Vol. 24 No. 2

South Dakota Pharmacist

Spring Edition 2010

Ride the Wave

Hang Loose!

of Opportunity!

South Dakota Pharmacists Association
Cedar Shore Resort 2010

In this issue:

SOUTH DAKOTA
PHARMACIST
Volume 24 Number 2

SDPhA CALENDAR

South Dakota Pharmacists Association
320 East Capitol
Pierre, SD 57501
(605)224-2338 phone
(605)224-1280 fax
www.sdpha.org

"The mission of the South Dakota Pharmacists Association is to promote, serve and protect the pharmacy profession."

South Dakota Board of Pharmacy
4305 South Louise Avenue
Suite 104
Sioux Falls, SD 57106
(605)362-2737
www.pharmacy.sd.gov

Please note: If you are not on our mass e-mail system check our website periodically for district meetings and other upcoming events. They will always be posted at: *http://www.sdpha.org*.

April

9-10 SD Society of Health-Systems Pharmacists (SDSHP) Annual Meeting
Rapid City, SD

11 SDPhA Mobridge District Meeting
Bob's Steakhouse, Gettysburg, SD

15 SDPhA Sioux Falls District Meeting
Ramada Inn and Suites (1301 W Russell Street)

15 SDSU College of Pharmacy Auction
Ramada Inn and Suites (1301 W Russell Street)

21 SDPhA Rosebud District Meeting
KC's Koffee, Burke, SD

25 SDPhA Huron District Meeting
Ryan's Hanger, Huron, SD

26 SDPhA Black Hills District Meeting
Minerva's, Ramkota, Rapid City SD

May

26-28 ASCP'S Midyear Conference and Exhibition
Phoenix, AZ

31 Memorial Day

June

4-6 **SDPhA 124th Annual Convention**
Cedar Shore Resort Chamberlain/Oacoma, SD

* Cover photo courtesy of SDPhA

SOUTH DAKOTA PHARMACIST
The *SD PHARMACIST* is published quarterly (Jan, April, July & Oct). *Opinions expressed do not necessarily reflect the official positions or views of the South Dakota Pharmacists Association.* The Journal subscription rate for non-members is $25.00 per year. A single copy can be purchased for $8.

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PRESIDENT'S PERSPECTIVE

Chris Sonnenschein
SDPhA President

Greetings SDPhA membership,

It is with a heavy heart that I compose this letter for the Spring 2010 Journal. This will be the last time I am graced with this privilege during my presidency. In just a couple of months we will inaugurate our Incoming President, Earl Hinricher.

The last few months have been productive for your Association Board and Office. Legislative session has come to a close. As many of you know a significant amount of work went into the Prescription Drug Monitoring Program bill. There is a well established need for a program such as this. It will be a valuable source of information to assist pharmacists and providers in delivering quality care while ensuring patient safety. We are pleased the Board of Pharmacy will administer the program and look forward to the opportunity assist in program development in any capacity needed. I would encourage you to attend this year's 2010 SDPhA Annual Convention June 4-6 in Oacoma. We will be offering a continuing education program on Prescription Drug Monitoring. Due to the fact that the bill has passed, we anticipate this session will be an interactive discussion including the next steps toward planning and implementation.

Earl and I recently attended the 2010 APhA Annual Meeting in Washington DC where we also had the opportunity to meet with our Congressional Delegates. It was a very interesting time to be in our nation's capitol. Policy makers were suffering from "Healthcare Reform Fatigue". While respecting the work that went into this debate, Earl and I capitalized on the opportunity to highlight the role pharmacists play in driving quality healthcare. Our message was well received. Now that the senate bill has passed and the President has signed it into law, it is important that pharmacy continues to focus its advocacy efforts on the areas that directly impact the practice of pharmacy and the patients that the profession serves. I believe the bill references "pharmacists" six times specifically around MTM. However, "medication" is referenced roughly forty times, and "drug" is referenced over 400 times. This demonstrates significant opportunity still exists for pharmacy. I encourage you to engage. Reach out to our Congressional Delegates through their district offices. The interest expressed by practicing pharmacists directly impacted by such legislation often leaves a profound impression.

In closing, I would like to thank you again for the opportunity to serve the Association as President. I would also like to thank the other Board members as well as Sue and Jenny. I look forward to seeing you all at Convention.

Professionally,

Chris Sonnenschein, PharmD, PMP
President
South Dakota Pharmacists Association

DIRECTOR'S COMMENTS

Sue Schaefer
Executive Director

"Hang Loose Ride the Wave of Opportunity"...Convention is right around the corner!

"Incredible line-up" was a comment we heard this week while sharing convention information with one pharmacist...we believe you'll realize that too when you check out the continuing education opportunities located within this year's annual meeting.

We Aim To Please... We've listened while you've shared your thoughts on what you'd like to learn about. Take in CE's on COPD, Diabetes Education, Prescription Disposal, New Drugs, Law Update, Vitamin D therapy, Prescription Drug Monitoring, Student Jeopardy and more!

And we're throwing in a healthy dose of fun to make your weekend complete! We'd love to have you all join us in June for your association's annual get-together...sun, surf (Missouri River-style) and a beautiful waterfront location...what more could one wish for... and did I mention a Golf Event? Phun Run along the River Trail? Dueling Pianos act? It all awaits...mark your calendar now for June 4-6, 2010 at the Cedar Shore Resort. You can register online at www.sdpha.org, and make your room reservations at the Cedar Shore by calling 605-734-6376.

What's Going On? This issue of the *South Dakota Pharmacist* is full of information on what's going on in Pharmacy. We've just witnessed a historic event with the passage of healthcare reform. What's in store for pharmacy one can only guess at this point, but I've placed some information in this issue to share with you what we DO know currently. Please take time to take a peek... it seems overwhelming, but we must focus on the positive side of this. There are some important provisions for pharmacy that actually recognize your skills and expertise as medication experts and knowledgeable consultants.

I'd like to share with you the conclusion of our jointly-supported Health Care Reform Principles developed when early discussions on HCR began, which I believe is a very important mantra for all practice settings:

"All Americans need access to prescription medications and to pharmacist-provided patient care services to help them optimize therapeutic outcomes and reduce the risk of adverse events from medication therapy. Health care reform provides an opportunity to advance these goals. Pharmacists are a highly trained and valuable resource, yet they are currently underutilized. Health care reform discussions should focus, in part, on strategies to maximize efficiency and safety of drug distribution while providing patients with access to the full benefit of pharmacist-provided patient care services to achieve better health care."

Now's your chance to show your patients what pharmacy can do to make their lives even better.

And in closing I'd like to extend our **Congratulations to the Phi Lamda Sigma crew for placing first in the national "Leadership Challenge".** We look forward to working with them on mentoring opportunities and finding creative ways to improve new practitioner involvement in pharmacy organizations.

Sue

Contribute to the 2009-2010 South Dakota Pharmacists Association District Dues and SDPhA Commercial and Legislative Fund!!

Visit our website at www.sdpha.org

Thank You for Your Support!

South Dakota Board of Pharmacy

Ron Huether
Executive Secretary

NEWS FROM THE BOARD
Board meeting dates: Board meetings are scheduled for April 16 in Sioux Falls and June 3 in Pierre. Please check our website for the time, location and agenda.

NEW REGISTERED PHARMACISTS
The following candidates recently met licensure requirements and were registered as pharmacists in South Dakota: Katherine Chiu, Beth Graham, and Jeanne Leoni.

NEW PHARMACIES
Pharmacy licenses have been issued recently to: James Stephens, pharmacist-in-charge, Vilas Pharmacy, 100 Main Street, Faith, SD; and Marla Hayes, pharmacist-in-charge, The Remedy Shoppe – Mission, 153 Main Street, Mission, SD. Both of these locations will serve as telepharmacies.

PRESCRIPTION DRUG MONITORING
During the next several months the Board will be drafting administrative rules to support the prescription drug monitoring law passed during the recent session of the SD Legislature (HB1231). The bill specifies that the Board of Pharmacy will be the agency that is responsible for implementing the Prescription Drug Monitoring Program (PDMP). South Dakota will join the list of about 35 other states that maintain a data base of controlled substances dispensed to patients. The Board will be seeking your participation as we develop data reporting and access requirements. Please call our office or speak with our Inspectors if you have questions or concerns about PDMP.

PARTIAL FILLING OF CONTROLLED SUBSTANCES
Our inspectors often receive questions related to partial filling of controlled substances in schedules III, IV and V. The Code of Federal Regulations (21 CFR) § 1306.23 states the partial filling of controlled substances listed in schedule II, IV, and V is permissible, provided that:

a. Each partial filling is recorded in the same manner as a refilling,
b. The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
c. No dispensing occurs after 6 months from the date on which the prescription was issued.

AUTOMATED MECHANICAL DISTRIBUTION DEVICES
Our inspectors find that some pharmacies utilizing devices such as Pyxis, Omnicell, ScriptPro, Parata, Baker, etc. do not maintain proper documentation or supervision by the pharmacist. Administrative Rule 20:51:17:02 states: (2) The automated mechanical distribution device shall be stocked with a limited supply of drugs only by a health care facility pharmacist or a person authorized by the pharmacist permittee. The health care facility pharmacist shall maintain electronic or written stocking records which contain the following information in the pharmacy for two years:

d. The name of the person stocking the drug or medicine;
e. The name, quantity, and strength of the drug or medicine; and
f. The date of stocking;

Please ensure as the pharmacist permittee, all necessary documentation is being captured by the staff you have designated with access to the device.

CONTROLLED SUBSTANCES AND PATIENT IDENTIFICATION
As recently as 10 years ago (data from 1995-2004) controlled substances prescriptions consisted of approximately nine percent of all prescriptions written by prescribers. More recent statistics suggest that percentage has risen to 23 percent; almost one in four prescription orders are for a controlled substance medication.

A certain percentage of these orders are obtained by drug shoppers and diverters. Are we as pharmacists, being as diligent as possible to guard against this growing problem? Many pharmacies have implemented policies and procedures requiring patients to present a valid photo ID when presenting prescriptions for controlled substances. This process is very similar or identical to requirements for purchasing pseudoephedrine. A simple sign is posted at the "pick up area" stating something similar to "Our pharmacy verifies positive identification on all prescriptions for controlled substance medications". Is it reasonable to assume if we ask even our most familiar patients to provide identification to purchase a package of Sudafed, we should also ask an unfamiliar patient for positive identification before obtaining a prescription for Oxycodone or any other controlled substance?

PHARMACEUTICAL TAKE-BACK PROGRAMS
A number of South Dakota pharmacists have expressed interest in pharmaceutical take-back programs, which are

Continued

South Dakota Board of Pharmacy

Continued

designed so that members of the public can bring unused or expired drugs to a central location for appropriate disposal. The South Dakota Board of Pharmacy reminds pharmacists to be aware of several things.

Federal controlled substance laws and rules prohibit a pharmacy from receiving controlled substances from anyone who is not a registrant of the United States Drug Enforcement Administration (DEA). (With limited exceptions involving drugs that are the subject of a manufacturer's recall or that were dispensed by the pharmacy in error.) This means accepting controlled substances from patients or members of the public is prohibited except for the two examples listed.

