Proposed “Patient Bill of Rights for Prescription Drugs” under ACA

Two years after enactment of the Affordable Care Act (ACA), almost every state in the union has implemented one or more items from the law’s early insurance market reforms, referred to by the Commonwealth Fund as “The Patient Bill of Rights.” Some of these early market reforms include coverage for dependents until age 26; coverage for persons younger than age 19, regardless of preexisting conditions; prohibition of lifetime limits on essential health benefits; access to a gynecologist without a referral; access to copayment-free preventative services; increased flexibility in choosing a pediatrician; and expanded coverage of emergency services.

Continued on page 2
IN MY VIEW  Frederick S. Mayer, RPh, MPH

Proposed “Patient Bill of Rights for Prescription Drugs” under ACA

Continued from page 1

I would like to propose that the following issues be put into a “Patient Bill of Rights for Prescription Drugs” under ACA:

1. All prescription (Rx) and nonRx drugs, along with over-the-counter (OTC) drugs and herbals, will include a consultation with a pharmacist and healthcare professional as required by OBRA ’90.

2. All Rx drugs, OTCs, and dietary supplements will have a patient history review and documentation by pharmacists and healthcare professionals as required by OBRA ’90.

3. All Rxs, OTCs, and dietary supplements will be available with readable labels for glaucoma, macular degeneration, and vision diseases for readability in a 12-point font.

4. All Rxs will have Rx translation available for foreign-born or language-impaired patients/consumers.

5. Six classes of Rx drugs approved under Medicare Part D will not be swapped for other drugs, once the patient is titrated on those meds. These are antineoplastics, antiretrovirals, immunosuppressants, anticonvulsants, antipsychotics, and antidepressants.

6. Medication therapy management (MTM) will be performed for all new and old patients by pharmacists and healthcare professionals trained in pharmacology and registered with their BOPs.

7. Pharmacy and therapeutic committees (P&T committees) will be available, with consumer/patient input, to put together prescription drug formularies that are noncommercial in nature.

8. Appointed by a state/government entity under ACA, these P&T committees will be available/transparent to all patients/users.

9. New bio-drugs coming onto the market will be available to all chronic care patients, and also be available with prior authorization and treatment authorization requests (TAR).

10. Co-pays will be available, accessible, and affordable to all chronic care patients, and also be available with prior authorization and treatment authorization requests (TAR).

11. Prior authorization and TARs should be available through pharmacies and healthcare providers, with a 20-30 minute approval rating (currently standard under Medi-Cal).

12. Pain medication, both narcotic and non-narcotic, will be available to all chronic care patients, and also be available with prior authorization and treatment authorization requests (TAR).

13. Take-back programs for patient Rxs should be available at all U.S. pharmacies, with county public health facilities incinerating unwanted, outdated, and unused drugs.

14. Any financial incentives healthcare providers obtain for recommending, prescribing, or switching a medication should be disclosed to the patient in writing.

15. Patients and physicians seeking an appeal must have immediate telephone access to an insurance healthcare administrator who can explain or overturn a treatment denial.

16. Insurer-mandated therapeutic substitution must be limited to no more than two step-edits, per Medicare guidelines, in order to ensure timely access to working treatments when insurer-preferred medications fail.

17. Only the treating provider should be able to determine the duration of therapy for any recommended treatment.

18. Insurer co-pay or co-insurance increases should occur only during the enrollment period, with clear notification to the beneficiary, to prevent cost changes that could disrupt treatment.

19. Compounded Rxs will be available from licensed, certified, and trained pharmacists for all ACA patients.

20. Consultant pharmacists should be available to skilled nursing facilities for monthly reviews and quarterly reports for all patients. These services should be compensated.

