Strategies for improving patient communication, compliance, and satisfaction

WHAT YOU SAY vs. WHAT PATIENTS HEAR

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How did you become involved as a judge for the Aspire Higher program?
I was approached by Ortho Dermatologics, and I thought it was a wonderful opportunity. I really liked that they were giving back to the community and that I could help people who want to further their education.

What is your favorite part about being a judge for Aspire Higher?
I really enjoy the whole experience, but two things come to mind: Seeing the impact the scholarships have on the lives of the people who win, and reading their stories.

One of last year’s winners left a voicemail for the judges. I was in the middle of grocery shopping when I heard it, and I started crying because it was so touching. Also, reading about how a problem with a person’s skin impacts each aspect of their life urges us to seek the best possible treatment for our patients even more. I think that what Ortho Dermatologics is doing is exceptionally worthwhile.

As part of its commitment to the dermatology community, Ortho Dermatologics created the Aspire Higher scholarship program. The program sponsors scholarships for new college students, graduate students, and mothers returning to college. Patients who have been treated for skin conditions are eligible to apply.

Dr. Linda Stein Gold began serving as one of several judges for Aspire Higher in 2016. She also performs clinical research and cares for patients at the Henry Ford Health System.

It's so satisfying to see how the Aspire Higher scholarship can change somebody's life by helping them further their education.

What are your thoughts about Ortho Dermatologics' commitment to the dermatology community through this scholarship program?
I'm thrilled to be part of it. I'm thrilled to have had the opportunity to hear the patients' stories, to understand their journey, and to be part of making their educational dreams come true. I think this is a major gift that Ortho Dermatologics gives back to the community, and it's important to get the word out to our patients that this is available. Ortho Dermatologics really does care about our specialty.

Hear from 2017 winner Robby Ruffolo at aspirehigherscholarships.com
Why Dermatology World?

Change is a recurring theme in this month’s Dermatology World. Change seems to be a given these days; perhaps it always was, but it’s hard to imagine a time in medicine in which so much has changed as quickly as has happened in the past few years. Not just the science on which we base our work, but the structure in which we practice our craft is fundamentally changing every day. How we cope with these changes is key, and our feature article “Embracing change” offers some very positive strategies that you may want to consider. Our incoming AAD President, Dr. Suzanne Olbricht, eloquently reminds us that the AAD offers many resources to help us navigate these potentially challenging times. We are not alone in this struggle, and the AAD has our back.

As I begin my tenure as physician editor, a good friend asked why I would want to take on yet another role in my arguably overscheduled life. Surely, I have enough going on without adding even more deadlines to meet...probably true, but I am incredibly honored be allowed to serve the Academy and its members in this role. This opportunity arose following unanticipated changes in my life (including a move to the beautiful Pacific Northwest). Some of these changes were good, others more challenging; however, as is often the case, with change comes new, and in this case, exciting, opportunities.

I will confess upfront to a strong bias; I am big fan of the AAD and I am an avid reader of DW. Over the years, DW has served as my primary resource for information about things relevant to practice management, health care policy, and patient care. I read JAAD to keep up on science; I read DW for pretty much everything else. DW highlights important clinical and scientific developments, but also goes beyond the scientific “what” to delve into the “how” and “why” about a variety of topics germane to our profession. I am not alone in appreciating the value of DW; a majority of our membership, including 75% of our members under age 40, identify DW as their go-to resource for practice management issues.

Why should you read DW? The simple answer is that it is written for you.

Our award-winning, monthly publication is the product of the collaborative efforts of our dedicated AAD staffs, professional writers, and fellow AAD members who identify and write about topics they feel are important to all dermatologists. Each month we offer several full-length feature articles, along with our informational columns that provide invaluable advice on all things legal, regulatory, and financial. My thanks to our colleagues including Drs. Alex Miller and Cliff Lober who regularly and freely contribute their time and expertise in these areas. We are also privileged to have a hard-working and wonderfully diverse Editorial Advisory Workgroup, which includes 12 of our colleagues who spend countless hours ensuring that DW is relevant, timely, and of benefit to our membership.

Under the thoughtful leadership of our outgoing editor Dr. Abby Van Voorhees, DW has grown significantly since 2011. The publication itself has morphed from a paper tabloid to a glossy, eye-catching monthly magazine, and the DW brand has expanded to include DW Weekly, the weekly electronic digest of timely and important news, which reaches all members, and DW Academy Insider, a weekly roundup of what the Academy has to offer you. We are fully digital, and yes, we have an app for that. Download it at www.aad.org/members/aad-apps/dermatology-world. I have no crystal ball with which to predict what we will look like in a few years; however, be assured that we will always strive to be the best, most relevant, and hopefully the most readily accessed resource possible for our members.

Be happy. And read Dermatology World.

KATHRYN SCHWARZENBERGER, MD, PHYSICIAN EDITOR
WHAT YOU SAY VS. WHAT PATIENTS HEAR
You think you’re communicating clearly with patients — but are they getting the message?

THE COMPOUNDING CONUNDRUM
Safety concerns at big compounding facilities have led to real challenges for small practices trying to prepare medications for patients.

EMBRACING CHANGE
With so much changing in health care, how can dermatologists adapt — and be happy about it?
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2017 Awards for Excellence
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- Magazines, Journals and Tabloids – Print – 32+ pages
- Writing Grand Award

2016 Awards for Excellence
- Feature Writing
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2015 Awards for Excellence
- Writing – Feature Writing
- Writing – Departments and Columns
- Magazines, Journals and Tabloids – Print – 32+ pages

2017 ASHPE Gold award
Best Cover: Photo
Take a pill! – April 2016

2016 ASHPE Silver award
Best Cover: Photo
Teledermatology - April 2015

2015 ASHPE Gold award
Best Cover: Photo
Joining Up - July 2014

2016 AM&P Excel Bronze Award, Design Excellence

2017 Eddies Digital Honorable Mention; Association/Non-profit – Newsletter

2016 and 2015 Eddie Honorable Mention, Association/Non-profit (B-to-B) – Single article

2016 Eddie Honorable Mention, Association/Non-profit (B-to-B) – Series of articles

2015 Eddie Honorable Mention, Association/Non-profit (B-to-B) – Full issue

2014 Eddie Honorable Mention, Association/Non-profit video

2017 Ozzie Silver Award, Best Redesign: Association/Non-profit

2013 HOW InHOWse Design Award – Cover/Feature Design


2016 and 2017 Graphic Design USA Award – Infographics

2014 Graphic Design USA American Web Design Award
Do you require staff to wear a uniform?

“Yes, and they really like it. Each staff member chooses the style that fits them best from a selected group.”

– Corey Hartman, MD, Birmingham, Ala.

“No, most medical assistants wear the scrubs of their choice. I think an official uniform would be more unifying.”

– Anna Karp, DO, New York, N.Y.

“Yes, we all wear black scrubs. #ninja #derm”

– H.L. Greenberg, MD, Las Vegas, Nev.

“Yes! My whole office wears matching navy scrubs, gray fleece jackets, and a name badge. We get many compliments from patients.”

– Lauren Kyle, MD, Overland Park, Kan.

“Most definitely they all need to wear a uniform. This allows for a clean and consistent appearance in the office, and avoids occasional poor choice of clothes or shoes that may occur.”

– Karyn Grossman, MD, Santa Monica, Calif.
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Malignant melanoma is one of the most serious diagnoses that dermatologists face on a regular basis. While many cases of malignant melanoma are curable with excision, there are still a significant number of patients with malignant melanoma who develop metastatic disease, often leading to death. Many research studies have evaluated the most important risk factors for assessing the prognosis of individual melanomas using clinical and histopathological data. The American Joint Commission on Cancer (AJCC) provides guidance on staging and classification of tumors such as malignant melanoma. The most recent edition of the AJCC staging system (January 2018) has removed mitotic rate as a criterion for staging primary cutaneous malignant melanoma.

A recent paper from Vanderbilt University analyzed 17,204 thin malignant melanomas (thickness less than 1.0 mm) in the National Cancer Database, for high risk features and lymph node status (doi.org/10.1016/j.jaad.2017.11.041). Mitotic rate showed a strong linear relationship with the odds of having a lymph node involved by melanoma. While this paper does not address survival analysis, it highlights the importance of mitotic activity in a melanoma. It is recommended that pathologists should continue to report mitotic rate for primary cutaneous invasive malignant melanoma. Treating dermatologists and surgeons should expect this information in their patients’ pathology reports to assist in optimal counseling and management.

**Out with IVIg, in with cyclosporine.** A pivotal study [Nat Med. 2008;14:1343–1350] found that Fas ligand does not play a major role in epidermal necrosis, and identified granulysin as the main cell death mediator involved in toxic epidermal necrolysis. Granulysin is a cytolytic protein produced by cytotoxic T lymphocytes and NK cells. Interest in cyclosporine increased due to its theoretical benefit in TEN with its function of inhibiting T lymphocytes and its potential anti-apoptotic effects. The trend in the literature away from IVIg continued when a retrospective review [J Am Acad Dermatol. 2014;71(5):941-7] on the treatment of TEN with IVIg versus cyclosporine found cyclosporine to have greater mortality benefit. A recent systematic review and meta-analysis found no survival benefit with the use of IVIG [JAMA Dermatol. 2017; 153(6):514-522]. However, cyclosporine and systemic corticosteroids were found to be promising options for SJS/TEN. A recommended dose of cyclosporine is 3-6 mg/kg ideal body weight/day divided into two daily doses over 7 days followed by a tapering dose. Monitor blood levels (aim: plasma concentration 150-200 ng/ml, measured before morning dose). Consider adding intravenous corticosteroids (50 - 250 mg/day) for a few days [J Invest Dermatol. 2017;137:2047-2049].

Here’s more bad news about syphilis: a 100 percent increase in ocular syphilis in North Carolina from 2014 to 2015 (Clin Infect Dis. 2017;65:1676-82). In 2014, 21/1799 (1.2%) syphilis cases in North Carolina had ocular syphilis; in 2015, it was 42/2433 (1.7%). Uveitis was the most common diagnosis in patients with ocular syphilis, which was more common among males, whites, those over age 40, and those living with HIV. The ocular syphilis uptick in North Carolina mirrors nationwide trends (www.cdc.gov/std/syphilis/clinicaladvisoryos2015.htm). That should concern dermatologists, for two reasons. First, ocular syphilis, and neurosyphilis, can occur during early stages of syphilis, alongside (or even before) cutaneous manifestations. For that reason, CDC recommends a neurologic and ophthalmic review of systems, as well as a targeted neurologic examination, in every patient with syphilis. Patients with ocular symptoms, or with neurologic signs or symptoms, should be referred for additional evaluation and management. Second, increases in ocular syphilis have occurred in the context of an overall syphilis epidemic. Primary and secondary syphilis — the infectious stages of the infection — has increased in the United States every year from 2000 (5979 cases) to 2016 (27814 cases). The epidemic has disproportionately affected men who have sex with men (MSM), who accounted for 58% of primary and secondary syphilis cases in 2016; of MSM diagnosed with syphilis, 47% were co-infected with HIV (www.cdc.gov/std/stats16/Syphilis.htm). Dermatologists should be on the lookout for syphilis in general, and keep their eyes peeled in particular for ocular and neurologic manifestations of the disease.
In recent years, FDA restrictions on compounding have severely restricted dermatologists’ ability to access and mix preparations (i.e., buffering of lidocaine with sodium bicarbonate or dilution of triamcinolone with lidocaine).

What can dermatologists do to regain access to office-use compounded drugs for patients?
Write your local representative in support of H.R. 2871, Preserving Patient Access to Compounded Medications Act, which would ensure access to medications while maintaining the safety of compounded medications, using the Academy’s advocacy website: https://takeaction.aad.org/composeletters.aspx?AlertID=1512

Why did this happen?
In response to the 2012 New England Compounding Center fungal meningitis outbreak, Congress passed the Drug Quality & Security Act (DQSA). The DQSA gave the FDA oversight over “outsourcing facilities (503B),” to regulate manufacturers of larger batches of compounded drugs. The FDA misinterpreted Congressional intent by prohibiting section 503A compounding pharmacies from dispensing office-use compounded drugs without a patient-specific prescription. The FDA incorrectly assumes that section 503B outsourcing facilities can meet the needs of physicians and their patients. However, outsourcing facilities are designed to produce large quantities that make their business models sustainable, rather than the small quantities needed by physician offices. As a result, physicians and patients are facing issues accessing needed drugs. (Learn more about these issues on p. 38.)

What else do I have to look out for?
State pharmacy boards have followed the FDA’s interpretation of the federal compounding law. As a result, some state pharmacy boards have also prohibited in-office compounding, further complicating dermatologists’ ability to obtain certain compounded medications. Restrictions vary widely state-by-state and it’s essential that you advocate at the local level (state medical society) to protect your rights. Make sure your state medical society is addressing these issues!

The wide variety of new and highly effective psoriasis medications — and the corresponding advertising push by pharma — can make older medications, such as methotrexate, appear atavistic at best and at worse a disservice to our patients. However, the rising costs of pharmaceuticals compels us to consider these older therapeutic options in certain situations. But, how do we know who are the best candidates for these medications, and when can we make a judgment about their efficacy? In the December JAAD, Gordon et al derived a formula for predicting which psoriasis patients are most likely to respond to methotrexate (2017;77(6):1030-1037). They found that patients on an escalating dose of methotrexate who achieved PASI25 at week 4 were highly likely to go on to achieve PASI75 at week 16. Given that PASI75 is currently considered the gold standard for treatment response, this tool provides a quick and easy way to determine if a patient should stay on methotrexate, or whether a different medication should be considered. The dose was started at 7.5 mg/week and increased to 10 mg/week at week 2, then to 15 mg/week at week 4. The dose was further increased to 20 mg/week at week 8 and 25 mg/week at week 12 if PASI50 was not achieved. At week 4 the rates of serious hematologic and hepatotoxic effects were very low. This prediction tool provides an excellent opportunity to ensure that we continue to provide highly effective and safe care to our patients while helping to control costs. dw
Modifier 25, revisited

BY ALEXANDER MILLER, MD

Alexander Miller, MD, addresses important coding and documentation questions each month in Cracking the Code. Dr. Miller, who is in private practice in Yorba Linda, California, represents the American Academy of Dermatology on the AMA-CPT® Advisory Committee.

When you do a minor surgical procedure with a zero- or 10-day global period (biopsy, shave removal, lesion destruction, simple excision, a simple, intermediate or complex repair, Mohs surgery) and you also perform a distinct and separately identifiable evaluation and management (E/M) service, you would usually append a 25 modifier to the appropriate CPT® code (99201-99215) characterizing the level of separate E/M service provided.

Lately, some payers have been focusing upon modifier 25 use, and have implemented or are intending to institute reimbursement limitations, payment reductions, and/or focused chart audits. As we dermatologists use modifier 25 more than any other specialty, we are particularly vulnerable to insurance company limitations on its use. Consequently, it is imperative that our charting justify both the medical necessity for a separately identifiable E/M service and appropriately document that service.

The E/M service provided should “stand on its own.” This means that one should subtract from the overall E/M provided all E/M services included in the valuation of the procedure. What is left, if any, determines the level of billable E/M. The decision to perform a minor surgery based upon a focused evaluation, examination, and diagnosis of a lesion or related lesions is usually included in the procedure code and is not separately billable. Also included are preoperative and routine postoperative care done within a global period. The separately billable E/M service should be supported by essential chart documentation: history, examination, and medical decision making. A diagnosis different from that linked to a procedure is not required for appropriate modifier 25 use.

