AMERICAN HEALTH CONSULTANTS®

DRUG UTILIZATION REVIEW

Pharmaceutical Care Across the Continuum

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Seeing opportunities in specialization, pharmacists are turning to oncology

National cancer conference highlights therapy advances, outcomes

Pharmacists seeking opportunities through specialized knowledge are discovering oncology, a field offering a vast patient population and a wide range of disease variations. When the Board of Pharmaceutical Specialties (BPS) in Washington, DC, offered its first examination in oncology pharmacy in 1998, 118 of 207 candidates successfully completed the certification process.

Coordinated under the umbrella of the American Pharmaceutical Association (APhA), BPS has been offering annual pharmacy specialty exams since 1976 in nuclear pharmacy, nutrition support pharmacy, pharmacotherapy, and psychiatric pharmacy, but never before had so many pharmacists pursued a new specialty certification. To date, nearly 3,000 pharmacists have been credentialed in all five areas now offered.

"[The oncology exam drew] the largest number of people to come out for a new specialty exam in our history, so there clearly is not only a great interest in oncology pharmacy practice at the specialist level, but I think recognition that this is going to be a valuable credential down the road," says **Richard Bertin**, BPS executive director.

The simple breadth of the field of oncology, in terms of the nearly two dozen different strains of cancer being fought, along with the large patient population and availability of research funding makes oncology an opportunistic pursuit for clinical pharmacists.

Consider these facts:

• The American Cancer Society says half of all American men and one-third of all women will develop some form of cancer in their lifetimes. To combat the disease, drug therapies, biotechnology, and research are ever-expanding.

• Last year, according to the Pharmaceutical Research and Manufacturers Association (PHARMA) in Washington, DC, 316 new drugs went into development, 130 of which were aimed at breast, lung, and colon cancer. PHARMA says $1.4 billion is spent annually by drug companies on cancer-fighting agents. Specifically, 59 new drugs went into development for breast cancer, topped only by skin cancer research with 60 investigational drugs. Just over 30 drugs each were aimed at colon

cancer, leukemia, lymphoma, prostate cancer, and solid tumors.

Other specialties are attracting their share of pharmacists, as well.

"We're seeing considerable growth in all types of pharmacy specialties," says Bertin. "One reason is the requirement that patients be managed by general physicians, who depend more and more on specialist pharmacists to provide drug therapy information to them and their patients in clinics, but from there, if a pharmacist wants to be effective in the oncology area, you really do have to focus and get specialized within the field," he says of the many areas of cancer treatment, such as sarcomas, skin cancer, lymphoma, and cancers linked to specific organs or other tissues.

A national conference this year in Atlanta by the American Society of Clinical Oncology (ASCO) speaks to the considerable fine-tuning being discovered within the various avenues of drug therapy. Of the nearly 200 papers submitted, clinical trials included drug therapy aimed at tumor-growth enzymes, DNA formulations, proteins, stem cell therapy, vaccines, and chemotherapy sensitizer drugs. Also submitted were large numbers of studies taking new approaches to combination therapies pairing drugs on the market with those in Phase III trials.

University pharmacy departments also are taking notice of the opportunities in oncology. The University of Colorado School of Pharmacy, for example, is offering an oncology specialty residency to its PharmD students.

"Our major area of focus is adult medical oncology," says residency director **Carol Balmer**, PharmD. "The emphasis is on supportive care, the antineoplastic drugs and cancers treated with those drugs, prevention and management of antineoplastic toxicities, and investigational cancer therapies. Residents are also exposed to gynecologic oncology, surgical oncology, bone marrow transplantation, community oncology, and pediatric oncology," she says, adding that much of the hands-on work is done at the University of Colorado Cancer Center.

Balmer describes the typical duties of an oncology pharmacist as monitoring patient lab results based on drug therapy and recommending changes when necessary for those admitted to the hospital. As oncology team members, pharmacists also accompany physicians on patient rounds for drug therapy consultations and meet patients in cancer clinics to assess their responses to drug therapy.

The BPS recognizes residencies as part of its certification process, which also includes a 200-question exam, basic license and graduation requirements, and physician collaboration time spent constructing patient-specific drug therapies and drug use protocols.

Conference speaks to field's breadth

If a theme emerged from the 35th annual ASCO meeting, it was that no experimental therapy is without merit and all should be pursued as researchers continue to look for novel ways of fighting cancer.

