



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Communication and Public Education Committee Report

Ken Schell, PharmD, Chair
Hank Hough, Board Member
Andrea Zinder, Board Member
Susan Ravnan, Board Member

Report of the
Communication and Public Education Committee Meeting of September 14, 2007

The Communication and Public Education Committee met September 14, 2007. Minutes from this meeting are provided in **Attachment 5**.

ITEM 1: Discussion and Action on the Board's Public Forum on Medicare Prescription Drug Plans

For Information:

Since late 2005, the board has been working with various stakeholder groups to aid patients in receiving benefits under the federal Medicare Modernization Act, and specifically the Medicare Part D plans, that were implemented in January 2006.

The board has held six public forums over the last 2 years to discuss difficulties patients and providers are having with the plans, in hopes of finding resolutions. However, any structural changes to the program need to be made at the federal level.

At the April 2007 Board meeting, the board directed staff to convene a public forum, in conjunction with a member of the California Congressional Delegation, perhaps Pete Stark or Speaker Nancy Pelosi. The goal would be to discuss implementation issues impacting patient safety that warrant legislative correction.

Since the July Board Meeting, President Powers and Ms. Herold have discussed these issues with Congressman Stark. A copy of the problem statement that was sent to Congressman Stark is in **Attachment 1**.

Congressman Stark's assessment was that the White House would not make any modifications to the program, so holding a forum would not likely produce much. He did

encourage the board to continue its outreach activities in this area, and to consider holding similar discussions with other state boards of pharmacy.

ITEM 2: Report and Action of Items Discussed at the Communication and Public Education Committee Meeting of June 27, 2007.

1. Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

FOR ACTION:

The committee identified the development of consumer fact sheets to be a major priority of the committee.

Over the past four years, the board has worked with UCSF's Center for Consumer Self Care to have their interns develop facts sheets for consumers. This project offered the board the opportunity to receive professional reviews of consumer outreach materials and get topical and accurate health information out to the public. UCSF also saw the project as an opportunity for their students to add valuable experience to their resumé's.

However, only nine fact sheets have actually been completed since the project was initiated, and the project has not progressed as quickly or as expansively as the board had hoped. Since September 2006, no additional fact sheets have been produced, although 11 additional fact sheets are in varying stages of completion. Since April, we also have been unable to correct addresses on the existing fact sheets and otherwise finalize the new ones for publication.

During the September 2007 Communication and Public Education Committee, Dr. Schell described what has been done to invigorate this program.

In August 2007, Chairperson Schell and Ms. Herold met with Dr. Soller at the UCSF Center for Consumer Self Care. During the meeting, Dr. Soller indicated the need for the Center for Consumer Self Care to be viable, and as such, some projects that were formerly produced without a stipend, could no longer be pursued.

Dr. Soller proposed that while the Center for Consumer Self Care was interested in continuing to work on developing fact sheets, they could no longer do so without a subsidy. UCSF suggested that a contract be developed to produce 16 fact sheets over the next year for a fee of \$25,000.

Meanwhile, following up on a committee recommendation from June 2007, Board Members Schell and Ravnán and Ms. Herold have since contacted the

six other schools of pharmacy. Most are very interested in working with the board on some sort of intern project along the line of developing consumer fact sheets.

Regardless of what the board wishes to do with respect to a future contract with UCSF, the committee will move ahead to offer other schools of pharmacy the opportunity to participate in this project. The staff will develop a template for future fact sheets, and work with the schools of pharmacy to initiate this intern project. The template will include the general format for the fact sheet, and require an annotated copy with footnotes citing the origin of information. The board will then confirm, edit and otherwise review this information, and then finally format each into a standardized fact sheet.

Board Member Hough suggested that the board develop an annual competition to acknowledge these fact sheets and select the very best for a specific award. The committee strongly supported this concept.

At this board meeting, the committee asks for board discussion about whether to move forward with both projects or develop the intern fact sheet program alone and not enter into a contract with UCSF at this time.

2. Update on The Script

FOR INFORMATION:

The next issue of *The Script* is currently being written and will be published and mailed in January 2008. The focus will be on new laws, questions and answers about pharmacy practice asked of the board, and new regulation requirements. There will also be articles about e-pedigree implementation and the board's forthcoming fee increases.

3. New Board Web Site Under Development

FOR INFORMATION:

Early in 2007, the Governor's Office released new requirements for state government Web pages. The board is redesigning its Web site again to conform to the new look for state agencies. The deadline for conversion to the new format is November 2007; the board's Web site will be ready.

A subscriber alert will be sent out once work is completed and the new Web design is in place.

4. Development of New Consumer Brochures

FOR INFORMATION:

An update of work underway or recently completed is provided below.

- Board of Pharmacy Informational Brochures

Completed:

Board Analyst Karen Abbe has completed updating and overseeing the redesign of the informational brochure about the board and the complaint process brochure. Copies are provided in **Attachment 2**.

Undergoing final review are:

1. An update of the board's informational brochure about the state's program for Medicare-eligible patients to obtain the MediCal price for prescription medicine if they must pay out of pocket (updating what is known as the SB 393, Speier, Chapter 946, Statutes of 1999). The brochure is being reviewed by the Department of Public Health.
2. A fact sheet on a Traveling Medicine Chest, from a list developed by Board Member Graul with input from Board Member Ravnan.
3. A fact sheet on Vaccinations and Travel Outside the US.
4. A fact sheet on Counterfeit Drugs

- Information for Examination Applicants

Executive Officer Herold recently wrote an article for the CSHP Journal on an insider's view of applying to become a pharmacist. This article will be reformatted into a fact sheet for applicants **Attachment 3**.

