

SPECIALTY PHARMACY NEWS

News and Strategies for Managing High-Cost Biotech and Injectable Products

Contents

- 3** How Do OneOncology's Electronic Negotiations Work?
- 4** Little Chance Expected For Passing Home Infusion, SP Bills in '08
- 4** New FDA Specialty Drug Approvals
- 5** HIV, Oncology Are Among Areas That Will See Therapeutic Impact
- 6** Chart: Specialty-Tier Coinsurance Rates in Medicare PDPs
- 7** Mixed Outlook Seen for M&A Activity in SP, Home Infusion
- 8** FDA Is Reviewing New Data on ESA Risks With Some Cancers
- 8** BSC Offers Aggregate Tiered Fee Schedule for In-Office Injectables
- 9** Table: TNF Inhibitors Placed By National PDPs on Specialty Tiers
- 10** Company Unites Oncology Segments in Integrated Approach
- 12** News Briefs

Managing Editor

Angela Maas

Executive Editor

James Gutman

Director, Databases and Directories

Susan Namovicz-Peat

Outlook 2008

Plans Will Focus on Oncology Management, Evening Pharmacy and Medical SP Benefits

Although most plans have instituted higher tiers in their formularies for specialty drugs, their management beyond tiering varies widely, experts say. With no new major legislative or regulatory changes in health care impacting plans this year, insurers are saying that they will incorporate more tools for managing high-cost specialty pharmaceuticals. Among those tools are methods to even out the incentives for using the pharmacy or medical benefit for specialty pharmaceuticals and to incorporate more clinical management in oncology.

Based on her conversations with health plans, Debbie Stern, vice president of managed care consulting firm Rxperts, says she "anticipates that in 2008 we will see more [health plan] activity related to specialty, as other hot buttons" — such as Medicare — "have cooled down."

When it comes to specialty pharmacy costs, she says, "a lot of payers don't have a good handle on their per-member, per-month costs and their trend rate year to year." Plans "need to ensure that appropriate attention is paid to these products...and look at ways to manage and track" them, she explains.

continued on p. 11

Oncology Firm Pledges Transparency, Efficiency via Online Electronic Negotiations

A new company in the oncology sector is turning to technology in the hopes of bringing efficiency and transparency to the industry — and ultimately better prices to physicians and health plans. And although opinions vary on its chances of success, it has managed to make some waves in a very short amount of time.

Launched in May 2007, OneOncology, Inc. offers distributors the opportunity to bid on provider orders for hundreds of oncology drugs through online reverse auctions (see box, p. 3). Products will be up for negotiation every two months. The company's first electronic negotiation event began on Dec. 11, and the second one is scheduled for February.

For the first electronic negotiation event, 140 practices representing 604 physicians and \$1.5 billion in annual purchasing registered to participate.

"We are creating an open, dynamic, competitive marketplace," says Ben Favret, vice president of sales for OneOncology, Inc. "We have seen a large spread in the marketplace. We want to reduce or eliminate this spread so there is one consistent price."

Favret, who has worked in oncology for about 20 years, most recently as the head of sales and marketing for Matrix Oncology, co-founded the company with CEO Steven Kirchof, who has 15 years of oncology experience and also worked at Matrix. They own the company with a small group of investors, none of which are affiliated with any manufacturer, distributor, physician, oncology company, group purchasing

organization (GPO) or insurance company, says Favret, who emphasizes that OneOncology is a neutral party.

Favret says that a confluence of events motivated the men to launch OneOncology. Oncology distributors began buying GPOs (*SPN 5/06, p. 6*), and “controlled markets aren’t good for any market,” he asserts, noting that “two players control almost 90% of the market.” With these acquisitions, there was “no objectivity, no transparency” anymore — and “no one represented practices anymore.”

The oncology market was gaining in significance due to several factors: more than 650 products in the oncology pipeline, an aging population, and the shift of cancer from an acute to a chronic disease. These factors, says Favret, make community oncologists — who treat approximately 85% of cancer patients — crucial.

At the same time, he says, the 2003 Medicare reform law “virtually crippled a lot of small practices, which were paying above their reimbursement rates for some drugs.”

According to Favret, “all of these factors together drive the need for efficiency and reduced costs.”

“Four years ago, our business model would not have worked,” he maintains.

Favret and Kirchof took their understanding of the oncology sector and “looked for technologies, things that would work in this space.” Electronic negotiation technology is “a proven, well-documented technology used in hundreds of other marketplaces,” says Favret, with average savings ranging from 3% to 35%. In other industries, he says, it has taken about four to five electronic auctions to bring about significant changes. Still, he says, “even a 1% savings to a community oncologist is substantial when he or she is spending \$1 million annually.”

Health plans have a “huge stake” in this process, says Favret. “They ultimately are the ones paying for cancer care. Community oncology has saved payers billions and improved the quality of care at the patient level... The oncology pipeline is massive... Payers benefit when drugs come to market.”

Timing Said to Be Right

A number of factors forecast success for the process of electronic negotiations, says Favret:

(1) *The product is easily specifiable.* “The FDA has done this for us,” he says. “If you’re buying Camptosar, you’re going to get the exact same drug, no matter who you are buying it from.”

(2) *The ability exists to aggregate volumes very quickly.* In less than seven months, according to Favret, OneOncology was able to sign up oncology practices with more than \$1.5 billion in annual purchasing power. This says two things, Favret asserts: “that oncologists spend a lot of money on drugs — about \$2.5 to \$3 million per physician annually — and that they are looking for solutions.”

(3) *The supply and demand sides need to be in check.* “On the distribution side, you need access to product and excess capacity in the market,” he says. There are more than 1,000 distributors in the market and “huge excess capacity.” The demand (or physician practice) side must also see the importance in purchasing drugs at better rates. Physicians “were rich on [profit] margins four or five years ago. Now, they have taken about a 35% cut on the drug side” since the 2003 Medicare reform law was enacted, he says. Considering that “70% to 75% of a practice’s expense statement is drug buying, and 50% to 60% of a practice’s profit comes from their drug business,” the demand for purchasing power is there.

(4) *The technology must be available.* Users need access to the technology, and they got it, he says, when CMS began requiring practices to file claims electronically.

Distributors pay OneOncology a pre-established fee that is revealed to the distributor in a request for a quote prior to the bidding. Although Favret would not reveal

Specialty Pharmacy News (ISSN: 1937-6685) is published 12 times a year by Atlantic Information Services, Inc., 1100 17th Street, NW, Suite 300, Washington, D.C. 20036, 800-521-4323, www.AISHealth.com.