Presented at the conference were encouraging early trial results, including the use of anti-angiogenesis nose drops to treat Kaposi's sarcoma, minute radioactive cones used to fight liver metastases, standard diabetes drugs to cause cancer cells to age, and efforts to make bone marrow cells resistant to chemotherapy.

Also discussed among a wide range of approaches was a novel ovarian cancer vaccine that uses synthetic antigens to mimic cancer-associated epitopes to trick the immune system into mounting an early response against the cancer.

"Each of these examples illustrates the use of a different biochemical or biological target to treat cancer patients," says **Derek Raghaven**, MD, chief of medical oncology at the University of Southern California Norris Comprehensive Cancer Center. Raghaven acted as moderator of a panel on the next generation of cancer therapies.

"These types of trials represent a paradigm shift away from traditional therapy and toward approaches tailored to individual cancers, all of

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which has been made possible by translational research, moving promising concepts from the lab directly to clinical trials," he says.

One of the more anticipated sets of trials at the conference, though, had disappointing results. Five studies were submitted on the combined use of stem cell support therapy — as peripheral blood stem cell support or bone marrow transplant — with high-dose chemotherapy primarily to treat metastatic breast cancer patients as well as those with high-risk primary breast cancer.

Based on the success of earlier Phase II trials, the Phase III results were expected to further the gains of stem cell support, but instead they proved inconclusive in four of five independent studies just as the use of stem cell support has been increasing as an adjuvant treatment for high-risk primary breast cancer patients.

The studies showed that high-dose chemotherapy treatment with stem cell support was not better than conventional chemotherapy. The American Cancer Society subsequently has deemed the results inconclusive and is backing further study, which the National Cancer Institute has begun through clinical trials.

Tamoxifen studies encouraging

More encouraging in the field of breast cancer were studies showing the much-publicized drug tamoxifen, approved last year as a prevention drug for patients showing a high or increased risk of contracting breast cancer, is doing the job it was approved to do.

"The research presented confirms that tamoxifen has tremendous potential in reducing the risk of breast cancer for increased-risk women," **Lori Goldstein**, MD, associate director of the Fox Chase Cancer Center in Philadelphia, told assembled ASCO members. "The additional data is also encouraging, demonstrating that the drug can also prevent pre-cancerous lesions from becoming cancerous, but [tamoxifen] is not without side effects. Data still indicate that women on tamoxifen are at increased risk of developing endometrial cancer and blood clots, but the incidence of these events is low," she said.

Other studies presented at the conference include the following:

1. **The combination of injectable topotecan hydrochloride with paclitaxel as a positive approach to first-line treatment of extensive small cell lung cancer.** Study results showed median survival rates of one year or more for topotecan hydrochloride vs. the average of eight to 10 months with standard chemotherapy. Topotecan hydrochloride is in the class of drugs known as topoisomerase I inhibitors, which attack cancer cells by inhibiting the topoisomerase I enzyme needed to replicate the DNA of cells inflicted with cancer. The drug is available on the market as Hycamtin by SmithKline Beecham, but it has not been approved for first-line treatment. It is approved for use against ovarian metastatic carcinoma following the failure of chemotherapy or for use as a secondary therapy in small cell lung cancer following chemotherapy failure.

2. **Paclitaxel in combination therapy with carboplatin in the treatment of advanced ovarian cancer vs. the chemotherapy drug cisplatin based on the decreased toxicity found with the paclitaxel-carboplatin match.** Patients given the new combination experienced less gastrointestinal, genitourinary, and metabolic disorders such as kidney damage during trials, which randomized 800 patients to one or the other combination. The study also reports a successful three-hour infusion for the combination, vs. the standard 24-hour infusion used for paclitaxel and cisplatin.

3. **An advance in the restoration of tumor sensitivity to chemotherapy in cases of soft-tissue sarcoma using a combination of the investigational drug biricodar dicitrate (Incel, Vertex Pharmaceuticals) with standard doxorubicin.** The combination is effective through Incel's ability to enhance the activity of doxorubicin against resistance. The drug works by blocking enzymes that decrease the sensitivity of tumors to chemotherapy.

