Though the sentiment is cliché, it remains true that there’s only one chance to make that first impression.
FIRST IMPRESSIONS

In focusing on employee appearance, according to dermatologist Matt Leavitt, DO, who runs multiple Advanced Dermatology and Cosmetic Surgery locations in Florida and Ohio, it’s vital to recognize the importance of non-verbal interaction between staff and patients. Employees with the right demeanor and appearance put patients at ease even before they’re able to offer assistance. >>
“People in general have a very short window on the first impression. It’s usually pegged at three to four minutes,” Dr. Leavitt said. “And some of that time might include a patient watching an employee or seeing how they interact with someone else or carry themselves. That’s one of the things that we try to teach our employees. The dress really has some significant influence on those first few minutes before they even talk to the patient.”

Dr. Leavitt’s stance puts him in stride with much of the pop-psychological work done lately on the topic of first impressions, such as author Malcolm Gladwell’s claim in *Blink* that first impressions occur so quickly, we often “think without thinking.” It also puts him in sync with research done by social psychologist Amy Cuddy, PhD, assistant professor at the Harvard Business School. According to research first presented at the annual PopTech conference in 2012, people forming first impressions of another person are unconsciously gauging two areas — how warm and trustworthy the person seems and how competent they are. Dr. Cuddy said that these two areas account for between 80 and 90 percent of one’s overall first impression.

The importance of well-dressed, friendly practice employees cannot be overstated, according to Dr. Leavitt. Codifying a standard of appearance, he said, helps reach across cultural and generational lines more effectively.

“We see everyone from little kids to older people, as well as men and women from different religions and cultures. There’s a tremendous variability in terms of who walks through our door. What is acceptable to someone of one age, culture, or mindset might not be to someone else,” Dr. Leavitt said. “One of the things we try to explain to people is that we don’t want to offend anyone by the way we dress, but even more so, we dress in a similar way and it’s very consistent, and we try to go for something seen as very professional.” The goal, similar to keeping the office clean and answering the phone promptly, is to convey competence through mastery of the basics. “It’s all about how people view our practice,” Dr. Leavitt said.

**EMPLOYEE INVESTMENT**

Most practices have, at the very least, an informal set of dress regulations. Many have a written policy, especially in larger practices. In creating a formal dress code, according to human resources expert and About.com columnist Susan Heathfield, it’s much more productive for managers to farm the job out to a diverse group of practice employees representing each area of the office.

“Creating standards for dress this way involves building support for it across the whole organization, no matter the size. What’s interesting is that most of the time, the physicians will get back a set of standards that are higher than they would have set themselves,” she said. “When a wider group of employees creates it, they feel some degree of responsibility for monitoring it.”

When creating a dress code, according to Cinda Cannon, director of quality assurance for Skin and Cancer Associates/Advanced Dermatology Management in Miami, it’s less important to focus on the term “dress code” and more important to consider it a baseline standard of professional appearance.

“Every one of our offices tailors their own dress policy, but the main thing is that it’s professional-looking, whether it’s scrubs in the exam rooms or a front office outfit. Inform your staff at the beginning of the hiring process to avoid low-cut attire in the office setting. Communicate with them as to what is considered acceptable jewelry to include piercing that is visual or affects one’s communication,” Cannon said. “The physicians feel that it’s very important to recognize that no matter if you work in the front or back, your appearance is the first thing that will catch a patient’s eye and assist in their impression in addition to any services rendered.”

While it may be tempting for physicians or even practice managers to create, enact, and enforce the dress code themselves, Heathfield said that those who do often regret doing so.

“You don’t have to have one or two physicians or managers trying to be the people that keep everyone in line if the employees have investment in the process,” Heathfield said. “Every physician I know wants to see patients; they don’t want to be the dress code police. Even for a practice manager, creating that role for yourself is one of the worst, most frustrating things you can do.”

Once the standards have been set by existing employees, Cannon said, it’s important to make them clear to new hires during the hiring or training process. Doing so, she said, will eliminate the sort of cultural or generational differences that might lead someone to think a manner of dress is acceptable when it isn’t allowed in the practice.

In the adoption process, Heathfield said, some of her clients have partnered with local retailers to demonstrate different examples of the professional
dress standard via an impromptu “fashion show” in the office during a lunch period or after hours.

CORRECTING COURSE
Correcting an employee's job-related actions can prove difficult for a physician or practice manager unused to the task. With employee appearance, doing so effectively is essential for continued success or measurable improvement. In areas of dress code enforcement, the issue should be addressed as quickly as possible, according to Cannon.

“When you have staff that come in with too much perfume, have them wash it off to minimize the smell, or if they’re wearing scrubs that don’t look pressed or professional, have them take a break when not disruptive to the patient flow, get a change of clothes, and come back. Most staff who wear scrubs will normally have a spare pair available so the disruption should be minimal. It’s important to keep to your standards,” Cannon said.

Addressing issues of grooming or hygiene, however, can be a veritable minefield of hurt feelings and resentment. Hygiene and personal appearance standards, according to Cannon, are often standards that employees are not aware they were failing to meet successfully. Actions taken to address the issue, she said, must be done quickly, honestly, and privately.