Copyright © 2008 by Atlantic Information Services, Inc. All rights reserved. No part of this publication may be reproduced or transmitted by any means, electronic or mechanical, including photocopy, FAX or electronic delivery without the prior written permission of the publisher. **Specialty Pharmacy News** is published with the understanding that the publisher is not engaged in rendering legal, accounting or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought.

Managing Editor, Angela Maas; Executive Editor, James Gutman; Director, Databases and Directories, Susan Namovicz-Peat; Publisher, Richard Biehl; Marketing Director, Donna Lawton; Fulfillment Manager, Gwen Arnold; Production Coordinator, Melissa Muko.

Subscriptions to *SPN* include free e-mail delivery in addition to the print copy. To sign up, call AIS at 800-521-4323. E-mail recipients should whitelist aisalert@aispub.com to ensure delivery.

To order **Specialty Pharmacy News**:

- (1) Call 1-800-521-4323 (major credit cards accepted),
- (2) Order online at www.AISHealth.com, or
- (3) Staple your business card to this form and mail it to:
AIS, 1100 17th St., NW, Suite 300, Wash., DC 20036.

Subscription Rates

Payment Enclosed* \$465
Bill Me \$495

*Make checks payable to Atlantic Information Services, Inc.
D.C. residents add 5.75% sales tax.

Call 800-521-4323 (or visit the Marketplace at www.AISHealth.com) to order **Specialty Pharmacy News on CD**, a searchable CD with all issues of the newsletter published from January 2005 through June 2007. (\$89 for subscribers; \$389 for non-subscribers.)

any specific amounts, the fees vary based on market conditions.

Practices must complete three steps to be fully registered and able to participate: (1) register online, (2) sign a letter of intent, and (3) submit the practice's user history. As of early January, Favret says that 282 practices representing 1,128 community oncologists have been entered into the registration system. Out of that total, 140 practices representing 604 physicians have gone through all three steps. It is these 140 practices that represent the \$1.5 billion in annual purchasing that the company cites. When the 282 practices' purchasing power is considered, "the total is closer to \$3 billion," says Favret.

"I certainly think that there is a place for price transparency," says Mark Armstrong, a senior attorney in Houston with Squire, Sanders & Dempsey, LLP. "However, whether a company like OneOncology is successful will depend on its ability to increase competition among distributors to offer lower prices than they would offer through normal distribution channels."

However, according to the OneOncology Web site, "Practices are under no obligation to order anything from OneOncology unless its prices are lower than their current prices."

Nick Opalich, specialty pharmacy consultant for Strategica Health Partners, says, though, that "it's not about the drug cost, other than that only large practices can garner the best price because of volume" and "can

also diversify their practice base." He says that "large practices are approximately 38% of overall drug purchases in the buy-and-bill arena. If you do the math, that leaves 62% of the volume within the practice setting of five or less physicians. The reverse-auction angle in the small-practice market doesn't align itself appropriately with other incentives. Why does a distributor want to bid a lower price and then service a small account?"

Still, distributors are participating. Favret says that three Verified-Accredited Wholesale Distributors have registered, and that two others are in the registration process. Since OneOncology is under a pledge of confidentiality, he says that it cannot disclose the identities of participating companies, regardless of whether they are distributors or oncology practices.

Oncology Supply, a unit of AmerisourceBergen Specialty Group that is by all accounts the largest drug distributor in the oncology market, is one company that has said it will not participate. In July 2007, an Oncology Supply account manager sent an e-mail that raised a number of concerns about OneOncology. In August, the company posted a letter on its Web site from President Bill Stickler, who said that business associates "may have been subjected to misinformation regarding our position on OneOncology." He said that the two companies had "discussed at length [OneOncology's] ideas around their business model" but that "we completely reject their notion that they can or will bring value to our relation-

How Do OneOncology's Electronic Negotiations Work?

Through hosting online reverse auctions, OneOncology, Inc. is trying to bring transparency, efficiency and cost savings to the oncology market. Acting as a neutral party, the company allows registered oncology practices to place orders for oncology drugs, which registered distributors are then able to bid on. The company held its initial electronic negotiation event on Dec. 11, and companies re-bid on contracts every two months. In early January, the company was still evaluating the results of that event.

OneOncology offers 128 product groupings, which include a total of 700 National Drug Codes. The drug categories "are set up to create the most competitive, dynamic marketplace we can," says Ben Favret, co-founder and vice president of sales for OneOncology. Drugs may be grouped by therapeutic class (for example, OneOncology groups taxanes together and 5-hydroxytryptamine₃ (5-HT₃) receptor antagonists

together); by disease state; by manufacturer (the company places all Amgen Inc. products in one category); and by product volume. Not all oncology products are available through reverse auctions, he says, explaining that the company "will use other technology for access to" limited-distribution and limited-allocation drugs.

The auctions vary in their formats. Some might be like an auction on eBay, which would close in a few days at a specified time, while others may be much shorter, perhaps a live event of an hour. Still others may start with OneOncology posting a specific cost for a product, and the first distributor to enter a bid at that amount or below wins.

"We don't place or take orders," says Favret. "We are facilitating a transaction." This process, he says, reduces errors, improves service and provides more transactional efficiency.

Contact Favret at favret@oneoncology.net or visit www.oneoncology.com.

ship with you... In no way do we support their business model and we have no plans to participate with them in their endeavors."

William Sullivan, principal consultant with Specialty Pharmacy Solutions, LLC, says that "the concept is intriguing" but that "I can also see the resistance to the idea by the well-entrenched distributors like AmerisourceBergen. They have huge share and probably worry about anything that will upset the apple cart. Smaller distributors, however, could look at this as an opportunity. If I were one of them, I'd plow back virtually all my marketing expense (no need to pay sales people a commission) into a deeper discount and try to capture a big order. Do that a couple of times a year, and the year could be made. Or you could go out of business if you continue to lose bids! So much depends on how many practices they can sign up. Time will tell."

In an acknowledgment of specialty pharmacies' roles in the oncology market, OneOncology says on its Web site that it "will launch a specialty pharmacy electronic trading hub that will provide convenience and one point of contact. This will create more time and more efficiency for both the patient and the practice. We expect to launch this service soon."