Fred Mayer has been a practicing pharmacist for over 50 years. He is president of Pharmacists Planning Service, Inc., a nonprofit public health, consumer, and pharmacy education organization. He is also a member of Drug Topics’ editorial advisory board. Contact him at ppsi@aol.com.
Honors - Paul Lofholm

Paul Lofholm, PharmD, FAC, Past President of California Pharmacists Association (CPhA) and Clinical Professor, UCSF, Touro University, and University of Pacific Schools of Pharmacy and recipient of the American Pharmaceutical Association’s Remington Medal for 2011 will be awarded the distinguished person of the year by Pharmacy Planning Services, Inc (PPSI) for 2011

Paul’s award will be given out at the PPSI annual breakfast during the American Pharmacy Association (APhA) annual meeting March 3, 2013 at the JT Marriot Hotel in Los Angeles during the annual APhA meeting.

Dr. Lofholm is being recognized for his commitment to the profession of pharmacy as an agent of change, educator, innovator, clinician, pharmacy leader, policy maker, and community activist.

All friends and colleagues are invited to attend the PPSI free breakfast sponsored by Drug Topics Magazine and PPSI.

PPSI member attention Public Health Priorities 2013:

To access 54 public health pharmacy educational and informational public health programs, including 2013 PPSI campaigns including Adherence, Stroke Month, Don’t Smoke, Poison Prevention, STD, Men’s Health, Diabetes, Take-back of drugs, Privacy, etc. please go to PPSI’s website: www.PPSIinc.org.

New current educational programs on Poison Prevention, Smoking cessation, confidentiality issues, and its latest PPSI 2013 program on Men’s Health.

To download PPSI’s February 7, 2013 presentation at the American College of Apothecary (ACA) in Dana Point, California please click here.
When these patients subsequently show up at the pharmacy counter with bags full of unwanted medications, they are usually turned away.

The result? Patients remain in a state of confusion produced by conflicting messages from the federal government and environmental resources regarding the proper disposal of pharmaceutical waste.

Where it goes

Many pharmacists tell patients that medication could be safely disposed of by grinding it up and mixing it with coffee grounds or cat litter — an FDA-approved disposal method if no medication take-back program is available.

This method is not the answer that patients are looking for, and they are forced to continue their old habits of improper disposal or simply leave the pharmaceutical waste in their medicine cabinets.

These negative behaviors have created two major public health issues: surface water contamination by pharmaceutical compounds and drug diversion.

According to a recent CDC study, approximately 27,000 unintentional drug overdose deaths occurred in the United States in 2007, which equates to one death every 19 minutes.

It has also been over 10 years since the 2002 U.S. Geological Survey found that 80% of waterways contained measurable amounts of prescription drugs. This problem has been going on for quite some time, and many states still have not mandated a solution to the improper disposal of pharmaceutical waste.

That is, nothing had been done until San Francisco Bay area pharmacists and pharmacy students at Touro University California joined forces with Nate Miley, the president of the Alameda County Board of Supervisors, to draft legislation that made Alameda County the first county in the United States to require safe medication disposal.

Bay Area leads the way

Pharmacists from the Marin County Pharmacists Association provided valuable input into the drafting of the countywide Safe Drug Disposal Ordinance, as they were the first to establish drug take-back programs at various independent and retail pharmacy locations in their county.

During a series of stakeholder meetings that took place during May 2012, supporters of the ordinance met with drug manufacturers to come to agreement over the exact language of the policy draft. Pharmacy students from Touro University California attended these meetings, provided testimony at the hearings, and led a grassroots letter-writing campaign to support the proposed legislation.

Drugmakers held liable

On July 24, 2012, the Alameda County Board of Supervisors passed this groundbreaking policy designed to hold producers responsible for disposal of unwanted drugs and to reduce the number of accidental deaths caused by poisoning among older adults from overdoses of over-the-counter, prescription, and illicit drugs. In addition, this safe medication disposal program aims to decrease access and availability of drugs to youth of all ages. Failure to comply with the countywide ordinance will cost drugmakers $1,000 a day in fines.

Currently, San Francisco, San Mateo, and Contra Costa counties have contacted Alameda County about adapting the ordinance to their needs.