Modifier 25 applies only to E/M services done in association with minor surgical procedures, those with a zero- or 10-day global period. Separate E/M services done on the same day as a 90-day global period major surgery (flap, graft) are identified with modifier 57. Unlike with minor surgeries, evaluation and management leading to a decision to perform a major surgery is separately billable with modifier 57 when done on the day of or the day before the major surgery.

Example 1

A new patient comes in with a chief complaint of a gradually growing, recurrently bleeding lesion on his nose. You examine the nose and face and diagnose a probable basal cell carcinoma, which you then biopsy. You routinely offer a complete skin examination to new patients, and the patient accepts your offer. The examination reveals multiple seborrheic keratoses on the trunk and solar lentigines on the face. You code CPT 11100 for the biopsy and 99203-25 for the rest of the evaluation, specifying ICD-10 diagnoses L82.1, seborrheic keratosis, and L81.4 for the solar lentigines. The insurer requests a chart review, and then rejects payment for the E/M (99203-25), judging it not medically necessary. What? But you did this separately identified and well-documented work!

Correction

In the January article "Pulling back the curtain on private equity," California Skin Institute was misidentified as being owned by Goldman Sachs. In fact, California Skin Institute remains a physician-owned and controlled practice following a February 2017 investment by Goldman Sachs. The article has been corrected online.
**Answer: The devil is in the details.** The insurer considered the complete skin examination to be a skin screening examination, and screening exams are not a covered service under the patient’s insurance plan. Since the chart stated, “complete skin screening offered, accepted and done,” it implied that the examination was an optional screening instead of a reasonable and necessary service. Had you charted that in view of the suspected skin cancer a complete skin examination was indicated, and was done, this would likely have justified criteria for coverage. It is helpful to document the medical decision making leading to a distinct E/M service, but not always specifically necessary, as in when the need for the separate E/M is clearly validated by the presenting diagnosis, such as a suspected malignant melanoma that leads to a further probing history, complete skin examination, and action plan.

**Example 2** You examine a new patient in the Medicare Administrative Contractor Noridian’s jurisdiction (Western U.S.) with psoriasis and discover multiple actinic keratoses, which you freeze with liquid nitrogen. You also manage the patient’s psoriasis. You code CPT 17004 for destruction of 16 actinic keratoses and 99203 for the E/M of the psoriasis.

**Answer: Correct.** Noridian Medicare does not require appending modifier 25 to a new patient E/M code. Some other Medicare Administrative Contractors and all private insurers require modifier 25 in association with a new patient E/M. All insurers (including Noridian) require that modifier 25 be appended to established patient (CPT 99211-99215) E/M codes, when appropriate.

**Example 3** You do an interim history and extensively examine photodamaged skin of the scalp, face, neck, trunk, and extremities of an established patient complaining of multiple scaly lesions and diagnose actinic keratoses. You then freeze 12 actinic keratoses with liquid nitrogen. You bill CPT code 17000 and 17003x11 for the destructions and 99213-25 for the patient evaluation and skin examination.

**Answer: Incorrect.** No separately identifiable, distinct history and examination E/M service beyond that included in pinpointing the lesions and deciding to perform the cryodestruction was done. Consequently, no level of E/M billing is appropriate.

**Example 4** A privately insured new patient with a history of a spreading, diffuse, pruritic eruption is evaluated. Following a detailed new patient history, past medical history, review of systems, and a complete skin, eyes, oral mucosa, nails, and lymph node basins examination you suspect a cutaneous T-cell lymphoma. You biopsy two sites from a broad lesion and code CPT 11100 for the biopsies and 99203-25 for the E/M.

**Answer: Correct.** There was substantial separately identifiable, medically necessary E/M done and documented beyond that limited to a decision to perform the biopsies. Only one biopsy was coded because multiple biopsies done on a single lesion are billable as only one unit of biopsy, 11100 (NCCI Policy Manual for Medical Services).
You do an interim history and a complete skin, oral mucosa, and eyes examination along with lymph node basins palpation on a patient with a history of treated malignant melanoma. The patient had no specific complaints, but was scheduled for a regular examination as follow-up for the previously diagnosed melanoma. You identify one atypical pigmented lesion, which you biopsy. You bill CPT 11100 for the biopsy and 99213-25 for the E/M, linking it to ICD-10 diagnosis Z85.820, personal history of malignant melanoma.

**Answer: Correct.** Although the patient had no current complaints, the separately identifiable E/M was medically reasonable and necessary based upon a past history of malignant melanoma, which requires a lifetime of vigilance. This situation is different from a non-covered skin screening examination done for the purpose of possibly finding atypical skin lesions in a person with no prior history of relevant skin disease.
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Trending: Pharmacy benefit managers under the microscope

STATE NEWS ROUNDUP

BY VICTORIA PASKO, MANAGER, STATE POLICY

At a time of rising prescription drug costs and increased use of utilization management tools such as step therapy and prior authorization, lawmakers are scrutinizing all players in the health care chain for ways to protect the patient. For years, the role of the pharmacy benefits manager (PBM) has avoided scrutiny. Not so in 2018. Numerous states are considering legislation that increases transparency, places restrictions on payments retained by these organizations, and/or would remove “gag rules” on pharmacists so that they would be allowed to tell patients about alternative prescription drugs or payment options without violating contracts. The American Academy of Dermatology Association (AADA) is closely following this legislative trend, as these bills ultimately affect patient access to treatments, an Academy priority.

What is a PBM?

A pharmacy benefits manager (PBM) is an entity that procures prescription drugs at a negotiated rate for dispensation, administers prescription drug benefits, processes pharmacy benefit claims, develops formularies, and performs utilization management services, among other tasks.

Arizona (HB 2022), New York (A 8781/S 6940), and Missouri (HB 1542) are all considering legislation that states that PBMs may not charge or collect from enrollees a copay for a prescription or pharmacy service that exceeds the amount that the pharmacist or pharmacy received from all payment sources for filling the prescription or providing the service. Further, in each of these bills, PBMs would be barred from prohibiting a pharmacist or pharmacy from informing enrollees of the difference between the enrollee’s cost sharing requirement of a prescription and the amount the enrollee would pay out of pocket. In Arizona’s bill — which is yet to be referred to committee — the pharmacist would be allowed to sell the prescription to an enrollee who chooses not to use coverage to cover the cost. Similarly, Missouri’s bill — which has also not been referred yet — allows pharmacists to sell the drug to the enrollee without using a health benefit plan to cover the cost, provided that the cost is less than the covered person’s co-payment for the drug. Additionally, PBMs may not restrict pharmacists from discussing alternative drug options. The New York bills contain similar provisions, stating that PBMs cannot prohibit pharmacists from disclosing the availability of therapeutically equivalent alternatives or alternative methods of purchasing the prescription, including paying a cash price. New York’s bills have been referred to each chamber’s Health Committee.

Mississippi’s legislature is considering three similar bills (HB 426/HB709/SB 2076) that would allow pharmacists to disclose information to a customer regarding the cost of a prescription or the availability of alternative medications and alternative methods of purchasing the prescription. The bills have been referred to the Insurance and Public Health Committees. Virginia is considering similar legislation (HB 1177), which also states that pharmacists can, without penalty, disclose information on the clinical efficacy of a more affordable alternative drug if one is available. This bill has been referred to the House Committee on Health, Welfare, and Institutions.

In addition to requiring PBMs to register with the state, legislation in Florida (SB 1494) would require pharmacists to inform customers of a lower-cost alternative for their prescription and whether the cost-sharing obligation exceeds the retail price of the prescription without using drug coverage. Additionally, PBMs would not be able to require subscribers to pay for a prescription drug at the point of sale in an amount greater than the lesser of: the applicable cost-sharing amount, the allowable claim amount for the prescription drug, and the retail price of the drug without drug coverage or programs that otherwise reduce the cost of a drug to the patient. The bill has been referred to the committees on Health Policy, Banking and Insurance, and Appropriations.
Pharmacy benefits manager

**Arizona:** PBM operating in the state would be required to disclose methodologies on drug pricing and rebates received.

**Mississippi:** Would allow pharmacists to disclose information to a customer on the cost of a prescription or the availability of alternative medications and alternative methods of purchasing the prescription.

**Missouri:** PBMs would not be allowed to charge/collect copay for prescription/service that exceeds amount that the pharmacy received. PBMs would be barred from prohibiting pharmacist/pharmacy from informing enrollees of cost differences between cost sharing and out-of-pocket.

**New York:** PBMs would not be allowed to charge/collect copay for prescription/service that exceeds amount that the pharmacy received. PBMs would be barred from prohibiting pharmacist/pharmacy from informing enrollees of cost differences between cost sharing and out-of-pocket.

**Nebraska:** PBMs operating in the state would be required to disclose methodologies on drug pricing and rebates received.

**Florida:** Would require PBM registration; would require pharmacists to inform customers of a lower-cost alternative for their prescription and whether the cost-sharing obligation exceeds the retail price of the prescription without using drug coverage.

**Virginia:** Pharmacists would be allowed to disclose information on the clinical efficacy of a more affordable alternative drug if one is available.

**Alaska:** Would require PBM registration; PBMs would be required to share drug-pricing methodology to network pharmacies.

---

**Florida** is considering another bill (HB 351) which aims to rein in conflicts of interest. PBMs would not be able to require enrollees to use a pharmacy in which the PBM has an ownership interest (or vice versa). They may not utilize contracts that provide an incentive to an enrollee to encourage them to use a retail pharmacy, mail-order pharmacy, specialty pharmacy, or other entity providing pharmacy services in which the PBM or pharmacy has an ownership interest in the other. Further, PBMs must ensure that all drugs on a list are readily available for purchase by a pharmacy in the state from a national or regional manufacturer or wholesaler and disclose to network pharmacies the sources utilized to determine the predetermined reimbursement costs for multisource generic drugs. The bill passed the House Innovation Subcommittee.

In **Alaska**, HB 240 would require PBMs to register with the state and make available to each network pharmacy the methodology and sources used to determine the drug pricing list. The bill has been referred to the House Committee on Labor and Commerce.

**Nebraska** is considering LB 324, the Pharmacy Benefit Fairness and Transparency Act, which states that PBMs operating in the state must abide by a number of restrictions and disclose methodologies on drug pricing and rebates received. For example, within seven days after a price increase or decrease notification by a manufacturer or supplier, a PBM must adjust its payment to the contracted pharmacy consistent with the price increase or decrease. PBMs must disclose to covered persons and the contracted pharmacy the method used to calculate total dispensing fees, the cost of the prescription drug, administration fees, and any other fee payment. Financial benefits received by the PBM including rebates, discounts, credits, fees, grants, or chargebacks shall be disclosed to the covered person. Further, the PBM may not make it harder for covered persons to use mail-order pharmacies by mandating accreditation or charging higher copays. PBMs must also disclose their pricing methodology and reimbursement amount for single-source and multisource prescription drugs and compounds and specialty drugs. The legislation remains in the Banking, Commerce, and Insurance Committee.

The **New York** legislature is also considering a bill (A 2661) that prohibits PBMs from substituting or causing the substitution of one prescription for another during dispensing, nor may they alter or cause the altering of the terms of a prescription, except with the approval of the prescriber. PBMs and their contracting pharmacies must have a reasonable process to appeal, investigate, and resolve disputes regarding multi-source generic drug pricing. The bill has been referred to the Assembly Committee on Ways and Means. dw
State Advocate Spotlight

Dermatology World features a grassroots advocate and their efforts to support the specialty’s advocacy agenda at the state level each month in ‘State Advocate Spotlight.’

Name: Howard Rogers, MD
State: Connecticut
Spotlight: Modifier 25

Reimbursement for modifier 25 has been under fire by insurers for several years, as payers view it as double reimbursement. The AADA continues to make appropriate reimbursement a top advocacy priority. Howard Rogers, MD, chair of the AADA Patient Access and Payer Relations (PAPR) Committee has dedicated countless hours and energy to advocate on behalf of dermatology against these detrimental policies.

Dermatology World: Why has modifier 25 been targeted by payers? What is the justification and what is the Academy’s response?

Dr. Rogers: To date, five companies have implemented or announced a modifier 25 reduction policy with two main justifications. First, citing a 2004 OIG report, insurers assert that there is significant abuse and inappropriate utilization of this modifier. Second, insurer medical directors share a mistaken belief that there is significant overlap in the practice expense between a same-day office visit and procedure.

The AADA has responded that proper coverage and reimbursement of modifier 25 are critical to dermatologists’ ability to provide efficient, patient-centered care. We have educated insurers that the code valuation process removes any overlapping overhead from procedures typically billed with an E/M, and therefore, no reduction in payment is warranted. Moreover, the AADA has expended significant resources to educate its members on proper use of modifier 25 and feels that inappropriate use of this modifier is not systemic.

Dermatology World: What has been your role in advocating for appropriate reimbursement for modifier 25 advocacy? What steps has the PAPR committee taken to fight these policies?

Dr. Rogers: As chair of PAPR, I have led the national response to the modifier 25 policy issue. Our strategy has included helping craft comment letters for the AADA and state dermatology societies, building a coalition of medical societies, giving educational webinars on modifier 25 policy and its use, and helping author the AMA modifier 25 House of Delegates resolution. Lastly, I have participated in numerous meetings with insurer medical directors and executives advocating for reversal of the modifier 25 reduction.

Dermatology World: The AADA has been actively opposing forms of this policy, which have been in effect in some states since 2012. Why is this now a priority issue within the house of medicine?

Dr. Rogers: Since 2012, this has been a priority issue and we have been sounding the alarm that this policy was going to spread, if not effectively combatted. Many other societies may have not been aware of the policies or its impact on their physicians. With Anthem’s policy announcements in 2017, the house of medicine stood up and took notice. Now, organized medicine is united in its opposition to the modifier 25 reduction policy and the momentum is on our side.

Dermatology World: As a leader on this issue, how can AAD members contribute to the Academy’s efforts to prevent policies like this and others that reduce appropriate reimbursement?

Dr. Rogers: There are many grassroots actions that members can do to help. First, it is important to let the Academy know about policy announcements that could affect reimbursement and coverage of services. The AADA cannot monitor the policies of every insurance company. Second, join the AMA and your state dermatology and medical societies that have been critical in our opposition to modifier 25 reimbursement reductions. Unless you are a member, these societies lose the ability to effectively advocate for you. Finally, become active; become a leader; and cultivate relationships with your medical directors, state legislators, and regulators. Remember, effective advocacy starts years before a problem surfaces. dw
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What role can dermatologists play in diagnosing a cancer syndrome like BAP1?

BY KATHRYN SCHWARZENBERGER, MD

In this month’s Acta Eruditorum column, Physician Editor Kathryn Schwarzenberger, MD, talks with Hensin Tsao, MD, PhD, and Alexandra Haugh about their recent JAMA Dermatology article, “Genotypic and Phenotypic Features of BAP1 Cancer Syndrome: A Report of 8 New Families and Review of Cases in the Literature.”

Dr. Schwarzenberger: What is BAP1 and does it have any role in normal skin?

Dr. Tsao and Haugh: BAP1 is a nuclear deubiquitinating protein encoded by the BAP1 gene that functions as a tumor suppressor. As a deubiquitinase, the BAP1 enzyme removes ubiquitin molecules that can act as “tags” on other proteins, marking them for degradation or controlling their cellular function. The exact mechanisms by which BAP1 acts as a tumor suppressor are still under investigation but the protein has been shown to be involved with several cell processes, including DNA repair, cell cycle control, cell growth, and cell death.