4. **A colorectal combination therapy that adds the investigational drug trimetrexate glucuronate (NeuTrexin, U.S. Bioscience) with traditional therapies leucovorin and 5-fluorouracil (5-FU) as a triple combination.** The combination increased median survival from 10.1 to 12.9 months when trimetrexate was added. Researchers believe the drug works by increasing the activity of 5-FU by stimulating the body's naturally occurring compound phosphoribosylpyrophosphate, which converts 5-FU into metabolites that inhibit cancer cell replication.

These and other studies point out another

growing approach to oncology: Along with finding drugs that fight cancer, finding drugs that help other drugs fight cancer is becoming equally important. For oncology pharmacists, determining protocols or interactions within these new paradigms of therapy is becoming a clinical niche.

[For more details, contact: Board of Pharmaceutical Specialties, 2215 Constitution Ave. N.W., Washington, DC 20037. Telephone: (202) 429-7591. Web site: http://www.bpsweb.org. American Society of Clinical Oncology, 225 Reinekers Lane, Suite 650, Alexandria, VA 22314. Telephone: (703) 299-0150. Web site: www.asco.org.] ■

Troglitazone to remain on shelves for now

FDA panel votes against further monotherapy use

The controversial antidiabetic troglitazone (Warner-Lambert) can remain on the market, but it should not be used as a monotherapy for the reduction of insulin resistance, the Food and Drug Administration's Endocrinologic and Metabolic Drug Advisory Committee has recommended following a hearing earlier this year.

The panel voted 8-4 that the benefits of the drug outweigh its risks of causing acute liver failure if it is used with insulin or sulfonylureas.

The hearing was the result of mounting reports of adverse reactions associated with the drug, which to date include 43 reports of liver failure resulting in seven transplants and 28 patient deaths. The drug has had a checkered history since being approved by the FDA in 1997, the same year it was pulled off the market in the United Kingdom. (A 1998 petition to return the drug to the shelves there was denied.)

The drug debuted in the United States in January 1997, and by October a warning concerning liver failure and a recommendation for liver enzyme monitoring was added to the packaging. By December of that year, the warning was accentuated by a highlighted label on the packaging and the frequency of recommended monitoring increased. A "Dear Doctor" letter also was issued by the FDA in December, followed by a second in July 1998, as liver failure reports continued.

According to an agency summary of the advisory panel hearing, the FDA estimates that cases of liver failure are likely underreported by as much as one-tenth of the actual number, and physician compliance with baseline monitoring is "poor."

David Graham, MD, clinical regulatory specialist for the FDA's Office of Postmarketing Risk Assessment, testified at the hearing that health officials are uncertain whether alanine transaminase (ALT) monitoring can ensure the prevention of fatalities based on data that level changes provided a clear warning in only 12 of the 43 documented cases. And, he said, of those 12 cases, ALT levels went from a normal reading to one of irreversibly acute liver failure in four to 34 days, which could elude the timeliness of monitoring protocols.

The current monitoring recommendations call for checking ALT levels at baseline for eight months, every other month for four months, then "periodically" thereafter. Use of the drug is not recommended if patients show evidence of "acute liver disease" or if ALT is greater than 1.5 times a patient's upper-normal limit.

Liver function tests also are recommended if patients show symptoms of hepatic dysfunction. In addition, the FDA recommends weekly monitoring if ALT is between 1.5 and two times the upper limit of normal and complete stoppage of the drug if patients develop jaundice or ALT is greater than three times the upper-normal limit.

Warner Lambert's proposal

At the hearing, Warner Lambert submitted a proposal to increase the potential safety of the drug again based on warnings, patient education, and the advent of a trial period of dosing.

In detail, Warner-Lambert offered to examine and identify specific patient groups that would benefit from the drug; recommend a trial dosing period that would continue only if patients respond according to specific time periods; beef up warnings by cautioning against using the drug in patients with a history of liver disease or alcohol abuse; and begin a physician and patient education program based on a monitoring reminder system.

The FDA is expected to consider the panel's recommendation and determine the ultimate fate of the drug by the end of this year.

[For more information, contact the FDA Office of Postmarketing Risk Assessment at (301) 594-6822 or 594-5443 or Warner-Lambert at (973) 540-2000.] ■

First chronic stable angina guides published

Three organizations combine for in-depth review

For the first time, comprehensive guidelines for the treatment of chronic stable angina have been compiled and published as one source by a panel of the American College of Cardiology, American Heart Association, and the American College of Physicians-American Society of Internal Medicine.