Contact Favret at favret@oneoncology.net, Armstrong at marmstrong@ssd.com, Sullivan at wsullivan@specialtyRxolutions.com and Opalich at njopalich@aol.com. Visit www.oneoncology.com. ♦

Outlook 2008

Little Chance Expected for Passing Home Infusion, SP Bills in 2008

Although 2007 saw the introduction of various pieces of legislation affecting the home infusion and specialty pharmacy (SP) industries, many industry experts express little hope of any progress made on these bills in 2008.

Any time you go into an election year, there are two potential — and conflicting — actions that can happen with legislation, says Kevin Gorman, managing partner and founder of Putnam Associates, a pharmaceutical and biotech consulting firm. Either the existing administration will try to "ram through" as much legislation as possible, or legislation will be proposed but not acted on.

Most of the people who spoke with SPN contend that the latter scenario is likely in 2008 with issues of interest to the SP industry. "Things will be very slow because of the upcoming election," says Mark Armstrong, a senior attorney in Houston with Squire, Sanders & Dempsey, LLP. He says that 2008 may very well be "a long year of nothing from a health care legislation standpoint."

While there have been recent rumblings expressing optimism that 2008 will see passage of a bill establishing an approval pathway for biogeneric legislation (SPN 12/07, p. 12), "I don't think much will happen with the

NEW FDA SPECIALTY DRUG APPROVALS

◆ **On Dec. 13, the FDA approved BioMarin Pharmaceutical Inc.'s drug Kuvan (sapropterin dihydrochloride) for the treatment of phenylketonuria.** The drug was available the following day, and it will be distributed primarily through specialty pharmacies. The company says that each 100 mg tablet will cost \$29, with an annual cost of approximately \$57,000 for an average patient. Visit www.kuvan.com.

◆ **On Dec. 17, the FDA granted a supplemental indication for the Genzyme Corp. drug Thyrogen (thyrotropin alfa for injection) as a combination therapy with radioiodine to destroy remaining thyroid tissue in patients who have had a cancerous thyroid removed.** The drug was first approved in 1998 as a diagnostic tool for thyroid cancer patients (SPN 6/05, p. 1). A company spokesperson says that the pricing for the additional indication will be identical to that of the initial indication, which is approximately \$1,500 per treatment. The drug allows patients undergoing remnant ablation to continue

with their thyroid hormone therapy. Patients typically undergo one procedure. The drug is available through limited distribution by specialty pharmacies. Visit www.thyrogen.com.

◆ **Following the Dec. 27 expiration of the Roche Laboratories Inc. patent for Kytril (granisetron hydrochloride), the FDA granted approval to several generic versions of the antiemetic.** On Jan. 2, the agency approved a 1 mg tablet from Barr Pharmaceuticals, Inc., which says it expects to launch the drug during the first quarter of 2008. A company spokesperson would not provide pricing information, but drugstore.com lists two 1 mg tablets at \$131.99. On Jan. 3, the FDA approved a 1 mg tablet and a 1 mL single-dose vial from Teva Pharmaceutical Industries Ltd. The company has 180 days of marketing exclusivity for the injectable version. Teva has begun shipping the products. Visit www.barrlabs.com and www.tevapharm.com.

biogeneric issue this year, which is unfortunate," says Armstrong. "I think the legislation will die. There is not much focus on getting it passed."

"I don't think anything will get through," agrees Gorman. There is still "a lot of confusion" surrounding the issue, so "a lot of people are looking to Europe," which has established a method by which to approve biosimilars.

However, he says, there is an "interesting convergence of interest" in the biosimilars issue on "both sides of the aisle." While larger manufacturers of brand drugs have been perhaps the most vocal stakeholder on the issue, Gorman says that "the landscape is changing to some degree as far as the power and the size" of the generic manufacturers, such as Teva Pharmaceutical Industries Ltd. and Mylan Inc., as well as Indian companies such as Ranbaxy Laboratories and Dr. Reddy's Laboratories Ltd. (SPN 7/07, p. 6). "There are a lot more deep-pocketed companies in the generics field."

'Obvious' Need for Home Infusion Coverage

Providing adequate home infusion coverage to Medicare beneficiaries — who are now covered for only the drug but not the administration and supplies needed to infuse the drug — is "one of the most obvious things that needs to be done that I don't think we'll see happen," maintains Dexter Braff, president of The Braff Group, a health care mergers and acquisitions company. He attributes this to the numerous "big-ticket" Medicare issues that Congress already has on its plate, including physician payments, reimbursement on the home medical equipment side and Medicare Advantage. He says that H.R. 2567, the Medicare Home Infusion Coverage Act of 2007, which was introduced in June (SPN 7/07, p. 1), may be "sneak[ed] into another bill," but he doesn't hold out much hope of that happening.

Russ Bodoff, executive director of the National Home Infusion Association (NHIA), one of the industry organizations that helped craft the legislation, agrees that in a presidential election year, "getting legislation passed is often difficult." He says that NHIA is developing a strategy to get this bill approved. Although he could not comment on specifics now, he says that it will be a two-year campaign with the goal of 2009 for the legislation's passing. "In another couple of months, we will be able to lay out a roadmap, including approaches to drive the legislation."

"On the positive side, more and more members of Congress and their staffs have been educated on providing infusion treatments in alternate-site settings," maintains Bodoff. "Very few question the need." In addition, he says, "there is a growing coalition of organizations that have come together in supporting the bill."

Likewise, says Braff, "Congress' plate is way too full" to take on much-needed intravenous immunoglob-

ulin (IVIG) legislation (SPN 12/07, p. 10) that addresses issues of supply and reimbursement. "Congress is facing some no-win situations," he says, "which means that certain sectors are going to lose."

Contact Braff at (888) 922-5169 and Bodoff at (703) 549-3740. Contact Armstrong at marmstrong@ssd.com and Gorman at kgorman@putassoc.com. Visit NHIA at www.nhianet.org. ♦

Outlook 2008

HIV, Oncology Are Among Areas That Will See Therapeutic Impact

Although there was a limited number of specialty drugs approved in 2007, many of the therapies offer promising new approaches to a variety of patients. While some health plans may put a moratorium on coverage for drugs that have been on the market for only a short while, the apparent effectiveness of these therapies may require insurers to be more proactive in their assessment and potential reimbursement of such drugs.

With numerous therapies in the pipeline and a pair of new treatments approved in the second half of 2007, HIV is one condition that should garner attention in 2008.

On Aug. 6, the FDA approved Pfizer Inc.'s Selzentry (maraviroc) tablets, which have an annual price of about \$10,600 (SPN 9/07, p. 6). On Oct. 12, the agency approved Isentress (raltegravir) from Merck & Co., Inc., a tablet with an annual price of approximately \$10,000 (SPN 11/07, p. 11). Both drugs are first-in-class therapies and are indicated in combination with other antiretroviral agents for the treatment of HIV.