DEA does have a process in place through which a local law enforcement agency can get permission to conduct take-back programs. The law enforcement agency may then work with a pharmacy or pharmacist to conduct the take-back program. Law enforcement officials must be present during a take-back event because there is no way to guarantee that controlled substances will not be brought to the collection site. Pharmacists may assist by identifying controlled substances so that they can be handled separately from other drugs collected.

Pharmacists can also help determine the proper method of disposal. Drugs such as warfarin, hormones, chemotherapy agents, etc. should not be disposed of by flushing or placing in landfills because of environmental concerns.

The Board encourages pharmacists to work with local law enforcement to help organize these programs. We ask that you keep our office informed of your participation and so we share information with other pharmacists who are interested in providing this service in their community

SDPhA Management Rotation

By John C. Sandstrom

During my P4 year, I had the opportunity to complete an association management rotation during the South Dakota legislative session with SDPhA Executive Director Sue Schaefer. This was a highly insightful and rewarding experience. Here is a brief look at what I did during my time with SDPhA.

Legislative session is a hectic time in Pierre. The ability to manage several projects at once is absolutely essential. On a daily basis, I had to check the status of the literally dozens of bills that the association was following to ensure that ED Schaefer and I were at any necessary committee meetings. Of particular interest this year was House Bill 1231, which creates a prescription drug monitoring program for the state of South Dakota. Many hours were spent analyzing this piece of legislation to guarantee that the best interests of pharmacists were adequately represented.

My other major project during this rotation focused on a tuition reimbursement program for pharmacists practicing in underserved communities. South Dakota currently provides tuition reimbursement for physicians, nurse practitioners, and physician assistants practicing in underserved communities, but not pharmacists. Given the state budget situation, it was not realistic to approach the state for funding this year. However, I drafted a proposal for pharmacist tuition reimbursement, based on the physician concept, with funding provided by the South Dakota Board of Pharmacy. This proposal is still in the infancy stages, but I am confident that it will continue to move forward. The value of a pharmacist as a healthcare provider has increased exponentially as we have broadened our scope of practice.

As previously mentioned, this rotation was a highly valuable experience. Opportunities to work with lawmakers and representatives of other healthcare professions were literally endless. Further, the benefits and value of a state association membership are much clearer to me now as I prepare to begin my career as a pharmacist.

Best Regards,
John C. Sandstrom

SDSU College of Pharmacy welcomes professional class

The South Dakota State University College of Pharmacy will host its annual White Coat Ceremony for the doctor of pharmacy class of 2013 at 5:30 p.m. on Friday, Jan. 29, in the Performing Arts Center on the SDSU campus.

The ceremony welcomes first-year students into the professional pharmacy program by giving them their occupation's designated white coats. The white coat formalizes the beginning of each student's commitment to professionalism in the field of health care.

"The white coat received is worn for clinical activities and shows that the student is enrolled in the SDSU pharmacy program," said Dean Dennis Hedge, Pharm.D.

University of Nebraska Medical Center Professor of Pharmacy Practice Jeffery N. Baldwin, current president of the American Association of Colleges of Pharmacy, will address the audience about becoming a 21st century pharmacist.

"The white coat symbolizes the pharmacist's key position in medication therapy management and patient care," said Baldwin.

"I'll challenge the Class of 2013 to embrace a vision that includes pharmacist reimbursement based on improved patient outcomes and disease prevention."

The event is organized by co-chairs and second-year, professional program students Nicholas Hite, Richland, Wash., and Terry Hoffman Sleepy Eye, Minn., as a component of the professionalism development effort of the SDSU chapter of the American Pharmacists Association – Academy of Student Pharmacists.

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SDPhA Convention Line-up
Cedar Shore Resort & Convention Center
(tentative)

June 4-6, 2010 – Oacoma, SD

All Educational Programs
Hale
Jeopardy - The Deck
(weather permitting)

Friday, June 4th

Friday Morning: Golf Event
Municipal Golf Course

Vendor Time: 11:00 a.m. – 3:00 p.m.
Glass, Howe and Wheeler

Lunch provided with noon CE
(family dining - Wheeler)

11:30 a.m. - 1:00 p.m.
"Medication Disposal Options"
David Hames, Sharps Compliance, Inc

2:00 p.m. – 3:00 p.m.
"Chronic Obstructive Pulmonary Disease"
Kim Messerschmidt, PharmD

3:30 p.m. – 4:30 p.m.
"Pharmacy Law"
Dave Helgeland, RPh

Friday Evening

6:30p.m. – 10:00 p.m.
Dueling Pianos Show - Oacoma
(Buffet & Awards Presentation)

Saturday, June 5th

6:30 a.m. – 7:30 a.m. Phun Run
River Trail

7:00 a.m. – 8:30 a.m.
Breakfast
(Wheeler)

8:00 a.m. – 9:00 a.m.
"Vitamin D Therapy"
Dr. Mary Wuebben

9:00 a.m. – 10:00 a.m.
"Prescription Drug Monitoring Program"
SD Board of Pharmacy

10:00 a.m. – 11:00 a.m.
"New Drug Update"
Joe Strain, PharmD

11:00 a.m.– 12:00 p.m.
"Diabetes Education"
Invited Speaker

12:00 p.m. – 1:30 p.m.
First Business Meeting and Lunch

1:30 p.m. – 3:00 p.m.
"Pharmacy Jeopardy"
SDSU College of Pharmacy
Student Pharmacists

3:00 p.m. – 3:30 p.m.
SDSU/Mills Family Ice Cream Social

3:30 p.m. - 4:30 p.m.
Second Business Meeting

Saturday Evening:

5:00 p.m.
Past President's Soiree
Missouri Winds

6:30 p.m.
Children's Pizza Party - River Run

6:30 p.m.
Social/Banquet
Glass/Howe/Wheeler

Sunday, June 6th

Breakfast: 7:15 a.m. – 9:00 a.m.

8:00 a.m. - 9:00 a.m.
"Sound Financial Planning"
Pat Reding, Pharmacists Mutual

9:00 a.m. – 11:00 a.m.
"Immunization Update
Roundtable Discussion"
Kelley Oehlke, PharmD

124th Annual South Dakota Pharmacists Association Convention

Registration Form

Cedar Shore Resort, Chamberlain/Oacoma, South Dakota June 4th-6th, 2010

All SDSU Student Registrations are FREE!
(Hotel not Included)
Registrations must be submitted prior to May 9, 2010

	SDPhA Member	Spouse or Guest	Children	SDAPT Member	Pharmacy Technician	Pharmacy Student	Non SDPhA Member	
Full Registration*								
Before May 9, 2010	$150	$90	$20	$90	$150	Free	$225	_____
After May 9, 2010	$175	$110	$25	$110	$175	Free	$250	_____
One Day Registration**								
Fri., June 4, 2010	$100	$50	$10	$50	$90	Free	$145	_____
Sat., June 5, 2010	$115	$65	$20	$65	$105	Free	$160	_____
Sun., June 6, 2010	$50	$25	Free	$50	$50	Free	$75	_____
Extra Tickets								
Sat. Breakfast	$15	$15	$10	$15	$15	Free	$15	_____
Sat. Lunch	$15	$15	$10	$15	$15	Free	$15	_____
Sat. Awards Banquet	$30	$30	$10	$30	$30	Free	$30	_____

Name:_____
Address:_____
City:_____State:____Zip_____
Business Name:_____
Business Address:_____
City:_____State:____Zip_____
Business Phone:_____
Home Phone:_____
Email Address:_____
Spouse/Guest Name:
_____

For Hotel Reservations Call:
Cedar Shore Resort
1500 Shoreline Drive (605) 734-6376

Cancellation Policy:
Cancellations will be accepted without penalty prior to May 16, 2010.
A $25 cancellation fee will be applied to all cancellations after May 16, 2010.
Refunds will be issued after June 15, 2010.

I would like sponsor a student. I have included an additional gift of _____
I would like to contribute to the SDPhA Commercial & Legislative Fund.
I have included an additional amount of _____

Total Due $_____

Please send payment and registration to:

South Dakota Pharmacists Association
PO Box 518, Pierre, SD 57501
Tax ID#: 46-0191834

*Full Registration includes all educational sessions, exhibits, meals and evening events

**One-day Registration includes educational sessions, exhibits, meals and evening event, if applicable.

I will be participating in the golf event on Friday Yes___ No____
I will be participating in the phun run on Saturday Yes___ No____

History of Pharmacy in South Dakota

Continued

1860

1861

- The United States Congress created the Dakota Territory (DT) including the present-day North and South Dakota. Yankton was named the capital.

1862

- Charley Bramble, New York opened the first drug store in DT at Yankton.

1870

1872

- Legislature passed a law requiring a pharmacist to have a license to sell intoxicating liquor. The same year a law passed allowing the town supervisor the authority to act as the Board of Health, with no power to control the sources of filth and causes of sickness.

1876

- Kirk G. Phillips and Dr. A.M. McKinney opened the first drug store on Main Street in Deadwood.

1879

- Legislature authorized pharmacists to sell liquor for medicinal purposes but only upon a doctor's prescription. They could not sell wine for sacramental purposes.

The First Pharmacy Class 1889

1880

1881

- Citizens of Brookings donated an eighty acre tract of land northeast of the city for college purposes.

1883

- Legislature approved the sale of $25,000 in bonds to finance the construction of a college building.

1884

- The Territorial Agricultural College at Brookings opened. Dr. George Lilley was selected president and his salary was $1,500 per year. The staff consisted of two paid instructors and two volunteers. The tuition for non-residents was $5.00 per term and for residents it was free. Room and Board was $2.50 per week.

1885

- Legislature created a three member Territorial Board of Health consisting of the Attorney General and two Governor appointees.

1886

- **Thirty eight pharmacists met at the Alex Mitchell Hotel in Mitchell, DT to form the association.**
- **The membership fees were $2.00.**

1887

- The statute created two association districts within the Territory. Dakota Pharmaceutical Association district (present-day North Dakota), Southern District Pharmaceutical Association (present-day South Dakota). Each district had a Board of Pharmacy.
- The second annual meeting of the Association was held in Sioux Falls on September 6th.
- There were 127 pharmacists. All but six who were proprietors of drug stores, paid their $2.00 membership fee and joined the Association.

1888

- The college offered a two-year course in Pharmacy. It was designed to fit young men and women for the business of becoming druggists.
- Third annual meeting was held in Huron in August.

1889

- The United States Congress opened the land between the Black Hills and the Missouri River for settlement.
- Fourth Annual meeting was held in Aberdeen at the Opera House in August.
- Statehood approved! South Dakota and voters selected Pierre as temporary capital and Arthur Mellette as Governor.
- The first five students graduated from the college of pharmacy and were awarded a certificate of completion for the two year course.

History of Pharmacy in South Dakota

1890

1890

- Voters select Pierre as permanent capital.
- Legislature passed a law that only registered pharmacists could compound, dispense and sell drugs and medicines.
- New SD Pharmacy Law, created "S.D. State Pharmaceutical Association and the Board of Pharmacy". They were both managed by Executive Secretary, who was the only paid officer, earning $500.00 per year.
- Governor Mellette appointed A.H. Stites, Sioux Falls, O.H. Tarball, Watertown, and D.K Bryant, Huron as the first Board of Pharmacy members.
- The first meeting of the S.D. Board of Pharmacy was held on October 1st. There were 424 pharmacists registered, most of whom where registered Territorial pharmacists.
- Board examinations were conducted in Sioux Falls, Pierre, Aberdeen, Huron and were mailed to the Black Hills. The neatly bound exam book cost $1.50 and it contained 1,500 questions and answers on pharmacy, botany, and chemistry.