Cardiologist **Raymond Gibbons**, who chaired the guidelines panel, says the effort was done for two reasons: to chronicle up-to-date information on what works and what doesn't in a field with constantly expanding treatments.

As one example, Gibbons cites lipid-lowering trials, which have shown reduction in mortality and heart attacks. "Physicians need to recognize that lipid-lowering therapy is now clearly proven to improve patient outcome," he says.

On the other hand, he adds, "although there's been a wave of enthusiasm for vitamins E and C, the panel felt current evidence doesn't support their use in routine therapy." Same for electron beam computed tomography, which Gibbons says also lacks documented clinical benefits despite its recent popularity.

The guidelines are divided into four sections: diagnosis, risk stratification, treatment, and patient follow-up. Each offers patient conditions as treatment factors, the pros and cons of treatment regimens, and recommendations for combination or monotherapies among other topics.

The guidelines apply to "adult patients with stable chest pain syndromes and known or suspected ischemic heart disease" as well as patients with "ischemic equivalents such as dyspnea on exertion or arm pain with exertion." Recommendations on how to assess coronary artery disease (CAD) also are included.

The diagnosis section includes recommendations for lab tests and test result evaluations of hemoglobin, fasting glucose and fasting lipid panels, and chest X-rays and stress imaging toward the evaluation of the extent of ischemia. Other diagnosis recommendations include using adenosine or dipyridamole myocardial perfusion imaging and invasive diagnosis by way of coronary angiography. Throughout all of the diagnosis routines, medication uses and levels are spelled out.

The risk stratification section deals with patient demographics and medical history with a focus on hypertension, diabetes, hypercholesterolemia, peripheral arterial disease, and previous myocardial infarction, along with factors such as exercise testing and following EKG results and the presence of comorbidities that could limit life expectancy or revascularization.

The treatment section, which is the largest entry, "Recommendations for Pharmacotherapy to Prevent MI and Death and Reduce Symptoms," is of particular interest to pharmacists. The latest clinical trial assessments of the use of aspirin, beta-blockers, calcium antagonists, nitrates, lipid-lowering therapies, clopidogrel, nondihydropyridine calcium antagonists, and warfarin are included, again in terms of monotherapies and combination therapies as well as each drug's pros and cons.

The patient follow-up section outlines recommendations for ongoing drug therapy, echocardiography, exercise testing, stress imaging, and coronary angiography.

The guidelines' text is supplemented by graphics, including diagnostic and treatment flowcharts, symptomatic CAD prediction charts, and plotting of survival ratios and nomogram variations, among others.

[For a copy of the guidelines, contact the American College of Cardiology, 9111 Old Georgetown Road, Bethesda, MD 20814. Telephone: (301) 897-5400.] ■

New technology sparks confidentiality debate

NABP guidelines on the table

The debate over trying to balance patient confidentiality with legitimate needs for patient information has intensified as new technologies continue to streamline the use and availability of patient records.

Along with established uses by third-party payers or pharmacy benefit managers, new programs like patient reminder e-mails or the recent boom in Internet pharmacy have led organizations such as the National Association of Boards of Pharmacy (NABP) to search for ways to separate legitimate need from the potential for marketing abuse by drug companies, for example.

"Some kind of balance needs to be struck between what is important for providers to share about a patient and what is information that does not need to be shared. . . . between what is used for clinical purposes and what is used for marketing purposes," said **Rod Shafer**, executive director of the Washington State Pharmacists Association, at a recent meeting of the National Wholesale Druggist's Association.

Balancing administrative needs, privacy

As part of its policy statement on patient confidentiality, the Academy of Managed Care Pharmacy has stated, "AMCP believes that proposed legislative or regulatory restrictions pertaining to the use of patient-identifiable information must be carefully considered so that they will not hinder the effective administration of pharmacy benefits and impede patient protections."

"Anxiety about the lack of privacy has led people to . . . withhold information, give inaccurate information, and even ask doctors to put inaccurate diagnoses on claim forms."

Finding a way to do that has been frustrating on the federal level, as patient confidentiality bills coming out of Congress continually have died since 1995. More and more, it's looking like refill reminders and similar compliance programs — despite documentation that they save the health care industry a lot of money — will have to be sacrificed to avoid cumbersome proposals such as written permission every time a pharmacist wants to review a patient's file to formulate counseling options, interventions, or therapy modifications, says **Janlori Goldman**, a policy analyst with the Georgetown University Institute for Health Care Research & Policy.