"Isentress demonstrated strong clinical results in patients that have shown resistance to other medications," says Kevin Gorman, managing partner and founder of Putnam Associates, a pharmaceutical and biotech consulting firm. "It was fast-tracked through the FDA and is just now making its way" across the country. Selzentry, which has some "baggage" in terms of its side-effect profile but is still an effective option, is indicated when a diagnostic test shows a patient has a particular HIV strain.

"The uptake and penetration of therapies will happen extraordinarily quickly in" the area of HIV, says Gorman.

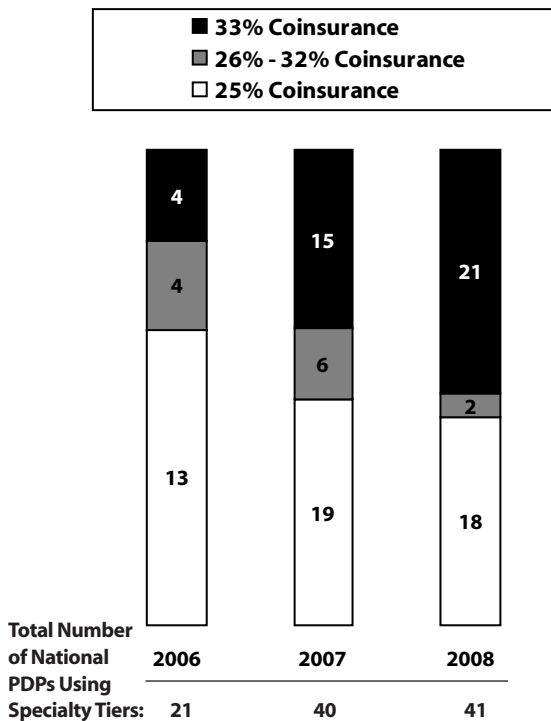
With newer and more expensive therapies coming onto the market, plans need to be more vigilant in their attention to these drugs so that patients can have access to these therapies as soon as possible, he contends.

"Many plans have instituted a policy of 'we're not going to cover new drugs for the first six months that they are on the market,'" says Gorman. "This means it is

incumbent for innovators to get to the plan...and show their therapeutic evidence of effectiveness and have economic discussions with plans...It is good for the patient, medicine and overall outcomes for drugs to be accepted [by plans] early on."

Specialty-Tier Coinsurance Rates in Medicare PDPs, 2006-2008

The number of unique, national Medicare Prescription Drug Plans (PDPs) with an additional tier in their formularies for high-cost specialty pharmaceuticals has almost doubled from 2006 to 2008, according to an analysis by the Henry J. Kaiser Family Foundation. Of the 47 PDPs surveyed, 41 in 2008 — up from 21 in 2006 and 40 in 2007 — have a specialty tier. CMS clarified in 2007 that drugs costing more than \$500 per month (\$600 per month in 2008) may be placed in a specialty tier. In PDPs with a specialty tier in 2007, about 150 drugs — 12% of all covered drugs — fell into that tier, according to an analysis for the Medicare Payment Advisory Commission. Cost sharing for these drugs has increased since 2006. Visit www.kff.org/medicare/7711.cfm.



SOURCE/METHODOLOGY: The Henry J. Kaiser Family Foundation, "Medicare Part D 2008 Data Spotlight: Specialty Tiers," prepared by Elizabeth Hargrave, Jack Hoadley, Katie Merrell and Juliette Cubanski. Released December 2007. Data based on the authors' analysis of 2006-2008 data from CMS on the national Prescription Drug Plans.

Oncology is another area that should see new therapies approved in the next year. The FDA is expected to make a decision in March on Treanda (bendamustine HCl). The orphan drug has fast-track status and is being considered for patients with chronic lymphocytic leukemia (CLL). If approved, it would be the first new therapy approved for this indication since 2001.

Gorman says that another CLL product that may hit the market this year is HuMax-CD20 (ofatumumab). Genmab A/S and GlaxoSmithKline PLC are co-developing the therapy, which has been fast-tracked for this indication. He expects the companies to file their application soon. "CLL is an area that needs some good new therapies," he says, "so it's likely to be acted on quickly."

Supplemental Indications Expected

Additional indications for already-approved therapies — many of them in oncology — are also expected in 2008, according to Gorman. A lot of these products work in multiple cancers, especially the blood cancers, says Domenick Bertelli, a principal with Putnam Associates. This makes it "hard for manufacturers to determine which area to prioritize. It's hard to prioritize research and development dollars," he says.

In addition to CLL, Cephalon, Inc. is also studying Treanda for approval in non-Hodgkin's lymphoma (NHL), multiple myeloma and small cell lung cancer.

Initially approved in 2005 for advanced kidney cancer, Nexavar (sorafenib) was granted approval in November for liver cancer. The drug from Bayer HealthCare AG and Onyx Pharmaceuticals, Inc. "is the first product to show promising activity in liver cancer," says Gorman, and 2008 should yield the first results in these patients.

HuMax-CD20 is also in clinical development for the treatment of NHL, rheumatoid arthritis (RA) and diffuse large B-cell lymphoma. Genentech Inc.'s Avastin (bevacizumab), already approved for colorectal and non-small cell lung cancers, is in trials for about eight to 10 indications, and breast cancer patients may be the first group to get it, perhaps in the first quarter of the year. Another Genentech product, Herceptin (trastuzumab), is in a combination trial with Avastin, says Gorman, and RA infusible Orencia (abatacept) may see a subcutaneous form. Bertelli says there are two or three RA drugs in the pipeline that are similar to some existing therapies, and they should hit the market in 2008 or 2009.

Contact Gorman at kgorman@putassoc.com and Bertelli at dbertelli@putassoc.com. ♦

2000-2007 Survey Results: Pharmacy Benefit Trends & Data has just been published and is shipping now. For the first time, the full results — plus analyses — from all AIS quarterly surveys of pharmacy benefit management companies are available in a single 442-page resource that will give

you a thorough understanding of the pharmacy benefit industry and how it has evolved. The accompanying CD contains all of the raw survey data in spreadsheet form. For more information, go to the MarketPlace at www.AISHealth.com and click on "books," or call AIS at 800-521-4323.