1891

- John Wyeth and brother paid for a one-page advertisement in the SDPhA Annual Proceeding announcing that they were manufacturers of elegant pharmaceutical preparations.

1894

- List of pharmacists showed 415 Territorial certificates. Twenty Six had been engaged in practice before 1887 when the Territorial Board of Pharmacy was created.
- Nettie C. Hall, Wessington Springs was the first woman officer of SDPhA. She was elected second vice president at the Huron Meeting.
- The license renewal was raised from $2.00 to $3.00.

1895

- Five SDSU students were awarded a Ph.G. [pharmacy graduate] degree, and the class of 1895 was recognized as the first class graduating in pharmacy.

1898

- Pharmacists from 40 counties attended the meeting in Mitchell. The association had five standing committees: Legislative, Education, Trade Interests, Finance and Auditing, and Pharmacy and Queries.
- There were 411 pharmacists practicing in 153 South Dakota towns in 52 counties. The college training of the 411 pharmacists was as follows: 19 with Ph. G. [Pharmacy Graduate], 37 with M.D. and most of the 355 pharmacists were carry-over pharmacists with Territorial certificates.

- The Department of Pharmacy announced that Ph.G. graduates could obtain a B.S. in pharmacy with two more years of study.

A.H. Stites prescription bottle from his pharmacy in the Carpenter Hotel, Sioux Falls, 1890. Stites was a member of the first South Dakota Board of Pharmacy.

1886-1899 Annual Meetings

- 1886- Mitchell
- 1887- Sioux Falls
- 1888- Huron
- 1889- Aberdeen
- 1890- Watertown
- 1891- Madison
- 1892- Sioux Falls
- 1893- Yankton
- 1894- Huron
- 1895- Lake Madison, Madison,
- 1896- Madison
- 1897- Sioux Falls
- 1898- Mitchell
- 1899- Watertown

1896 SDPhA convention group at Madison, SD

SDPhA Legislative Days 2010

The 2010 Legislative Days was held on February 2nd and 3rd in Pierre

2010 Legislative Session

Robert C Riter
SDPhA Lobbyist

2010 was a very successful legislature year culminating with passage of the prescription drug monitoring program legislation. HB 1231, resulted from work by this Association and other interested groups during the interim toward the creation of a prescription drug monitoring program. Those discussions continued during the early part of the legislative session and ultimately lead to the bipartisan introduction of HB 1231.

Representative David Lust of Rapid City and Senator Kathy Miles of Sioux Falls took the leadership role in introduction of HB 1231. Efforts at improving the bill continued throughout the legislative process with our urging. The bill was amended by the House Health and Human Services Committee, by the full House floor and by the Senate Judiciary Committee. Ultimately it passed both houses in consistent form and will become law on July 1, 2010.

It is a comprehensive measure intended to provide protections to the public and minimize the abuse of prescription drugs. One of the amendments sought was to ensure that rather than it being a criminal offense it would be a matter reported to the dispensers' licensing board, if a dispenser knowingly failed to submit prescription drug monitoring information or submitted incorrect information. Another amendment ensured the advisory council included a dispenser selected not only by the Board of Pharmacy, but another who is a member of this association. Another amendment allows the Board of Pharmacy to promulgate rules addressing criteria, procedures and forms for submitting data to the program, standards for information collection, as well as other guidelines and safeguards for maintaining the confidentiality of program information.

A language change also eliminated the requirement that a dispenser report all of the data elements included in the 2005 version of the electronic recording standards for prescription monitoring programs, to limit it to only those identified data elements as adopted by the Board from that 2005 version. This gives the Board the discretion to, by rule, limit reporting of only the specific elements it deems most appropriate.

We were pleased that the sponsors and the other members of the legislature were willing to accept most of our proposals for amendments. We think it became a better bill because of them.

The prescription drug monitoring program established requires that on a weekly basis each dispenser submit the required information to the central repository, maintained by the Board of Pharmacy. The Board may waive the requirement for good cause shown by the dispenser. The information reported relates to controlled substances included in Schedules II, III and IV of South Dakota law.
As mentioned, the data elements required to be reported will be as established by the Board of Pharmacy in rule.

While the Board of Pharmacy is the entity managing the program, an advisory board established under the law which consists of at least twelve (12) designees, including one member of the South Dakota Pharmacists Association and another dispenser selected by the Board of Pharmacy, shall make recommendations to the Board of Pharmacy as to how to best use the program to improve patient care and reduce the misuse, abuse or diversion of controlled substances. The advisory council shall also make recommendations to the Board regarding safeguards for release of information to only persons who are entitled to access so as to maintain the confidentiality of program information.

The Board of Pharmacy is also charged with establishing and maintaining procedures to ensure the privacy, confidentiality and security of patient information collected. The Board may, however, provide data to certain entities, including prescribers, dispensers, state boards, regulatory agencies, and law enforcement and judicial authorities under certain circumstances. The Board shall, however, maintain a record of each request for information and if a person authorized to have that prescription monitoring information knowingly discloses it in violation of the law, they shall be subject to a Class 6 felony.

The act also provides that a prescriber, dispenser or other healthcare provider may not be held liable in damages in a civil action on the basis that the individual did or did not seek to obtain information from the central repository. Furthermore, unless a lack of good faith is shown, a dispenser is not subject to civil liability by reason of furnishing information under the conditions of the act, receiving or using such information, failing to furnish the information or furnishing information that was factually incorrect.

The Attorney General testified that he had certain grants available to fund the program for the next several years. We advised that while we knew such a program was important and the pharmacists were willing to step up and become part of the solution, we did not want the ultimate expense of the program to be imposed upon this profession. The discussion was that assuming the program proved itself to be effective and worthwhile, after the Attorney General's funding runs out, the legislature will determine a longer term funding source.

As is evident, the legislature spent substantial time and effort on this matter and put together what appears to be a workable response to the issues presented by prescription drug abuse. We urge all members to study it carefully and ensure proper compliance therewith.

SB 83 provides for the self-administration of prescription asthma and anaphylaxis medication by students. It further establishes procedures that must be followed to implement such a program in a school setting.

HB 1045 revises the definition of anabolic steroids and adds to the Scheduled Drugs: tapentadol, lacosamide and fosporpofol, including its salts, salts, isomers, and salts of isomers. That bill became effective immediately upon approval by the Governor on February 25, 2010. The legislature also considered a requirement that health insurance coverage be provided for contraceptive drugs and devices. That measure was defeated in committee but was forced out to the House floor, which ultimately refused to consider it.

Two other measures of interest were introduced. One would have limited damages resulting from medical malpractice and another would have provided that if a company providing healthcare coverage becomes insolvent the healthcare provider would be unable collect the monies owing directly from the patient. Both of those measures were defeated.

The legislature did pass SB 186, which provides some relief to small business people by reducing the maximum 2010 unemployment insurance surcharge from $150 to $100 per employee and reduces it to $82.50 maximum during the year 2011. The bill also makes certain modifications in the wage base and other changes which hopefully will ensure the tax burden more accurately reflects each employers' experience.

As you can see, we were very busy with efforts on your behalf this year. Your executive, Sue Schaefer, and your officers were actively involved. We also particularly appreciated the efforts of those members and students who traveled to Pierre to meet with the legislators during the legislative session. Legislators respond well to contact from their constituents.

We also very much appreciated the opportunity to work with the Commercial and Legislative Branch again this year and are pleased the results were consistent with your efforts and expectations.

Thank you.

South Dakota State University
College of Pharmacy

Dennis Hedge
Dean

Greetings from the College of Pharmacy!

The semester is rapidly nearing conclusion and the countdown has started. Before long, we will be saying goodbye to our temporary home, "The Barn", and moving into the Avera Health and Science Center. Construction has gone very well and we are still on target to move at the beginning of July. Our new home features two 90-seat lecture auditoriums, a pharmaceutical science teaching laboratory, a pharmacy practice skills laboratory, student resource rooms for both Pharm.D. and Ph.D. students, support rooms for our student services team, and numerous gathering spaces for students to study and relax between classes. All of us at the College are looking forward to giving tours and demonstrating the instructional technology that will make the Avera Health and Science Center one of the premier health science education buildings in the country.

Speaking of "The Barn", our students continue to enjoy the historic basketball arena and put it to good use. Our Phi Lambda Sigma (Pharmacy Leadership Society) chapter recently sponsored "Hoops for Haiti", a three-on-three basketball tournament with all proceeds donated to the Haiti Relief Fund. It was a very fun event for a great cause. In addition, I should also note that PLS placed first in this year's national "Leadership Challenge". The chapter received a plaque and $1000 to implement their challenge proposal "Transitioning Student Leaders to Practitioner Leaders". Congratulations to the chapter and their advisor Dr. David Helgeland.

We were also very pleased to learn that the SDSU chapter of the American Pharmacists Association-Academy of Student Pharmacists was named First Runner-Up in the Chapter of the Year category for colleges/schools of our size (Division AAA). This recognition was made at the APhA Annual Meeting in Washington, D.C. Advisors for the SDSU APhA-ASP chapter are Dr. Teresa Seefeldt and Dr. Kelley Oehlke. This award continued an amazing run for us at the College where all of our student organizations have received a national honor within the past year.

As I write this, we are also in the midst of selecting our incoming class of 80 P1 students for fall 2010. Once again this year, the applicant pool is incredibly strong. All of us at the College are grateful that some of you were able to join us and assist with the interview process. I am sure that those of you that have helped interview applicants would agree that it is very refreshing to visit with so many bright young people that believe in our profession. Without a doubt, it would appear that our future is in good hands.

As always, please stop by and see us if you are on or near our campus. We would enjoy visiting with you.

Regards,

Dennis Hedge, Dean of Pharmacy

Academy of Student Pharmacists

Kayley Lyons
APhA-ASP President

Greetings from APhA-ASP,

It was a great surprise for the eleven students coming back from APhA Annual Meeting in Washington D.C. to get off the plane and find all the snow had melted. Although I became anxious for spring, I was reminded of what a great winter we had for our SDSU APhA-ASP chapter. We started the semester off with a stunning White Coat Ceremony thanks to our hard working co-chairs, Terry Hoffman and Nicholas Hite. The White Coat Ceremony symbolizes the entrance into the profession of pharmacy for P1 students. The ceremony started with appetizers for students and their families while they were serenaded by a string quartet. Then Dr. Jeffrey Baldwin, the president of AACP, gave an inspirational speech on professionalism. The ceremony culminated with each student receiving a white coat kindly donated by Walgreens. Dr.. Baldwin was so impressed with our chapter that he graciously donated us his honorarium to be used towards sending a student to the Utah School of Alcohol and other Drug Dependencies.