"Anxiety about the lack of privacy has led people to engage in a series of privacy-protective behaviors," says Goldman. "They withhold information, give inaccurate information, and even ask doctors to put inaccurate diagnoses on claim forms."

During the last 12 months, bills have been introduced into nearly every state legislature concerning patient confidentiality. A Texas bill introduced this spring, for example, would make it illegal for pharmacists to use patient-identifiable information without written consent and would not allow the use of patient data for quality assurance programs.

Groups like AMCP have opposed this bill and others like it by stating that while they support patient rights, they fear that mandated written consent would rarely be granted. The lack of consent would thwart disease prevention programs and accreditation outcomes reporting, they say.

NABP has passed a set of guidelines it is offering to state boards and federal agencies for consideration. "By putting together guidelines, we're giving state boards some direction in case they are confronted with this issue," says NABP executive director **Carmen Catizone**.

"We also wanted to send a clear message to any congressional committees about the position of the boards and what we liked and didn't like about what we thought might protect confidentiality and what might be a threat," Catizone explains.

Pharmacists as gatekeepers

The guidelines as proposed attempt to set up safeguards against abuse while maintaining access for clinical reasons, and they attempt to set up pharmacists — historically among the most trusted professionals in opinion polls — as major gatekeepers. The guidelines call for the following actions:

- creating secure methods of accessing, transmitting, analyzing, storing, and deleting information;
- maintaining confidential information separately from information deemed nonconfidential;
- allowing access to confidential information only by pharmacists or technicians supervised by pharmacists;
- giving patients the opportunity to withdraw from a given program at any time with assurances that their medical information will remain secure;
- requiring pharmacists to maintain lists of participating patients and take responsibility for their accuracy as well as their safety.

[For more information on the guidelines, contact the National Association Boards of Pharmacy at 700 Busse Highway, Park Ridge, IL 60068. Telephone: (847) 698-6227.] ■

Oversight plays catch-up to Internet pharmacy

NABP offers standards for on-line services

Industry and government regulators have begun scrambling to oversee the exploding on-line pharmacy market.

Already this year, a half dozen high-profile Internet pharmacies have become available, offering new and refill prescription delivery, e-mail patient reminders, 24-hour pharmacist consultation, links to informational databases, and sales of herbals and traditional drug store health and beauty products. A majority of the sites require physician confirmation after an on-line order is placed, but many less-reputable sites don't, which has largely spurred the rush to regulate.

As an extension of established telemedicine or mail-order pharmacy, the on-line market has some hospital pharmacists concerned about the possible widening of the information gap. "It's another reason to be very careful about a patient's drug history, current medications, and any problems they've had," says **Nancy Jordan**, PharmD, BCPS, director of drug information services at Holyoke (MA) Hospital. "More and more, it's hard to keep up with how much home care is being done, whether it's by over-the-counter herbals, mail orders or, now, on-line delivery," she says.

The companies behind the sites — ranging from startups to pharmacy benefit managers to drugstore chains like Drug Emporium — have secured working agreements with insurers in which plans are billed and co-payments are charged to credit card accounts. Internet sites also have had quick success with drug distribution sites while receiving regulatory approval to operate from individual state pharmacy boards.

One on-line service, DrugEmporium.com, has partnered with the established and popular drkoop.com, which carries the cachet of former U.S. Surgeon General C. Everett Koop. The Koop site offers drug recommendations for specific disease states and related health care information. As for Jordan's concerns about securing complete patient drug regimens to avoid harmful reactions, drkoop.com counters with its Drug Checker service, an integrated database that reviews regimens for possible adverse reactions.

But two larger concerns have industry organizations and federal regulators worried that sites offering virtual consultations with physicians can thwart traditional doctor-patient relationships and that some opportunistic drug companies will place ads on the sites.

This summer, PlanetRx.com announced a deal whereby drug company Parke-Davis will exclusively partner with the service. PlanetRx.com will offer links to sites dealing with a variety of specific disease states; those sites will include ads for Parke-Davis drugs.