“You don’t want to offend an employee or spark any issues with co-workers. It’s counter-productive. To me as a manager, it’s how you present the information,” Cannon said. “Don’t make them feel as though they’re being put on the chopping block.”

In addressing hygiene specifically, Heathfield said, it’s imperative that the manager or physician take immediate personal responsibility for corrective action. Leaving the issue and hoping it will correct itself, she said, often leads to resentment among employees and the worst-case endgame.

“This can be one of the worst things a manager has to deal with. What many managers do, which is the wrong approach, is say ‘a bunch of people have complained to me about the fact that you don’t smell very good.’ The employee immediately goes on a mission in their mind to hunt down all these co-workers who would say this about them,” Heathfield said. “Instead, take responsibility for expressing the opinion and asking the employee if there is a medical reason why this might be so. The employee might in fact share a reason. It’s not about trying to loop in the rest of the office. Tell the employee that for him or her to succeed in the current work environment, there needs to be a change.”

Worse, Heathfield said, is when a manager fails to take any action and allows employee displeasure to curdle into resentment. When employees begin gossiping about a co-worker’s hygiene, she said, they tend to “mob together,” and end up attempting corrective actions that only make the office environment toxic.

“First they gossip about it and then they agree on a very bad solution. They do things like leave deodorant or a nasty anonymous note in their desk or mailbox,” Heathfield said. “Any manager that is not willing to address these problems directly, honestly, and with compassion is leaving themselves open for this.”

SEEING RESULTS
Though progress in addressing employee appearance happens incrementally, the results over time can often be dramatic, according to Dr. Leavitt. Four years ago during his multiple weekly visits to the various practice locations, he said, he was usually confronted with an employee appearance issue each time. The fault, he said, was with himself and his partners for failing to adequately train and develop the skills of the middle managers who handle administrative duties at the individual practices.

Through better training and a focused effort to address office décor and cleanliness and employee appearance — and better train practice administrators to handle such issues — things have improved dramatically. Now, he said, seeing or hearing of one issue in a month would be rare. Blind surveying of patients, he said, helped to measure the interim results of the change and suggest new directions for improvement.

“What’s worked best for us by far, especially lately, is getting everyone to try to see themselves as a team,” Dr. Leavitt said. “They’ve begun to see that how they look, act, and treat each other makes a big impression with the patient.”

Measuring results, according to Cannon and Heathfield, can be as simple as looking around the office and asking oneself if the environment presented is the one they themselves would like to see as a first-time patient. If employees who have to be talked to about their dress correct the action without attempting to push the limits of the dress code, Cannon said, they’ve internalized the importance of the dress code and the fact that it’s taken seriously in the office.

From there, Heathfield said, a quarterly meeting with employees to solicit feedback provides a marker to use for measurement of progress and an occasion to consider change.

The bottom line, Dr. Leavitt said, is creating a welcoming environment that turns first-time patients into long-term visitors to the practice.

“The last parameter we ask patients on our feedback surveys, the one which we consider the biggest signifier, is if they would refer another patient to our practice,” Dr. Leavitt said. “It gets more challenging as many patients get to primary care first for a number of dermatologic issues. There are challenges to be overcome, and we try to go really deeply with the idea that every patient must be treasured.”

DERMATOLOGY WORLD // June 2013
DOLLARS or DONUTS?

Sunshine Act requirements bring new scrutiny to physicians’ relationships with pharmaceutical companies
While the new National Physician Payment Transparency Program, established as part of the Patient Protection and Affordable Care Act (ACA), puts the onus for payment tracking on industry, dermatologists would be wise to track payments they receive from pharmaceutical companies, as their reputation could be at stake.

On Feb. 1, the Centers for Medicare and Medicaid Services (CMS) announced a final rule for what was previously known as the Sunshine Act, designed to create greater transparency around the financial relationships between drug and device manufacturers and certain health care providers, namely physicians and teaching hospitals. Specifically, manufacturers of drugs, devices, biologics, and medical supplies covered by Medicare, Medicaid, or the Children’s Health Insurance Program will be required to report to CMS any payments or other transfers of value they make to such providers. Manufacturers and group purchasing organizations must also disclose physician ownership or investment interests. In turn, CMS will post this information on a public website beginning in September 2014. Those who do not comply can face penalties upwards of one million dollars. >>
It is essential for the public to understand the importance of collaborative relationships in developing new therapies.
they would no longer be able to obtain quality speakers because just showing up at a meeting would affiliate the speakers with an organization that they had nothing to do with, Martin said, adding that the AADA advocated for this change along with ACCME and other groups.

This exemption was welcome news to the Pharmaceutical Research and Manufacturers of America (PhRMA), according to Marjorie E. Powell, PhRMA’s senior assistant general counsel.

**EASILY MISINTERPRETED**
Information is lacking regarding just how CMS plans to “reveal the nature and extent of relationships.” PhRMA is hopeful that when CMS posts this information it will do so with contextual explanations because otherwise it can be easily misinterpreted, Powell noted.

For example, a dermatologist could receive a significant payment for conducting research, but it may cover only the lab expenses. Without that explanation, the payment could be misconstrued. “It’s the perception of impropriety,” Dr. Webster said, where there is none, that makes the way information is presented so important.

“This is where the context of the data is critical,” Martin added. “It is essential for the public to understand the importance of collaborative relationships between physicians and industry in developing new therapies.”