Germline mutations in BAP1 are associated with an increased risk of melanocytic BAP1-mutated atypical intradermal tumors (MBAITs), uveal and cutaneous melanoma, mesothelioma, renal cell carcinoma, and basal cell carcinoma, in addition to several other tumors.

BAP1 likely plays several important roles in normal skin, evidenced by the prevalence of MBAITs and cutaneous melanoma in patients with germline inactivating mutations of the BAP1 gene. The exact mechanism through which an absence of BAP1 leads to tumorigenesis in the skin is still unclear.

Sporadic forms of several of the most common tumors associated with BAP1 deficiency, however, are strongly associated with environmental carcinogens that result in DNA damage, suggesting that the loss of BAP1’s function in the DNA damage response system may play an important role in the syndrome.

Dr. Schwarzenberger: Tell us more about MBAITs. Will we know one when we see it? Will our dermatopathologist recognize it?

Dr. Tsao and Haugh: Individuals with germline mutations in BAP1 often develop several flesh-colored or reddish-brown well-circumscribed papules with a characteristic histomorphology. These tumors were called melanocytic BAP1-mutated atypical intradermal tumors (MBAITs) when first described in the literature but have also been referred to as BAPomas and BAP1-deficient tumors (BDTs).

Individual MBAITs are admittedly often not particularly noticeable on clinical examination. They are most similar in appearance to dermal nevi and can range significantly in size (often between 2-10 mm). MBAITs are thought to arise primarily from BRAF-mutated conventional nevi that undergo subsequent biallelic loss of BAP1. A peripheral area of pigment globules representing the BRAF-mutated progenitor nevus can therefore sometimes be seen on dermoscopic examination. Biallelic inactivation of BAP1 leads to a central population of large, epithelioid melanocytes with more spitzoid cytomorphology. These cells typically lack pigment and result in a central flesh-colored, often structureless, area on dermoscopic examination.

Immunohistochemistry demonstrating loss of the BAP1 protein in the large epithelioid melanocytes is a very useful tool in evaluating these lesions and makes them much more identifiable histologically than
they often are clinically. Lesions that contain both conventional nevomelanocytes and a population of larger, epithelioid melanocytes that resemble Spitz tumors may warrant immunohistochemical staining. Despite the concerning histologic features that MBAITs share with Atypical Spitz Tumors and melanoma, these lesions are considered slow growing and benign.

As MBAITs may be somewhat innocuous on clinical examination, an important feature to suggest an underlying germline predisposition is the presence of multiple lesions. The number of MBAITs in individuals with germline mutations in BAP1 is thought to increase with age and can number anywhere between 5 to over 50. MBAITs are also generally the first tumors to appear in patients with germline mutations in BAP1, highlighting the important role that dermatologists can play by recognizing the syndrome before the onset of its associated malignancies.

Dr. Schwarzenberger: Most of us are familiar with BRCA1 and BRCA2 gene mutations and the increased risk of cancer our patients with these may have. Are these genes related to BAP1?

Dr. Tsao and Haugh: BAP1 actually stands for BRCA1 Associated Protein-1. The protein was given this name because it was found to bind to one of the domains of the BRCA1 protein. Despite BAP1’s association with BRCA1, studies evaluating the specific interaction between the two proteins have been inconclusive. Germline BAP1 mutations have not been conclusively associated with an increased risk of malignancies seen in BRCA1 carriers such as breast, ovarian, or pancreatic cancer.

Most autosomal dominant cancer susceptibility genes, such as BRCA1 and BRCA2, cause tumors in specific tissues or organs. The BAP1 syndrome, however, continues to be associated with new malignancies in a variety of different tissue types, suggesting that it may be more similar to syndromes such as Li-Fraumeni that result in an overall increased risk of cancer.

If this is the case, however, it is unclear why germline mutations in BAP1 are associated with such a high frequency of mesothelioma, uveal and cutaneous melanoma, and MBAITs specifically. Further studies that prospectively evaluate the incidence of different tumors in this syndrome as well as further elucidate the mechanisms by which loss of BAP1 leads to tumorigenesis are necessary to better define the syndrome.

Q Dr. Schwarzenberger: If we suspect a patient might have a BAP1 mutation, what initial workup is appropriate?

Dr. Tsao and Haugh: If there is a high degree of suspicion for a germline mutation in BAP1, the first step would involve discussing genetic testing with the patient. If the patient is interested, testing can be facilitated either through referral to a genetic counselor or through several commercially available assays that can potentially be performed in clinic. This is dependent on available resources and the individual physician’s level of comfort and familiarity performing genetic testing and counseling patients about results.

As the syndrome was only very recently identified, there are no official guidelines for screening in this population. However, most authors suggest that individuals with germline mutations in BAP1 undergo total body skin examinations at least every six months and are referred to ophthalmology for routine yearly uveal melanoma screening. No concrete screening guidelines have been developed for the associated internal malignancies, yet this is an area of active investigation and discussion. Given the multiple organ systems that are often involved with this syndrome, multi-disciplinary collaboration amongst physicians with knowledge of the BAP1 syndrome is a crucial component to provide optimal care for this population.

Q Dr. Schwarzenberger: Skin findings are helpful in diagnosing many familial cancer syndromes, such as Birt Hogg Dubé, Cowden’s syndrome, Muir-Torre syndrome, and now BAP1 syndrome. What role do you think dermatology should play in helping to identify and define these syndromes?

Dr. Tsao and Haugh: One of the most exciting aspects of the BAP1 syndrome for dermatologists specifically is that the only benign tumors yet to be associated with the syndrome are also the first to appear in many patients and may actually be the most prevalent of all the associated tumors. As these benign tumors arise in the skin, dermatologists play a very crucial role in identifying the syndrome and prompting genetic testing before any of the malignant tumors arise. Dermatologists can also carefully screen these patients for melanoma and counsel them about the importance of avoiding UV exposure and other...
carcinogens such as tobacco given their underlying predisposition to cancer. As screening guidelines for the internal malignancies are developed, identifying these individuals early in their lives may represent a life-saving intervention.

Like the BAP1 syndrome, the skin tumors involved in Birt Hogg Dubé and the hamartomas that characterize Cowden’s syndrome are benign and generally appear before any associated internal malignancies. Dermatologists therefore arguably play the most important role in caring for these patients because early identification can prompt screening and counseling for the associated malignant tumors. Whereas most other specialists who identify a germline cancer predisposition do so only after their patient presents with one or several malignant tumors, dermatologists have a unique opportunity to identify these patients either before the onset of any malignancies or before their internal tumors have become large enough to result in clinical symptoms.

Additionally, if there is any debate as to whether genetic testing is warranted in a specific patient based on a personal or family history of malignancy, a careful dermatologic examination can provide further evidence to prompt genetic testing. In syndromes where skin findings are known to be ubiquitous, dermatologists can also play an important role in providing evidence against a genetic predisposition if the patient lacks any of the characteristic skin lesions.

In thinking about cancer syndromes, I usually take a full spectrum cancer history (i.e. ask about all cancers beyond skin cancers) and look for a couple of features — early onset of cancer (usually <45 years), multiple primary tumors (e.g. multiple melanomas), cancers on one side of family and aggregation of rare tumors. It is not unusual, for instance, to have melanoma and breast cancer in the family since breast cancer is pretty common. However, to have mesothelioma, kidney cancer, uveal melanoma, and cutaneous melanoma on one side of the family would be highly unusual. I recommend genetic counseling to get a more detailed pedigree and to coordinate education and return-of-results if genetic testing is appropriate.  

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Can posting about patients on social media get you into trouble?

By Daniel F. Shay, Esq.

Every month, Dermatology World covers legal issues in Legally Speaking. This month’s author, Daniel F. Shay, Esq., is a health care attorney at Alice G. Gosfield and Associates, P.C.

From the humble beginnings of now-nearly-forgotten sites such as Friendster and MySpace, long before the age of SnapChat and Instagram, social media has now become a fixture of everyday life, with approximately 77% of adults in the United States using a social media site in 2016. Physicians, too, have sought to capitalize on the power of social media to enhance their ability to connect with patients, seeking both clinical and economic benefits from such interactions. Enterprising physicians, including dermatologists, have also sought to bolster their own online profiles by utilizing the power of social media and new media platforms such as YouTube. Physicians also use social media to discuss the practice of medicine with one another. These interactions, however, all come with associated risks under both HIPAA and medical malpractice analyses. This article discusses the risks involved, and offers practical guidance for dermatology practices struggling with how to square the potential benefits of social media with the risks it can impose.

**HIPAA concerns**

More than 20 years since it was passed into law, most physicians have a reasonable grasp on how HIPAA operates within the four walls of their office. They understand that janitorial staff do not need a business associate agreement. They’re familiar with how to issue a notice of privacy practices. They’re comfortable with the notion that merely calling a patient by name from the waiting room does not constitute an improper disclosure under HIPAA. Within the social media context, however, they may not recognize the range of risks they face. Social media offers new avenues by which protected health information (PHI) may be shared (properly or improperly), and a multitude of new fact patterns to consider when drafting HIPAA compliance plans.

First, it is essential to remember that all posts on social media are unsecured PHI by their very nature; social media posts lack the encryption necessary to qualify as secured PHI. Therefore, any improper disclosure of PHI on a social media platform must be analyzed under both the Breach Notification and Privacy Rules. Second, a failure to address social media in a physician practice’s policies and procedures may implicate the Security Rule, which applies to electronic PHI (ePHI) — including both secured and unsecured ePHI — and requires that physician practices establish policies and procedures to address breaches and issues relating to data control.

Physician practices should develop policies and procedures to avoid improper disclosures of ePHI on social media. Such improper disclosures are most likely to be unintentional. For example, we represented a physician clinic where a front desk staff member posted a picture of an apple given to her by one of the clinic’s patients, alongside a comment about how much she loved her job and the people she met through it. Unfortunately, the apple in the photo sat atop a daily charge sheet, which included patient names, medical record numbers, and dates of birth. Fortunately in this case, this information was mostly obscured by the apple itself, and no single element was completely visible; only partial information could be seen, and not enough to individually identify any single patient. Still, the incident illustrates how normal usage of social media can prove much riskier within a physician practice.

Other disclosures may be intentional, hard to believe though that may be. For example, a physi-
A physician working in a Chicago hospital emergency room was fired for posting photos of an intoxicated patient on his social media account. This example obviously represents an extreme case; most physicians and office staff could reasonably be expected to know better. However, they might still intentionally post information to social media accounts without realizing that the information itself is PHI.

For example, taking a “selfie” photo with a patient and posting it to a social media account would be an improper disclosure of PHI. This type of behavior on social media is entirely normal in most instances, but it is improper within the HIPAA context. Likewise, some enterprising physicians may seek to promote themselves by demonstrating, for example, the efficacy of the treatments or products they offer, such as through YouTube videos, which they might also post to social media accounts. These videos may depict patients clearly, may include patient names, patient testimonials, etc. There are two key questions in such circumstances: (1) is the patient information enough to individually identify the patient, and (2) if so, has the patient signed a HIPAA authorization to permit the disclosure? Thus, an image or video just of a patient’s rash and its response to a topical cream or other treatment is likely not a disclosure of PHI, as long as there are no other identifying marks or information shown. However, pictures of a tattoo removal where the tattoo itself is unique, or results of reconstructive or cosmetic surgery that show a patient’s face may well be disclosures of PHI.

This touches on a commonly held misconception among physicians: verbal consent, or even informal written consent to post the information is insufficient to satisfy HIPAA; instead, the physician must obtain an authorization from the patient. Under HIPAA, authorizations must contain certain required elements, such as a clear description of the information that will be used and how it will be used, an expiration date (if applicable — or “none” if inapplicable) for the authorization, the individual’s signature and date of signature, and statements that the individual’s continued treatment is not conditioned on their signing of the authorization. Thus, without an effective authorization, a video of a patient where the patient can be clearly identified will be an improper disclosure of PHI. Similarly, as silly as it may sound, a patient’s inquiry on a social media page regarding their condition (e.g., “Do you have the results of that biopsy?”) does not implicitly grant permission under HIPAA for the physician to respond substantively. Instead, such an inquiry should be responded to either by stating that the practice never discloses patient information where it could be viewed by the public (such as on social media) and directing the patient to call the office, or by suggesting the patient contact their regular doctor through a patient portal, if applicable.

**Malpractice concerns**

In addition to the HIPAA concerns raised by the use of social media, interaction with patients through social media platforms can raise malpractice risks. Although many physicians are appropriately wary of using social media to interact with patients in any clinical sense, the risk remains. However, there are different malpractice risks, depending on whether the individuals who interact with the physician on social media are current patients, or people with whom they do not have a physician-patient relationship.

In cases where no current physician-patient relationship exists, the goal of the physician should be to avoid establishing one based solely on the social media interaction. Unfortunately, given the relative youth of the social media environment, case law governing when and how physician-patient relationships are established on social media remains sparse. However, analogies can be drawn from other “minimal contacts” cases. For example, attending physicians responsible for providing oversight of residents have been found liable for the actions of residents, in spite of having never laid eyes on or otherwise interacted with the patient. Physician-patient relationships have been established even when there was no direct interaction with the patient, and no physical contact, such as in the case of a physician providing ship-to-shore medical services to a ship’s purser on a fishing trawler located in the Bering Strait, attempting to treat a patient’s diabetic ketoacidosis. Similarly, a physician who provided a telephone consultation to an emergency room physician assistant treating a patient with an eye injury was enough to establish a physician-patient relationship.

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relationship. It is not difficult to imagine how similar analyses would apply to interactions with individuals through social media.

With established patients, the goal would be to avoid harming the patient. This creates a highly fact-specific inquiry, regarding the precise nature of the interaction and whether the physician’s response met the standard of care. Still, it is difficult to see how social media platforms would be appropriate for providing clinical advice even to established patients.

Social media has also become a platform by which clinicians interact with each other, both to provide moral solidarity, and to offer specific clinical guidance or information when discussing cases. This, too, can create potential malpractice liability. A well-meaning post on a social media website, where one clinician seeks to offer friendly advice to another, could be seen as a consultation that establishes a physician-patient relationship, depending on the circumstances and whether the patient is harmed. See more on this under “Social media groups.”

Practical advice

Physician practices must establish clear, firm policies regarding the use of social media, both during and after company hours. It is likely impossible to create a complete ban on social media usage during company time, however. Even if the practice can block social media websites from the desktops they use, the prevalence of smartphones makes it much harder to completely stop all staff access to social media sites.

An additional wrinkle regarding what companies may prohibit with respect to employee activity on social media arises from the rules of the National Labor Relations Board (NLRB). Briefly, employees are permitted to engage in “concerted activities” to provide mutual aid or protection to each other. With respect to social media, the NLRB has interpreted this language to mean that social media policies must be narrowly tailored so that they do not also prohibit “concerted activities.” In practical terms, this means that a non-disparagement rule, whereby the employee is not allowed to speak ill of the company on social media, is likely to be found to be too broad, since it would prohibit “virtual picketing” in the form of an employee protesting work conditions. On the other hand, policies that prohibit disclosure of PHI except under certain limited circumstances would be entirely permissible.

Physician practices are likely to face generational hurdles as well, with younger employees and clinicians joining practices, as well as younger patients seeking treatment. While older people who did not grow up with social media as a fact of life may remain reticent to even establish an account, let alone broadcast details of their lives, younger generations view social media as simply a part of their daily lives. They may not think twice about posting this or that random thought, picture, complaint, piece of advice, or entertaining anecdote. The goal of practice policies and training efforts, therefore, must be to train staff to stop and think before posting.