Outlook 2008

Mixed Outlook Seen for M&A Activity in SP, Home Infusion

Mergers and acquisitions (M&A) activity in the home infusion sector was more robust than it was in the specialty pharmacy industry for 2007, and most industry insiders expect the trend essentially to continue for 2008.

Although health care M&A company The Braff Group is still tallying deals from the past year, President Dexter Braff contends that "2007 will be a record-breaking year" with M&A activity in home infusion. And, he says, "2008 should equal or surpass 2007 in terms of the deal volume and activity." He adds that even after industry activity slows, "I don't think [infusion therapy] will go away. It has relatively long legs."

"I don't think the pace of acquisitions slows down" this year, says National Home Infusion Association Executive Director Russ Bodoff. "The dramatic changes of the past few months will carry into 2008." Due to factors such as the demographics of the aging population and the rich pipeline of infusion drugs, "a lot of folks are seeing the potential in the home infusion area," he says. Because "the largest players have all been involved" in deals so far, "we may see more smaller, regional acquisitions taking place," predicts Bodoff.

Investors Are Still Excited About Home Infusion

Continuing with the theme from 2007, "the investment community is still very excited about infusion therapy" for two reasons, according to Braff. First, home infusion companies themselves have "the opportunity for growth and the ability to sustain stronger, long-lasting margins." This quality, he says, contrasts with the specialty pharmacy industry, in which companies will usually see high margins for therapies for only a limited time. Second, a home infusion company may offer companies an "entry into the home care arena." Because the industry is not dependent upon Medicare reimbursement to a large extent, it has not suffered some of the problems seen in other home care areas.

What makes the home infusion sector interesting, says Braff, is that attention is coming from multiple strategic points — private equity, other infusion therapy companies and broader home care companies (*SPN 11/07, p. 1*). "This is a really strong signal for a healthy mergers and acquisitions market that has a broad base," he says.

Braff, however, says he is "not sure where the specialty pharmacy market is heading. I've seen a lot more enthusiasm around it for many years." That enthusiasm, though, "seemed to shift from specialty pharmacy to traditional home infusion. We're seeing deals [in specialty pharmacy], but not unbridled enthusiasm."

The lukewarm response to specialty pharmacy is "largely a function of [profit] margin compression," asserts Braff, as "private payers clamp down on reimbursement. It didn't help that Tysabri didn't take off. And IVIG [i.e., intravenous immunoglobulin] and Synagis reimbursement were skinned down."

Still, he says, there is activity in that sector. And "a lot of mergers and acquisitions activity has a lot to do with intangible frenzy, desire, enthusiasm, momentum. It's a qualitative thing.... An observer of the mergers and acquisitions market would be well advised to watch for emotion and enthusiasm."

Oral Oncology Firms Are Gaining Traction

One area that Braff says has "seen some interesting activity" is among "certain providers in the area of oral oncology" (see story, p. 1). Some companies were "quadrupling in size" over the past year. Because of thin margins in this area, he says, a company must be efficient. Nevertheless, says Braff, "quite a few companies have gained market traction" and could see "enormous growth."

Mark Armstrong, a senior attorney in Houston with Squire, Sanders & Dempsey, LLP, says he expects to see more consolidation in the specialty pharmacy industry — and, consequently, more concern on the part of manufacturers, who are raising "a lot of questions as to the distribution of specialty pharmacy" drugs. Consolidation of specialty pharmacies with wholesalers — most recently seen in McKesson Corp.'s acquisition of Oncology Therapeutics Network (*SPN 11/07, p. 1*) — with other wholesalers following suit has been of particular concern to some drug companies, he maintains.

However, Kevin Gorman, managing partner and founder of Putnam Associates, a pharmaceutical and biotech consulting firm, says that "we will see a lot of digestion take place rather than a lot of acquiring" in 2008. Companies may be looking to "fill in holes" in their capabilities, he says. "We've gone through a few years of binging. Now it's time to digest and 'right size' organizations."

Although many of the larger companies acquiring smaller specialty pharmacies "are not doing anything to disrupt their services and are keeping their core competencies," says Debbie Stern, vice president of managed care consultant Rxperts, "if the care and quality start to decline, a new provider will pop up and compete with them. In the specialty pharmacy arena, as PBMs purchase major specialty pharmacies, there have been issues of service

levels declining. New specialty pharmacies" continue to launch, many with an emphasis on "unique niche capabilities," she says. And while "one-stop shopping with PBMs is easiest for smaller companies...larger plans have the ability, staff and structure to support small providers."

There will always be a place for smaller providers, asserts Braff, who points to the home medical equipment industry, in which providers have been consolidating for 20 years, and "there are still strong local, independent providers." He adds that there "likely will be more independent providers cropping up, new entrants with an entrepreneurial spirit. A strong, vigorous mergers and acquisitions market creates competition," which is good because capital is available, as are exit opportunities, Braff says.

Contact Braff at (888) 922-5169, Stern at (949) 788-2909 and Bodoff at (703) 549-3740. Contact Armstrong at marmstrong@ssd.com and Gorman at kgorman@putassoc.com. ✧

FDA Is Reviewing New Data on ESA Risks With Some Cancers

Barely two months after the most recent product-label changes for erythropoiesis-stimulating agents (ESAs), the FDA said on Jan. 3 that it was reviewing new data on the drugs' risks in two demographic groups of cancer patients — and, depending on its findings, "may take additional action."

The FDA says that it will discuss the data, as well as the risks and benefits of ESAs — Epogen (epoetin alfa), Procrit (epoetin alfa) and Aranesp (darbepoetin alfa) — at a public advisory committee meeting that will be held within the next few months. Although the FDA has not confirmed a date, some analysts have speculated that meeting will be in March.

ESA manufacturer Amgen Inc. gave the FDA information on Nov. 30 regarding a study of women with breast cancer who received chemotherapy before surgery, and on Dec. 4 it gave the agency information on study results on patients with advanced cervical cancer who received chemotherapy and radiation. According to the FDA:

- ◆ *After three years, 14% of the breast cancer patients given Aranesp as an anemia treatment had died, compared with 9.8% who were not treated with that therapy.*
- ◆ *Those breast cancer patients who received Aranesp experienced more rapid tumor growth than those who did not get Aranesp.*
- ◆ *After three years, 66% of the advanced cervical cancer patients who received a blood transfusion were alive and "free of cancer growth," compared with 58% of the patients who were given Procrit.*

According to Janet Woodcock, M.D., the FDA's deputy commissioner for scientific and medical programs, chief medical officer and acting director of the Center for Drug Evaluation and Research, "this new information further underscores the safety concerns regarding the use of ESAs in patients with cancer." The agency, she says, "may take additional action" following its review. But "in the meantime, FDA recommends that health care providers review the risks and benefits of ESAs outlined in the product label and discuss this information with their patients," she adds.