Once in the public domain, this information can be used freely, and perhaps out-of-context, by political figures, advocacy organizations, media, and others to present misleading or sensational conclusions, Martin said. Disclosure of industry payments to physicians may spur investigations into potential violations of federal and applicable state laws, including the anti-kickback statutes, False Claims Act, and the Stark law. Anti-kickback laws bar payments to an individual and/or entity for referral of goods and/or services from federal health care programs. The False Claims Act addresses billing irregularities that call into question the medical necessity of treatments. The Stark law prohibits physicians from referring Medicare beneficiaries to entities in which they or family members have a financial interest. A physician who shows high utilization of certain procedures or medications, or has a large investment in a pharmaceutical or device company, could trigger a CMS audit. “Even a hint of inappropriateness could be a problem for physicians,” Martin warned.

**PROTECTING ONESELF**
Even though the responsibility for compliance is placed on industry, it would behoove dermatologists to track payments made to them. “It’s very important that dermatologists take this reporting seriously,” Martin advised. Beginning this August, dermatologists should keep a list of all payments they receive, which companies they receive them from, and for what services, he said. CMS deems physician record-keeping so important that it is considering developing an app to assist physicians, Martin added. The agency has already established a helpdesk for physician inquiries. Physicians may send their questions to OpenPayments@cms.hhs.gov.

Although Powell agrees that physicians should keep their own records, she points out that it is not always a straightforward task. For example, if a manufacturer’s representative brings donuts into the office, the dermatologist probably doesn’t know what those donuts cost. If the rep brings donuts in once a month, spending less than $100 a year, then that amount is exempt from reporting. But if the dermatologist is paid $100 to serve

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**REPORTING TIMELINE**

- **Data collection begins**
  - Aug. 1, 2013
  - January 2014
- **Data (from August-December 2013) due to CMS from pharmaceutical companies**
  - March 31, 2014
- **CMS makes data public**
  - Sept. 30, 2014
on an advisory panel for the same company that paid for the donuts, then both the donuts and the consulting fee must be reported.

In January 2014, dermatologists should register with CMS to review their payment data for accuracy. Check www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-Payment-Transparency-Program/index.html for registration instructions. Collecting the required data and reporting it accurately is a big undertaking with ample opportunity for mistakes, Martin noted. Therefore, dermatologists should anticipate that there will be discrepancies.

Starting in April 2014, physicians will have a 45-day period in which to review the data before it goes public and dispute any claims they think are inaccurate. Although physicians may have an additional opportunity to dispute the data after that point, it will already be out there as undisputed, Martin cautioned.

One reason for discrepancies is that companies must report payments using the physician’s name and specialty associated with his or her National Provider Identifier stored on the National Plan and Provider Enumeration System (NPPES) website. After obtaining a license, physicians may change and/or add specialties or change their name when they get married, but don’t necessarily update their listing, Powell said. Consequently, CMS could potentially be using outdated information. She advised dermatologists to make sure their information in NPPES is current to ensure they are identified correctly.


In addition, different companies may report their data differently. According to Martin, some companies plan to report payments and transfers of value in ranges, perhaps reporting what a physician received as “$10–$1,000.” Others have set up systems that will produce more specific reports, listing the doctor, what he or she received, and its exact value. Additionally, Martin said, some companies will count only the value of items provided directly to and accepted by a physician; others may count the value of lunch for the entire office staff and report it as being provided to the physician.

“This is a work in progress,” Martin said. “CMS has said they intend to work out kinks as the process moves forward and is seeking input from stakeholders.” The AADA, he noted, is actively engaged in working with CMS to streamline and standardize the process.

Despite these issues, dermatologists should be prepared to answer any questions their patients may have regarding their relationships with pharmaceutical and device companies should they arise, Powell said.

UNINTENDED CONSEQUENCES
Physicians and industry alike are concerned about potential unintended consequences of this legislation on research, education, and other scientific activities. Twenty-four percent of clinical researchers in the United States would be less likely to participate in research if their gross revenues were disclosed, according to a 2010 survey conducted by the Association of Clinical Research Organizations. Losing one-quarter of the nation’s clinical investigators could slow innovation and delay the delivery of needed treatments, the association noted.

“Physicians need to continue to be involved in research because that’s how health care moves forward,” Powell added. Similarly, physicians may be reluctant to present at meetings about new developments for fear of being considered biased because of their research. In addition, some physicians don’t want their patients to see that they served as a consultant with a pharmaceutical company because it could be negatively construed, Dr. Webster said.

In fact, relationships between physicians and industry have led to the development of new drugs and innovative medical devices used to diagnose and treat diseases, including dermatologic ones. When Dr. Webster graduated from medical school in the 1960s, dermatologists were treating the symptoms of psoriasis. “Now with biologics, we are treating the causes of the disease,” he said. Treatment advances like that have resulted from the collaboration between dermatologists and pharmaceutical companies, he said.