Criticism that the plan presents a conflict of interest by comparing the ads to displays in "brick-and-mortar" drug stores or in health care magazines. "People have to realize that accessing an on-line pharmacy is just like walking into the corner drug store," says **Mitchell Reed** of the on-line pharmacy soma.com, which also debuted this year. "There are some medical conditions for which only one drug is appropriate and there is no conflict, but we do have to be very careful that a dispensing pharmacy does not become an advertising billboard," he says.

AMA writing prescribing rules

On the issue of virtual consultations, the House Commerce Committee has directed the General Accounting Office to undertake a review of Internet pharmacy sales to confirm that physicians are signing off on prescriptions being sought by consumers.

The American Medical Association, voicing the same concern over the availability of on-line drugs without a consultation or a prescription on some sites, was readying its own set of physician prescribing rules for its annual conference in Chicago as this issue of *Drug Utilization Review* went to press.

Organizations like the National Association of Chain Drug Stores (NACDS) are neither condemning nor applauding the sites, pointing out that with a projected delivery time of three to five days, on-line pharmacies likely will concentrate on refill and maintenance customers, which constitutes 75% of the prescription market, according to NACDS.

The National Association of Boards of Pharmacy (NABP) has launched an oversight registration campaign that aims to separate legitimate sites from those resembling on-line telemarketing by offering virtual consultations with physicians.

"While a growing number of legitimate sites are coming on-line to dispense prescriptions and over-the-counter medications, the medium has attracted a visible band of unlicensed and unscrupulous people interested in a quick profit," says NABP president **Kevin Kinkdale**. "These sites operate for a short time at one address, disappear, and set up under another name to escape detection."

For discerning consumers, it may be easy to be wary of sites called "Viagra Online" or "MD Healthline," which offers only Viagra and Celebrex and a physician's consultation fee of $65. Ordering drugs from the MD Healthline site, previously known as MD Pharmacy, is as easy as one, two, three: Simply read and agree to a liability waiver, complete a "medical consultation form," and "receive your order within a few days," the site advertises.

Another site, called "First Pharmacy of the Internet," says it can supply any prescription medication, "however we specialize in those medications which are difficult to obtain in some countries."

Confidentiality also an issue

But even for sites everyone agrees are legitimate — those that verify or require patient verification with a prescriber, for example — there are still issues of patient confidentiality **(see related article, p. 117)** and unauthorized or unknown drug switching.

Akin to a seal of approval, the NABP's Verified Internet Pharmacy Practice Sites (VIPPS) program is an ambitious undertaking the organization plans to have running on its own Web site by the end of this year.

The program essentially will offer a public list of on-line pharmacies NABP has reviewed and accepted as legitimate VIPPS sites. Along with being listed with NABP, accepted sites will be allowed to display a VIPPS seal.

The program has two levels of oversight. On one hand, the VIPPS list will include only on-line pharmacies that have met individual state board standards. After that, services must apply to the VIPPS program and comply with a host of NABP criteria such as patient confidentiality, drug security, and assurance that the site offers consultation with a pharmacist and that NABP is able to confirm that all RPhs are licensed.

Because the Internet is borderless, the VIPPS program states that when conflicts between individual state laws and federal laws must be resolved, NABP generally will side with whichever law is more stringent.

The organization is working on safeguards for generic or therapeutic substitution allowed within existing guidelines that will speak to patient awareness, prescriber authorization, and third-party paying. Also on the drawing board are ways to track prescriptions so one person doesn't submit a script to multiple on-line services.

"Patient information, whether in electronic or paper format, has little or no federal protection."

Additionally, NABP says it will provide ways for patients to report any adverse reactions and for the member site to take action, as well as ways to ensure that drug utilization review occurs when necessary. Lastly, participating services must notify NABP of any informational changes to a Web site, or personnel changes such as the pharmacist-in-charge, to maintain its VIPPS endorsement. Details can be found at www.nabp.net.

Aside from the NABP's efforts and the interpretation of existing licensing and approvals within state pharmacy boards for on-line pharmacy, oversight and regulation are largely in the rhetorical stage, with confidentiality, specific licensing, and traditional doctor-patient relationships getting most of the attention.

"Patient information, whether in electronic or paper format, has little or no federal protection," says **Linda Kloss**, executive vice president of the American Health Information Management Association, a Washington, DC, medical records oversight board. "The growth of on-line medical and pharmaceutical practices underscores the need for comprehensive and preemptive confidentiality legislation," she says.

