

POLICY & PRACTICE



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Allergan Sues Over Botox Gag

Allergan, the manufacturer of Botox (onabotulinumtoxinA), has sued the Food and Drug Administration, claiming that the agency's restrictions on off-label promotions are inhibiting the company's ability to "proactively share truthful and relevant information with the medical community," according to a company statement. FDA's constraint that Allergan discuss off-label uses for Botox only in general terms violates the first amendment and hurts patients, Allergan claimed. To fully inform physicians, the company said it needs to describe dosing guidelines, patient selection criteria, and proper injection technique. "We believe that the inability to share such important information proactively with the medical community violates the First Amendment and potentially diminishes the quality of patient care," said Douglas S. Ingram, Allergan's executive vice president. Allergan is not the first to take on the agency's off-label restrictions. The Washington Legal Foundation, a libertarian advocacy group, has regularly challenged the policy as unconstitutional.

County Plans Teen Tan Ban

Officials in Howard County, Md., plan to ban indoor tanning for all residents under age 18 years, except by prescription. The proposed regulation in the suburban Washington county would rule out tanning by any minor unless a licensed physician prescribed the rays. Tanning salons would have to register with the county every year. The state's health board, which must approve the plan, has set a public hearing for Nov. 10. Where other state and community laws exist, parents must consent to children's tanning, but minors aren't barred from salons, said Howard County Health Officer Dr. Peter Beilenson.

Women Feel Psoriasis Distress

A National Psoriasis Foundation survey has determined that women with psoriasis and psoriatic arthritis are more likely than men to suffer emotional and psychological effects. According to the survey, 20% of women with mild to severe disease said psoriasis is a very large problem in their everyday lives, compared with 12% of men. Two-thirds (67%) of the women said psoriasis negatively affects their overall emotional well-being, compared with 57% of men. The sexes were closer to agreement that psoriasis interferes with their capacity to enjoy life: 59% of the women and 52% of the men said so. "This level of emotional distress has implications for the progression and treatment of the diseases themselves, as stress can be a trigger for flares of both psoriasis and psoriatic arthritis in many patients," Dr.

Mark Lebwohl, professor and chairman of dermatology at the Mount Sinai School of Medicine and chair of the National Psoriasis Foundation Medical Board, said in a statement.

Resistance Cuts Antibiotic Sales

Antibacterial drugs will soon see a slump in sales caused in part by declining effectiveness and generic competition, according to market research company Kalorama Information. The segment had sales growth of just over 3% in 2008 and 2009, but sales will rise only 1.1% in 2010 and will decline by 0.6% in 2011, Kalorama estimated in its report "Worldwide Market for Anti-Infectives (Antifungals, Antibacterials and Antivirals)." The company pegged the 2009 world market for antibacterial drugs at \$24.5 billion. Global sales of all classes of anti-infectives were forecast to hit \$53.3 billion, up from \$45.3 billion in 2006. Kalorama predicted that antiviral sales will grow vigorously, with increases of 18% in 2009, 12% in 2010, and 9% in 2011. By 2013, worldwide antiviral sales should hit \$34.1 billion.

Most Doctors Provide Charity Care

Almost 6 in 10 physicians reported providing charity care—defined as either free or reduced-cost care—to patients in 2008, according to the 2008 Health Tracking Physician Survey from the Center for Studying Health System Change. On average, physicians who provided charity care reported 9.5 hours of such care in the month preceding the survey. That amounts to slightly more than 4% of their time spent in all medically related activities, according to the report. The survey also found that 44% of physicians reported receiving some form of performance-adjusted salary. About one-quarter said they received a fixed salary, while 20% received a share of practice revenue.

Doubts on Effectiveness Research

Although comparative effectiveness research may give doctors and patients better information about what treatments work best, it's not clear that it will result in better health or less spending, according to the Rand Corporation. Its study concluded that new incentives will be needed to change the behavior of patients and providers. Federal law, however, prohibits using the results of federally funded comparative effectiveness research to guide payment policies, so it will be hard to develop incentives for driving down health spending, the study said. In the near term, any reduction in spending created from such research would be offset by the costs associated with generating, coordinating, and disseminating the findings.