Physicians are the link between the bench and bedside, and many play a key role in developing effective treatments and devices, Martin added. These are appropriate relationships and physicians should be paid for their efforts. Still, all stakeholders need to be aware of the potential for commercial bias resulting from COI and take steps to guard against it. With regard to the public reporting of such payments, he said, dermatologists should focus on the accuracy and context of the reporting, and should avoid even the perception of wrongdoing. dw
Relationship with house of medicine vital to dermatology’s future

It has always been important for dermatologists to have a good relationship with our colleagues across medicine. But in this time of health care reform and reimbursement pressures, it may be more important than ever for our specialty to build bridges with others. There are formal, institutional ways to achieve this. There are also, as I will address later in this column, actions that only you can take to build relationships that will keep our ties with the rest of medicine strong.

One of the key venues where the house of medicine gathers to deliberate on important issues facing our profession is the American Medical Association House of Delegates, which meets this month. Our AMA representation is determined in large part by the number of dermatologists who are members of the AMA and designate the Academy as their primary organization of membership. It is important that as many AAD members as possible join the AMA and that our sister societies all secure seats in the House of Delegates, as our representation there is what gives us official standing in processes such as CPT coding that affect our members.

Dermatology is represented by the Dermatology Section Council, which is the collective voice of dermatology in the AMA House of Delegates; members deliberate regarding the issues before the House and often vote as one to increase the specialty’s influence. They deserve our gratitude, and include American Academy of Dermatology delegates Andrew P. Lazar, MD, MPH, (the section chair), Cyndi J. Yag Howard, MD, (the section vice-chair), Jack S. Resneck Jr., MD, and Marta J. Van Beek, MD, MPH; our alternate delegates, Hillary Johnson-Jahangir, MD, PhD, Adam Rubin, MD, and Sabra Sullivan, MD, PhD; our young physician section delegates, Lindsay Ackerman, MD, and Seemal Desai, MD; and our resident and fellows section delegates, Jennifer Ahdout, MD, and Erica Dommasch, MD. They also include the American Society for Dermatologic Surgery Association delegation of Jessica Krant, MD, Chad Prather, MD, Anthony Rossi, MD, Divya Srivastava, MD, William Waller, MD, and Nita Kohli, MD; Society for Investigative Dermatology delegates Daniel Bennet, MD, and John Fenyk, MD; American College of Mohs Surgery delegate Michel McDonald, MD; Navy delegate Josephine Nguyen, MD; Army alternate delegate Nathaniel Miletta, MD; state delegates Billie Jackson, MD, Elizabeth Kanof, MD, Hazle Konerding, MD, Danny McCoy, MD, and Leah McCormack, MD; and Georgia Tuttle, MD, whose long service has led to her holding a position on the AMA Board of Trustees.

Cooperation among dermatology societies, like that seen at the AMA, is critical to the specialty’s ability to respond to the challenges of the changing health care environment. In that spirit, the Academy now gives observer status on the Council on Government Affairs, Health Policy, and Practice to sister societies that have a dedicated health policy office or lobbyist. It is important for dermatologic societies to act in a coordinated fashion to avoid mixed messages and to project a stronger voice.

These organizational efforts to build specialty unity and collaborate with others in medicine are important, but they are made immeasurably more fruitful by the efforts of each of you. We are a small specialty; there are only 10,000 or so of us practicing in the United States and we represent less than 2 percent of practicing physicians. We tend to practice away from hospitals, making us less visible to our colleagues, and we risk being marginalized. Every interaction you have with a physician from another specialty is an opportunity for you to represent the AAD. If you see a referral quickly and return a helpful report and a satisfied patient to the referring physician, dermatologists are seen a great resource, interested in ensuring effective and efficient care. If you see patients in the hospital, volunteer in your community, or offer to help with free skin cancer screenings, those in the hospital and the community will see dermatologists as the sort of people who do those things. If we are perceived negatively by our colleagues, they may think of us more as a place to redirect the pain of any future spending cuts rather than as partners in ensuring effective health care. That will be bad news for our patients — and bad news for dermatology’s future. Each of us has opportunities to make a difference in how our specialty is perceived, and I extend thanks, on behalf of our specialty, to each of you who makes the extra effort to represent us well.

DIRK ELSTON, MD

DERMATOLOGY WORLD / June 2013 35
The road ahead
EXECUTIVE DIRECTOR'S REPORT

IT WAS THE MIDDLE OF WINTER when I arrived at Academy headquarters. A major snowstorm hit that first day and it took me two-and-a-half hours to drive home. This allowed me ample time to question the wisdom of this major career move.

Over the years I worked on health care policy and also spent 25 years working for professional associations serving lawyers and CPAs. So, as I inched home through the snow, as I pondered whether if I had chosen the right path to get there, I also wondered, “Did I choose the right path by moving to a health care association?”

Over the next weeks, I embarked on my crash-course in the Academy. I interacted with our leadership; I attended the Annual Meeting, encountered young physicians at our Leadership Forum, interacted with our corporate partners, participated in some D.C.-based advocacy efforts, and listened as the Board of Directors thoughtfully debated and then unanimously acted on the issue of pathology billing.

I spoke with Academy members and asked that they share with me their day-to-day challenges — EHRs, a rapidly changing practice environment, threat of lower reimbursements, scope of practice changes, health care reform and all that flows from it. I began to fully comprehend the wide array of change and uncertainty our profession faces in the legislative and regulatory arenas, let alone the daily workplace setting.