In early February, our chapter sent 45 student pharmacists to Legislative Days in Pierre! The night before Legislative Days our chapter was given a legislative update on issues that could affect how pharmacy is practiced in South Dakota. A delicious dinner was also provided at the legislative update, and I would like to thank the South Dakota Pharmacists' Association (SDPhA) for providing the meal and our hotel accommodations. Early the next morning we arrived at the state capital to perform blood glucose screenings, blood pressure screenings, and provide information about immunizations to people at the state capital. Legislative Days was again a great success and a wonderful learning experience for student pharmacists.

The Tobacco Cessation Committee hosted the second annual Anti-Tobacco Night for area middle school students. Co-chairs John Weitgenant, Kristin Brown, and Ryan Rasmussen did a fantastic job of planning a fun night without tobacco for the 71 students. The middle school students competed in a heated dodge ball tournament, participated in a tobacco facts scavenger hunt, and enjoyed dancing the rest of the night away. SDSU's mascot "Jack" even paid a visit to the middle school students.

During Spring Break eleven of our students attended the APhA National Meeting in Washington D.C. It was great to see such a strong pharmacy presence in our nation's capitol. We enjoyed networking with students from other Colleges of Pharmacy who had great ideas for our chapter on advocacy, patient care, and event planning. We also attended leadership and team building workshops and were fortunate enough to hear our resolution on direct to consumer advertising be debated in the APhA-ASP House of Delegates. All of hard work last year was commended because our chapter was awarded first runner-up for the Chapter Achievement Award in our division! Thank you to all 322 students from the past year for their dedication and commitment for making this achievable. We also appreciate the great support from our alumni and College of Pharmacy.

Once again, the ASP fundraising committee is organizing the Annual APhA-ASP Auction, our major fundraiser. Just like last year, this will be a two night event taking place in Sioux Falls on April 15th following the Sioux Falls SDPhA meeting at the Ramada (1301 West Russell St.) in Sioux Falls beginning at approximately 7:30pm. The second night will be in Brookings on April 28th during our final ASP meeting at 6:30. All of the proceeds from the auction go to our chapter and are used to reduce costs for attending events sponsored by APhA-ASP like regional and national meetings. The auction is open to all and should be a fun filled night with many great items up for bidding; including a traditional Indian meal from Dr. Dwivedi, private airplane trip to Okoboji, rounds of golf, gift certificates, clothing, gift baskets, and a variety of other items. Your attendance would be greatly appreciated. Also, the fundraising committee will have some of their All Pharmacy Cookbooks for sale at the event. If you have any questions about the auction or interested in a cookbook, please contact Joe Rose at jdrose@jacks.sdstate.edu.

Our chapter is once again on the path of success this year. The chapter elected new officers, and I am excited to be working with these bright individuals. They have exciting new ideas, and I am looking forward to see the ideas come to life. Also, I would like to thank the outgoing officers for all their effort and commitment to our chapter over the past year. Each one was a pleasure to work with and made the year a great success.

Sincerely Yours,

Kayley Lyons
APhA-ASP President
South Dakota State Chapter

SD Association of Pharmacy Technicians

Phyllis Sour

SDAPT President

Spring flowers bring May flowers and I am sooooo ready for spring. We have had and unusually harsh winter with cold temps, more snow than normal, treacherous ice, wind and then more ice and wind. It seemed never ending and now I am ready for warm sunshine and the signs of green grass, trees budding and spring flowers to make their appearance, a glorious new beginning.

We have had several new members join SDAPT and I would like to extend a welcome and thank them for their support of our organization. We always welcome your comments and suggestions to make SDAPT a unified, functional organization to be proud of.

SDAPT is proud to be a co-sponsor for the technician certification review session held at the SDSHP convention on April 9th in Rapid City. We sponsored the breakfast for our fellow technicians and potential future members attending the review. Good luck to those taking the certification exam.

We have two projects that we need to act on soon and I would appreciate in-put from our members. The first is nominations for our honorary member award that is normally presented at the SDPHA convention in June. The individual receiving this award is someone who has supported and shown a special interest in pharmacy technicians. The second project is the renewal of our affiliation agreement with SDPHA. The affiliation agreement is due to be renewed this fall. Please contact any of the officers with your thoughts or suggestions on these issues.

As we are all anticipating the arrival of spring and summer, we are making plans and filling our calendars with upcoming events. I would like to encourage every one to consider attending the SDPHA convention which will be held June 4th-6th in Chamberlain/Oacoma, It is a great event to meet with other in the pharmacy profession and enjoy the excellent continuing education that is offered. So, mark the date on your calendar, I look forward to seeing you there.

Remember to check out our website www.sdapt.org

Phyllis Sour

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SDMEDX Go-Live Update

As you know, the South Dakota Department of Social Services (DSS) is replacing the current Medicaid Management Information System with a new system called South Dakota Medical Electronic Data Exchange (SD MEDX). New dates have been established related to SD MEDX implementation which you will find below. Please know that these dates are subject to change, and if they do, Department of Social Services will continue to keep you informed.

- **Wednesday, March 31, 2010** (tentative date): SD MEDX Website launches.
- **Wednesday, March 31, 2010** (final date): Ceasing paper applications for new provider enrollment.
    - Paper applications for new provider enrollment will no longer be accepted allowing all provider information to be converted to SD MEDX.
    - Applications received during the freeze period will be returned to the provider.
- **End of April 2010** (tentative timeframe): SD MEDX Provider Enrollment and Re-Enrollment training begins.
    - Training will be provided in three ways: face-to-face, conference calls and online through training modules, quick reference guides and checklists.
    - Type of training, time and location will be specific to the provider type. We will notify you when it is your time to begin the SD MEDX training.
- **Beginning of May 2010** (tentative timeframe): SD MEDX Provider Enrollment and Re-Enrollment begins.
    - Billing Agents will be the first to enroll. Other provider types will follow and will be notified approximately one month prior to their specific re-enrollment period.
    - New provider enrollments will be accepted online at this time as well.

As previously mentioned, you will continue to receive direction and correspondence from our Department regarding appropriate time on provider enrollment, re-enrollment and training. To receive the latest information, please visit dss.sd.gov/sdmedx. Please use this link as a resource for the most recent updates and information on SD MEDX.
Thank you for your continued partnership and support as we implement SD MEDX. If you have questions, please contact our Provider Response Team at 1-866-718-0084.

SD Society of Health-System Pharmacists

Jodi Wendte
SDSHP President

Greetings from SDSHP:

Here is a brief update of our most recent as well as upcoming activities.

In collaboration with SDPhA and the SDSU College of Pharmacy, we have offered a series of free continuing education programs presented by the pharmacy practice residents from Avera McKennan and Sanford hospitals. In March, we completed our third and final program for the year with remote access to Rapid City, Brookings, Watertown and Mitchell. We look forward to providing these opportunities again next year.

We have identified a goal for the organization in the next year to take on a more environmentally friendly and economic approach to correspondence with our members. We propose to provide membership and meeting registrations in addition to information regarding other organizational events via email. It is understood that electronic communication is not an option for all members, so the proposal includes a final mass mailing that will allow the option to opt out and continue to receive paper copies of correspondence via traditional mailings. As always, we appreciate your feedback regarding these changes.

Recently the SDSU chapter of Phi Lambda Sigma competed in a national "Leadership Challenge" competition and took first place. The result of this is the opportunity to work with the student organization to create a mentorship program between SDSHP officers and students. The goal is to improve new practitioner involvement in pharmacy organizations.

Mark your calendars for the annual Gary Van Riper Golf Open to take place July 23, 2010. As details become finalized, we will make information and registration forms available to you online. We hope to see you and your team there!

On behalf of SDSHP, thank you for your continued support of the organization as well as the support you have shown to me as SDSHP President. It has been a rewarding time of personal and professional growth. I would especially like to acknowledge and thank two outgoing board members, Kelley Oehlke, Treasurer and Eric Kutscher, Past President. Both have dedicated many years to making SDSHP the strong organization it is today.

Please visit our web page for up-to-date information on continuing education opportunities and organizational events.

Jodi Wendte

Jodi Wendte, Pharm.D., BCPS
President
South Dakota Society of Health-System Pharmacists
www.sdshp.com

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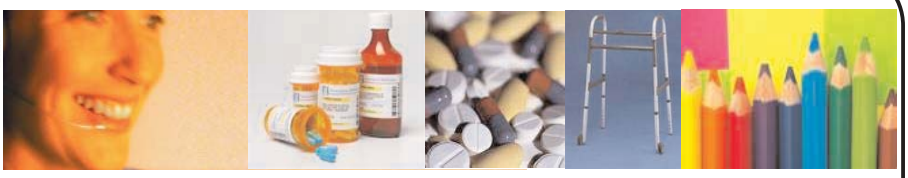

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Health Care Reform- What does it mean for pharmacy?

APhA's Unofficial Overview of the Key Pharmacy Provisions in the Patient Protection and Affordable Care Act (P.L. 111-148)

- **Section 1311:** Plans in the health exchanges must implement a quality improvement strategy such as medication and care compliance initiatives.
- **Section 2503:** "Fixes" Average Manufacturer's Price (AMP) – generally makes the calculation more reflective of true retail community pharmacy costs.
    - o Delays use of the federal upper limit (FUL) by requiring that three (previously was two) generics are in the marketplace before the Food and Drug Administration (FDA) establishes a federal upper limit (FUL).
    - o Sets reimbursement at 175% (was 150%) of the weighted average AMP that are available for purchase by retail community pharmacies on a nationwide (previously was state) basis.
    - o Creates new definitions of "retail community pharmacy" and "wholesaler."
    - o Expands what is excluded in the calculation of AMP, such as certain prompt pay discounts.
- **Section 3012:** Establishes a Center for Medicare and Medicaid Innovation within CMS
    - o To test payment and service delivery models to determine their effect on program expenditures and quality of care.
    - o The models of care may include "utilizing medication therapy management services."
- **Section 3023**: Establishes a national pilot program for integrated care during an episode of care provided to a beneficiary around a hospitalization in order to improve the coordination, quality, and efficiency of health care services.
    - o A payment methodology tested under the pilot program shall include payment for the furnishing of applicable services such as medication reconciliation.
    - o NOTE: We need to get clarification but it looks like Medicare "providers" are the only ones eligible for payment for these services.
- **Section 3024:** Establishes an Independence at Home demonstration program.
    - o Defines an Independence at Home medical practice as being comprised of physician(s) or nurse practitioner(s) being part of a team that includes pharmacists.
- **Section 3026**: Establishes a Community-Based Care Transitions Program.
    - o An application for the funding must include a detailed proposal for at least one care transition intervention, which may include "conducting comprehensive medication review and management (including, if appropriate, counseling and self-management support)."
- **Section 3109:** Exempts certain pharmacies from CMS' durable medical equipment, prosthetics, orthotics, supplies (DMEPOS) accreditation requirements; exemption criteria include:
    - o Total billing by the pharmacy for DMEPOS are less than 5% of total pharmacy sales.
    - o The pharmacy has been enrolled as a DMEPOS supplier for at least five years during which a final adverse action has not been imposed.
    - o The pharmacy attests to this information and submits supportive material.
- **Section 3201:** Establishes care coordination and management performance bonuses for Medicare Advantage plans.
    - o Eligible programs include "medication therapy management programs that are more extensive than is required under [Medicare Part D MTM]."
- **Section 3301:** Establishes a Medicare Coverage Gap Discount Program (changes to this section and Section 3315 were made in the budget reconciliation bill).
    - o Applies to covered Part D drugs dispensed

on or after July 1, 2010

- Such discounted prices (50% of the negotiated price) shall be provided to then beneficiary at the pharmacy or by the "mail order service" at the point-of-sale.
- The Secretary must establish procedures
  - Under which discounted prices are provided at pharmacies or by mail order service at the point-of-sale.
  - To ensure that, no later than the applicable number of calendar days (14 days for claims submitted electronically; 30 days for claims submitted otherwise) after the dispensing of a drug, the pharmacy or mail order service is reimbursed for an amount equal to the difference between:
    - The negotiated price of the drug; and
    - The discounted price of the drug.
- Beneficiaries must still pay a dispensing fee.
- *See also Section 3315 below.*

- **Section 3310:** Establishes a Long-Term Care (LTC) Waste Reduction Program in Medicare Part D.
  - Directs the Secretary to require Medicare Part D prescription drug plans [appears only to apply to stand-alone plans, not Medicare Advantage (managed care) plans] to utilize specific, uniform, dispensing techniques, as determined by the Secretary, in consultation with relevant stakeholders (including representatives of pharmacists, and retail and LTC pharmacy, such as weekly, daily, or automated dose dispensing when dispensing covered Part D drugs to enrollees who reside in a LTC facility in order to reduce waste associated with 30-day fills.
  - Applies to plan years beginning on or after January 1, 2012.