On Nov. 8, the FDA strengthened warnings for ESAs in cancer patients (*SPN 12/07, p. 5*) that expanded upon revised labeling made in March (*SPN 6/07, p. 1*). These new data, says the FDA, were not addressed in the most recent label change, which considered six studies. But all eight studies showed faster tumor growth or shortened survival in patients with breast, non-small cell lung, head and neck, lymphoid or cervical cancers who received ESAs in doses to achieve a hemoglobin level of 12 grams per deciliter or greater.

Visit www.fda.gov. ✧

BSC Offers Aggregate Tiered Fee Schedule for In-Office Injectables

Costs for office-administered specialty injectables have come under scrutiny the past few years. And although this is an area that plans have traditionally viewed as untouchable because many of these drugs are oncology therapies, government-program and some commercial health plans have tried different methods of reimbursement to try to recoup some of the overpayments that they say are part of these drugs' administration.

But while many commercial plans are content to sit back and let others take a stab at managing these drugs, Blue Shield of California (BSC) has taken an aggressive approach to its management of in-office injectables. According to J. Lance Salazar, Pharm.D., senior clinical pharmacist in injectables/immunization management for BSC, this approach can lead to a successful oncology injectables program as well.

"We have a pretty competitive market in California," said Salazar. "We want to match or exceed our competitors' cost position with a value-based approach." He discussed BSC's approach on Oct. 19 at the Center for Business Intelligence's 2nd Annual Forum on Effective Oncology Benefit Management, held in Chicago.

One advantage that BSC has is its medical and pharmacy claims are integrated, he said, so rather than having a PBM manage its pharmacy claims, BSC manages this benefit internally. Its pharmacy and therapeutics committee develops and approves medication policies for coverage determination of drugs adjudicated under both benefits.

The plan manages its unit costs by using a network contract rate and manufacturer discounts on the pharmacy side and a fee-for-service fee schedule — which now applies to its PPO members only — for providers on the medical side for in-office injectables. Drugs reimbursed in a home health or outpatient site do not fall under this methodology.

An eye on the specialty pharmaceutical pipeline shows the importance of attention to specialty injectables. According to data from consulting firm BioMedical Insights, Inc., out of the 101 unique biopharmaceuticals in late-stage development in the United States, about 70% will require administration by a health care provider. About 95% of those 101 agents will be administered via injection or infusion.

BSC has implemented various fee schedules for office-based injectable drugs over the past few years. “The strategy has been to match our competitors’ cost position with a value-based approach,” said Salazar. The health plan moved from a reimbursement of Average Wholesale Price minus 5% in 2003 to AWP minus 12% in 2004 and then to AWP minus 15% in 2005. Then on July 1, 2006, the plan shifted to an “aggregate tiered approach” of Average Sales Price (ASP) plus “26%” — a level that “some may think is awfully generous,” he said.

According to Salazar, before the plan arrived at this approach, it considered others. The first tactic was to “cherry-pick” the top 20 drugs used and apply selective pricing, but the plan had “no network management buy-in” for this, he said, as oncologists thought they were being singled out. Another option was to use a third-party vendor with a “leased” fee schedule. An “analysis

showed 9% savings over the current fee schedule of 85% AWP,” he said. “The cost was somewhat large, but based on the savings, we thought it was doable.” The BSC steering committee, however, rejected the option.

At this point, said Salazar, the plan found out that “one of our major competitors had switched to ASP plus 25%....Our CEO said to go 1% better.”

In addition to trying to stay competitive in California’s market and to achieve cost savings or reduce trend, BSC wants to reduce the number of patients transitioning to other sites of care, such as hospital outpatient departments, and have limited or no network disruption while gaining network management buy-in.

Salazar explained that BSC reimburses office-based injectables on a three-tier drug schedule, with a targeted aggregate of 126% of ASP. The tiers are ASP plus 12%, 26% and 67%. Under this approach, he said, the “less expensive generics receive a higher margin,” and “costlier products would be reimbursed at greater than 85% AWP.”

The tiered methodology “promotes the use of long-standing, effective treatments by paying a larger percentage above ASP for certain drugs,” Salazar maintained.

In Tier 1, or what Salazar referred to as the “break-even tier,” drugs reimbursed at ASP plus 12% include Rituxan (rituximab), Remicade (infliximab), Avastin (bevacizumab) and Erbitux (cetuximab) — single-source, branded therapies.

Tier 2, or ASP plus 26%, includes erythropoiesis-stimulating agents, intravenous immunoglobulin, vincristine and etoposide — mixed generic and brand drugs.

continued

TNF Inhibitors Placed by National PDPs on Specialty Tiers in 2007-2008

According to an analysis by the Henry J. Kaiser Family Foundation, the number of Medicare Prescription Drug Plans (PDPs) that place the three tumor necrosis factor (TNF) inhibitors for rheumatoid arthritis on a specialty tier has increased since 2006. Among the 41 plans in 2008 with an additional tier for specialty drugs, only one placed Enbrel (etanercept) and one placed Humira (adalimumab) on a tier other than the specialty tier. View the data at www.kff.org/medicare/7711.cfm.

Drug Group	Drugs Ever on Specialty Tier	2007			2008		
		Number of Plans (Out of 40) Placing Drug:			Number of Plans (Out of 41) Placing Drug:		
		On Specialty Tier	On Other Tier	Off Formulary	On Specialty Tier	On Other Tier	Off Formulary
TNF Inhibitors	Enbrel (etanercept)	36	3	1	40	1	0
	Humira (adalimumab)	37	3	0	40	1	0
	Remicade (infliximab)	37	2	1	41	0	0

SOURCE/METHODOLOGY: The Henry J. Kaiser Family Foundation, “Medicare Part D 2008 Data Spotlight: Specialty Tiers,” prepared by Elizabeth Hargrave, Jack Hoadley, Katie Merrell and Juliette Cubanski. Released December 2007. Data based on the authors’ analysis of 2006-2008 data from CMS on the national Prescription Drug Plans.

Tier 3 has drugs reimbursed at ASP plus 67%. These included taxol, cytoxan, and carboplatin — drugs with generic equivalents. This tier was “designed to keep members in the office setting,” Salazar said.