In the HIPAA context, this means having an understanding of how information flows through social media networks, and how quickly it can be disseminated. It also means training clinicians and staff alike to recognize what constitutes PHI in the social media context. It is not enough to simply say “names, dates, unique medical conditions, etc.” A more effective approach may be to use “fake” PHI in context, and demonstrate how quickly information can spread, such as by showing what happens when a post containing PHI is published on a public Twitter account, or a Facebook profile with limited privacy controls. Similarly a “find the PHI” exercise could prove educational, as the practice again posts “fake” PHI somewhere in a social media post, and clinicians and staff members must identify the improper disclosure. When policies and procedures have been established, they must also be enforced; improper disclosures of PHI must be dealt with according to practice policies.

In the malpractice context, the easiest way to avoid social media risks is simply to refuse to engage in any clinical activity online. For example, if a patient posts a picture to the practice’s social media page showing a skin condition and asking for advice, the appropriate response is simply to suggest that the patient call the office to set an appointment, rather than to respond substantively. This is particularly true with individuals who are not yet patients; again, the goal is to avoid establishing a physician-patient relationship online. For more serious inquiries, (e.g., “Am I having a heart attack?” or some other emergent condition), it is likely best to recommend going to the emergency room, rather than responding with a specific diagnosis. This would seem like obvious advice to most, and yet there is at least one account of a physician who was asked on Twitter whether certain symptoms were signs of a heart attack, who responded “If movement, deep breath, swallowing makes pain worse or better, it is NOT a heart attack.”
One certainly hopes the physician was correct...

For individuals who are already patients, again, the goal is to avoid causing harm. Toward this end, it is probably still safest to recommend calling the office or setting up an appointment, rather than engaging on social media. Alternatively, the patient could be directed to the practice’s patient portal (if it has one). It is also likely safe from a malpractice perspective to offer general information (e.g., JAMA articles, a link to a WebMD entry, etc.) if a patient inquires about a given condition, although any such response should be made in a way that satisfies HIPAA (e.g., not in any way that is publicly visible and unsecured).

Social media groups

One particular aspect of social media has drawn both recent attention and some degree of criticism. Industry-oriented groups have become more popular in recent years, such as groups consisting of physicians within different specialties, or physicians of a common background. These groups can be helpful in discussing one’s life as a physician among other colleagues sharing similar experiences. However, physicians are collegial by nature, and some members of these groups also discuss clinical activities with their peers. Such discussions can carry risk both from a HIPAA perspective and a medical malpractice perspective, depending on the specific content of the discussions. The practical advice addressed above can and should be applied to communications posted in such groups.

From a HIPAA perspective, clinicians need to be careful not to disclose PHI. As noted above, PHI is individually identifying information about the patient. This goes beyond the more obvious information like names and birthdates, and should also extend to visual information like unique birthmarks or other physically identifying features. The specific privacy controls of the social media group must also be considered in the event of an improper disclosure.

For example, Facebook permits such groups to be public, private, or “secret.” Public groups allow non-members to search for the group itself, and view the content posted on such groups. Private groups are able to be found through searches on Facebook, but restrict the content of posts to group members only. “Secret” groups cannot be found by searching — individuals are instead invited to join by existing members or group administrators, and likewise restrict content to members. Knowing how visible such information is can help assess how far information may have spread if PHI is improperly disclosed. It may also be necessary to craft an effective HIPAA authorization. Consider the difference between an authorization to post to a secret group containing only 50 members, versus an authorization permitting disclosure to a public group.

From a medical malpractice perspective, communication on such groups could form the basis for a medical malpractice action. This, however, is a highly fact-specific inquiry, and would likely depend on jurisdiction-specific case law that interprets how “curbside” consults are treated under the jurisdiction’s precedents. While it is likely safe to offer general information about similar cases a physician may have treated, it is likely unwise to offer conclusive diagnoses or specific advice for treatment, so as to avoid potential liability. Ultimately, the physician directly treating the patient will bear liability, but such “crowdsourced” advice opens up the potential for additional liability for the “crowd.” Unfortunately, even if a court ultimately determines that members of such a group who offered general advice do not bear liability, the issue of (for example) whether the group member had a physician-patient relationship with the injured plaintiff may still have to be litigated, if the plaintiff claims that they were injured as a result of the member’s advice to their doctor. Lastly, any advice offered by group members will likely remain preserved in written form, acting as potential evidence in such a malpractice claim, the same as an email exchange between physicians could. The safer approach, therefore, is likely to avoid clinical discussions in such group settings.

Conclusions

As social media usage among patients and practitioners alike continues to increase, physicians are likely to face more and more interaction with patients over social media. Similarly, physicians may be tempted to establish a social media presence to reach a wider market. The reality is also that more patients and more clinicians and staff members are going to be people who have grown up with social media as part of their lives, and for whom its use is second nature. Physicians must confront this reality head-on and develop policies and procedures to navigate the integration of social media into their professional lives — a task with which experienced legal counsel can help. dw

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FDA approved: A misleading claim?

BY VICTORIA HOUGHTON, ASSISTANT MANAGING EDITOR

Dermatology World talks with Steven R. Feldman, MD, PhD, Lindsay Strowd, MD, and Elise Martin, BA, about the term ‘FDA approved’ and how some companies’ use of the term for over-the-counter products may be somewhat misleading.

Q DERMATOLOGY WORLD: What is required for a prescription product to be marketed as ‘FDA-approved’?
Dr. Feldman, Dr. Strowd, and Martin: The FDA approves both prescription and OTC products. Prescription products require animal pharmacology and toxicology studies, review of manufacturing information, trial protocols, clinical trials, and review of the proposed drug name, label, and packaging.

Q How does an over-the-counter (OTC) product become ‘FDA approved’?
Dr. Feldman, Dr. Strowd, and Martin: OTC products can be FDA-approved in two ways: through the new drug application (NDA) process described above or under an OTC monograph. OTC monographs consist of acceptable ingredients, doses, formulations, and labeling for certain drug categories. If an OTC product fulfills these guidelines, it is automatically deemed safe and effective for that drug category and can be marketed without undergoing the NDA process. For example, if a product contains 325 mg of aspirin, that product can be marketed as a pain reliever.

Q Can you provide an example of how the ‘FDA approved’ designation for an OTC product was technically accurate, yet misleading?
Dr. Feldman, Dr. Strowd, and Martin: One newly advertised OTC topical treatment for eczema, Atopis, claims FDA approval — indeed, this approval was announced in the Dec. 6 issue of Dermatology World Weekly — yet no information about the product exists on the FDA website. The company advertises its ingredient myriphytase extract as its key ingredient; however, the inclusion of the ingredient glycerin, which falls under the OTC monograph for eczema, allowed FDA approval of the product. As no information about the product can be found in the FDA registry, FDA approval was likely gained under an ‘OTC skin protectant drug product’ category completely unrelated to the myriphytase extract.

We did find one company-sponsored open label study of the cream, published in the International Journal of Phytocosmetics and Natural Ingredients (not a Medline-referenced journal), comprised of 20 subjects with mild-to-moderate eczema. The study reported 8% of patients developed severe eczema after two weeks of treatment; the mean improvement in quality of life for the...
study population (assessed with the Dermatology Life Quality Index) did not achieve a clinically important difference.

The advertisement of this product exemplifies the ability for companies to advertise a seemingly new FDA approved medicine by inclusion of an OTC monograph acceptable ingredient.

Q Can you describe the 'OTC skin protectant drug product' category in more detail?

Dr. Feldman, Dr. Strowd, and Martin: Skin protectant products are defined as products that temporarily protect injured skin or mucous membranes from harmful or annoying stimuli. Products containing cocoa butter, colloidal oatmeal, calamine, and glycerin, among others, fall in the skin protectant monograph. Glycerin, found in the cream mentioned above, allowed the product to be marketed for eczema under the guidelines of the skin protectant monograph, permitting claims such as those quoted above. A product that contains glycerin, along with any combination of other ingredients that are generally regarded as safe, can make claims permitted for skin protectants.

Q Can you cite an example of a similar claim in the past?

Dr. Feldman, Dr. Strowd, and Martin: This is not the first case of this occurring in dermatology and likely will not be the last. The promotion of some new extract as safe and effective for the treatment of a disease is reminiscent of claims for a product that was advertised as a banana peel extract effective for psoriasis; it could claim FDA-approval for psoriasis because it included another ingredient, coal tar, for which there was an OTC monograph.

Q What is your recommendation to physicians who may receive news items and/or press releases about OTC products that have been 'FDA-approved'?

Dr. Feldman, Dr. Strowd, and Martin: Because of the impact of eczema and other dermatologic conditions, patients and their physicians are eager to find new, better treatments. However, claims of ‘FDA approval’ of new products should be approached with skepticism. We advise consumers and providers alike to be wary that the term “FDA-approved” may be misleading.
Tax reform: What you need to know

BY JASON P. WAINSCOTT, JD

Every dermatologist needs to know 2017 saw widespread changes to the federal tax code. There are many cuts and additional exemptions — for individuals and corporations — but it’s important to note not all are permanent.

Whether you are an employee, or own a practice, or have retired, you need to be aware of the recent changes so you can actively plan for 2018. While the changes have been the subject of extensive media coverage, it can be difficult to parse through commentary to get the facts. The following is a quick summary of a few meaningful provisions of the Tax Cuts and Jobs Act of 2017.

Personal income taxes
Most notably, the taxable income levels for the brackets for married taxpayers filing jointly are now:

<table>
<thead>
<tr>
<th>2018 tax rates for</th>
<th>Married filing jointly</th>
<th>Single</th>
</tr>
</thead>
<tbody>
<tr>
<td>10%</td>
<td>$19,050 to $19,050</td>
<td>$9,525 to $9,525</td>
</tr>
<tr>
<td>12%</td>
<td>$19,050 to $77,400</td>
<td>$9,525 to $38,700</td>
</tr>
<tr>
<td>22%</td>
<td>$77,400 to $165,000</td>
<td>$38,700 to $82,500</td>
</tr>
<tr>
<td>24%</td>
<td>$165,000 to $315,000</td>
<td>$82,500 to $157,500</td>
</tr>
<tr>
<td>32%</td>
<td>$315,000 to $400,000</td>
<td>$157,500 to $200,000</td>
</tr>
<tr>
<td>35%</td>
<td>$400,000 to $600,000</td>
<td>$200,000 to $500,000</td>
</tr>
<tr>
<td>37%</td>
<td>$600,000 and above</td>
<td>$500,000 and above</td>
</tr>
</tbody>
</table>

The personal income tax rates are currently set to expire Dec. 31, 2025, if Congress does not extend them. These rates are separate from the 3.8% Medicare tax that applies to higher income taxpayers on earned income in excess of $250,000 when considering both the employer and the employee portion. They are also separate from the Net Investment Income tax imposed under the Affordable Care Act on unearned income such as rents, royalties, investment income and capital gains of higher income taxpayers. The Affordable Care Act penalty for the individual mandate was reduced to $0.00 (starting in 2019).

The estate tax was not repealed. Instead, the Act increased the exemption to $11 million per person (adjusted for inflation) beginning in 2018 (and sunsets after 2025). The exemption applies to estates of persons dying after Dec. 31, 2017.

The standard deduction increased to $24,000 for married taxpayers filing jointly and $12,000 for single filers. The individual Alternative Minimum Tax was retained with exemptions for incomes up to $500,000 for single filers and $1 million for joint filers (these exemptions expire on Dec. 31, 2025). State and local income, sales, and property tax deductions are now capped at $10,000 for personal filers. The Child Tax Credit has increased from $1,000 to $2,000 ($1,400 of that credit is refundable). No change was made to holding periods with respect to other capital gains.

Regarding mortgage interest: for indebtedness incurred (and in some cases refinanced) after Nov. 2, 2017, the Act limits the amount of mortgage indebtedness to $750,000 (down from $1 million) for the

Dermatology World covers financial issues for dermatologists in this quarterly column. Jason P. Wainscott, JD, is an attorney, author, and general manager of the financial planning firm OJM Group.
period from Jan. 1, 2018, through Dec. 31, 2025. In addition, interest on home equity indebtedness will no longer be deductible.

**Corporate taxes**

Many of the most significant changes came on the corporate side. For dermatologists who own their own practices, which are taxed as C corporations, the corporate income tax rate was lowered to 21% (from 35%) with a 2018 effective date, and the corporate Alternative Minimum Tax was repealed. Therefore if your practice was previously taxed as a personal service corporation at a flat rate of 35%, the new 21% rate means an effective 40% rate decrease for you! Of course, compensation you receive from the practice will still be taxed at your individual rates and profits distributed to you from the practice will be subject to tax at qualified dividend rates which did not change.

For pass-through entities, there is a 20% deduction for qualified business income; the deduction is generally limited to the greater of 50% of W2 wages or 25% of W2 wages plus 2.5% of the cost of tangible depreciable property. Note, qualified business income does not include income from certain “specified services” businesses (e.g., lawyers, doctors, actors, athletes, etc.). Dermatologists will only see the benefit of this deduction if their taxable income is below $157,500 for single taxpayers and $315,000 for married taxpayers. If your dermatology practice is taxed as an S corporation, a partnership, or a sole proprietorship, you are a pass-through entity and fall under these rules. Even if your taxable income

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**Tax law and charitable giving**

In the immediate wake of the passage of the new tax law, some experts speculated that the increase in the standard deduction would cause a big drop in charitable giving, as donors who stopped itemizing deductions would no longer be able to deduct their gifts. Others speculated that lower rates would offset this effect and those who benefit from a reduction in taxes would share some of the gains with their favorite charitable organizations.

The AAD, like many medical associations, relies on charitable giving to make many of its programs possible including Camp Discovery and the SPOT Skin Cancer™ campaign as well as other humanitarian and educational programs and services. Despite the new tax law, there are many ways to give to the AAD and still realize tax benefits. Contact us at (847) 240-1037 to discuss your gift. As always, consult your financial advisor to ensure you maximize the tax benefits of your giving.
allows you to take the qualified business income deduction, it will not be applicable to guaranteed payments from your partnership or to W2 wages received from your S corporation.

Regarding interest deductibility — in general, no deduction is allowed for interest expense of a business to the extent it exceeds 30% of the business’s adjusted taxable income plus floor plan financing interest. A widely reported prior provision with respect to a further limitation on worldwide interest was not included in the final bill.

The Act includes a significant tightening of the limits on the deduction for meals and entertainment. The 50% deduction continues to apply to business-related food and drink expenses. However, entertainment expenses and membership dues related to entertainment are no longer deductible. Fringe benefits for employees related to transportation, on-premise athletic facilities, and other conveniences are no longer permitted as business deductions unless they are included as income for the employee receiving the benefit.

As it relates to expensing in general — immediate expensing of 100% for qualified property placed in service after Sept. 28, 2017 (new and used tangible personal property) through 2022, phasing down by 20% each year through 2026. You can now amortize research and experimental expenditures.

Expenditures paid or incurred after Dec. 31, 2021, must be capitalized and amortized over a five-year period.