- **Section 3315:** Provides for an Immediate Reduction in the Part D Coverage Gap.
  - For the plan year beginning January 1, 2010, increases the initial coverage limit by $500 (thereby delaying a Medicare Part D beneficiary's entrance into the "doughnut hole").

- **Section 3502:** Establishes a Community Health Team to Support the Patient-Centered Medical Home.
  - Establishes a grant program to establish community-based, interdisciplinary, interprofessional teams to support primary care practices.
  - To be eligible, an entity must ensure that the health team that it establishes is interdisciplinary and interprofessional; such teams may include pharmacists.
  - A health team must
    - Provide support necessary for local primary care providers to provide access to pharmacist-delivered medication management services, including medication reconciliation.
    - Provide 24-hour care management and support during transitions in care settings including:
      - A transitional care program that provides onsite visits from the care coordinator, assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospital, nursing home, or other institution setting;
      - Assuring that post-discharge care plans include medication management as appropriate.

- **Section 3503:** Establishes a Medication Management grant program.
  - Run through the new Patient Safety Research Center.
  - Provides grants or contracts to eligible entities to implement medication therapy management (MTM) provided by pharmacists, as a collaborative, multidisciplinary,

interprofessional approach to the treatment of chronic disease, to improve the quality of care and reduce overall cost in the treatment of such diseases.

- The program is to commence no later than May 1, 2010.
- Establishes grant eligibility criteria.
- Services are similar to what are included in the profession's Core Elements.
- Eligible patient population is broad.
- In designing and implementing the grants, stakeholders, including pharmacy and pharmacist organizations, must be consulted.
- Requires entities to submit a report to the Secretary; the Secretary then must report to Congress, which must evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest when providing MTM services and if so, provide recommendations on how to address the conflict.
- NOTE: The grant program is NOT yet funded.

- **Section 3508:** Establishes a demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals.
  - Schools of pharmacy are eligible for the grants.
- **Section 4103:** Provides Medicare coverage for a new annual wellness visit.
  - The "personalized prevention plan" contains certain elements including a list of all prescribed medications.
- **Section 5101:** Establishes a National Health Care Workforce Commission.
  - The definition of "health care workforce" includes "pharmacists."
  - The definition of "health professionals" includes "clinical pharmacists" and representatives of "schools of pharmacy" and "pharmacists."
- **Section 5305:** Directs the Secretary to award grants or contracts to entities that operate geriatric education centers.
  - The funds are to be used to offer short-term intensive courses that focus on geriatrics, chronic care management, and long-term care that provide supplemental training for faculty members in schools including schools with programs in pharmacy.
  - The program can be located in schools of pharmacy.
  - At least two courses a year, at no or nominal cost, must be offered for family caregivers to provide practical training. Such training shall include instruction on the safe and effective use of medications for older adults.
  - A geriatric education center must develop and include materials on medication safety issues in older adults.
  - Grants may also be available to foster greater interest in health professionals in entering the field of geriatrics, LTC, and chronic case management. Pharmacists are eligible for these grants.
- **Section 5315:** Establishes a U.S. Public Health Sciences Track that will grant advanced degrees that uniquely emphasize team-based services, public health, epidemiology, and emergency preparedness and response. It will be organized so that no less than 50 pharmacy students will graduate annually.
- **Section 6005:** Establishes new Pharmacy Benefit Manager (PBM) Transparency Requirements.
  - PBMs must provide to the Secretary and the plan with whom the PBM contracts dispensing rates (retail versus mail order pharmacy), generic dispensing rates, the rebates/discounts that PBM negotiates and how much is passed through to the plan sponsor or patient, the difference between what the plan pays the PBM and what the PBM pays pharmacies.

Health Care Reform- What does it mean for pharmacy?

Continued

- **Section 10328**: Improves Medicare Part D MTM by
  - o Requiring plans (beginning two years after the date of enactment of this law) to offer MTM services to targeted beneficiaries that include, at a minimum:
    - ▪ An annual comprehensive medication review furnished person-to-person or using telehealth technologies by a licensed pharmacist or other qualified provider. The review:
      - Must include a review of the individual's medications and may result in the creation of a recommended medication action plan; and
      - Must include providing the individual a written or printed summary of the review results.
    - ▪ Follow-up interventions as warranted based on the findings of the review or the targeted medication enrollment and which may be provided person-to-person or using telehealth technologies.
  - o The prescription drug plan must have in place a process to assess, at least quarterly, the medication use of individuals who are at risk but not enrolled in the MTM program, including individuals who have experienced a transition in care, if the plan has access to that information.
  - o The plan must have in place a process to
    - ▪ Automatically enroll targeted beneficiaries into the program; and
    - ▪ Permit such beneficiaries to opt out of the program.

Medication use Patterns in Elderly South Dakota Medicare Patients

By Jane R. Mort, PharmD; Stephan D. Schroeder, MD; Ryan Sailor, BA

Abstract:

Optimizing medication use through the evaluation of Potentially Inappropriate Medications (PIMs) has been the focus of a great deal of research. The Centers for Medicare & Medicaid Services (CMS) has created its own definition of PIMs from a variety of existing criteria and has contracted with each state's Quality Improvement Organization (South Dakota Foundation for Medical Care in South Dakota) to work on reducing PIM rates. In South Dakota, 16.4 percent of Medicare beneficiaries who filled a prescription (April 1, 2008, through September 30, 2008) received a PIM. Of the patients receiving PIMs, 13.6 percent received PIMs from two or more categories, and 88.3 percent filled a prescription for at least one of the five most common PIM categories. These five PIM categories were propoxyphene, skeletal muscle relaxants (select agents), nitrofurantoin, oral estrogens and antihistamines (select agents). While there may be rare occasions when these agents are justified, safer or more effective alternatives exist.

Introduction

In 2001, the Institute of Medicine estimated that preventable adverse drug events (ADEs) affect 1.5 million people annually.[1] Adverse drug reactions are more common in the elderly population, due to physiologic changes and multiple chronic conditions.[1] In an attempt to identify situations where the risk from a medication exceeds its benefit, numerous lists of potentially inappropriate medications (PIMs) have been created, such as the Beers list (1991, 1997, 2003), 2006 Health Plan Employer Data and Information Set (HEDIS) measures[2] and Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP).[3]

The Beers list, a consensus-based set of criteria,[2] appears to be the most-researched list of medications with site dependent prevalence ranging as high as 24 percent for community patients to 40 percent for nursing home residents.[3] Studies evaluating adverse outcomes associated with use of Beers list medications have yielded mixed results.[2,3] One review article examining 18 studies noted an association of Beers list medications with the occurrence of adverse drug reactions and health care cost but variable associations with hospitalization.[2] Other studies have found admissions to hospitals or emergency departments (EDs) for ADEs are occasionally due to medications on the Beers list but are more often due to other medications (Ireland hospital admissions – 12 percent due to STOPP criteria, [6] percent due to Beers criteria[3]; US ED – 33.3 percent due to warfarin, insulin, digoxin, 3.6 percent due to Beers criteria[4]). While these results suggest other medications also deserve attention, Beers criteria medications did account for a portion of the admissions and are easily avoided.[3,4]

Centers for Medicare & Medicaid Services (CMS)– Patient Safety and Medications

In August of 2008, the Centers for Medicare & Medicaid Services (CMS) contracted with state Quality Improvement Organizations, including the South Dakota Foundation for Medical Care (SDFMC), to begin work on a three-year project under the 9th Statement of Work. As part of the patient safety project, SDFMC is working to improve performance on two Medicare Part D claims-based quality measures – PIMs and drug-drug interactions. The PIM criteria created by CMS contain medications from several lists, including the Beers criteria and HEDIS measures.1 This article focuses on PIMs.

Results - South Dakota PIM Use

According to United States 2000 census data, there were 108,131 residents of South Dakota who are elderly (defined as a person 65 years of age or older).[5] Of the 57,125 elderly South Dakota Medicare Part D beneficiaries living in the community and in nursing homes who received a prescription from April 1, 2008, through September 30, 2008, 16.4 percent (9,382) received one or more PIMs. Of the patients receiving a PIM, 13.6 percent (1,278) received PIMs from two or more categories. PIM agents filled by the largest number of beneficiaries are listed in Table 1 and account for 88.3 percent of all SD beneficiaries who filled a prescription for a PIM. It should be noted that of the 9,382 beneficiaries who received a PIM, 43.4 percent (4,071) had a prescription for propoxyphene and the vast majority of these beneficiaries received a propoxyphene/acetaminophen combination (94.2 percent). The second largest number of beneficiaries received prescriptions for skeletal muscle relaxants, with three-quarters (75.7 percent) of these beneficiaries receiving a prescription for cyclobenzaprine. Nitrofurantoin, oral estrogens and antihistamines rounded out the top five categories.

Table 1.
Distribution of Potentially Inappropriate Medications in South Dakota Based on Part D Claims

Medication Category	Among Beneficiaries Taking a PIM, Percent (n) with the Specified Medication*	Basis for Inclusion as a PIM
Propoxyphene-containing products	43.4% (4,071)	*No advantage and more side effects compared to alternatives*[6]
Skeletal muscle relaxants *(Cyclobenzaprine, Methocarbamol, Carisoprodol, Metaxalone)*	17.4% (1,631)	*Poorly tolerated (anticholinergic, sedation, weakness) at effective doses*[6]
Nitrofurantoin-containing products	16.2% (1,524)	*Renal issues*[6,7]
Oral estrogens *(including combinations)*	12.3% (1,156)	*Cancer (breast, endometrial), not cardioprotective*[6]
Antihistamines *(Promethazine, Hydroxyzine)*	9.5% (888)	*Anticholinergic effects*[6]

* Beneficiaries could be counted in more than one medication category.