Supporters of safe drug-disposal programs have applauded Alameda County’s leadership and are encouraging other counties in the state and the nation to proceed with the adoption of similar ordinances, in the hope that this will lead to national action.

Kevin Carrasco is a 2013 PharmD/MPH candidate at Touro University California College of Pharmacy. E-mail him at kevin. carrasco@tu.edu.
PhRMA files suit on drug take-back program

Drug-disposal law OKd in Alameda County
Stephanie M. Lee
Updated 1:07 pm, Wednesday, July 25, 2012

A nationally unprecedented law telling the pharmaceutical industry it must pay to get rid of prescription drugs won approval from Alameda County lawmakers Tuesday.

The county's Board of Supervisors cast their final votes, 5-0, on the Safe Drug Disposal Ordinance, which requires producers of drugs sold or distributed in the county to pay for the safe collection and disposal of unused medications. Failure to comply will cost drugmakers $1,000 a day in fines.

The law, based on a British Columbia program, shifts the cost of disposal from taxpayers to drug companies. Currently, residents can discard pills they no longer need at 28 publicly funded drop-off locations, which cost an estimated $330,000 to run annually.

Environmentalists, health advocates and residents heralded the new law for its attempts to protect consumers' health and the environment. By ensuring private funding for disposal programs, it intends to keep old or unused drugs beyond the reach of youths and senior citizens, who could misuse or abuse them, as well as out of drains where they could pollute waterways.

"Today is a huge accomplishment, not only for Alameda County, but for everyone who cares about the issue of safe drug disposal," said Nate Miley, the ordinance's sponsor and president of the Board of Supervisors. "It's time for drug companies to take responsibility for their products and to dispose of leftover drugs they manufacture."

Andria Ventura, program manager for the water-pollution prevention group Clean Water Action, noted that pharmaceutical companies will have to do more, such as make drugs that absorb more efficiently into the body, to eliminate drug chemicals entirely from public waters.

"We shouldn't have drugs in our water," she said. "While this won't take care of the entire problem, it certainly is the low-hanging fruit that we can take to make a significant dent in addressing the problem."

Pharmaceutical industry officials opposed the law, arguing that it does not guarantee drugs will be correctly used, nor will it affect drug chemicals that end up in the water through people's excretion.

They also called the law vague. Drugmakers will be permitted to run a disposal program independently or with other companies. Each manufacturer can also decide how the program will work, such as by setting up a series of drop-off locations or providing customers with prepaid envelopes to give people a way to ship off old medications.

They have until July 1, 2013, to submit plans to the county for approval.

"Instead of waiting to see what works, we're running off without good data to put a program into place that's very vague, very general and, ultimately, going to be very difficult for us to provide," said Ritchard Engelhardt, vice president of government affairs for BayBio, which represents Northern California's bioscience industry.

But the program has worked in British Columbia since 1997, involving many of the manufacturers also present in Alameda County, said Heidi Sanborn, executive director of the California Product Stewardship Council. Now it's time to put those lessons to work in California, she said.

"If they can create drugs," she said, "they can figure out how to collect pills."

Stephanie M. Lee is a San Francisco Chronicle staff writer. E-mail: sle@sfcchronicle.com Twitter: @stephaniemlee

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NATIONAL TAKE-BACK INITIATIVE
Upcoming Take-Back Day - April 27, 2013 (10:00 AM - 2:00 PM)
Sponsored by PPSI/DEA/FDA and your local Pharmacists
21st Annual - WILLIAM R. BACON MEMORIAL BREAKFAST
Saturday, March 16, 2013; Breakfast: 6:30 a.m. - 9:00 a.m.
Marriott Hotel, Monterey, California

“TYING TOGETHER ISSUES IN PHARMACISTS’ STANDARDS OF PRACTICE & PHARMACEUTICAL CARE”

Sponsored by:
Pharmacists Planning Service, Inc. (PPSI) & Pharmacy Defense Fund (PDF)
Marin County Pharmacists Association (MCPhA)
Independent Pharmacists Association (IPA)
University of California School of Pharmacy Alumni Association
Academy of Employee Pharmacists (AEP/CPhA)