What now?
We tried to touch on the themes that could affect you and/or your practice, but we could not fit in everything. What does this all mean? How will it affect you, your family, and/or your business? It’s impossible to discern from a quick article. Our hope is you will see the extent of the changes and reach out to your tax preparer to start planning now. If you usually procrastinate and wait until the last minute to prepare — you could be unpleasantly surprised. Start thinking about it now. dw
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WHAT YOU SAY vs. WHAT PATIENTS HEAR

Strategies for improving patient communication, compliance, and satisfaction
The scene is set. Already running behind in the day’s schedule, a dermatologist sees their next patient. However, the patient — being seen for warts — is full of questions. They also have a benign appearing mole, and a toenail has been looking funny. From the physician’s perspective, the day needs to continue moving and the original problem — the wart — is routine. The rest will have to wait for another visit. From the patient’s perspective, the physician is cold, condescending, and dismissive of their concerns. Both patient and physician leave the appointment feeling the other has been unreasonable. How could this situation have been avoided?

“Good communication with patients is obviously a big part of what we do,” says Kanade Shinkai, MD, PhD, professor of clinical dermatology at the University of California San Francisco. “There’s an immense reward that comes from connecting well with patients, but also in this day and age of value-based care, patient satisfaction scores are now tethered to reimbursement. So in addition to making their care more effective, it’s also very important for dermatologists to pay attention for that reason.”

As effective communication between providers and their patients takes on additional significance, dermatologists discuss their own strategies for better seeing eye-to-eye with patients, including:

- Practicing clinical empathy
- Joint decision-making
- Agenda-setting
- Conscientious phrasing
- Body language
- Checking patient comprehension

By Emily Margosian, content specialist
Don’t get lost in translation

“I think that getting on the same page with patients is a challenge for many dermatologists, because it’s very hard for us to really understand patient perceptions,” says Neil Prose, MD, professor of pediatrics and dermatology at Duke University Medical Center and affiliate at the Duke Global Health Institute. “We think we know, but we often get it wrong.” When a disconnect occurs between what a physician says and what the patient walks away with, oftentimes compliance, outcomes, and trust all suffer. Bridging this disconnect should be a key goal for all providers, as unfulfilled expectations may impact a patient’s overall level of satisfaction with their care, even more strongly than the technical success of a treatment (Expert Rev Pharmacoecon Outcomes Res. 2012;12(2):149-58).

Practicing clinical empathy is often the first step toward bridging this divide, and has begun gaining increased traction as an essential foundation to building physician-patient trust. More than just good bedside manner, “empathy is a cognitive attribute, not a personality trait,” explained Mohammadreza Hojat, a research professor of psychiatry at Jefferson Medical College, in a 2015 CNN report. “One of the worst things you can do as a provider is to downplay the patient’s concerns.” John Koo, MD, professor of dermatology at the University of California San Francisco, board-certified in psychiatry and dermatology, elaborates. “In psychiatry it’s called ‘empathic failure.’ Empathic failure can occur when the provider may think they’re doing the patient a favor — perhaps by saying, oh you only have a little bit of acne — but the patient takes it totally negatively, like you don’t understand, you have no idea what I’m going through. The provider may mean well, but it’s a great way to create an even bigger problem and drive the patient away.”

Good physician-patient communication — or lack thereof — can have legal implications as well. “Most patients are willing to forgive a medical error if they feel they’ve been treated with respect, but when a patient believes their views have been devalued, their perspective ignored, or that they have been abandoned, anger — not injury — drives their decision to sue,” explained a 2015...
A Medical Liability Monitor article. “The real story here is that when patients are asked about the root cause underlying their decision to litigate, most report it was because of the way the physician made them feel.”

In addition to filing fewer malpractice claims, patients who feel their expectations have been met and they have been treated with respect by their providers are more likely to follow treatment recommendations and remain loyal patients. A physician’s demeanor, phrasing, body posturing, and tone of voice can all have a great impact on their patients — consciously or not. “There’s the world of medicine, and then there’s the lifeworld of the patient,” explains Dr. Prose. “The world of medicine is full of science, techniques, solutions to problems. The lifeworld of the patient is largely composed of worries, anxieties, and financial concerns.” What may be just another appointment, or another box to check in a busy day for a dermatologist, may in fact be a highly emotional moment of crisis for a patient. “The job of the dermatologist is to bridge those worlds by using particular techniques that allow them to work on things together,” says Dr. Prose. “I like to imagine the metaphor of sitting across the table from the patient, and the problem is in the middle of the table. Figuring out what it takes to get on the same side of the table, looking at the problem together, is what this is all about.”

Say this, not that: navigating potential patient problems

While all doctors have their pet peeves when it comes to patients, some stand out among the rest. “When I do seminars with dermatologists, one of the main concerns is the patient who comes in with a list of concerns,” says Dr. Prose. “There may be a big disparity between the things that are the most concerning to the dermatologist — such as a potential melanoma — and the things that may be of more concern to the patient, which may be something as simple as cosmetic treatment for wrinkles, or a toenail fungus, or something else entirely.”

Given that an appointment is a finite amount of time, and that unmet expectations are a major cause of patient dissatisfaction — how can dermatologists align their clinical priorities with those of the patient in a way that fosters a sense of partnership, rather than dictation? Joint decision-making is one solution. This technique typically follows a script in which both patient and provider are given space to express their main aims for the appointment, and then jointly decide which will be addressed that day. “I think there are points in the conversation where joint decision-making becomes critical, typically when a patient is deciding to begin a medication like a biologic, or a systemic medication for a condition like psoriasis or eczema,” says Dr. Prose. “You have to be really sure

In general, Dr. Koo suggests the following steps for physicians engaging with delusional patients to reach an outcome agreeable to both parties:

Prepare yourself mentally before the visit. “Whenever most dermatologists hear that one of these patients are waiting to see them, they feel a great aversion,” says Dr. Koo. “If you go into the room looking like you’re not interested, then things go downhill very quickly. A lot of times these people feel like they’re getting shooed out of the office, because they are.”

Project positive body language. “Pretend you’re meeting your favorite Hollywood star. Smile, let your eyes shine, because body language doesn’t cost you any time, and can really help in the long run.”

Be pragmatic... “I purposely tell the patient that I’m not an entomologist; I’m not a parasitologist; I’m not even an infectious disease specialist, and if they’re mainly interested in the cause, I can’t help them,” says Dr. Koo.

But empathetic. “I typically connect with the patient by explicitly telling them that I understand their misery, and sometimes that alone can drive the patient to tears because they’ve been dismissed so many times previously by other providers. The provider and patient often don’t know how to connect with each other in this situation, and most of the time the patient goes untreated, or will be given topical steroids or topical antibiotics — which is no use because they really do need antipsychotics.”
that everybody’s on the same page before embarking on that treatment. To me, there are some very specific things to say to facilitate that process.”

**Example Phrases**

Some example phrases that dermatologists might use to facilitate joint decision-making with patients include:

- “This is my biggest concern. What is yours?”
- “We're going to have to make a choice about what we cover today.”

In general, eliciting patient preferences is the first step to shared decision-making. Using the phrases “I wish,” or “we,” indicates a desire to partner with the patient. Overall, dermatologists can circumvent a variety of potential patient problems by re-affirming a commitment to decide together on a treatment plan throughout the appointment, even if in actuality it is the doctor making most of the decisions. “It may sound something like this: I think you need a different medicine for your psoriasis; I think it will be very helpful, but it has some side effects. Let me explain why I think it would be helpful and what the side effects are, and then we need to decide together where to go from here,” explains Dr. Prose. “That particular phrase ‘decide together’ may be a formality, because in many cases the patient just wants your opinion and will do what you say, but the act of just saying that really changes the conversation. It may even potentially decrease the liability or blame you might otherwise face if the treatment doesn’t work as well as predicted.”

Another strategic technique for dealing with unrealistic patient expectations is agenda setting. “Agenda-setting is a really essential communication skill for physicians,” says Dr. Shinkai. “I think all providers know well the ‘hand-on-the-door phenomenon’ when you have an encounter with someone, and you’re walking out the door and the patient says, ‘oh by the way I have a concerning mole I need you to look at,’ which turns out to be a melanoma — it starts a whole new visit at that moment.” To avoid any surprise or emergency add-ons to a visit, it is helpful for both patient and physician if the appointment goals are discussed at the outset.

**Body language do’s and don’ts**

- **Greet the patient** — “Good eye contact, a good handshake, and a smile to greet the patient,” recommends Kanade Shinkai, MD, PhD.

- **Don’t hide behind the EHR** — “We need to find ways to work with the computer without it interfering with communication with the patient,” says Neil Prose, MD. “If something really important arises in conversation, that’s when one needs to stop typing and turn your entire body toward the patient. Studies show that the part of your body that’s most important in identifying where your focus is, is where your knees are facing. So instead of just turning your head away with your body still facing the computer, you have to turn completely toward the patient to embark on any kind of serious conversation.”

- **Address the patient at their level** — “There’s nothing more potentially demeaning to a patient, than for them to be laying on an exam table, and we’re kind of hovering over them and talking down at them, especially about counseling,” says Dr. Shinkai.

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**WHAT YOU SAY vs. WHAT PATIENTS HEAR**

*www.aad.org/dw*
While providers always want to exercise their best professional judgment in addressing medically urgent concerns first, establishing a rapport with patients can help them from feeling blindsided if the dermatologist determines that a different focus for the appointment is necessary. “I think it’s important to facilitate the visit in a way so that the patient knows what you’re getting at, which is something that dermatologists don’t always know as much about,” explains Dr. Shinkai. “Really setting aside time in which you’re going to decide on the priorities of the visit is key.”

Agenda-setting can benefit physicians in other ways as well. “Learning this particular skill can help you prevent running over and behind in your clinic, which is something that I think does contribute to provider burnout, so I think it’s a really essential skill from both a provider and patient standpoint,” says Dr. Shinkai.

What about a patient who is already upset going into the appointment? Pinpointing when a patient encounter is going awry and how to salvage it is key to a successful physician-patient encounter. For example, perhaps an appointment started late due to delays outside of the physician’s control, and the patient is visibly upset. Rather than glossing over the situation, simple acknowledgement of the issue — and the patient’s reaction to it — can be critical. Dr. Prose recommends that dermatologists utilize the following script when walking into an appointment with a clearly agitated patient:

1. Say “I’m sorry,” or “I apologize”
2. Take responsibility
3. Acknowledge the impact on the patient
4. Express commitment to improve
5. Ask permission to proceed

“If one perceives that the patient is upset, instead of immediately becoming defensive or launching into an explanation, what one really needs to do is simply say back what you’ve heard,” says Dr. Prose. “One of the big fears that we all have when we go to the doctor is the worry that nobody’s heard what you’ve said, and nobody’s listening. It’s much better to say, ‘So what you’re telling me is that you’re upset because the medication is similar to the one you’ve had in the past, and you feel that none of the creams are helpful.’ At that point the patient knows you’ve been listening, and it tends to really shift the tone of the conversation in a much better direction.” While this approach may initially take more time than simply proceeding on according to one’s own agenda, it may ultimately save time by diffusing frustrations before they gain sufficient steam to derail the appointment entirely.

**Making sure the message is being received correctly**

As with many things in life, it’s not necessarily what you say, but how you say it. Tone, verbal inflection, and phrasing often make a more lasting impression on patients than the technical success of their care (Expert Rev Pharmacoecon Outcomes Res. 2012;12(2):149-)

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“While the notion of asking permission before explaining things to the patient or moving on to a different part of the appointment is kind of a formality, I always say it’s like borrowing a chair at a restaurant from the next table,” says Dr. Prose. “If it’s available, it’s always ok, but you have to ask. So in the same way, asking permission before explaining is a graceful way of getting to the informational part of the conversation.”

Patients also often pick up on their physician’s body language, and make their own inferences about the appointment based upon it. Getting off to a good start with a patient can be as simple at choosing to take a seat. “There’s actually wonderful evidence that shows encounters in which a provider is sitting down actually seem longer to the patient than an encounter of the same exact length in which the provider is standing up,” says Dr. Shinkai. (For more tips on positive body language cues, see sidebar.)

More than 40% of patients experience negative health outcomes due to misunderstanding, forgetting, or ignoring health care advice (Ther Clin Risk Manag. 2005;1(3):189-199), and 75% of Americans have trouble taking their medicine as directed, compromising their own well-being and further straining the health care system (Public Health Rep. 2012;127(1): 2-3). However, there are communication techniques that

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### Terms that have different meanings for scientists and the public

While patients often struggle with medical jargon, even seemingly ordinary words or phrases may create confusion among members of the wider scientific community and the public. See the chart below for some examples of terms that carry different scientific and colloquial meanings.

<table>
<thead>
<tr>
<th>Scientific term</th>
<th>Public meaning</th>
<th>Scientific meaning</th>
</tr>
</thead>
<tbody>
<tr>
<td>Enhance</td>
<td>improve</td>
<td>intensify, increase</td>
</tr>
<tr>
<td>Positive feedback</td>
<td>good response, praise</td>
<td>vicious cycle, self-reinforcing cycle</td>
</tr>
<tr>
<td>Theory</td>
<td>hunch, speculation</td>
<td>scientific understanding</td>
</tr>
<tr>
<td>Uncertainty</td>
<td>ignorance</td>
<td>range</td>
</tr>
<tr>
<td>Error</td>
<td>mistake, wrong, incorrect</td>
<td>difference from exact true number</td>
</tr>
<tr>
<td>Bias</td>
<td>distortion, political move</td>
<td>offset from an observation</td>
</tr>
<tr>
<td>Manipulation</td>
<td>illicit tampering</td>
<td>scientific data processing</td>
</tr>
<tr>
<td>Scheme</td>
<td>devious plot</td>
<td>systematic plan</td>
</tr>
<tr>
<td>Anomaly</td>
<td>abnormal occurrence</td>
<td>change from long-term average</td>
</tr>
</tbody>
</table>

dermatologists can use to boost patient comprehension and improve compliance. One simple way to test whether a patient has correctly understood what’s been discussed during an appointment is to have them “teach-back” to the provider.

Dr. Prose frequently uses teach-back technique with his patients. “I often take the responsibility on myself, and say something like, ‘I’m not very good at explaining this, so I need for you to say back to me how you’re going to use the cream or how you’re going to take these pills.’ It’s remarkably helpful.” According to Dr. Prose, not only does this method help dermatologists check the patient’s comprehension before they leave the office, but it also helps reinforce the physician’s instructions for the patient, and invite further questions at the end of the conversation. “I think it’s something we don’t do very often, and it doesn’t take very long. People appreciate it, and you’ll learn a lot by hearing back what patients think they heard from you,” he says.

Example Phrases

Some example phrases that dermatologists might use to facilitate teach-back technique with patients include:

- “We’ve discussed a lot of points today, and this is a complicated medicine to start. I want to make sure I did a good job explaining it to you; would you be willing to explain it back to me as if you were the physician and I were the patient?”
- “I’m just going to ask a few key questions to make sure I explained everything well today. So you’re going to use this medication for how many weeks?”

“At the end of the visit, checking patient understanding is really important,” says Dr. Shinkai. “Particularly when you ask them if they have any questions, keep the door very open. One effective way to do that is to ask, ‘What questions do you have?’ as opposed to, ‘You don’t have any questions, do you?’ There’s a subtle but powerful difference in the language there in which the patient is really being invited to ask questions versus being almost shut down.”

Ultimately, better understanding and perceptiveness can go a long way in improving physician-patient relationships. While patients may misconstrue what their providers say, physicians should also be mindful of falling into the same trap, says to Dr. Prose. “I had an acne patient whom I had known for many years, and during one appointment I asked her how she was doing and she said ‘fine.’ When I left the room to talk to the resident, she said to me, ‘You know I think you missed something, because when you asked her how she was doing she was getting very teary, and I’m not sure you noticed that.’ I went back in, asked the question again, and took the time to listen to what she was saying,” he recalls. “It turns out she was terribly depressed and needed help. We actually managed to accomplish getting her referred to a psychologist by the end of the visit, and it’s something for me that reinforced the importance of simply paying attention.”