In the first tier, reimbursement was similar to AWP minus 15%. The second tier had some savings over AWP minus 15%, while Tier 3 had the “largest overall modeled savings over AWP minus 15%,” said Salazar.

When BSC compared 2006 costs with those from 2005, it realized a 5.7% decrease in overall spend on in-office injectables, with a 4.3% reduction in oncology injectables administered in the office. The plan “realized 117% ASP [as the average] as the mix of utilization differed from the forecasts,” Salazar said. The plan also hit its goal of decreasing place-of-service shifts from physician offices to facilities. Ultimately, contended Salazar, the schedule “reimburses at appropriate market value.”

Contact David Seldin for Salazar at (415) 229-5366. ♦

Company Brings Together Oncology Segments in Integrated Approach

As costs for oncology care continue to rise while the industry remains somewhat fragmented, one company hopes to bridge the gap among the various segments in order to bring efficiency to oncology management.

One-year-old New Century Infusion Solutions (NCIS) bills itself as the only integrated single-specialty provider (ISSP) in the oncology market. Joseph Perez, CEO and founder of NCIS, tells *SPN* that this ISSP model exists in other areas of health care such as cardiology, but that NCIS is the first such company in oncology.

“Oncology is a very sensitive area and is very highly fragmented,” maintains Perez. This fragmentation, he says, leads to misaligned incentives among payers, medical oncologists and radiation therapists, and pharmacies. NCIS — which is owned by Perez and a few other investors, none of which are pharmaceutical companies or health plans, he says — offers comprehensive oncology management of all of these stakeholders.

According to Chris Nee, Pharm.D., chief operating officer of NCIS, the silo management that typifies the oncology industry puts insurers at risk of not knowing their member costs when it comes to specialty pharmaceuticals. As reported in the third annual edition of the *EMD Serono Injectables Digest*, published in April 2007, 22% of survey respondents did not know their per-member per-month cost for specialty pharmaceuticals covered under the pharmacy benefit, 39% did not know PMPM costs for those specialty drugs that fall under the medical benefit, and 33% did not know PMPM costs for specialty drugs under both benefits (*SPN* 6/07, p. 5). Considering the

costs of oncology drugs, which is one of payers’ highest-cost categories of drugs, insurers are under tremendous financial risk in the current environment.

Decrease in Time From Diagnosis to Therapy

According to Perez, NCIS’s approach reaps both short- and long-term dividends. He points to the “bureaucracy involved when someone is diagnosed with cancer,” where a patient navigates a maze of referrals and physicians. It might be 10 to 18 days from the initial diagnosis to the time a patient first receives treatment under this system, says Perez. But this “complicated nature, these details are what an ISSP is designed to address,” he says. Through NCIS, a patient will receive initial treatment in fewer than seven days from the diagnosis, says Perez.

“The earlier cancer is detected, the better the chances are of being treated correctly,” says Perez. “Some of the newer oncology agents prolong life by two or three months” and come at a tremendous financial cost, adds Nee. “If you catch the cancer earlier, there is more time to decide” the best treatment approach.

Many health plans’ medical directors are generalists, says Nee. They must “manage diseases from A to Z, and a lot [of the directors] are not up to date on the latest developments for treatments,” he says.

NCIS, though, employs hematologists, oncologists and radiation therapists as medical directors. Their knowledge and experience allows them to immediately review and approve referrals and therapy regimens, while simultaneously notifying the primary care provider and the specialist, says Nee.

As soon as the medical director approves the therapy, the order is processed in the NCIS pharmacy department. The company contracts with a handful of vendors to deliver the medication.

NCIS says it also pays claims in a timely manner. “Typically providers are paid within 30 days at best,” says Perez, and often the process is only getting started within that time. According to Perez, however, NCIS will pay the claims within 14 days.

NCIS brings the concepts of continuous quality improvement and evidence-based medicine to its management process, says Nee. “Our goal is to focus on getting patients treated in the most appropriate, clinical-based way,” he explains. This also involves identifying instances in which off-label use is clinically efficacious.

To give patients the most appropriate treatments, the company uses the following:

- ♦ **Clinically accepted guidelines:** The NCIS clinical team uses guidelines from associations such as the American Society of Clinical Oncology, the National Comprehensive Cancer Network and the American Society of He-

matology to “look for the most efficient, effective way to provide care,” says Nee.

◆ **Peer-to-peer review:** A network of oncologists not directly employed by NCIS offers second- and third-level peer review should disagreements on therapy arise during the clinical team’s initial review. Patients’ care will continue throughout the process, says Nee, rather than stopping until the disagreements are resolved.

◆ **Clinical trials:** If patients don’t fit into any of the published protocols, says Nee, NCIS will get these patients into clinical trials so they can be treated this way.

Company Capitulates Services

NCIS has a fully capitated arrangement with its clients, under which the cost is fixed for 12 months, says Perez. All of the oncology services fall under this agreement, and NCIS “guarantee[s] savings to our clients,” he says.

“Capitating oncology actually makes sense,” contends William Sullivan, principal consultant with Specialty Pharmacy Solutions LLC. “This has been tried in other specialties, and the proof of concept is already established.”

He adds that “capitating oncology pharmacy alone is a real crap shoot. Patient tumor type and severity are significant variables that impact drug choices and are therefore tough to predict. If you can’t predict accurately, your capitated rate probably won’t cover costs, and the model falls apart — not a good thing. You really need to take a comprehensive approach, such as proposed, to have a chance for success.”

NCIS launched in November 2006 with one client. While Perez says he cannot disclose the client’s identity, he does say that it is a south Florida subsidiary of a national HMO that has operations in three counties in that area. Perez says that the client is “looking to expand to the other two counties” in south Florida in which it has subsidiaries.

On Oct. 8, the company signed a contract with another national payer (which NCIS also would not identify) with three subsidiaries in the same area as the first client.

According to Sullivan, in capitating oncology, “one obstacle, and it’s a big one, is marketplace acceptance. Where the market seems to have no issue with capitating primary care services, it seems to be unable to embrace doing the same for specialists. In oncology, there is even greater resistance to change. However, change in oncology is inevitable, and breakthrough approaches are needed to create ‘win-win’ solutions for health plans and oncologists alike.”

Contact Perez and Nee through Lissa Burt at lissa@bentoncommunications.com. Contact Sullivan at wsullivan@specialtyrxsolutions.com. ♦

Plans Seek More Uniformity on SP

continued from p. 1

More specifically, says Stern, there may be “more involvement of pharmacists on the medical side” of specialty pharmacy management. Also, plans will focus on making specialty drug management — regardless of whether claims are adjudicated under the pharmacy or the medical benefit and where the site of administration is — “relatively uniform across these benefits.” This will not be achieved, however, by shifting medical claims to the pharmacy benefit, she says, a practice some plans turned to a few years ago. Plans instead will turn to “similar management oversight and reimbursement.”