Discussion

Comparing the prevalence of PIMs in South Dakota to national data is difficult given variations in medication criteria utilized, study durations and populations examined.[8] For example, the 1991 and 1997 Beers criteria, which served as the basis for many studies, do not contain nitrofurantoin or oral estrogens.[9,10] Yet, these two agents are among the most commonly prescribed PIMs in South Dakota, based on the number of beneficiaries. Reported prevalence of PIMs in the United States have been as high as 24 percent and 40 percent for community and nursing home residents, respectively.[3,8] Studies in Europe have reported lower rates, but this may be due in part to the difference in available medications.[11] South Dakota's prevalence of 16.4 percent of beneficiaries filling PIM prescriptions falls within the United States range.[8] Of the patients receiving PIMs, 13.6 percent in South Dakota received PIMs from two or more PIM categories, which is within the range

of 15 to 26 percent of patients reported in the literature.[8] However, this range is from studies published in the 1990s and, therefore, it is difficult to extrapolate these results to current practices. [8] It is of interest that the use of these medications has persisted despite continued emphasis via revised criteria,[6] multiple studies documenting frequent use[8,11] and articles identifying potential negative outcomes.[2]

According to research examining PIM use, propoxyphene is among the most commonly prescribed PIMs[8] which is consistent with results in South Dakota. Propoxyphene's efficacy has been questioned, and concerns have been raised regarding its side effects.[6] In July 2009, the FDA issued a requirement for a stronger "box warning" regarding the potential for propoxyphene overdose.[12] In addition, the FDA has requested further efficacy testing of propoxyphene and is requiring manufacturers to provide a patient medication guide as to the importance of taking propoxyphene as prescribed.[12] The American Geriatrics Society (AGS) released new practice guidelines on persistent pain in the elderly, which recommend acetaminophen for musculoskeletal pain.[13] Nonselective nonsteroidal anti-inflammatory drugs (NSAIDs) and COX-2 selective inhibitors are to be used rarely and when these agents are used, they should only be prescribed for very select patients.[13] If a nonselective NSAID is used, it should be accompanied by an agent to prevent gastrointestinal problems (i.e., proton pump inhibitor or misoprostol). [13] For moderate to severe persistent pain that affects the patient's function or quality of life, AGS experts recommend considering opioid therapy and mention products containing hydrocodone, oxycodone, fentanyl and morphine.[13]

In South Dakota, prescriptions for skeletal muscle relaxants were filled by the second largest number of beneficiaries taking PIMs. Fick, et al. noted concerns about these skeletal muscle agents, including frequent adverse effects (anticholinergic, sedation and weakness), which limit effectiveness among the elderly.[6] Alternatives to these skeletal muscle relaxants depend on the type of underlying problem. For example, spasticity may be managed with baclofen or tizanidine.[14]

Nitrofurantoin prescriptions were filled by the third largest number of beneficiaries. Issues regarding nitrofurantoin include lack of efficacy with glomerular filtration rates (GFR) less than 20 to 30 ml/min and toxicity (e.g., peripheral neuropathy) due to accumulation with a GFR of less than 50 ml/min.[7] While there may be situations when nitrofurantoin is useful for cystitis (sulfa allergy, local resistance to trimethoprim-sulfamethoxazole (TMP-SMX) > 20 percent),[15] elderly patients need to have their creatinine clearance (CrCl) evaluated because nitrofurantoin is contraindicated when the CrCl is less than 60 ml/min.[7] In addition to peripheral neuropathy, nitrofurantoin has been reported to cause liver damage, pulmonary changes (e.g., pulmonary fibrosis, interstitial lung disease) and hemolytic anemia.[7] Alternatives to nitrofurantoin depend on sensitivity patterns but may include TMP-SMX, TMP, amoxicillinclavulanate and limited fluoroquinolone use.[15] Oral estrogens and antihistamines prescriptions complete the top five PIM categories in South Dakota based on the number of beneficiaries. Table 1 provides a rief overview of concerns for these two categories. Alternatives to oral estrogen depend on the reason for administration. For example, hot flashes may be managed with such agents as selective serotonin reuptake inhibitors, and bone loss may be treated with bisphosphonates.[14] The antihistamines on the CMS list are the more sedating agents with anticholinergic activity.[6,7,14] Options with less sedation and anticholinergic activity include cetirizine and loratadine.[7,14]

The agents described above are examples of preferred alternatives for the PIMs affecting the largest number of beneficiaries in South Dakota. However, careful evaluationof each patient by the prescriber is necessary to identify the best approach.

Conclusion

These results indicate that of the South Dakota Medicare beneficiaries who filled one or more prescriptions during the six-month time frame, (16.4 percent) received a PIM prescription, and the vast majority of these beneficiaries (88.3 percent) filled a prescription for at least one of the five categories of medications listed in Table 1. While there may be infrequent situations that justify the use of these agents, it is generally accepted that there are safer, more effective alternatives. Continued judicious review of these five medications/categories will reduce the use of these agents and potentially the occurrence of adverse outcomes. SDFMC will be working with practitioners to decrease PIM use. Data collection for the project will continue through March 2010.

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"In the January 2010 issue of the SD Pharmacist, we failed to include the statement that "Propoxyphene and Pain management in the Elderly" by Jane Mort, PharmD, and Stephan D. Schroeder, MD was reprinted with permission from the South Dakota State Medical Association (SDSMA) and South Dakota Medicine, the journal of the SDSMA". We apologize for this omission.

AND THE LAW

By Done R McGuire Jr., R.PH., J.D

This series, Pharmacy and the Law, is presented by Pharmacists Mutual Insurance Company and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

Nevada Rules on Pharmacists Duties.....

The Nevada Supreme Court has ruled on the case asking whether seven chain pharmacy owners and one independent owner were rightfully dismissed from the civil case, Sanchez v. Wal-Mart Stores, et al . The case arises from a June 2004 car accident caused by Patricia Copening. She was driving along a busy Nevada highway while under the influence of prescription medications. The accident killed one man, Gregory Sanchez, Jr., and injured another, Robert Martinez.

Prior to the accident, in June 2003, the Nevada Prescription Controlled Substance Abuse Prevention Task Force sent letters to 14 Las Vegas area pharmacies informing them that Copening may be abusing drugs. The letter informed the pharmacies that Copening had received approximately 4,500 hydrocodone tablets from 13 different pharmacies during the previous year. She continued to receive multiple prescriptions for hydrocodone-acetaminophen and carisoprodol between June 2003 and June 2004 when the accident occurred. She appeared confused. The police found prescription bottles and loose tablets in the vehicle. She was found to have hydrocodone in her system. She served nine months in jail after pleading guilty to reckless driving.

A civil case was filed by the Sanchez family, Mr. Martinez and his family against Copening, the doctors prescribing for her, and the pharmacies. The district court dismissed the pharmacies because Nevada law did not impose a duty on the pharmacies to take action after receiving the Task Force letter.

The Supreme Court of Nevada reviewed the case and answered two questions; First, did the pharmacy have a duty to act to prevent their patient from injuring members of the general public, and Second, did Nevada law allow third parties to maintain a negligence per se claim. The case was decided by a 5-2 margin, with a strong dissent.

The majority and the dissent agreed that under Common Law principles, a person has no duty to control the dangerous conduct of another person or to warn others of the dangerous conduct. There is an exception to this rule however. If there is a special relationship and the harm is foreseeable, the there is a duty to act. The majority and dissent diverged on the analysis of whether a special relationship existed in this case because they weren't consistent on which parties form this special relationship. The majority talked about the relationship between the pharmacy and the victim, while the dissent talked about the relationship between the pharmacy and the patient. The majority notes that the pharmacy had no relationship with the victims and that they were, in fact, unidentifiable prior to the accident. This is an important point in the analysis because it is clear that there is a special relationship between a pharmacy and its patients.

The majority noted that the pharmacy had no requirement to act after it received the Task Force letter. However, they pointed out in a footnote that the regulations had changed since this incident, but declined to opine as to whether the decision would be different because of the rule changes. The ruling in the case was that the pharmacies had no duty to act because the law didn't require them to act and there was no special relationship formed that would require them to act. The majority also ruled that a negligence per se claim could not be maintained because the laws in question were not intended to protect against the injuries that the plaintiffs had sustained.

While the pharmacies were dismissed in this case, the case should serve as a wakeup call to pharmacists. The dissent made some strong arguments, and even the majority hinted that the answer might be different under today's laws. The court here said that the pharmacies did not have a duty to act upon information received from the task force, so they never provided guidance as to what a pharmacy should do if it were required to act. This issue is very likely to come up again and the next court could find that the pharmacy was required to act. Prescription drug monitoring programs work by providing information that a single pharmacy or prescriber is unlikely to obtain on their own. In the past, a single pharmacy was usually unaware of all of a patient's activities in acquiring controlled substances and didn't have enough information to take any action. In the present case, the pharmacies were notified that the patient was getting prescriptions filled at 12 other pharmacies around town. It is very possible that this additional information might provide the basis for a court or legislature to make a major change in the law of negligence.

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FINANCIAL FORUM

This series, Financial Forum, is presented by Pro Advantage Services, Inc., a subsidiary of Pharmacists Mutual Insurance Company, and your State Pharmacy Association through Pharmacy Marketing Group, Inc., a company dedicated to providing quality products and services to the pharmacy community.

Pay Yourself First!

No matter how hard you try to avoid it, sometimes it seems like your day-to-day living expenses just eat away at your entire paycheck. Before you know it, the money in your paycheck seems to vanish, and you don't even know where it went. And while you're focused on just making ends meet, putting money away for the future may be the last thing on your mind. Even so, you need to remember that taking care of your longer-term financial goals is just as important as meeting your current needs.

Ever since the days of putting pennies in a piggybank, you've likely received plenty of advice on the value of saving your money. But when mom and dad aren't taking care of the necessities any more, and you have your own bills to pay, it's easy to lose track and forget to save. As a reminder of just how important it is to put part of your income aside – and to do it sooner, rather than later – take a look at an example of just how the numbers shake out.

For this example we'll use two investors – one who starts early and lets her savings grow, and another who waits until later to begin. Let's say the early investor puts away $5,000 per year for five years, and then allows that investment to grow for 15 years without putting in another penny. The late investor, on the other hand, waits for 10 years before he even begins his savings plan. He then invests $5,000 a year for 10 years, putting his total investment at $50,000 – exactly twice as much as the early investor.

Assuming an eight percent average annual rate of return on their investments, if we jump ahead now to 20 years from the time our two investors started, the difference in their accounts is substantial. Our early investor would have accumulated a total of roughly $100,493 in her account by this time. Keep in mind she hasn't put a penny of her own money in for the last 15 years. Meanwhile, the late investor's account has grown to only $78,227, and he has been contributing each year for the past ten years. That means that our early investor only put in half as much of her own money, and came out well over $20,000 ahead.

Now, this example is only meant to illustrate the advantages of saving regularly and starting early. This does not reflect the performance of any specific investment, nor does it take into account the eventual effects of taxes. It does, however, make the point very clear – by delaying 10 years in getting started, the late investor loses out on the benefits of compounding over a longer period of time.