Signs of a good apology

Apologizing is never fun. However, there are steps dermatologists can take to make sure that if they are in a situation where they do need to apologize to a patient, that it is done correctly in order to minimize any further conflict.

1. Simply say “I’m sorry,” without making excuses
2. Take responsibility for the issue
3. Name the emotion the patient is feeling (e.g.: “I can see that you’re feeling frustrated that we’re getting off to a late start.”)
4. Acknowledge the impact of the mistake on the patient
5. Affirm a commitment to improve in the future

(Dermatologists may want to check with their medical liability insurance provider to ensure that their apology does not violate the terms of their insurance policy. For more on “apology laws,” see www.aad.org/dw/monthly/2013/december/what-to-do-when-things-go-wrong.)
The COMPOUNDING CONUNDRUM

Dissecting the compounding guidelines that pit safety concerns against patient access
In the fall of 2012, health officials and physicians received word that a mysterious number of cases of fungal meningitis and infections were being reported throughout the country. After some digging, the U.S. Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA) zeroed in on the culprit. Steroid injections accidentally tainted with mold, traced back to the New England Compounding Center, had been distributed throughout the country resulting in a massive number of meningitis cases. When the outbreak was finally contained, 800 people had been sickened by the compounded drug and 76 people had died. >>
As a result of this national public health tragedy, the safety of compounding facilities and compounded medications is being scrutinized by federal and state regulators and legislators. “I think the meningitis outbreak in New England was the presumptive trigger,” said Murad Alam, MD, member of the Academy’s Compounding workgroup. “I think there was certainly the perception that the problem was larger than one isolated bad outcome and actually a systemic failing in the level of regulation of these pharmacies.” As a result, Congress passed the 2013 Drug Quality and Security Act (DQSA) which tightened the FDA’s oversight of compounding facilities, giving the FDA the green light to take steps to restrict physician in-office compounding and office-use compounding. “The intent of the framers of that legislation was to have a relatively narrow interpretation such that compounding pharmacies that were producing higher-risk products — for intravenous use or intrathecal use — would be held to higher safety standards,” Dr. Alam said. “Instead, what happened was that the interpretation by the FDA and other regulatory agencies was much broader than anticipated by the framers.”

Consequently, in the name of safety, physician access to compounded medications and their ability to prepare drugs in their offices are under threat. Dermatology World takes a look at what’s happening with compounding regulations — and what the Academy is doing to ensure physician access to compounded medications.

Office-use compounded medications
During the inception of the DQSA, the Academy kept a close eye on its implementation and effects on medicine. “We regularly kept in touch with the Hill, the American Medical Association (AMA), and other specialties with a particular interest in compounding,” said Christine O’Connor, associate director of congressional policy for the American Academy of Dermatology Association (AADA). “Our message on Capitol Hill was that we support safe and effective compounding medications but warned against the unintended consequences. We were given promises that the DQSA would not restrict the practice of medicine. However, as the FDA began to implement the law, we started to see problems arise.”

As a result of the oversight it was granted under the DQSA, the FDA issued final guidance in December 2016 that slowed the pipeline between physicians and the entities where they procure compounded medications as office stock without having a patient-specific prescription: Section 503A traditional compounding pharmacies. According to the final guidance, Section 503A compounding pharmacies cannot dispense office-use compounded medications to physician practices without a patient-specific prescription. “Essentially, after being evaluated, patients are required to come back for treatment after a patient-specific prescription is filled with a section 503A compounding pharmacy,” said Natasha Pattanshetti, JD, AADA manager of regulatory policy.

Instead, in order to obtain office-use compounded medications to have on hand to be able to evaluate and treat patients with compounded medications in a single visit, physicians are often forced to turn to Section 503B outsourcing facilities. “The 503B facilities are subject to stricter FDA oversight, like adverse event reporting, current good manufacturing practices, and also routine inspections, which all cost more,” said Pattanshetti. “As a result, obtaining compounded medications through the 503B outsourcing facilities is cost prohibitive because they charge much more than 503A compounding pharmacies.”

According to Pattanshetti, the 503B outsourcing facilities also produce larger volumes of the drugs — likely more than an individual physician’s office needs to have on hand. Additionally, “the problem with outsourcing facilities is that obtaining compounded drugs from them is like a scavenger hunt. All you have is the FDA website listing the name of the outsourcing facility and current status of whether or not they have the drug you need,” said Pattanshetti. “You have to find out for yourself their contact information, what medications they offer, as well as pricing and volume information and product descriptions. They can ship interstate, which is good, but you still have to call around, and with an already busy practice, it’s just not workable for our membership.”

503A vs. 503B

- **503B outsourcing facilities are subject to stricter regulations than 503A compounding pharmacies** — such as mandatory adverse event reporting, current good manufacturing practices, and routine inspections. These additional regulations are costly and therefore the medications are more expensive.
- **503B facilities produce larger volumes of drugs than 503A facilities** — often more than an individual physician’s office needs on hand.
- **Sourcing from 503B facilities can take more time as the pricing and volume information and product descriptions are not readily available.**
For the most part, the FDA’s final guidance has affected physicians’ ability to have critical medications such as cantharidin, betacaine, and lidocaine and tetracaine combinations. However, beyond the administrative headaches and cost barriers, the new office-use compounding regulations are affecting patient access. “Dermatologists are no longer able to get office-use compounded drugs from 503A facilities and they ultimately can’t provide drugs to patients in the office setting,” said Pattanshetti. “Some physicians have reported that they’ve stopped using cantharidin to remove warts and as an alternative are freezing them which ends up being more painful, especially for pediatric patients.”

The Academy has remained vigilant to the unintended consequences of the DQSA and has been working to reverse the negative effects it has had on patient access. In January, Bruce A. Brod, MD, chair of the AADA’s Congressional Policy Committee, testified on physician office-use and in-office compounding before the Health Subcommittee of the U.S. House of Representatives’ Energy and Commerce Committee. Additionally, the AADA has been working with the DQSA coalition — which is made up of pharmacy and physician groups — to remedy the issue. “We supported efforts by Congressman Morgan Griffith (R-Va.) and Congressman Henry Cuellar (D-Texas) to introduce HR 2871, the Preserving Patient Access to Compounded Medications Act.” The bill affirms that physicians may have access to office-use compounded drugs from state licensed pharmacies where allowed by state pharmacy laws and regulations, prior to receipt of a valid prescription. “It is long overdue for Congress to hold oversight hearings on the unintended consequences of implementation of the DQSA,” said O’Connor, “but things are coming to a head and the people who are able to fix this are now paying attention.”

Take action: HR 2871

Urge your representative to cosponsor HR 2871, which would help ensure that physicians and patients have continued access to compounded medications. Visit the AADA Advocacy Action Center at www.takeaction.aad.org.

In-office compounding

While the FDA’s interpretation of the DQSA has resulted in reduced physician access to office-use compounded medications, it has also hit close to home, as the FDA has issued a draft guidance that threatens dermatologists’ ability to prepare drugs in the clinical setting, such as buffered lidocaine and reconstituted botulinum toxin. “The DQSA says that no drug can be compounded in insanitary conditions. This FDA draft guidance implementing the statutory language applies to ‘compounding entities’ and physician offices are considered compounding entities, despite the fact that drugs prepared in dermatology offices are low risk and in low volumes,” said Pattanshetti. Essentially, per this definition, physicians would be subject to the same equipment and process requirements as large compounding facilities when conducting in-office preparations. “Physicians would need to follow all of these strict requirements to prepare anything that is not made pursuant to a manufacturers’ labeling — from diluting a drug with

COMMON COMPOUNDING

The following are the most commonly used ‘office-use’ compounded medications that dermatologists have traditionally obtained prior to receipt of a patient-specific prescription from their local 503A compounding pharmacy to administer to patients in a clinical setting:

- BLT (as a combination of Benzocaine, Lidocaine, and Tetracaine)
- Cantharidin (topical)
saline to mixing sodium bicarbonate with lidocaine and epinephrine. Under the draft guidance, there currently is not an exception for physician in-office preparations but that is something we are advocating in support of,” Pattanshetti said.

“One of the insurmountable obstacles in these guidelines is that you would need to have laminar flowhoods and a special room for in-office preparations,” Dr. Alam said.

“For a small dermatology practice, this would essentially be impossible in terms of the facility, space, equipment, and time required.” Indeed, while some simple dermatologic procedures are currently performed in 20 or 30 minutes, preparing compounded medications for such a procedure, like a biopsy that requires anesthesia, could now take much longer than the entire rest of the procedure, says Dr. Alam. Additionally, under the prescription requirement final guidance, physicians would only be allowed to have a 30-day supply of in-office compounded medications, which could affect buffered lidocaine and reconstituted botulinum toxins. “Logistically, in terms of space, equipment, time, and effort, these guidelines are excessive, unreasonable, and unnecessary, and for practical purposes what they mean is that in-office mixing just can’t be done.”

Again, while these guidelines pose logistical headaches for physicians, the effects are greater on the patient, says Dr. Alam. “There are many procedures that provide a lot of patient benefit that wouldn’t be able to be done. For instance, many dermatologists mix lidocaine with bicarbonate for minor cutaneous procedures, thereby reducing patient pain by perhaps 50%. This helps a lot of patients who have anxiety about needles. If you start the procedure by hurting the patient, it makes it hard for them to proceed with the rest of the procedure and they may not come back for the follow up or for treatment of a subsequent skin cancer.”

Additionally, physicians would not be able to dilute pharmaceutical products with water. “Steroids for injections typically come in two strengths: 10 mg/ml and 40 mg/ml. If you needed a different strength to treat a scar or cyst or keloid, which literally happens on a daily basis in most dermatologists’ offices, you wouldn’t be able to do that. The patients who have that cyst or keloid that’s painful and bothersome and mitigates their range of motion and makes it hard for them to sleep are potentially just out of luck,” Dr. Alam said. “A number of minor, safe, very well-tolerated and successful procedures that alleviate patient discomfort and improve patient quality of life could soon simply not be available to patients.”

Fortunately, for physicians and patients, the FDA’s guidelines are just that: guidances. “FDA regulates the drugs themselves and physicians are regulated by state regulatory boards,” said Pattanshetti. However, the FDA is working in collaboration with both the United States Pharmacopeia (USP) – an independent, non-government body that makes recommendations pertaining to the potency and purity of drugs. “USP does not have federal or state government oversight. They set standards and then the federal and state policy makers can adopt the standards,” Pattanshetti said.

Unfortunately, USP is currently revising its chapter 797 on sterile preparations of compounded drugs and will most likely affect the practice of medicine in the office setting for in-office-preparations. A second round of draft revisions is expected within the next year but the AADA is hopeful that USP will incorporate more physician input. “State pharmacy boards often use these USP rules as the basis for their own state guidelines,” said Dr. Alam. “which essentially makes them the law of land on a state-
by-state basis. That’s a concern.” According to Lisa Albany, JD, AADA director of state policy, some state boards of pharmacy have proposed to adopt chapter 797. However, “we have asked the state pharmacy boards to refrain from adopting 797 until the language is finalized.”

While these guidelines are currently in a holding pattern, the Academy has taken steps to battle these recommendations at all levels. “We have met with the FDA to educate them on the access issues and the safety of in-office compounding,” said Pattanshetti. “There are no documented examples of safety issues in dermatology in-office compounding.” Additionally, the Academy is advocating for a 24-hour exception where if the drug is prepared and administered within 24 hours, physicians would not be subjected to these in-office equipment and process requirements. “We have studies that show that buffered lidocaine and botulinum toxins will not grow bacteria for up to four weeks. We are asking for at least 24 hours because policymakers want a one-size-fits-all-specialties approach and do not want in-office preparations stored in a clinical setting for longer than that,” said Pattanshetti.

FDA definition of compounding

“Compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.” Read more at www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm

Section 503A Bulk Drug Substances list

In addition to regulating access to traditional compounding facilities and recommending strict guidelines for in-office compounding, the FDA — with input from the FDA Pharmacy Compounding Advisory Committee (PCAC) — has been working on a list of drugs that can be compounded by physicians and pharmacists. Down the road, if an ingredient is considered for addition to the list but is not approved to the list, physicians will not be allowed to compound the drug. While the Section 503A Bulk Drug Substances list is still in its infancy and has not been finalized, there are dermatology-related drugs that are currently going through the process of being added to the list.

The process, according to Seemal R. Desai, MD, member of the PCAC, involves a number of steps. Dr. Desai was nominated to the PCAC by the AADA and the American Society for Dermatologic Surgery Association, and is the only dermatologist on the committee. “Companies, compounding associations, and the pharmaceutical industry can nominate ingredients and products for inclusion onto the bulk substance list. The FDA researches every nomination and will present to the PCAC their opinion of the drug based on stability, access ease, toxicology studies, and other related studies around it. Ultimately, in the FDA’s presentation they will give their recommendation that either yes, it should be included, or no, it should not be included.” Following the FDA’s presentation, physicians, pharmacists, lawmakers, and patients can testify on whether or not to include the ingredient on the list during the Open Public Hearing. “Then the PCAC members vote and we have to give our rationale for those votes. The FDA usually takes the PCAC’s recommendations to include something and it will then go through a final rulemaking process.”

To date, the AADA has testified on cantharidin, trichloroacetic acid (TCA), and glycolic acid. The FDA PCAC voted in favor of adding glycolic acid and TCA to the list in 2016. “Cantharidin is expected to be added to the list,” Pattanshetti said. “But with cantharidin, we still have issues with the office-use prohibition and as a result, you cannot obtain it without a patient-specific prescription from 503A compounding pharmacies.”
A drug that the PCAC voted against including on the list, which remains up for discussion, is quinacrine — which is sometimes compounded with hydroxychloroquine for lupus patients — as its use has been linked to safety concerns, deemed by experts as outdated. Victoria Werth, MD, works with patients with autoimmune skin diseases, and for her patients with lupus, access to quinacrine is imperative. “I have hundreds of patients on the drug and it really works. This compounding approach — which we’ve used since 1993 — none of us have really had any problems with it,” Dr. Werth said. “Back in the Vietnam era, quinacrine was given in much higher doses, and there were a few reports of aplastic anemia but they were rare.” Additionally, “it’s still a concern for the FDA that someone could use quinacrine for the sterilization of women, which has been done in India. It’s just not a realistic problem here.”

To justify its use, Dr. Werth has testified before the PCAC on the safety of compounded quinacrine, using preliminary research she has conducted at the University of Pennsylvania. “I testified at the original PCAC about a year and a half ago and then went back with new data that we had organized from the patients who I see at Penn. We also went through records to see how much physicians were dispensing, because one of the concerns at least from the PCAC and the FDA is that once it’s approved and on the list, then anyone can prescribe it.” According to Dr. Werth’s data, at the University of Pennsylvania, dermatologists, rheumatologists, and several internal medicine physicians were the primary prescribers, so concerns over mass use or misuse wasn’t an issue.

“We also wanted to document the safety profile. We went through hundreds of patients who have been on antimalarial drugs and were able to determine what the side effect profiles were for the three different antimalarials that we use and in combinations. It showed that there were no cases of aplastic anemia with quinacrine and quinacrine didn’t seem to have ocular toxicity. By and large it was quite safe.”