In disease states such as multiple sclerosis and rheumatoid arthritis that offer similar therapies, Stern says that she has heard of physicians presenting patients with information on various treatments, including their cost-share component, the frequency of administration and the site of administration with respect to various therapies, and then allowing the patients to decide for themselves which therapy they would prefer — “not necessarily the best methodology to choose a drug,” she says. “There are too many variables independent of the clinical efficacy of the drug, and these shouldn’t be decision-making factors.” Plans will look to “equal out all these things,” says Stern, so physicians can focus on prescribing the best drug, period.

As plans focus on clinical management, its application in oncology is “the next horizon,” says Stern. While payers have traditionally had a hands-off attitude toward oncology, issues such as cost, safety and appropriateness of therapies — not to mention the hundreds of cancer drugs in the pipeline — are prompting them to take a more hard-line approach. Insurers, Stern contends, will

Wall Street’s 2008 Health Plan Outlook: Which Plans Will Perform the Best and Why?

Join Carl McDonald of
CIBC World Markets, Brian Wright
of Jefferies & Company, Inc. and
Shellie Stoddard of Standard & Poor’s
for a January 16 audioconference.

Visit www.AISHealth.com

be more aggressive in deciding whether to reimburse claims for use based on an FDA-approved indication or well-studied, evidence-based support.

Amid concerns about the fast growth and high cost of oral oncolytics, plans will begin to manage these drugs similar to the way they manage pharmacy-benefit drugs, including prior-authorization requirements, contends Stern. Some plans, she says, have already implemented a short-fill requirement for the first prescription to determine the patient's tolerance for the drug.

Kevin Gorman, managing partner and founder of Putnam Associates, a pharmaceutical and biotech consulting firm, agrees that oncology management by insurers is "starting, but we've not seen a lot of aggressive pushback." In managing oncology, he says, payers "want to be on the leading edge, but not the bleeding edge. Plans don't want to be the poster boy for bad behavior, so they tend to tread lightly around this area."

"We see a lot of uncertainty surrounding what tools should be implemented," says Domenick Bertelli, a principal with Putnam Associates. "We hear concerns" that plans are "not sure about benefit designs" for oncology drugs.

In 2008, "pricing will continue to be a focus," says Mark Armstrong, a senior attorney in Houston with Squire, Sanders & Dempsey, LLP, particularly in "how pricing gets handled, both from the [Medicare] Part B reimbursement side and what effect this has on providers and payers."

Stern says that in 2008, more plans will continue to shift to Average Sales Price-based reimbursement. She

also says that she is seeing plans reducing their reimbursement to providers so that it is the same as the specialty pharmacy reimbursement rate. Physicians will still have the option of buying and billing or of using a specialty pharmacy provider, but this approach reduces the incentive on the physician side, and also benefits patients who are paying a coinsurance percentage.

Many manufacturers, says Armstrong, will focus on research and development in the areas of oral oncolytics and orphan drugs (see story, p. 5).

Personalized medicine is "an area to watch" as well, Armstrong says. "Testing for genetic markers to determine appropriateness" of targeted therapies will become more common, says Stern, as more payers will continue reimbursing for these tests. "The challenge for the pharmaceutical industry is producing a drug for a smaller audience," she contends.

Another challenge may be the inability of some of these tests to offer a definitive recommendation on whether a particular patient should be using the treatment. "Payers want to see 'yes or no' diagnostics, but a lot of it is 'maybe' diagnostics," says Bertelli.

Contact Gorman at kgorman@putassoc.com, Bertelli at dbertelli@putassoc.com, Stern at dstern@rxperts.net and Armstrong at marmstrong@ssd.com. ♦

An AIS audioconference on managing oral oncolytics will be held on Feb. 28. Registration will begin soon at www.AISHealth.com.

NEWS BRIEFS

◆ **Assured Pharmacy, Inc. says that it has opened its seventh specialty pharmacy.** Located in Las Vegas, the pharmacy is the company's first in Nevada, and it joins several other newly opened stores (*SPN 9/07, p. 12*). Contact Andrew Brown at (212) 495-0202.

◆ **On Dec. 20, Genentech, Inc. said that it had reached a solution to potential problems caused by a change in its distribution of Avastin (bevacizumab).** The company had said on Oct. 11 that as of Nov. 30, 2007, it would not allow compounding physicians to purchase the drug directly from wholesalers, although physicians and hospital pharmacies could still purchase it (*SPN 11/07, p. 12*). The move was prompted by ophthalmologists using Avastin off-label instead of the company's Lucentis (ranibizumab injection), which was approved to treat wet age-related macular degeneration (*SPN 8/06, p. 4*). Genentech says that physicians now can prescribe

Avastin and purchase it directly from authorized distributors, which can ship to a location designated by the physician, including compounding pharmacies, hospital pharmacies or the physician's office. Visit www.gene.com.

◆ **CMS will host an Open Door Forum on Jan. 10 for entities interested in bidding to be an approved vendor for the Medicare Competitive Acquisition Program.** Through Dec. 31, 2008, BioScrip, Inc. is the sole vendor for the program, which began in July 2006 as an alternative to the buy-and-bill model for the reimbursement of drugs administered in a physician's office (*SPN 5/06, p. 1*). The new vendor contracts would be effective Jan. 1, 2009, to Dec. 31, 2011. CMS says that the vendor bidding period will begin Jan. 14 and end Feb. 15. Register at <http://registration.intercall.com/go/cms2>.

**IF YOU DON'T ALREADY SUBSCRIBE TO THE NEWSLETTER,
HERE ARE THREE EASY WAYS TO SIGN UP:**



(1) Call us at **800-521-4323**



(2) Fax the order form on page 2 to **202-331-9542**



(3) Visit the MarketPlace at **www.AISHealth.com**

**IF YOU ARE A SUBSCRIBER
AND WANT TO ROUTINELY FORWARD THIS
E-MAIL EDITION TO OTHERS IN YOUR ORGANIZATION:**

Call Customer Service at **800-521-4323** to discuss AIS's very reasonable rates for your on-site distribution of each issue. (Please don't forward these e-mail editions without prior authorization from AIS, since strict copyright restrictions apply.)