"Sharing confidential information not only violates patient trust, it's against the law and could put our pharmacy licenses in jeopardy," responds **Tom Pigott**, president of on-line provider soma.com in Seattle. He says the service uses multiple layers of passwords that match only certain personnel to certain records, as well as overall Web site encryption and secured servers to dissuade hackers, for example.

George Barrett, president of the Federation of State Medical Boards, has likened on-line pharmacy to telemedicine, but without the medicine.

His organization fears that, unlike telemedicine, on-line prescribing could occur without an initial physician exam or diagnosis, laying to waste the traditional and ethical doctor-patient relationship.

The organization wants to see legislation ensuring that won't happen, and it is endorsing the idea of specific licensing for on-line pharmacy similar to that used for mail-order pharmacy.

The American Medical Association agrees and has endorsed language affirming that prescribing is only legal after a doctor-patient relationship has been established in the flesh.

Already this year, the NABP says, five state pharmacy boards have submitted cases to medical boards of doctors prescribing through on-line services without ever seeing the patient.

Who's who in on-line pharmacy

Pigott says soma.com has secured commitments from 20 insurance plans covering about 30 million people and has been approved for operation in 30 states. Services simply note on their Web sites in what states consumers can use them.

"We intend to work with third-party payers on the streamlining of claims processing, reducing the cost of prescription fulfillment, and improving patient outcomes," he says.

Pigott's and other on-line services are also touting patient reminder capabilities as a selling point, noting the recent growth in studies showing the negative impact on patient health, hospitalizations, and overall health care dollars that noncompliance brings. His service has contracted with an automated dispensing firm in Ohio that will include a photo of the packaged drug on the label, along with dosage information.

Medicaledge.com, owned by Integrated Medical Technologies and based in Lawrence, NY, touts its physician referral and medical history registry as selling points, along with an informational database of brand name and generic drugs and links.

Medicaledge.com, calling its service the "Drug Stop," accepts a prescription and then sends the consumer phone and fax numbers a physician must use to confirm the prescription. Aside from narcotics and liquid formulation, the company says it can deliver more than 200 types of drugs ranging from 30- to 90-day dosages covering anything from acne and allergies to HIV and prostate cancer.

The national PBM Express Scripts Inc. in St. Louis has gotten into the market with YourPharmacy.com, taking advantage of a built-in customer base of more than 30 million people. It also has launched DrugDigest.com as a companion informational site.

Express Scripts also is relying on its existing relationships within the health care industry and its experience in the clinical aspects of pharmacy to rise above the competition. "We intend to leverage our relationship with employers and managed care organizations and use the same facilities and safety checks used to send out more than 8 million prescriptions last year alone," says YourPharmacy.com president **Gregg Rotenberg**. "We expect to offer a screening to check for adverse reactions and for interactions with other prescription and nonprescription drugs," he says.

At the other end of the spectrum is Drugstore.com and PlanetRx.com, which bring no real pharmacy experience but a lot of business experience to the table. Drugstore.com was started by a former Microsoft executive, and Amazon.com quickly acquired 40% of the company. PlanetRx.com is being operated by a former official with Federal Express.

Drugstore.com is located in Microsoft's home-base of Redmond, WA, while the Oakland, CA-based PlanetRx.com will distribute out of Memphis, TN, home of Federal Express' main distribution arm.

[For more details, contact the National Association of Boards of Pharmacy at 700 Busse Highway, Park Ridge, IL 60068. Telephone: (847) 698-6227.] ■

NEWS BRIEFS

APhA texts on errors, protocols now available

Comprehensive texts on medication errors and drug protocols published by the American Pharmaceutical Association (APhA) became available this summer.

The 400-page volume, *Medication Errors*, edited by Michael Cohen, MS, FASHP, president of the Institute for Safe Medication Practices, is divided into five categories detailed in 20 chapters. Other contributors include automation consultant Mark Neuenschwander, Auburn University pharmacy professor Kenneth Barker, and Dennis O'Leary, president of the Joint Commission on Accreditation of Healthcare Organizations.

Book examines error causes, prevention

The book explores the following topics:

- the causes of medication errors;
- systems analysis approaches to correcting and preventing errors;
- a breakdown on the roles of prescribing, dispensing, administering, and labeling; specific errors relating to chemotherapy, pediatric patients, and immunologic drugs;
- an overview of error reporting systems and the role of risk management.