WELCOME
Aglaia Panos, Pharm.D.
President, Marin County Pharmaceutical Association (MCPhA)
Adjunct Professor, Touro University School of Public Health
Vice President, PPSI

INTRODUCTION
“CPhA’s Priority/Public Health Issues”
Jon Roth, CEO
California Pharmacists Association (CPhA)

Fred Mayer, RPh, MPH
President, PPSI

MODERATOR
Paul Lofholm, Pharm.D.
Past President, CPhA (emeritus) & Clinical Professor, UCSF
Recipient, APhA’s Remington Medal, 2011
Kentfield, California

Recipient of the William R. Bacon Student Community Award
“PHARMACY MILITANCY: TIME FOR ACTION”
Dan Hussar, PhD
Dean Emeritus, Philadelphia College of Pharmacy, University of the Sciences

“CALIFORNIA PRIVACY ACT”
Joanne McNabb
Director, Privacy Education/Policy Office
State of California, Department of Justice

“STANDARDS OF PRACTICE IN THE PHARMACY PROFESSION”
Mark R. Raus, R.Ph.
Treasurer, Independent Pharmacists Association (IPA)

“PHARMACY LITIGATION ISSUES”
Natallia Mazina, Esq.
Attorney & Counselor-of-Law

“REDUCING ERRORS AND THE PHARMACISTS’ ROLE”
Adam Kaye, Pharm.D.,
Professor, University of Pacific College of Pharmacy, Stockton, California

SUMMATION OF PROGRAM:
WHERE DO WE GO FROM HERE? WHAT NEEDS TO BE DONE? WHO WILL DO IT? WHEN?
Aglaia Panos, Pharm.D.

This meeting is being held in conjunction with the CPhA Annual Meeting
Marriott Hotel, March 2013, Monterey, California
Please visit PPSI’s Booth and pick up our new posters, pamphlets and literature on smoking cessation, diabetes and information on other public health posters along with our new AIDS/hepatitis/liver disease, CA Privacy Act & HIPPA
APhA PROGRAM

PPSI cordially invites all members and guests to a
Breakfast meeting to be held during the APhA Annual Meeting

PPSI/STAN HARTMAN SPECIAL DISTINGUISHED PERSON OF THE YEAR

Sunday, March 3, 2013; 6:30 a.m. - 9 a.m. (9-10:30 a.m. “Dual Degree in Pharmacy MPH/PharmD Programs”)  
JW Marriott Hotel, Los Angeles  
(concurrent with APhA’s 160th Annual Meeting)

“TYING TOGETHER PHARMACEUTICAL CARE & PUBLIC HEALTH ISSUES”

PPSI Distinguished Person of the Year Award Honoring  
Paul W. Lofholm, Pharm.D., FACA  
Past President, California Pharmacy Association  
Professor, University of California, San Francisco (UCSF)  
APhA 2011 Remington Honor Medalist

PRESENTED BY TBA

WELCOME & INTRODUCTION
“CPhA’s Priority/Public Health Issues”  
Jon Roth, CEO  
California Pharmacists Association (CPhA)

MODERATOR  
Aglaia Panos, Pharm.D.  
Vice President, PPSI, Oakland, California

Fred S. Mayer, R.Ph., M.P.H.  
President, PPSI San Rafael, California

SPEAKERS
“Reaching the Underserved: Lessons Learned in the Neighborhood”  
Nancy JW Lewis, PharmD, MPH  
Pharmacist Consultant and Adjunct Associate Research Scientist  
College of Pharmacy, University of Michigan  
Ann Arbor, Michigan

‘PRESCRIPTION DRUGS IN ENGLAND’S HEALTHCARE SYSTEM”  
Sarita Mohanty, M.D., MPH  
Medical Director, LA Care  
Los Angeles, CA