Dr. Werth went back to the FDA a second time to educate the FDA on the safety and efficacy of quinacrine, this time with a lupus organization and a patient. She returned a third time with the AADA to discuss the importance of continued access to quinacrine and review efficacy and new safety data. “I think the FDA is now aware of the importance of the drug. The head of the area that we’re talking to is a rheumatologist and she’s quite aware at this point. We’ve also published data about the efficacy of quinacrine as well. She’s aware of all of that, but it’s a slow process.”

The AADA has formed a coalition with the American College of Rheumatology, lupus patient-advocacy organizations, and compounding pharmacy groups to advocate for quinacrine’s inclusion on the list. As for other dermatology-related drugs, the Academy will continue to monitor movement with the bulk drug substance list. “When the meetings are announced we see what drugs are up for a vote and then decide if we’ll comment, either in person or in writing,” Pattanshetti said. “Then we monitor its way through the regulatory process and, if necessary, attend and speak at the open hearings during PCAC meetings. We’ll work with the industry nominator as well.”

For Dr. Alam, the office-use regulations, in-office guidelines, and bulk substance list represent a regulatory process that is trying to solve a problem that never existed. “While we support the need to assure patient safety, which we think is of paramount importance, and we respect the FDA’s efforts in that regard, we’d rather they focused on solving the compounding problems that pose a risk to patients rather than the mixing processes that don’t.” Dr. Alam is hopeful that the compounding conundrum that exists between safety and access will be resolved, but it won’t happen overnight. “Like all regulatory changes, it’s going to take a while. Regulators don’t like to move quickly in general, because if something goes wrong, they’re held accountable. That’s not necessarily bad for our patients. A grey area is still much better than having a black and white resolution that immediately eliminates the services we can provide. This grey area might persist for a very long period of time, and if it does, that might be the best that we can get.”

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Embracing CHANGE

Strategies to help dermatologists adapt — and be happy about it
It seems as if a day doesn’t go by without changes to regulatory requirements, delivery systems, or payment mechanisms, all of which impact how dermatologists practice or would like to practice. These changes can be perceived as interfering and overburdening, but they can also be seen as opportunities worth embracing.

Engagement strategies such as cognitive restructuring, problem solving, social support, and expression of emotion can help dermatologists cope with change, learn from it, and move forward in a positive way. These strategies develop resilience, enabling people to respond to stress in a healthy way so that they achieve their goals at minimal psychological and physical costs, noted Suzanne M. Olbricht, MD, AAD president and chair of the department of dermatology at Lahey Hospital & Medical Center in Burlington, Massachusetts. Resilient individuals bounce back with increased strength because they use their energy in a way that produces more energy instead of draining or depleting it, she added. >>
Embracing CHANGE

Reframing change
Dr. Olbricht views cognitive restructuring, which involves reframing changes in a positive light, as the most important of the aforementioned engagement strategies. Cognitive restructuring requires accepting that change happens. Change is a pervasive part of life; there is no way to avoid it. “Once we accept that change happens,” she said, “we learn to expect it as the natural course of events. The change is the same; it’s just how we think about it.” Turning that neutral position of “change happens” into a positive one requires considering that change is often good and then looking for the parts of change that are enjoyable. Ask yourself, how can these changes benefit my patients? My practice? Me?

Some physicians, however, struggle with the notion that change is inevitable and it’s best to embrace it, according to Steven K. Shama, MD, MPH, who was in private practice for more than 30 years in Brookline, Massachusetts, before retiring in 2010.

That’s because most physicians, being conscientious people, like to have as much predictability in their life as possible, especially as it relates to diagnosing and treating patients. This notion ties into the loss of control that physicians across the specialties are feeling. “We think we know the best way to treat our patients,” Dr. Shama said. “And we don’t like people telling us what the best care is, especially when they put financial benefits ahead of patient benefits.” But physicians cannot insulate themselves from what happens in the rest of the world (i.e., the government, pharmaceutical industry, and insurance companies) and they can’t totally control it, either, he explained.

Although physicians can’t prevent unwelcome change from creeping into their world, they can alter how they perceive it. Dr. Shama views change as a message that is always positive. “This change being asked of you is a message to make you even better than you currently are in this world,” he said. Change is an opportunity to learn, be creative, adapt, and improve.

PREPARING FOR and IMPLEMENTING change

Changes in medicine happen quickly and are often dictated by external sources. But sometimes you may want to make small tweaks internally to improve patient flow or even need to make a staffing adjustment because someone called in sick. How can you get everyone on board without these changes (large or small) becoming disruptive? According to Felisa Lewis, MD, MBA, former chief of dermatology at Fort Belvoir Community Hospital in Virginia, the key is to implement a culture that is patient-focused and emphasizes communication, teamwork, and flexibility.

Establishing this culture should focus on small daily efforts with large impact. A simple way of getting the staff on the same page is instituting a short daily huddle of the staff before the day starts. Gathering everyone together allows people to greet and get to know each other, allows short-notice changes to be communicated and adjustments made, provides situational awareness of the clinic flow, and reinforces the group as a clinic team (even if people are not working together per se). This 5-minute huddle should set the tone for the day.

The ideal person to run the huddle is the person who oversees the daily flow of the clinic. To maximize the benefit of the huddle, everyone from the reception desk staff to the physicians and other providers must be present. For efficiency, it helps to have a routine agenda of reviewing clinic schedules and assignments. If there are special patient considerations (e.g., specific instruments or medication), this is a good time to communicate those needs. Cross-leveling or staff coverage adjustments can be made and communicated to everyone. Finally, general announcements pertinent to everyone (e.g., reminders to put in timecards, clinic supply shortages/updates) can be made. If necessary, smaller team huddles [a physician and assigned medical assistants (MAs)] take place after the group huddle.
Finding the positive
Finding the positive can help dermatologists embrace change.

As an example, many physicians complain about the electronic health record (EHR), but as William M. Gould, MD, who is in private practice in Menlo Park, California, points out, his records are now more readable and complete than when he was just taking notes. It’s true that he is not happy about the extra time it takes to input his notes. “But I’m not going to let that get in my way of enjoying my work and seeing patients,” Dr. Gould said. To ensure that the EHR doesn’t interfere with him connecting with patients during office visits, he has chosen not to bring the laptop in the room with him. Instead, he takes notes on a piece of paper and puts them into the EHR after the appointment.

Another option to solve the problem that EHRs present is to use scribes to input the data, Dr. Shama said. It’s not the EHR that is the problem; it’s inputting the data. The EHR makes clear, concise patient information instantaneously available to other clinicians. Data in an EHR also help researchers of a particular disease to determine how it is being treated, the number of visits that are necessary, etc. These are benefits for both patients and physicians alike.

The federal government’s requirement to report quality measures using the Merit-based Incentive Payment System (MIPS) pays dermatologists more money if they, for example, follow-up with patients with melanoma and biopsy results, or track basal cell carcinomas. “These are things dermatologists should be doing anyway,” he said. “Yet because it’s imposed on us, we think it’s wrong.” MIPS offers a better system to recall these patients to ensure they don’t fall through the cracks. “All of these things take effort, but who said taking care of people would be effortless?” Dr. Shama asked.

The need to report quality measures is not going away, Dr. Olbricht added. But dermatologists can gain some control over the process by reading the quality

The clinic manager and/or physician should be alert for digressions or issues that come up during the huddle that may warrant further discussion or only concern a few people. The huddle is not the appropriate place to hash these issues out. Instead, they should be noted so that a dedicated time like a clinic meeting can be scheduled to discuss them.

Over time, these short daily interactions can be a conduit to implementing changes that require more effort from your staff. However, larger process changes such as the addition of a mid-level provider or a new business process don’t just happen by announcing it in a huddle — they must be led. “As physicians, we may not necessarily think of ourselves as leaders, especially if we are not the owner of the practice or in charge of the clinic,” noted Dr. Lewis. “However, by virtue of our expertise and experience, other staff will naturally look to us for guidance or model our behavior.” Drawing upon her MBA education and military leadership experience, Dr. Lewis advocates physician-led change through a more thoughtful process that can be broken down into three phases: preparation, implementation, and consolidation. Reinforcing those tenets of communication, teamwork, and flexibility will be invaluable during the change process.

The preparation stage is the most crucial. The whole process must be thought through from the rationale for implementing it to the consequences. When introducing the change, the leader must provide the vision and direction. Especially with externally forced changes, the focus is on the solution, i.e., the end state that must happen. What is left unstated is the purpose for the change. “As a leader, it is up to the physician to fill in the gaps to communicate the ‘why’ to the staff in a meaningful and personal way,” Dr. Lewis stressed. “Resistance to change often stems from not understanding the necessity for change.” Thus, providing a vision requires defining the problem as it relates to your clinic. The clinic’s mission statement can help put the change in context by explaining how it will support the mission, she said. More importantly, a sense of urgency (“why now?”) must be conveyed to make the case for why the status quo isn’t sufficient. For example, if the clinic doesn’t incorporate quality measures, you will have to pay a penalty to the government. As a result, you can’t afford to hire additional staff or may have to let someone go.

Continued on p. 50
literature and contributing to the discussion either in print or through committee work. Consider joining the AAD’s Patient Safety Task Force or working with your state society to develop measures that are important for your office, she suggested.

The same holds true for quality improvement (QI) projects. For many physicians, engaging in QI projects doesn’t seem to translate into better care, Dr. Olbricht said, adding, “It feels more like a box that has to be checked.” But that’s because many physicians have never done a QI project, so they don’t feel competent doing it. “By working with our colleagues, we can develop QI projects that are relevant and effective for our practice settings, which in turn promotes relevant and positive change,” she said.

One of the biggest frustrations for physicians is that their “prescription pad is only a suggestion pad,” Dr. Olbricht noted. Consider joining professional associations to engage in advocacy activities to work with pharmaceutical or insurance companies. “Trying to work through barriers can help you feel better because you’re putting energy into solving the problem,” she said. “Maybe something positive happens for a larger group of patients based on your efforts. If not, at least you’ll be able to help your patients navigate the system better.”

Continued from p. 49

The leader needs an administrative team to assist in planning, disseminating, and supervising the change. Here, the 20/60/20 rule is a good one to keep in mind. Dr. Lewis explained that this is a general guideline for the percentage of supporters (20%), fence-sitters (60%), and naysayers (20%) in an organization when change is introduced. In a clinic, supporters are often those with greater authority or responsibility such as the office manager and the head nurse. It may be equally obvious who the naysayers are. For the rest, it is important to understand the office politics, specifically who the key influencers are and where they stand. The daily huddles can help inform your understanding of who these influencers are, because they may not be in key positions. For example, it could be an MA who has been working at the clinic for a long time and trains new hires. Getting that influencer on the team, perhaps as the representative for the front-line support staff, can be helpful. That person can also serve as the leader’s eyes and ears, and be able to provide valuable insight. As the change effort goes on, the fence-sitters will be swayed to one side or the other (supporters or naysayers) by the group that has greater influence.

During the implementation phase, communication is critical. The communication to the staff should include the rationale and the briefing of the entire process, even if it doesn’t affect them individually. From an internal teamwork perspective, the change may affect individuals disproportionally but there may be opportunities for ancillary staff to assist if they know the process or are cross-trained. Particularly when the process involves patients, the external message to the patient must be consistent and conveyed in a patient-focused manner. One such change may to keep credit cards on file. On one hand, the staff should understand that the practice is losing money when patients get cosmetic procedures but leave without paying. But for patients who inquire about cosmetic procedures, it is more important that the MA inform them that the credit card will be charged when they check out as a convenience to them (as opposed to a surprise bill in the mail). In other instances, patients may not complain about a policy change to the physician, but they may do so to an MA. “You don’t want the MA telling the patient that the policy doesn’t make sense,” Dr. Lewis said. A scripted message for the staff to memorize may be helpful when changes involving patients are first made.

When planning and implementing change, it is important to empower staff, examine process flow, and reinforce teamwork such that the responsibility doesn’t fall on just one person, Dr. Lewis said. For example, if the physician is being asked to see more patients in a day, support staff may require additional training to assume tasks such as entering prescriptions for the physician to review and sign. To help the physician stay on schedule, when the MA rooms a patient who rattles off multiple problems, the MA should be empowered to educate the patient on the time limits of the visit and facilitate scheduling a follow-up visit to address concerns not covered. More support staff may be necessary to assist the physician with documentation in the EMR, patient education, etc. Once the physician has completed the
Seeking social support

Another strategy is to actively seek others who have gone through the same change, Dr. Olbricht said. “Not just to get information about how they managed the problem, but to gather social and emotional support,” she said. “Or even to whine a little bit before we move on.”

One way to find that social support is by attending professional society meetings. “I make a commitment to attend a couple of professional meetings every year, and I always come back inspired and feeling good about my specialty,” she noted. Studies have shown that physicians who pursue continuing professional development, particularly by attending continuing medical education meetings, have higher job satisfaction than those who don’t, Dr. Olbricht pointed out.

Support systems — whether they are colleagues, good friends, or family members — are essential. “Trying to handle everything on your own is very difficult,” Dr. Gould said. “It’s healthy to get things off your chest.” He has two partners with whom he discusses how to cope with the many changes facing physicians these days. They do a lot of problem solving, such as figuring out how to train staff to help with examination, made a diagnosis, and determined a treatment plan, he/she can move onto the next patient, while the assistant completes the visit. The support staff benefits by taking a more active role in caring for the patient, which conveys to the staff and the patient that it is the team, not just the physician, who is taking responsibility for each patient. “It’s important that staff, individually and as a team, feel ownership in patient care, but they need to be appropriately trained and empowered to provide that support,” she said.

Establishing realistic goals that can be achieved early in the process, or “quick wins,” is important to keep the team motivated and inspired to keep up the effort. Acknowledge and show appreciation for the hard work that has been put in. For example, if the goal is to decrease the incidence of superficial wound infections, then after one month without wound infections, Dr. Lewis suggests a small gesture such as bringing in breakfast for the staff. Recognizing and/or rewarding early adopters, both individually and as teams, can help spread the change by providing role models.

The final step — consolidating change — is the most difficult. Because it requires 60 to 70 percent of staff acceptance (of that initial 20/60/20 mix) to have a cultural shift, Dr. Lewis explained. You will know when this has occurred when new hires are indoctrinated to the new way to doing business from the start. Consolidation may also mean some long-standing employees leave because they are unable to adjust. But Dr. Lewis points out that personnel transitions should be expected, but not dreaded.

STRATEGIES to OVERCOME RESISTANCE

Understand the perspective of those affected by the change. How does it affect their routines or interactions in the office? Knowing this information will help with messaging and developing methods to facilitate changes in work patterns.

Communicate, communicate, communicate. Keep everyone informed about how the process is going and be willing to accept feedback and make adjustments along the way.

Make it uncomfortable for naysayers who are against the change. Provide clear objective standards and keep employees accountable to the organization and to each other.

Provide guidance and direction to people who are struggling. If necessary, provide more manageable objectives and pair them with early supporters who may be able to give more specific recommendations.

Evaluate progress with objective metrics that support the change effort, and keep the staff informed on the progress. One example might be an internal sign that shows “____ procedures without a wound infection.”
some of the tasks that take the dermatologists away from their clinical work.

Support from friends and family members can help alleviate some of the stress that physicians experience due to change, as well. But as a general rule, conscientious people such as physicians do not do well with expressing emotions as it can be perceived as a sign of weakness, much like how physicians show up to work even when they are sick, Dr. Shama said. Conscientious people often have a Superman or Superwoman complex. The world needs them and they will not disappoint, even if it means self-destructing to help others, he said.