As I attended my meetings and talked with our members, I quickly gained an appreciation for the diversity of AAD membership and the scope of issues we must tackle on their behalf. I realized that in this time of legislative and regulatory upheaval, in an era of new and unpleasant economic realities for dermatology as well as all of medicine, the role of a professional association has never been more important. And our need to remain united as a profession is essential. As AAD President Dr. Dirk Elston said in a recent email to members, “Now is the time for dermatologists to speak with one voice or risk being divided by many.”

Today, dermatologists and the profession face major challenges. There are legal, legislative, regulatory, economic, and technological changes going on that require careful understanding and guidance to navigate through. Simultaneously, our members must keep up with the latest in educational issues, scientific advances, and practice management trends.

In a short amount of time, I have come to learn that the Academy is providing leadership to its members in all of these areas. Whether you are adapting to EHRs, getting up-to-speed on ICD-10 or modifier 25, embracing telemedicine, or looking to protect your reimbursement rates, the Academy is there to advocate and assist.

In the weeks and months ahead, we may not win every legislative or regulatory battle but your professional association is out front advocating on your behalf. And by being out front...the Academy has “got your back.”

Yes, we have tough challenges ahead, but the right team is in place to address them. Our AAD leaders are informed, thoughtful, and diverse, truly representing the range of AAD membership. The AAD staff is impressive. As a newcomer, I walked through the doors last February, grateful to find that the staff, under the strong leadership of Deputy Executive Director Eileen Murray, was on top of the issues, and open to bringing me into the team picture to serve our members and advance our strategic goals.

So, now it is summer. The snow has melted, the trees are in bloom, and my ride home is pretty painless. In my first months here, I’ve been impressed by the important work this association undertakes. I have quickly learned the Academy is effectively addressing the critical issues of importance to dermatologists and tackling the challenges that confront the profession. It is an honor to be part of the team.

In short, I have seen the path that the AAD is on. The road ahead is filled with uncertain twists and turns thanks to health care reform and the other changes I’ve just described. But I am ready to help steer the organization, and confident that together, we are on the right path. dw
Honorary Member nominations sought
Due by Sept. 1
THE AMERICAN ACADEMY OF DERMATOLOGY seeks nominations for individuals to be considered for Honorary Membership. Nominees for Honorary Membership must meet certain criteria; primarily they must have demonstrated leadership and service that affirms an uncommon and sustained dedication to dermatology and the goals of the Academy. In most cases, this honor is bestowed for a lifetime of dedication and distinguished service. Although not a determining factor, nominees should have held a prominent office in the Academy.

Please submit Honorary Member nomination(s) online at www.aad.org/forms/honorarymembership by Sept.1, 2013. When submitting a nomination you are also required to submit a brief biography of the nominee, including their accomplishments and reasons they should be granted honorary membership.

The Board of Directors will select Honorary Membership recipients at its November meeting and they will be announced during the 72nd Annual Meeting, March 21–25, 2014 in Denver. —SHANNON GIGNAC

Registration, housing for Summer Academy Meeting 2013 open
REGISTRATION AND HOUSING for Summer Academy Meeting 2013, being held July 31-Aug. 4 in New York, is now available online at www.aad.org. Housing reservations can be made at the time of registration at AAD discounted rates. Early registration and housing will close on July 8 at 12 p.m. CT. From July 24 at 12 p.m. through July 31 at 12 p.m. all registration systems will be closed. On-site registration will begin at 12 p.m. ET on Wednesday, July 31.

Members can add a donation as they register for the Summer Academy Meeting; donations can support the Academy’s efforts to reduce skin cancer through SPOT Skin Cancer™, or help support a unique summer camp opportunity for young patients via the AAD Camp Discovery Endowment. —RICHARD NELSON

Applicants sought for research excellence award for young dermatology investigators
EACH YEAR THE ACADEMY recognizes outstanding basic and clinical/translational research by young dermatology investigators through the AAD Awards for Young Investigators in Dermatology. The purpose of the award is to acknowledge significant research advances in the science and practice of dermatology by those beginning their research careers.

Two young investigators will be selected as the recipients of a $6,000 award that will be shared equally with investigators’ current or past dermatology residency program. Eligible candidates include U.S. and Canadian dermatology residents, fellows, and dermatologists who have completed their research by age 35 or within seven years of completing a terminal degree. Research must be initiated after medical school and PhD thesis work.

The award selection panel will evaluate submissions for the originality of the research concept and soundness of research design, the quality and clarity of the submitted research report, and the perceived value of the research to dermatology. Clinical researchers are encouraged to apply.

Nominations for the 2014 awards are being accepted until Oct. 15, 2013. Detailed online submission information is available at www.aad.org/young-investigators-award; for more information contact Allen McMillen at amcmillen@aad.org. —ALLEN MCMILLEN
Obituaries

The Academy recently learned with sorrow of the passing of the following members of the dermatologic community.

Fillmore K. Bagatell, MD, Phoenix. Completed dermatology residency training at University Hospitals Case Medical Center. Died March 1.


Gene E. Burges, MD, PhD, Charleston, S.C. Completed dermatology residency training at Medical University of South Carolina. Died May 5, 2012.

Karl Holubar, MD, Vienna. Completed dermatology residency training at University Of Vienna. Died Jan. 6.

Harold G. Hurst, MD, Winnipeg, Canada. Completed dermatology residency training at University of Minnesota. Died Feb. 2.