—Alicia Ault

MANAGING YOUR
DERMATOLOGY PRACTICE

RAC Audits Go Nationwide

The Centers for Medicare and Medicaid Services thinks it is overpaying you. That probably comes as no surprise, nor will the news that CMS has devised yet another scheme for taking back money that they have already paid to you.

The new reel-in is called a recovery audit contractor (RAC) audit, and if this is the first you've heard of it, you probably don't practice in California, Florida, New York, Massachusetts, or South Carolina.

Those states were the sites of a pilot program conducted over the last 3 years to test the RAC system. The total amount that was recovered so pleased CMS that it has now authorized a nationwide rollout.

So RAC audits could be in your future no matter where you practice. And now is the time to examine your

Medicare claims to determine where you may be vulnerable in the event of an RAC audit of past claims and to minimize your risk of audit on future claims. Limitations on scope and look-back period should make that process relatively painless.

Here's how the program works: CMS has divided the country into four regions and put an RAC in charge of each one. Region A (Northeast states) is covered by Diversified Collection Services; Region B (the Midwest) by CGI Technologies and Solutions; Region C (the South) by Connolly Consulting Associates; and Region D (the West and Southwest plus Alaska and Hawaii) by Health-Data Insights.

Each RAC has its own unique procedures and criteria for audits. You can learn more about your RAC's idiosyncrasies, and confirm which region includes your state, at the CMS Web site: www.cms.hhs.gov/RAC/.

RACs are paid a percentage of any overpayments they can identify and collect from providers.

They are supposed to identify underpayments too, but in the pilot program that amounted to less than \$38 million, compared with over \$900 million in overpayments.

Although most audits are automatic, meaning an analysis of computer data only to identify administrative errors, the RACs are also authorized to undertake "complex" audits in which patient records are examined.

They will mostly be looking for only four basic transgressions:

- ▶ Incorrect payment amounts (either too much or too little).
- ▶ Noncovered services, including those that are not considered "reasonable and necessary."
- ▶ Incorrect coding.
- ▶ Duplicate payments.

The RACs are required to have good

cause to audit your claims. They cannot randomly select claims or focus only on high-paying claims. And they can only look back a maximum of 3 years—and no earlier than Oct. 1, 2007. That is a relatively short period of time requiring your review, and a relatively small number of transgressions that you need to look for.

So now is the time for your staff to start getting out Medicare EOBs (explanation of benefits) and determine where you might be vulnerable on the past 2 years' claims. And once you identify any vulnerabilities, you can take steps to audit-proof future claims.

So far, the RACs have mostly targeted hospitals, nursing homes, home health care organizations, and medical equipment companies, but anyone who bills Medicare is fair game. And

it's only a matter of time before state-run Medicaid programs become targets as well.

CMS has hinted that a majority of audits will take place in California, New York, and Florida, because 25% of all Medicare payments are made to those three states alone.

If a RAC wants to look at your records, they must make the request in writing and they must tell you what they are looking for. They are limited by law to auditing no more than 10% of the average number of Medicare claims you file each month. The law states they must pay the costs of copying records, both paper and electronic.

The law provides you 45 days to respond to a RAC's request for patient records. It also specifies a "discussion period," so if your records are requested, don't rush to send them. Call the RAC and discuss! The RAC's medical director is "required to be actively involved in examining all evidence used to make determinations," and you have a right to speak to him or her if you wish.

If a repayment is demanded, you have 120 days to appeal that determination, in the same way (and by essentially the same process) that conventional Medicare audit determinations are appealed.

In case you're wondering, RAC audits will not replace regular Medicare audits, which I discussed in my June 2004 column (available in the Archive Collection at www.skinandallergynews.com). However, the RACs will not be permitted to audit claims that have already been audited conventionally. ■

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