Specific chapters also offer hospital pharmacy case studies, patient roles in error prevention, and an overview of high-risk drugs. The publication costs $49 for student APhA members, $56 for APhA member pharmacists, and $70 retail.

Drug Treatment Protocols compiles 44 monographs developed from 1996 to 1998 by APhA offering peer-reviewed and referenced information framed by diagnosis and pharmacotherapeutic pathways.

The 44 protocols are grouped into nine categories:

- cardiovascular disease;
- endocrine disorders;
- metabolic disorders;
- gastrointestinal disorders;
- infectious diseases;
- self-treatable conditions such as colds and pain;
- complications related to vascular access devices;
- pediatrics;
- psychiatric and respiratory disorders.

The 467-page protocols book costs $140 for students, $160 for professionals, and $200 retail.

[To order either book, call (800) 878-0729.] ▼

State law enhances pharmacy practice

Legislation effective Aug. 1 in Minnesota promises to substantially advance the clinical opportunities of pharmacists wishing to be directly involved with patient care.

Passed as a collaborative practice agreement approach between pharmacists and physicians, the Pharmacy Practice Act will allow pharmacists to administer initial doses of patient medication, monitor and adjust drug regimens, assess and react to laboratory tests, and administer drugs in emergency situations. The law would not allow pharmacists to change a patient's prescription.

Most of the clinical duties would be allowed after a physician refers a patient to a pharmacist for follow-up or ongoing drug therapy. The law applies to community, retail, and hospital pharmacists.

"The new law will allow pharmacists to do more for the patient and use their expertise in badly needed areas such as identifying drug interactions and side effects and giving counseling on the best way to use medications," says **Julie Johnson**, chair of the Pharmacy Practice Act Task Force, which lobbied for the new law. She adds that another expected benefit of the law will be decreased numbers of office visits, which could help lower the cost of health care.

Task force members included the Minnesota Pharmacists Association, the Minnesota Society of Health-System Pharmacists, the University of Minnesota College of Pharmacy, the state pharmacy board, and the Minnesota College of Clinical Pharmacists.

[For more information, contact the Minnesota Pharmacists Association at (651) 697-1771.] ▼

Sickle cell drug hits fast track

A purified poloxamer intravenous drug in Phase III trials as Flocor by CytRx Corp. in Atlanta has been granted fast-track status by the Food and Drug Administration for its success in clinical trials at alleviating the vaso-occlusive acute pain associated with sickle cell anemia.

The drug won't cure the genetically inherited disease, but it is being hailed as a potential step in that direction for its ability to counter the disease-causing breakdown of hemoglobin in red blood cells, which causes the cells to become rigid and inflexible, which in turn impedes blood flow and causes acute pain.

CytRx expects to file a New Drug Application for Flocor by the end of this year. ▼

Managed care accreditation available

The Academy of Managed Care Pharmacy (AMCP) and the American Society of Health-System Pharmacists (ASHP) have developed a joint accreditation program for pharmacy residencies specific to managed care settings.

The program offers managed care organizations residency standards and learning objectives for post-graduate training, which both organizations say is needed to expand the total number of residencies available to pharmacy students. Last year, nearly 800 students applied for the 612 clinical pharmacy residencies largely available only in nonprofit or university hospitals, according to ASHP.

By establishing a separate managed care program, the organizations hope to make the total number of clinical residencies outnumber pharmacy school graduates to make sure the clinical focus of the profession continues to grow. The program is being conducted within ASHP's Commission on Credentialing.

[For more information, contact ASHP's Ellen Wilcox at (301) 657-3000, ext. 1224, or AMCP's Marlene Bloom at (703) 683-8416, ext. 302. Overviews of the program are available on each organization's Web site: ashp.org and amcp.org.] ■

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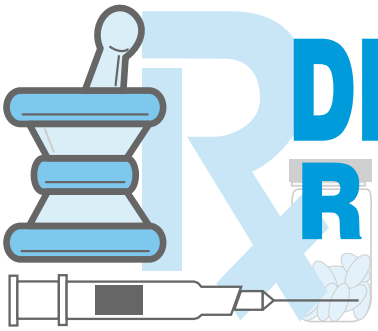

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