“PHARMACY MILITANCY: TIME FOR ACTION”  
Dan Hussar, PhD  
Dean Emeritus, Philadelphia College of Pharmacy, University of the Sciences  
Philadelphia, Pennsylvania

“PHARMACY LITIGATION ISSUES”  
Natallia Mazina, Esq.  
Attorney & Counselor-of-Law, San Anselmo, California

“Dual Degrees in Pharmacy MPH/PharmD Programs” Panel Discussion (9-10:30 a.m.)  
Stuart Feldman, Ph.D., RPh Dean, Touro University, New York, New York

SUMMARY, COMMENTS & CLOSING REMARKS  
Aglaia Panos, Pharm.D.

This meeting is held in conjunction with the APhA Annual Meeting  
March 1-4, 2013, Los Angeles, California

This program is sponsored by an unrestricted education grant from Drug Topics Magazine and Advanstar Medical Communication Group
December 13, 2012

California State Board of Pharmacy  
1625 N. Market Blvd. Suite N219  
Sacramento, CA 95834

Re: Hearing on Compounding and Manufacturing by Pharmacies

Dear California State Board of Pharmacy,

On behalf of the Pharmacists Planning Services, Inc. I respectfully request that this letter becomes a part of the record for December 13, 2012 hearing “Discussion on Compounding and Manufacturing Pharmacies.”

**Proposed Actions**

As you know, contaminated compounded drugs have been shipped to California which will inevitable injure and kill people in this state. More will be shipped unless, as PPSI requests, a public emergency is immediately declared to exist, based on all the evidence produced by PPSI and other witnesses at this hearing that the public of California is presently subject to great danger from improperly compounded drugs from out-of-state compounders. We request that you adopt emergency regulations which, among other things:

1). Suspend all out-of-state pharmacy licenses in respect to compounding drugs until these pharmacies can present evidence satisfactory to the Board that their compounding process meet the U.S. Pharmacopeial Convention (USP) for compounding sterile products;

2). All other regulations suitable to protect the public of this state from unsupervised, standardless out-of-state compounded medicine.
Board’s authority to enact emergency regulation and moratorium on out-of-state compounding pharmacies.

As you well know, the purpose of the Board is to protect public:

§ 4001.1. Protection of the Public is Board’s Highest Priority
Protection of the public shall be the highest priority for the California State Board of Pharmacy in exercising its licensing, regulatory, and disciplinary functions. Whenever the protection of the public is inconsistent with other interests sought to be promoted, the protection of the public shall be paramount.

Business & Professions Code § 4005 gives the Board powers to impose emergency regulations and moratoriums:

§ 4005. Adoption of Rules and Regulations
(a) The board may adopt rules and regulations, not inconsistent with the laws of this state, as may be necessary for the protection of the public…

(b) Notwithstanding any provision of this chapter to the contrary, the board may adopt regulations permitting the dispensing of drugs or devices in emergency situations, and permitting dispensing of drugs or devices pursuant to a prescription of a person licensed to prescribe in a state other than California where the person, if licensed in California in the same licensure classification would, under California law, be permitted to prescribe drugs or devices and where the pharmacist has first interviewed the patient to determine the authenticity of the prescription.

Conclusion
California law provides the Board of Pharmacy with the powers to adopt the emergency regulations and moratoriums to protect public health. The Board should use such powers and declare emergency situation and moratorium for all out-of-state compounding pharmacies.

The action the PPSI requests is not something which will restrain the budget of the pharmacy board because the burden will be placed on pharmacy to present the evidence that it complies with California regulations.

Also, this emergency regulation can be implemented according to the state Administrative Procedures Act.

Sincerely,

Natallia Mazina
Attorney for Pharmacists Planning Services, Inc.
A recent publication from the American Association of Colleges of Pharmacy (AACP) reminded me of the oath a pharmacist takes. It reminded me of some of the standards of practice issues that PPS’s committee has worked on for the past 14 years. Sometimes the oath is impossible to reconcile with requirements of some of the managed-care organizations.