Disciplined investment habits aren't always easy to come by, but there are several things you can do to improve your savings routine. One of the easiest ways to establish a savings plan is by taking advantage of the convenience of electronic funds transfer (EFT). You may be familiar with this type of service if you currently receive or make electronic deposits to your bank account. This service is also available from other financial services firms, and paying yourself first by using an EFT system can help you get in the habit of saving.

Direct deposit allows you the opportunity to deposit all or part of your paycheck to the account of your choice, so you could choose to set aside a certain portion to go directly to a savings account as opposed to your checking account. Another way to take advantage of EFT is to set up an automatic monthly deposit. This is a simple, disciplined way to add to your account, authorizing a specific amount to be transferred from one of your accounts to another (i.e. from checking to a savings or investment account).

Regardless of which method you choose – or even if you decide on completely different investment strategy – putting aside money now will help you prepare to reach your financial goals that lie further down the road.

Provided by courtesy of Pat Reding, CFP of Pro Advantage Services Inc., in Algona, Iowa. For more information, please call Pat Reding at 1-800-288-6669.

Continuing Education for Pharmacists

Patient Counseling: Natural Products: Barley to Betaine

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Goals.
The goals of this lesson are to present information on the claims mechanisms of action, typical ' dosages, and other items of interest on natural products and nutraceuticals alphabetically from barley to betaine, and to provide background information to assist in their proper selection and use.

Objectives. At the conclusion of this lesson, successful participants should be able to:

1. exhibit knowledge ofthe claims, mechanisms of action and typical dosages for natural products and nutraceuticals presented;
2. select from a list, the synonyms for these products; and
3. demonstrate an understanding of information that can be used when counseling patients about these products.


Gossel


Wuest

The paramount difference between drugs and natural products was explained in the first lesson in this series. Since natural products are a very controversial topic for some health professionals, the authors restate that the information presented is neither a promotion of, nor condemnation of, their use. It is merely an overview of what has been reported in both the public and scientific literature, and certainly not an in-depth treatise.

Products reviewed in this lesson are listed in Table 1. Additional sources (web sites) of information on natural products are provided in Table 2.

Barley

Barley *(Hordeum vulgare, Hordeum distyclium),* also known as pearl barley, pot barley and scotch barley, has been used as a food and a medicine for millennia. Records of its use as a cereal date back to 7000 BC. It is considered to be the first cereal grain cultivated by humans, with widespread use as a food staple in ancient Chinese and Middle Eastern cultures. At this point in time, barley is cultivated worldwide.

'I'oday, barley has been replaced

VolumeXXI,No.3 in the baking process in this country by wheat and rye, but it is still used extensively in making beer and other alcoholic beverages, and in cereals, malt sugar and animal foods.

Historically, barley has been used medicinally for treating boils, bronchitis, diarrhea and inflammation; to increase strength and stamina; for liver dysfunction; and topically for skin disorders. Nowadays, it is used to lower blood sugar, cholesterol and lipid levels and for weight control.

Barley leaves contain the provitamin beta-carotene, vitamins B $B_{J'}$ $_{2'}$ B_G, B_G, B12 and folic acid; the minerals calcium, iron, magnesium, phosphorus and potassium; and the enzymes nitrogen reductase (involved in nitrogen transfers) and superoxide dis mutase (involved in reduction of oxygen free radicals that are toxic to cells). Barley grain contains the fiber beta glucan which is also present in oat bran. It also contains an enzyme diastase (catalyzes conversion of starches into sugars), which allows it to ferment.

It is the fiber content of barley that reportedly provides activity in reducing cholesterol levels and controlling hyperglycemia in humans. In studies in rats, barley grain has been reported to reduce

Table 1
Natural Products Covered in this Lesson

- Barley
- Basil
- Bayberry
- Bee pollen
- Beta -carotene
- Beta glycans
- Betaine

Table 2
Representative Sources for Information on Natural Products

American Botanical Council	www.herbalgram.org
Facts and Comparisons	www.factsandcomparisons.com
Food and Drug Administration	www.fda.gov *(click* 011 *Food)*
National Center for Complementary and Alternative Medicine of the National Institutes of Health	www.nccam.nih.gov
PDR for Herbal Remedies PDR for Nutritional Supplements	www.pdr.net
Pharmacist's Letter	www.naturaldatabase.com

the risk of colon cancer, but this has not yet been demonstrated in humans. For weight control, it has been hypothesized that beta glucan slows the stomach emptying time, promoting a feeling of fullness and stabilizing blood sugar levels.

Basil

Basil *(Ocimum beeilicumi,* also known as common basil, garden basil, St. Josephwort and sweet basil, has been used in Chinese medicine for spasms of the stomach, kidney disorders and to promote circulation before and during childbirth. Topically, it was used to treat insect bites and snake bites. Basil reportedly originated in India, but is now cultivated around the world.

In Western folk medicine, basil is used as an antiflatulent, a diuretic, for treatment ofthe common cold, and as an appetite stimulant. It is used as an astringent in gargles.

The above-ground plant parts are used as a spice. In levels below 0.005 percent, basil has GRAS (Generally Recognized as Safe) status in the U.S., which means it can be used in processed foods as a flavoring agent.

Only the above-ground plant parts of basil are considered safe and useful for medicinal purposes. It is a rich source of vitamin C, calcium, iron, magnesium and potassium.

The typical dose of basilleaf' is one cup offreshly brewed, strained tea, two to three times a day between meals. The tea is prepared by steeping 2 to 4 grams of basil leaf in 150ml of boiling water for 10 to 15 minutes, then straining the tea before ingesting it.

Bayberry

Bayberry *(Myrica cerifera),* also known as candleberry, southern bayberry, southern wax myrtle, tallow shrub, vegetable tallow, wax myrtle and waxberry, grows throughout the eastern and southern U.S. Its berries contain a waxy substance used to make candles.

In folk medicine, bayberry bark and berries are used internally to treat diarrhea and colds, to reduce fever, and as a stimulant and tonic. Topically, the bark is used as a gargle for sore throat, as an astringent douche for vaginal discharge and on the skin for wound healing.

The mechanism of action for bayberry as an astringent is attributed to its tannin content. While bayberry may smell pleasant when burned in candles, the high tannin content is considered too toxic for oral ingestion.

Topically, the typical dose of bayberry bark is 600mg to 2 grams of powdered bark, steeped in boiling water, strained and cooled, then applied to the affected area three times a day.

Bee Pollen

Bee pollen consists of plant pollens, nectars and bee saliva collected from worker honeybee *(Apis meliierei* colonies. Records of its use have been found in ancient Egyptian and Chinese records, which refer to it as the "fountain of youth" and "ambrosia of the gods." Hippocrates reportedly used bee pollen as a healing substance. During the 1970s, the use of bee pollen in the U.S. surged due to heavy promotion and testimonials by athletes that supplementation with bee pollen increases stamina and performance.

The contents of bee pollen are not standardized. There is no doubt that it is an excellent source of nutrition for male drone bees in the colony's hive. Bee pollen contains up to 55 percent carbohydrates, 30 percent protein, 20 percent lipids, 6 percent vitamin C, 3 percent minerals (including boron, calcium, chlorides, copper, iodine, iron, manganese, magnesium, molybdenum, phosphorus, potassium, silicon, sodium, sulfur and titanium), along with all of the B vitamins, folic acid, choline, inositol, vitamins D, E and K, as well as trace amounts of organic substances. However, the actual composition of any given product varies depending on the plant sources ofthe pollen and geographic region of the bee colony.

In nature, the pollen collected by worker bees is combined with plant nectar and bee saliva which is packed into small dust pellets. These are then implanted in the hive for use as food by male drone bees serving the queen. The pollen is made up of germ seeds of plants, flowers or blossoms on trees.

For commercial sale, bee pollen is collected at the entrance of the hive when worker bees are forced to enter through a portal partially obstructed with wire mesh. This brushes the pollen off the hind legs of the bees into a collection vessel. When the use of bee pollen surged, methods of collecting the materials directly from within the hives were developed. Alternately, a process using wind-blown pollen to automatically pollinate plants was conceived. Many commercial products contain added nutritional

supplements. Some reportedly have over 100 ingredients listed on their label.

Orally, bee pollen is used as a nutritional supplement, to treat alcohol intoxication, to increase sexual function, to enhance the immune system, as an appetite stimulant, as a tonic to improve stamina and athletic ability, to prevent premature aging; and to treat hay fever.iallergic rhinitis, mouth sores, arthritis, enlarged prostate and painful urination, bleeding problems, menstrual problems, constipation, diarrhea and colitis. It is used topically for skin care and as a skin softening agent. While many reports of effectiveness have been made, they are not supported scientifically in clinical studies.

Even though it has been promoted to treat allergies, the large and varied contents of possible allergens in bee pollen have actually caused allergic reactions, including severe anaphylaxis. It is definitely contraindicated in persons with known allergy to plant or bee pollen.

Bee pollen is commercially available in granule, capsule, tablet, chewable tablet, liquid and powder forms. The typical dosage is 500mg, two to three times a day.

Beta-Carotene

Beta-carotene, also known as provitamin A, is a member of a class of substances called carotenoids. It is a fat-soluble pigment found primarily in nature in plants, algae and photosynthetic bacteria. In these bacteria, beta -carotene serves as a light-gathering pigment and to protect these organisms against oxygen, which would be toxic to them.

In fruits and vegetables, carotenoids are the pigments principally responsible for imparting their green, yellow, orange and red coloration. It is present in relatively large amounts in carrots, cant a - loupe, spinach, broccoli, palm oil and collard greens.

The average American diet reportedly provides 1.3 to 2.9mg of beta-carotene daily. The National Cancer Society and a number of governmental agencies recommend eating five or more servings offruits and vegetables daily to provide 3 to 6mg.

Beta-carotene is used to treat vitiligo (discoloration ofthe skin) and erythropoietic protoporphyria (a type of photosensitivity involving eczema, itching and rash), to reduce exercise-induced asthma attacks, and to decrease the risk of several types of cancer (including lung, prostate and breast), cardiovascular disease, cataract formation and agerelated macular degeneration. Clinical studies in humans have not yet substantiated the effectiveness of beta-carotene for these uses.

There is evidence that supports its antioxidant activity. It has been demonstrated that, in the body, beta -carotene neutralizes singlet oxygen ions, scavenges for peroxyl radicals and inhibits lipid peroxidases. However, evidence that it has a unique role in human nutrition or disease beyond its provitamin A function is lacking.

There are both natural and synthetic beta-carotene products on the market, but it is controversial as to whether there is any significant difference between the two.

Supplemental dosages of beta-carotene range from 3 to 15mg daily. But, doses up to 300mg have been used in the treatment of erythropoietic protoporphyria.

Beta Glycans

Beta glycans, also known as beta glucans, beta-l,3-glucans and beta-l,3/l,6-glycans, are naturally occurring carbohydrates derived from numerous plants, including barley, baker's yeast, mushrooms, oats and algae.

Beta glycans are used to activate the immune system in patients with HIV infection and cancers, to lower total cholesterol and LDL-cholesterol levels in patients with hypercholesterolemia, for wound healing following surgery or trauma, and to protect against colds and flu.