That culture has to shift to become more supportive of physician colleagues, Dr. Shama maintains. “When we hear colleagues are suffering, whether they’re addicted to drugs or alcohol, which can be negative responses to change, we need to help them rather than have the tendency to shun them.” Something as simple as bringing back the doctors’ dining room, where doctors gathered and talked with each other, would help bolster their professional support system. Dr. Shama remembers the doctors’ dining room where the chief of medicine was just known as Bob. Additionally, when colleagues do something wonderful, they should be praised. Colleagues should be acknowledged for the good that they have done not just when they are sick or near death, but rather while they are alive. “It’s not part of our persona to praise colleagues publicly, but it should be,” he said. “Change is actually teaching us that there’s more that we can do to honor our patients, ourselves, and our systems. That’s the good part of change.”

Practicing mindfulness
When it comes to honoring the patient-physician relationship, adopting a mindfulness approach to practicing medicine helps facilitate meaningful relationships with patients, Dr. Olbricht said. She cited a Canadian study that correlates appreciating the value of patient relationships with greater job satisfaction among physicians. “As dermatologists, we have this opportunity every day with each patient that we see,” she said.

Mindfulness is a purposeful activity that involves being acutely aware of what is happening presently and not about the last patient you saw or the phone calls you need to make later in the day. Dr. Olbricht explained. It involves being aware of your thoughts and experiences without judging them, the latter of which engages you in an emotional way. The medical literature supports the value of mindfulness practices, citing such benefits as reduced stress and improved physical and mental health, she said.

Mindfulness practices include medication, yoga, and tai chi, but when Dr. Olbricht is having a busy day with many distractions, she does something much simpler. Just before Dr. Olbricht enters the room to see a patient, she pauses, puts her hand on the doorknob, and leaves it there for a moment. “I feel that the doorknob is round and cold, and I actively engage in opening the door. I take a deep breath. Then I open the door. That resets my mind so I am present when I walk in,” she said.

“Whatever your routine is for seeing patients, it’s important to create an office environment that’s not chaotic. So when you see the patient, you can be present for that period of time.”

Dr. Olbricht starts every day with the following thought: Today, I will see patients who need me and I’ll be able to help them with their quality of life.

His interaction with patients is what Dr. Gould enjoys the most about being a dermatologist. “Every time you walk into a room to see a patient, it’s a little bit of an adventure. In the process of practicing medicine, the patient tells you all kinds of interesting things. That’s a real privilege.”

Dr. Gould focuses on the positive aspects of his work: continued learning and helping others. “Even when treating common, mundane skin conditions, it is satisfying because it satisfies my curiosity about the natural world and fulfills my desire to help others, which is why many of us became physicians,” he said. Using a mechanical or routinized approach to patient care can foster boredom, depression, and burnout. “You really have to look forward to doing your work every day,” Dr. Gould noted. “That’s what keeps me going at the age of 84.”
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I am delighted to take the reins as President of your Academy after such a productive Annual Meeting. Thank you, Dr. Henry Lim for your leadership and guidance as President last term. I have big shoes to fill, but I look forward to rolling up my sleeves and getting to work. I spoke with many of you in San Diego. I heard about the exciting research you have in the works, the opportunities you are creating in your careers, and the challenges you experience on a day-to-day basis.

Change surrounds us, in science, in technology, in culture, as well as in medicine. While new knowledge and new treatments that we can use for the good of our patients are very welcome, other changes in medicine are disconcerting and even painful. Our challenges include difficulties in getting our patients treated with appropriate medications and procedures, the shift to value-based payment models, private equity entrance into the practice of medicine, and excessive administrative requirements. Many of these changes represent a loss of control for us as physicians, and increase the level of burnout we feel. However, while the changes may be hard to stomach they will likely not cease. As Heraclitus said centuries ago, the only thing that is constant is change. We must accept that change happens, but it is incumbent upon us to be strategic, proactive, and adaptive to keep our profession and specialty strong.

This month’s issue of Dermatology World includes a feature article about embracing change and I hope that you will read it as it offers perspective as well as suggestions on how to manage the seismic shifts in medicine. Rest assured, however, that as you are facing these changes you are not facing them alone. The Academy offers a host of tools, resources, and opportunities that you can utilize to help you traverse the shifting tides.

For example, many of us are angered by policies that have been implemented that are taking precious time away from our patients. From increasing prior-authorization requirements to reporting requirements through the Quality Payment Program’s Merit-based Incentive Payment System (MIPS), we often find ourselves spending more time at our desks instead of with our patients. Fortunately, the Academy has developed the Practice Management Center, which provides tools such as a prior-authorization letter generator and MIPS compliance resources. I encourage everyone to spend some time perusing the website at www.aad.org/practicecenter. There is a tool or resource available to help with almost any practice headache.

In addition to the challenges inside our offices, we face strong outside forces that are changing the way we practice. Restrictive compounding regulations and increasingly detrimental private payer policies are hindering patient access to quality dermatologic care. We have also been battling inappropriate scope of practice expansions that threaten patient safety. We must come together as a specialty and advocate on behalf of our patients. Fortunately, you don’t have to travel to Washington, D.C. or your state capitol to campaign for good policy. The Academy has developed a robust Advocacy Action Center at https://takeaction.aad.org where you can send a quick message to your member of Congress on issues that are important to you and your patients. We as constituents have a powerful influence on legislators’ actions. Let’s make our voices heard and get involved in advocacy.

And speaking of facing change by being strategic, the Academy will be undergoing a formal process of evaluation, focusing on how to move forward with strength as we seek to serve the needs of our members and our patients. Data will be essential and your help in obtaining accurate information is paramount.

While the Academy can help us navigate our evolving environment, an important part of embracing change involves remembering the reason we became physicians. We cannot forget that our patients are our number one priority and the care that we provide them is our ultimate purpose. I look forward to facing change and its opportunities and challenges head on this year and I hope you will join me. Our patients are depending on us. dw
Change is everywhere in this issue of *Dermatology World*. The very first page features a new physician editor, Kathryn Schwarzenberger, MD, who takes the reins after more than seven years of successful leadership by Abby Van Voorhees, MD. The page before the one you’re reading features a column from a new president, Suzanne Olbricht, MD, who ponders this theme of change and what dermatologists can do about it. And if that’s not enough, there’s a whole feature article about embracing change on p. 46. Change, it appears, is the theme of the moment.

Having just returned from the Annual Meeting in San Diego, I’d like to take a moment to ponder how we embrace what’s changing and meld it with what is timeless. In your practices, more and more of what you do is mediated by an EHR and other technology. Your patients can make an appointment online, follow you on Facebook — you can even conduct check-ins with patients digitally. Combining these elements with face-to-face interactions can increase the value you offer your patients.

Similarly, your Academy can do a lot through email, social media, and a robust website, and all of these enhance the value of membership. For instance, I’ve been thrilled by the response we’ve seen to *Dermatology World Weekly* and *DW Academy Insider*, including the Question of the Week, and by the interactive engagement of members with our new Practice Management Center and the fact that thousands of you have made use of the tools we’ve developed. Being in San Diego with so many of you, and hearing how much you value these tools, assured me that we’re on the right track — and reminded me of the importance of community and face-to-face networking that is part of the value of a professional community and the strength of an association.

I hope you were able to join us in San Diego and experience this feeling. I hope you’re planning to be with us in Chicago in July for the 2018 AAD Summer Meeting and in Washington, D.C., next March for our 2019 Annual Meeting. Until then, follow our social media feeds at AADMember and keep an eye on your inbox. The combination of both is what makes today’s Academy membership so powerful. Our traditional in-person meetings are irreplaceable, but today’s up-to-the-minute digital and web-based products and services, delivered to you in real-time when, where, and how you need them in today’s world are vital, too. It’s the combination of the new and the old that makes the Academy such a powerful partner to you.

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**AAD names Dirk Elston, MD, next JAAD editor**

The *Journal of the American Academy of Dermatology* (JAAD) has announced that Dirk Elston, MD, will take the reins as editor-in-chief beginning with the July 2018 issue. The editor is appointed for an initial five-year term. Bruce Thiers, MD, has served in the position since 2008.

Dr. Elston has served as the deputy editor of JAAD since 2008. During that period, he also served on the AAD Board of Directors from 2009 to 2015, as AAD president in 2013-2014, and as *Dermatology World’s* Cracking the Code columnist in 2011 and 2012. He is also the author of 400 peer-reviewed publications, 84 textbook chapters, and, with two others, *Andrews’ Diseases of the Skin*. Read more from JAAD at [www.jaad.org](http://www.jaad.org).
OBITUARIES

BY JERRY GRAFF, MD

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

MARTIN ASCH, MD, of Sacramento, California, Dec. 27, 2017, at age 93; received medical degree from the University of Illinois, 1949; trained in dermatology at VA West Los Angeles Medical Center; practiced dermatology in Sacramento for 37 years; served as president and founding member of the Sacramento Valley Dermatological Society; taught dermatology at the University of California Davis School of Medicine where he served as a clinical associate professor of medicine. A veteran of WWII, he served with the 86th infantry division.

CHARLES D. DEFEO JR., MD, of New York, Dec. 12, 2017, at age 92; trained in derm at Kings County Hospital and NYU; entered private practice in NYC while serving on NYU voluntary faculty from 1957 to 1996; a recognized expert in bullous diseases, served as chief of Bullous Disease Clinic at NYU from 1970 until retirement; founding president of NY State Society of Dermatology.

CHARLES K. DORAN (“CK”), MD, of Claremore, Oklahoma, Aug. 11, 2017, at age 83; attended Univ. of Oklahoma medical school and trained in dermatology at a San Francisco hospital; founded the Tulsa Derm Clinic; loved hunting quail with bird dogs, travel, and fishing; enjoyed spectator sports of football and golf.

ARTHUR Z. EISEN, MD, of St. Louis, Nov. 12, 2017, at age 88; following training in internal medicine, began his research career at NIH followed by his derm residency at Harvard/Mass. General and became an asst. prof. there; became founder and chief of derm dept. at Barnes Hosp./Washington Univ. School of Med. in St. Louis in 1967; research focused on human skin collagenases, ultimately elucidating aspects of tumor invasion and metastasis; with his co-investigators determined complete primary structure of collagenase and stromelysin genes and how fibroblast enzymes affect important biological phenomena in skin and other tissues; internationally known and recognized for his pioneering work that remained a focus of his dept. for decades; from his full obituary: “Dr. Eisen was recognized as one of only a few individuals who collectively established a tradition of rigorous laboratory research in the U.S. in what had been an empiric specialty, and trained the next generation of scientists to carry on that tradition.”; former trainees established and endowed Arthur Z. Eisen Junior Investigator Award at the med. school to support career development of exceptional residents and fellows in the derm. dept.; held appointed and elected leadership roles at JID, SID, and the Assoc. of Professors of Dermatology, receiving many awards along the way including the Martin Carter Mentorship Award in 2003; was chief of derm until 1996 but was residency program director for almost 4 decades, training almost 200 residents who remain dedicated to his work.

HARRY R. FOERSTER, MD, of Tucson, Arizona, Oct. 12, 2017, at age 93; trained in derm at Univ. of Michigan and practiced 50 years, initially joining his father in practice in Milwaukee; retired to Tucson and Presque Isle, Wisconsin where he was an avid outdoorsman; enjoyed many wilderness canoe trips until age 90; was an accomplished painter, wooden boat enthusiast and sailor; loved his dogs; was described as a “kind, gentle, and unassuming man.”

CONTINUED ON p. 57
CONTINUED FROM p. 56

KEN HASHIMOTO, MD, of Ann Arbor, Michigan, Nov. 9, 2017, at age 86; born in Niigata, Japan where his father was prof. and chair of dermatology and president of Niigata Univ.; brother also a derm; immigrated to U.S. in 1956 and became a Fulbright Scholar; trained in derm at Univ. of MD and at Mass. General/Harvard; held faculty positions at Univ. of TN, then Tufts Univ. before becoming chair of dermatology at Wright State Univ. in Dayton, OH; moved as chair to Wayne State Univ. in Detroit in 1980 and retired in 2000 as professor emeritus; areas of interest included electron microscopy and histochemistry; with wife, Noriko, established Hashimoto Endowed Chair in Dermatology and Syphilology at Wayne State in 2007; “Research was the most important element of my job,” he remarked; a prolific writer of professional papers, book chapters, and books, and respected as excellent educator and clinician while training 100 residents and 40 research fellows; free time devoted to studying and publishing research; enjoyed farming and gardening; upon retiring, his department presented him with a John Deere tractor; loved raising birds, pet ducks, pheasants, and peafowl.

CANDACE W. KING, MD, of Pinehurst, North Carolina, Sept. 14, 2017, at age 56; won numerous academic awards from valedictorian of high school class to summa cum laude at Bryn Mawr to multiple honors at UNC Med. School; trained in derm at UNC, Chapel Hill; practiced for almost 30 years in Pinehurst with subspecialties in Mohs surgery, laser surgery, and minimally invasive cosmetic procedures; was visiting dermatologic consultant in Rural Health Clinics in India in 1999; loved nature, playing the harp, painting, and traveling with her two sons.


CATHERINE M. RUDDY, MD, of Ottawa, Ontario, Canada, Oct. 26, 2017, at age 63; trained in dermatology at The Ottawa Hospital; had a private practice in Ottawa.

MARTIN D. SAINÉ, MD, of Ishpeming, Michigan, Nov. 24, 2017, at age 63; trained in dermatology at Wayne State Univ.; practiced for Henry Ford Health Alliance Plan followed by private practice in Alpena and Marquette, Michigan; enjoyed skiing, swimming, music, and current events.

JERRY SCHIMMEL, PHD, of Kansas City, Missouri, Sept. 23, 2017, at age 94; as a young U.S. Army medic in WWII, he helped provide support for the 101st Airborne and Gen. George Patton; ultimately earned PhD in pharmacology at Univ. of FL in 1954; developed products and contributed to derm through many business ventures and as member of AAD and ADA; was president of DermArts Labs, a division of Marion Labs in Kansas City; in 1972 formed Dermatology, Front Row Center whose purpose was selling recorded educational presentations; his interests outside of helping to spread dermatology knowledge included jazz, hockey, photography, fishing, cribbage, and golf.

CHARLES A. SWANSON, MD, of Boxboro, Massachusetts, Oct. 23, 2017, at age 68; educated at MIT and Stanford Univ. Med.; trained in derm. at Brown Univ/Rhode Island Hosp.; had a private practice in derm in Newburyport, Massachusetts; hobbies included hiking, botany, geology, and gardening.

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. Jerry Graff, MD, assembles additional information for each obituary on behalf of DW. dw
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Who does what in a practice?

BY EMILY MARGOSIAN, CONTENT SPECIALIST

As the daily tasks required to keep a dermatology practice running continue to multiply, who is doing what on a day-to-day basis? According to the AAD’s 2016 Group Practice study, clear patterns emerge among staff at each level. Unlike clinical staff who focus on specific tasks, practice managers and admin staff are involved in almost all aspects of the practice. Dermatologists themselves “own” or share most responsibilities (with the exception of more mundane administrative duties), and overall, coding, large-scale purchases, training clinical staff, and entering quality measures are among their key responsibilities. See below for a more complete delineation of roles and responsibilities within a dermatology practice according to survey data. *dw*

Practice roles and responsibilities

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