George Rizk Mikhail, MD, Osprey, Fla. Completed dermatology residency training at Wayne State University. Died April 5.

Hugh Francis Molloy, MD, Sydney, Australia. Completed dermatology residency training at University Of Sydney. Died Jan. 3.


Zeev Pam, MD, Misgav Dov, Israel. Died Jan. 20.


Rudolph J. Scrimenti, MD, Mequon, Wis. Completed dermatology residency training at University of Pennsylvania. Died March 22.


R.A. Stevenson, Jr., MD, Victoria, Texas. Completed dermatology residency training at University of Texas. Died April 26, 2012.


Obituaries are published in Dermatology World after information is submitted to the AAD. Information on member obituaries should be submitted in writing to Member Resource Center, AAD Member Services Dept., P.O. Box 4014, Schaumburg, IL, 60168-4014, via fax at (847) 330-1090, or via email at mrc@aad.org.
Dr. Shalita honored with Gold Medal

In recognition of his service to the specialty and the American Academy of Dermatology, as well as his passion for the teaching and practice of cutaneous medicine, Alan Shalita, MD, was awarded the Gold Medal, the association’s highest honor, at the 71st Annual Meeting in Miami Beach, Fla.

Long considered a pioneering acne researcher, Dr. Shalita’s interest in the subject was fostered during his undergraduate years at Brown University, where he said his close relationship with professor William Montagna, PhD, encouraged him to explore the field further.

“I attended a lecture of his on the sebaceous glands and acne, and I got to meet some of the young up-and-coming leaders, as well all the giants of dermatology,” Dr. Shalita said. “Dr. Marion Sulzberger, Eugene Van Scott, Donald Pillsbury — you name them, they were there, and I got to wash the blackboards and show the slides. I thought that was inspiring. I had already committed myself to dermatology.”

He then attended medical school at the Bowman Grey School of Medicine at Wake Forest University, and completed his residency at New York University Medical Center. When he got to medical school, Dr. Shalita said, he found that he liked almost everything about medicine, but didn’t find anything he liked more than dermatology.

“In dermatology, I could do most of everything else I liked. I could do pediatrics, surgery, and general medicine. Dermatology tied everything together for me,” he said. “I was fortunate that at NYU, the chairman, Dr. Rudolph Baer, was wonderful about allowing young people to pursue their areas of interest.”

Dr. Shalita is currently a distinguished teaching professor and chief of dermatology at SUNY Downstate, a position he has held since 1975. He also serves as associate dean for graduate medical education and clinical affairs. He previously served the Academy as vice president, as well as chair of the Council on Communications and chair of the council on scientific assembly. He has lectured at the annual and summer meetings, and has published more than 100 articles in peer-reviewed journals. - JOHN CARRUTHERS

Media Highlight

For the first quarter of 2013, print and broadcast media coverage on dermatology generated more than 466 million media impressions throughout the United States. This level of coverage would not be possible without the many hours Academy members volunteer to participate in interviews with journalists throughout the country.

In the April issue of Good Housekeeping (circulation 4,354,740), “Smooth-Skin Secrets,” Deirdre Hooper, MD, Amy Derick, MD, Lisa Garner, MD, Erin Welch, MD, Karyn Grossman, MD, Ranella Hirsch, MD, Leslie Baumann, MD, and Paul English, MD discussed how different climates affect the skin and provided solutions to address the problems. - ROSE HOLCOMB

Members Making A Difference: Nnenna Agim, MD

NIGERIAN-BORN DERMATOLOGIST SERVES EAST DALLAS CLINIC PATIENTS

FOR UNIVERSITY OF TEXAS-SOUTHWESTERN
dermatologist Nnenna Agim, MD, volunteerism was the very first value instilled by her parents during her upbringing in Nigeria. As a dermatologist and faculty member, she still holds those values close, providing care to underserved patients at the Agape Clinic in Dallas. The clinic’s website claims that Texas is the “underserved capital of the United States.” Dr. Agim and other community dermatologists work tirelessly to do the best they can for these patients.

“We do the best we can with what we have, and the patient and their family don’t have to be scared about how they’ll pay the bill. We provide a safe place for them.”

- Dr. Agim’s interest in medicine began as a college student at the University of Houston, where she and a friend also hailing from Nigeria began to volunteer at a local hospital. The process of familiarizing themselves with the hospital care system, she said, made her determined to help alleviate patient suffering any way she could.

- “We got to meet these patients, hear their stories, and understand them. We weren’t nurses, or medical assistants, or doctors. We couldn’t do anything but be there for them. Yet just doing that was meaningful in and of itself. That stuck with me through medical school.”

- As Dr. Agim began her dermatology residency at UT-Southwestern, she learned of the Agape Clinic’s dermatology section, which had been started by a former resident in her program. She began attending bi-monthly, but soon found herself coming to the clinic as often as she could manage.

- Following a fellowship outside the area, Dr. Agim returned to UT-Southwestern and the clinic that had helped foster her spirit of community service. As a resident and staff member, she has been volunteering her services for seven years, providing quality specialist care for the underserved.