Baker's yeast derived beta-l,3/1,6-glycan is rated as Generally Recognized as Safe for use as a food additive by FDA. Some experts suggest it may potentiate airway allergy response.

The reported mechanism of action for beta glycans is that they increase the production of cytokines such as tumor necrosis factor (a substance formed in the immune system that destroys mutated cells, e.g., cancer cells) and some subsets ofT-cells (specialized cells important to the immune response system). They are also claimed to enhance the activity of macrophages (scavenger cells in the body that destroy invaders and set off the immune response). Since beta glycans are soluble fiber components in grains such as barley and oats, they could lower cholesterol levels. As far as therapeutic value is concerned, results of studies appear to be promising, but benefits in treating humans have not yet been confirmed.

The typical dosage for beta glycans is 75 to 250mg daily.

Betaine

Betaine, also known as glycan betaine, lycine, oxyneurine and trimethylglycine, is widely distributed in plants and animals. It was originally discovered in sugar beet juice.

In humans, betaine is a metabolite of choline and, therefore, is not a recognized essential nutrient. In otherwise healthy persons, sufficient amounts of betaine can be derived from endogenous choline. Betaine is involved in one of the metabolic pathways that converts homocysteine (an intermediate product of cysteine metabolism) into methionme.

The principle system for the manufacture of methionine in the body involves folic acid and vitamin B_{12}• While betaine is not an essential nutrient, its anhydrous form has been awarded orphan drug status by

the FDA for treatment of patients with homocystinuria (a rare genetic disorder caused by inborn errors in metabolism) who do not respond to other therapies. Unresolved homocystinuria results in mental retardation, thromboembolic episodes, fatty degeneration of the liver, and early death.

Orphan drug status means that the drug is not approved for general use in the public. The target population is so small (fewer than 200,000 patients worldwide) that the developer could never recover the costs of compliance with FDA's requirements for proof of safety and effectiveness. Additionally, the drug is so important to its patient population that it would be unethical to deprive the placebo group of patients, needed for full FDA approval, from receiving a life-saving drug.

Therefore, FDA allows availability of these orphan drugs by their sponsors under prescribed protocols. The sponsors receive incentives (such as tax credits and sole distribution rights) to help the few patients who would benefit from them. Sometimes, as in this instance, orphan "drugs" are natural products.

Aside from its orphan drug status, there are claims that betaine, along with choline and methionine, prevents fatty degeneration of the liver in persons without homocystinuria by inhibiting the deposition offat in the liver and accelerating its removal. The theory is that these substances mediate their beneficial effects by enhancing availability and action of the body's principle transmethylation (transferring methyl groups from one chemical to another) agent, S-adenosylmethionine (SAMe).

There is evidence that SAMe promotes the health of the liver, especially by its role in forming phospholipids, which are essential for development, maintenance and functioning of cell membranes. The role of betaine is related to the transfer of its methyl group to methionine, which is then converted to SAMe. While betaine has been found to have a liver protection activity in experimental animals against toxicity from ethanol and carbon tetrachloride, this action has not been demonstrated in humans.

As an orphan drug, the typical dose of betaine anhydrous (trade name Cystadane"), following the proper protocol in patients with homocystinuria, is 3 grams twice a day.

The above described anhydrous form of betaine should not be confused with another form, betaine hydrochloride. The latter is a delivery form of hydrochloric acid that is claimed to be a digestive aid when taken orally, alone or in combination with pepsin.

Betaine hydrochloride was once a common item on pharmacy shelves along with other pepsin products and combinations, until FDA's massive review of the OTC market in the 1970s. As an OTC, betaine hydrochloride was sold as a digestive aid to persons with little or no hydrochloric acid production in their stomach. The idea was that the hydrochloric acid provided by the betaine hydrochloride would aid conversion of pepsinogen into pepsin (occurs at pH 3 or less), which is required for proper digestion of dietary protein.

As a result of FDA's first ever review ofthe literature and manufacturer-supplied information on the safety and effectiveness of OTC product ingredients, betaine hydrochloride, as well as hundreds of other previously included ingredients, was banned as an OTC drug product. FDA's advisory panel of experts could find no evidence to support the effectiveness of betaine hydrochloride for any condition. FDA ruled that it could not be marketed as an aTC drug product.

Some manufacturers/distributors changed their labeling and altered the official status of their betaine hydrochloride from an aTC drug to natural product. Natural products such as herbal remedies and "natural" medicines are not under FDA jurisdiction as long as their distributors do not make any therapeutic claims on the label. The label must contain the notice that "this product is not intended for the diagnosis, treatment, cure, or prevention of any disease," and it must inform consumers that it has not been approved by FDA.

Instead, betaine hydrochloride products are promoted and labeled as being "a supplemental source of hydrochloric acid."

The typical adult dose for betaine anhydrous for homocystinuria is 3 grams taken twice a day. The dose is dissolved in 4 to 6 ounces of water immediately before ingestion.

The typical adult dose for betaine hydrochloride is 325 to 650mg once a day after a meal that contains protein. It is recommended that betaine hydrochloride not be taken on an empty stomach.

Betaine hydrochloride and betaine anhydrous are not interchangeable and care must be taken not to confuse them with each other.

Continuing Education Quiz

"Patient Counseling: Natural Products: Barley to Betaine"

1. Nowadays, barley is used to lower blood levels of all of the following EXCEPT:
   a. alcohol
   b.cholesterol
   c. lipids
   d. sugar

2. Barley grain is able to ferment starches because it contains which ofthe following enzymes?
   a. Cytochromase
   b. Diastase
   c. Oxidase
   d. Reductase

3. Basil is also known as:
   a. St. Jameswort
   b. St. Johnswort
   c. St. Josephwort
   d. St. Liverwort

4. The mechanism of action for bayberry as an astringent is attributed to its:
   a. ascorbic acid content
   b. beeswax content
   c. beta glycans content
   d. tannin content

5. Bee pollen contains which ofthe following substances in highest percentage?
   a. Carbohydrates
   b. Lipids
   c. Minerals
   d. Proteins

6. The typical dose of bee pollen is:
   a. 3 to 15mg daily
   b. 75 to 200mg daily
   c. 500mg two to three times a day
   d. 600mg three to four times a day

7. Beta -carotene is a member of the precursors for which of the following vitamins?
   a. A
   b.B
   c. C
   d.D

8. Claims are made that the mechanism of action of beta glycans involves all of the following EXCEPT:
   a. increased production of cytokines
   b. increased production oftumor necrosis factor
   c. enhanced activity of macrophages
   d. enhanced activity of cytochrome P450 enzymes

9. The soluble fiber component of grains such as barley and oats that could potentially lower blood cholesterol levels is:
   a. beta-carotene
   b. beta glycans
   c. beta leucine
   d. beta sitosterol

10. Betaine is involved in one of the metabolic pathways that converts homocysteine into:
   a. methacholine
   b. methenamine
   c. methionine
   d. methylcysteine

This course expires on: December 10, 2012
Target audience: Pharmacists and Pharmacy Technicians

The South Dakota State University College of Pharmacy is accredited by the Accreditation Council for Pharmacy education as a provider of continuing pharmacy education. The Universal Program Identification numbers for this program are: #0063-0000-09-035-H01-P, #0063-0000-09-035-H01-T..

To receive 1.5 Contact Hours (0.15 CEUs of continuing education credit, read the attached article and answer the 10 questions by circling the appropriate letter on the answer form below.

A test score of 70% or better will earn a *Statement of Credit* for 1.5 Contact Hours (0.15 CEUs) of continuing pharmacy education credit. If a score of 70% is not achieved on the first attempt, another answer sheet will be sent for one retest at no additional charge.

Learning Objectives - Pharmacists: *1. Exhibit knowledge of the claims, mechanisms of action and typical dosages for natural products and nutraceuticals presented; 2. Select from a list, the synonyms for these products; 3. Demonstrate an understanding of information that can be used when counseling patients about these products.*

Learning Objectives – Technicians: *1. Describe the common uses for barley, basil, bayberry; 2. Identify the major ingredients of bee pollen and list typical dose; 3. Evaluate the nature of soluble fiber (from grain such as oats, barley).*

"Patient Counseling: Natural Products: Beta-sitosterol to Black Cohosh" *(Knowledge-based CPE)*

Circle the correct answer below:

1.	A	B	C	D	6.	A	B	C	D
2.	A	B	C	D	7.	A	B	C	D
3.	A	B	C	D	8.	A	B	C	D
4.	A	B	C	D	9.	A	B	C	D
5.	A	B	C	D	10.	A	B	C	D

Course Evaluation – must be completed for credit.

1 Disagree - 7 Agree

Material was effectively organized for learning: 1 2 3 4 5 6 7

Content was applicable / useful in practice 1 2 3 4 5 6 7

Each of the stated learning objectives was satisfied: 1 2 3 4 5 6 7

List any learning objectives above not met in this course:

_____

Course material was balanced, noncommercial: 1 2 3 4 5 6 7

Length of time to complete course was reasonable for credit assigned: 1 2 3 4 5 6 7

(Approximate amount of time to preview, study, complete and review this course: _____)

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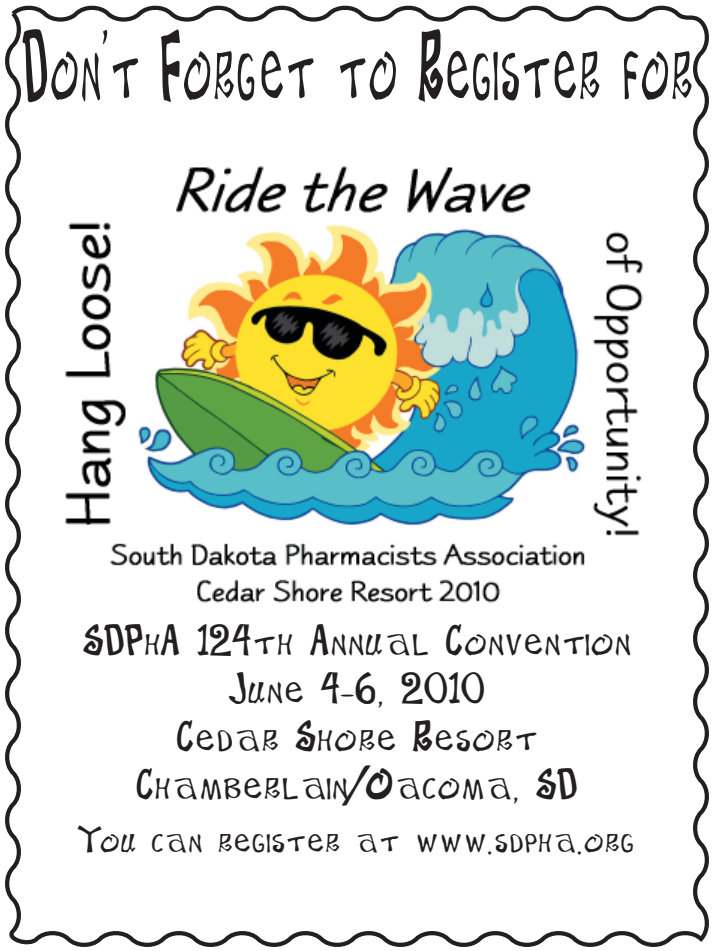

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Pierre, SD 57501-0518