How does one serve the oath of a pharmacist to maintain the highest principles of moral, ethical and legal conduct, well knowing that PCS has just put a “gag” order on all pharmacists requiring them to “never tell the patient that the original drug is not covered, the plan or PCS is requiring a change to a different medication, or their plan only covers the generic”?

How do I consider the welfare of humanity and belief of human suffering my primary concern when I am well aware that therapeutic substitution is taking place and, for some of my mental health patients, not in their best interest?

How am I to embrace and advocate for change in the profession of pharmacy that improves patient care when reimbursements are so low that I don’t have time to look at the care issues of consultation and DUR due to the managed care folks only paying for counting, pouring, typing, and a product?

A favorite aphorism of managed care is “managing pharmacists is like herding cats.” As a pharmacist, I’ve always liked the image because I’ve always admired the autonomy of cats. Inevitably, you realize that managed care doesn’t herd cats. It herds sheep. When managed care administrators run into a cat, they call the dogs to cut it out of the herd. They call the sheep “cats” because gratuitous flattery is a basic principle of business management.

It is a sad fact that managed care pharmacists are sheep. They have relinquished their pharmacy autonomy and authority to business managers. Commercialism has triumphed over professionalism. Patients are considered cost sinners and adversaries.

The basic tenet of the oath of a pharmacist by the AACP folks is to avoid the influence of monetary gain over professional action. The delusion of managed-care pharmacists from this duty is a well-kept secret.

The time has come for pharmacists to reassert their professional autonomy and integrity, and banish the money changers from the steps of the temple. The only way to do that is with a single-payer system. Regardless of what pharmacists have heard from their leaders, the Canadians love their healthcare system. It is a lot better than the managed mess we have — it costs less, it covers everyone, and it allows the pharmacist to treat the patient and take the oath a pharmacist vows with the full realization of the responsibility with which every pharmacist is entrusted by the public.

It’s time to revisit our oath as pharmacists and embrace and advocate the needed changes to improve patient care.

The ruling can be viewed at lusa.gov/TrdngO

Judge Stephen Trott in the 3-0 ruling.

The cuts, if they take effect, would apply retroactively to June 1, 2011, for most Medi-Cal providers. Lynn Carman, a lawyer for pharmacists, challenged the federal government's assertion that poor people would be unaffected and said his clients would ask the full appeals court for a rehearing.

"If this decision stands, it will not only destroy the Medicaid program in California, but it will destroy the Obamacare program for millions of Americans" who will become eligible for subsidized care when Medi-aid is expanded in 2014, Carman said. The federal-state Medicaid program is known as Medi-Cal in California.

"They will not be able to obtain quality health care or access to services because providers cannot provide services at less than what it costs to furnish it," Carman said.

Paul Phinney, president of the California Medical Association, said the ruling would "tragically impact access to care for millions of Medi-Cal patients." He urged Gov. Brown to reconsider the rate reductions.

But Gareth Lacy, a spokesperson for Brown, said the ruling "allows California to continue providing quality care for people on Medi-Cal while saving the state millions of dollars in unnecessary costs."

There was no immediate comment from state officials.

The suit by medical groups relied on a federal law that requires a state's rates for Medicaid to be high enough to provide quality care and to keep enough health care providers in the program to maintain adequate access for the poor.

Federal courts have accepted similar arguments in blocking Medi-Cal rate cuts in 2008, 2009 and 2010.

Bob Egelko is a San Francisco Chronicle staff reporter.
APhA PROGRAM

Sunday, March 3, 2013 ; 6:30 a.m. - 9 a.m.
(9-10:30 a.m. “Dual Degree in Pharmacy MPH/PharmD Programs”) 
JW Marriott Hotel, Los Angeles

21st Annual - WILLIAM R. BACON MEMORIAL BREAKFAST

Saturday, March 16, 2013; Breakfast: 6:30 a.m. - 9:00 a.m.
Marriott Hotel, Monterey, California