- “We’re able to diagnose, treat, and give patients samples of the medications they need. Now I’m faculty, and I have the ability to medically treat patients, but it’s still really fulfilling just to be able to see patients and be there for them, just like in college.” - JOHN CARRUTHERS

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PIH Health is a nonprofit health and wellness network consisting of a 550+ bed acute care hospital, multi-specialty medical group, hospice, home health and other services. Located in Whittier, California, just 30 miles east of Los Angeles, our exclusively-affiliated medical group is rapidly growing to meet community needs. In response to this growth, we have an immediate opening for a full-time Dermatologist.

Successful candidates will be well-trained, board-certified (or pending if new graduate) and interested in general medicine dermatology. We are looking for motivated team players who want to work in state-of-the-art facilities with other well-trained physicians and advanced practice professionals. In exchange, you will enjoy a work-life balance, great benefit and compensation package, and a grateful community of patients.

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Located midway b/w San Francisco, Napa, & Tahoe, we are seeking a BC/BE Dermatologist 3-5 days per week to join well established General & Cosmetic Derm practice. Outstanding staff, warm office environment, suburban setting, state-of-the-art surgery, laser & computer equipment. Partnership opportunity. Mentorship in advanced cosmetic & reconstructive procedures if desired. Productivity, hours, vacations all flexible based on your goals. Excellent opportunity for income and Family/Life Balance. To apply, please send CV, and short Bio with your goals to: californiaderm09@yahoo.com.

FOR MORE INFORMATION:
Contact: Carrie Parratt
Phone: (847) 240-1770
Email: cparratt@aad.org
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ANN ARBOR, MICHIGAN

Ann Arbor Dermatology is looking for a career oriented, conscientious, well-trained dermatologist to join a busy, growing practice. This position offers an opportunity to build a comprehensive practice that encompasses all aspects of dermatology including Mohs surgery and cosmetic work with a highly competitive salary plus bonuses, full benefits and early partnership. For more information please contact A. Craig Cattell, M.D. by phone (734) 996-8757, fax (734) 996-8767, or email: a2derm@aol.com.

MISSISSIPPI

BC/BE Dermatologist needed for medical/surgical position. Opportunity for MOHS and cosmetics. Generous compensation, signing bonus, relocation and benefits package. Office located in the college town of Laurel, MS. Contact is negotiable. For more information, please contact Joy at (513) 267-3658 or send your CV to: cfamrecruiting@aol.com.

DERMATOLOGIST

We are currently seeking a BC/BE dermatologist to join our practice, which is located in a peaceful rural Kansas community. This is an excellent opportunity to serve a large patient base in a clinic that offers the full spectrum of surgical and medical dermatology. Our physician-owned clinic draws from three surrounding states, and is staffed with a highly trained Nurse Practitioner and four dedicated nurses. It has a fully equipped CLIA-certified MOHS surgery lab, as well as state-of-the-art laser equipment. We offer a competitive salary with quick partnership potential, comprehensive benefits, and productivity incentive. Interested candidates are encouraged to contact Ms. Paula Park at (620) 624-9100 or by fax at (620) 624-9107 or by email at dermatology_center@yahoo.com.

SALES INFORMATION

UPCOMING DEADLINES FOR FUTURE ISSUES:

August .......................... June 25
September ..................... July 19
October .......................... August 23
November ..................... September 27
December ........................ October 25
PROFESSIONAL OPPORTUNITIES

Cambridge Health Alliance Dermatology

Cambridge Health Alliance (CHA) is a nationally recognized, award winning public health system and we are currently recruiting dermatologists to establish a Dermatology Division within the Department of Medicine. CHA is a teaching affiliate of both Harvard Medical School and Tufts University Medical School. Our well respected health system is comprised of three campuses and an integrated network of both primary and specialty care practices in Cambridge, Somerville and Boston’s Metro North Region. As we transition to becoming an Accountable Care Organization, dermatology services will be essential to the success of our Patient Centered Medical Home Model.

These positions are primarily clinical and will practice general dermatology in an ambulatory setting as well as inpatient and emergency department consultations. For the right candidate, leadership opportunities exist and we will consider either PT or FT. Ideal candidates will be BC, possess two years of post residency experience and substantial interest in building a Dermatology Division, developing quality improvement projects, Tele-dermatology services, as well as curriculum development for both medical student and resident education. Candidates must possess excellent clinical/communications skills, commitment towards our multicultural, underserved patient population and a strong interest in teaching. Ability to collaborate and work in a multidisciplinary team environment is required.

At CHA we offer a supportive and collegial environment with a strong infrastructure-including an EMR system, as well as the opportunity to work with dedicated colleagues committed to providing high quality health care to a diverse patient population. Excellent opportunities exist for teaching medical students/residents, and we strongly encourage both women and minorities to apply. Please forward CV's to Laura Schofield, Director of Physician Recruitment, Cambridge Health Alliance, 1493 Cambridge Street, Cambridge MA 02139. Telephone (617) 665-3555, Fax (617) 665-3553 or via e-mail: Lschofield@challiance.org. EOE. www.challiance.org

New Hampshire

We are seeking a part or full time Dermatologist to join our group of ten Board Certified Dermatologists in a professionally run practice with dermatopathology, Mohs, Medical Aesthetics, and consulting facial plastic surgeon. This opportunity would allow a highly qualified dermatologist to practice with excellent support staff in a collegial practice in New Hampshire with competitive salary, benefits and practice ownership. For more information, please contact: Glenn Smith, MHA, Administrator and Chief Operating Officer, at (978) 610-3701 or email to gsmith@apderm.com. www.apderm.com

New Jersey

Seeking BE/BC Dermatologist to join long established private practice in well populated N.J. town. Opportunity to purchase practice is also available. If interested, please contact us at Adacio44@aol.com. Please include CV and short letter of intent.

Southern New Jersey

Great opportunity for BC/BE dermatologist in Medford, NJ. Beautiful community near Philadelphia, PA and Cherry Hill, NJ. Well-established busy dermatology practice in a brand new facility, with associated medical spa. Opportunity for competitive salary, benefits, and practice ownership. FT/PT position available. Email inquiry or CV to suzanne@accentderma.com.

Flushing, Queens, New York


Columbus, Ohio

8 member growing practice has 2 positions: 1 general and 1 cosmetic dermatologist. FT or PT. Partnership desired. Excellent salary and benefits. Single location practice in a beautiful practice owned building. Email: rsiegel@csdermatology.com.

Next available issue: August
Contact: Carrie Parratt (847) 240-1770 cparratt@aad.org www.aad.org/dw

LAS VEGAS

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New Hampshire

We are seeking a part or full time Dermatologist to join our group of ten Board Certified Dermatologists in a professionally run practice with dermatopathology, Mohs, Medical Aesthetics, and consulting facial plastic surgeon. This opportunity would allow a highly qualified dermatologist to practice with excellent support staff in a collegial practice in New Hampshire with competitive salary, benefits and practice ownership. For more information, please contact: Glenn Smith, MHA, Administrator and Chief Operating Officer, at (978) 610-3701 or email to gsmith@apderm.com. www.apderm.com

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We are seeking a BC/BE Dermatologist to join our team of 3 dermatologists and 2 PA’s in a highly-regarded, well-established, multi-specialty practice. Our Atlanta office is located in the Buckhead area and is in close proximity to Emory University Hospital Midtown. The practice enjoys a high level of patient satisfaction and offers an attractive compensation package and benefit plan that provides for comprehensive health care, retirement, and vacation leave. Six weeks of vacation, six weeks of sick leave, and a five-day office schedule are provided. We are located within walking distance of local restaurants, shops, and sports facilities and enjoy easy access to Atlanta’s cultural amenities, including the symphony, opera, and museums. For more information, please contact Dr. Savitha Gudipati, Office Manager, 404-679-6750 or email bgudipati@21cdermatology.com.

Our full-service dermatology group seeks a BC/BE Dermatologist to join our practice of 15 dermatologists and 80+ support staff. We are near the intersection of three major highways, with easy access to the entire Atlanta metropolitan area and a variety of cultural and recreational activities. The practice includes a large volume of general dermatology and dermatologic surgery, as well as cosmetic dermatology, lasers, and immunology. The office is located on the first floor of a multi-specialty building, with state-of-the-art equipment, including lasers and optical coherence tomography (OCT). We are located within walking distance of local restaurants, shops, and sports facilities and enjoy easy access to Atlanta’s cultural amenities, including the symphony, opera, and museums. For more information, please contact Dr. Andrew C. Brown, Office Manager, 404-679-6750 or email abrown@21cdermatology.com.

We are seeking a Dermatologist to join our practice of 15 dermatologists and 80+ support staff. We are near the intersection of three major highways, with easy access to the entire Atlanta metropolitan area and a variety of cultural and recreational activities. The practice includes a large volume of general dermatology and dermatologic surgery, as well as cosmetic dermatology, lasers, and immunology. The office is located on the first floor of a multi-specialty building, with state-of-the-art equipment, including lasers and optical coherence tomography (OCT). We are located within walking distance of local restaurants, shops, and sports facilities and enjoy easy access to Atlanta’s cultural amenities, including the symphony, opera, and museums. For more information, please contact Dr. Andrew C. Brown, Office Manager, 404-679-6750 or email abrown@21cdermatology.com.
EHR ADOPTION RATE RISES IN DERMATOLOGY GROUPS

When the Academy surveyed members about electronic health record adoption in 2011, it found that about 38 percent had implemented an EHR system in their practices, and another 13 percent had acquired a system, for a total acquisition rate of 51 percent. When the Academy asked about EHR adoption again when it conducted the Dermatology Practice Profile Survey in 2012, though, acquisition rose four points — 55 percent of dermatologists reported that they had acquired an EHR.

What accounts for the increase? Dermatologists in group practices led the change, with 49 percent having acquired a system in 2012 compared to 36 percent in 2011. Solo practices also saw a slight rise, from 36 to 41 percent. (The results may correlate with age, as well; see the April Facts at Your Fingertips, which indicated that solo practice is more common among those over 50, with group practice more common among those under 50.)

The newer survey also found significantly fewer dermatologists in groups without plans to acquire an EHR system at some point; the figure dropped from 35 to 22 percent. Soloists, however, held nearly steady; 44 percent had no adoption plans in 2012, down from 48 percent in 2011.

A full table of adoption by practice type appears below. – RICHARD NELSON

EHR adoption by practice type

* Data from AAD 2012 Dermatology Practice Profile Survey. Figures do not add up to 100 percent due to non-responses on survey.
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