5. National Council on Patient Information and Education's Medication Adherence Report

FOR INFORMATION:

The National Council on Patient Education and Information released in August a report on medication adherence titled: *Report on Enhancing Prescription Medication Adherence: A National Action Plan* (**Attachment 4**).

According to NCPPIE, the lack of medication adherence results in \$177 billion annually in direct and indirect costs to the US economy, plus an additional \$47 billion each year for drug-related hospitalizations, 40 percent of admissions to

nursing homes and an additional \$2,000 a year per patient in medication costs for MD visits.

Some of the information in this report may be of value to the board as it works to redesign prescription container labels pursuant to SB 472 (Corbett).

6. Update on Public Outreach Activities

FOR INFORMATION:

From late June through October 2007, the board provided three presentations to professional associations, four presentations at major conferences, three presentations at meetings involving public policy discussions, and staffed a booth at five public information fairs.

A detailed list of the board's public outreach activities this quarter is provided in **Attachment 5**.

ITEM 3: Meeting Summary

FOR INFORMATION:

A summary of the Communication and Public Education Committee Meeting held September 14, 2007, is provided in **Attachment 6**.

ITEM 4: First Quarterly Update on Committee Goals for 2007-08

FOR INFORMATION:

The quarterly update report on the committee's strategic goals is provided in **Attachment 7**.

Attachment 1

Letter to Congressman Stark



September 3, 2007

EDITORIAL

Report Card on Medicare's Drug Plan

A large in-depth survey of older Americans has yielded a mixed appraisal of the new Medicare prescription drug benefit. The program has largely succeeded in its primary goal of providing drug coverage to Medicare beneficiaries who previously lacked it. But it has fallen short in providing subsidies to low-income Americans, in protecting people from high out-of-pocket costs and in matching the benefits offered by other private and public sources of coverage. These shortcomings will need attention as the program rolls forward.

The survey of more than 16,000 beneficiaries age 65 and older was conducted in the fall of 2006 by researchers from the Kaiser Family Foundation, the Commonwealth Fund and the Tufts-New England Medical Center. It reflected the experiences of beneficiaries during the program's first year of operation.

The program had a big impact in helping to reduce the percentage of older Americans without drug coverage — from 33 percent before the program started to 8 percent last year. That is a significant achievement and clearly left many beneficiaries better protected against health costs than they had been.

But many of the enrollees in the Medicare drug program were less protected against high drug costs than their counterparts in other plans. Some 8 percent of the Medicare drug beneficiaries, for example, spent at least \$300 a month on their medications, compared with only 5 percent for older Americans covered by employer plans or the Department of Veterans Affairs. This is probably because employer plans typically don't have a gap in coverage comparable to the notorious "doughnut hole" in Medicare coverage, and because veterans' coverage has low cost-sharing requirements.

The unfortunate consequence for patient health is that Medicare enrollees were much more likely to postpone medications because of the cost. Indeed, fully 20 percent of all enrollees in a Medicare drug plan reported that they had not filled, or had delayed filling, a prescription because of costs. That was a much higher rate than reported by older Americans in employer (8 percent) or veterans' (12 percent) plans.

Hefty subsidies for low-income beneficiaries have made a big difference in cutting costs for those who received them. But some 3.4 million to 4.7 million people who are eligible are not receiving the extra help, many because they are unaware of the benefit. The Medicare drug program is off to a reasonably good start, but any tendency to consider the job done is to be avoided.

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STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

July 26, 2007

The Honorable Fortney "Pete" Stark
US House of Representatives
39300 Civic Center Drive, Suite 220
Fremont CA 94538

Sent via fax to: 510-494-5854

Congressmember Stark:

We are aware of your interest and leadership in the implementation of the Medicare Modernization Act. In this capacity, we are writing to ask for your participation in a meeting with various California constituents on unresolved issues at time of your choice in the future.

For nearly two years, the California State Board of Pharmacy has watched the implementation of the Medicare Part D Prescription Drug benefits. During this period, the board has held six public forums encouraging problem solving and patient advocacy.

As the regulator of pharmacists and pharmacies in California and coupled with the board's mandate to protect the safety of consumers, the board is uniquely situated to hear the problems. The board agrees with the general consensus that patients are benefiting from the Part D prescription drug program. However, the board believes that additional problems remain that vitally need to be resolved.

The lack of resolution of these problems imperil the health of affected patients, often dual eligibles, skilled nursing patients and critically ill patients being discharged from hospitals who need specialized care. While the problems affect the health of Californians, the board is unable to effect resolutions because of the structure of this Medicare benefit.

The board recognizes that to resolve many of these problems, a federal legislative solution is needed. For this reason, we are requesting your participation in developing a solution.

We are interested in convening a meeting in California with the staff of the California Department of Health Care Services, California health care plans, patient advocates and health care providers, specifically pharmacies, for discussion and possible

resolution of components that prevent patients from receiving necessary, timely and mandated care.

For example, some of the problems the board is aware of include:

- 1) Prior authorization requirements that delay patient drug therapy – patients must wait days for approval of the prior authorization process initiated from the prescriber's office unless the pharmacy is willing to risk providing medicine without knowing whether it will be ultimately covered.
- 2) Unacceptable sales tactics used by insurance agents selling Medicare plans; for example, dual eligibles being targeted for sales of private fee-for-service plans that their physicians will not accept.
- 3) Patients who are enrolled in a plan but whose coverage in the plan has not yet been activated are unable to obtain their medicine.
- 4) The Part D benefit is too complex to enable true comparison shopping by patients of the 55 competing plans in California. The number of plans and lack of standardization of benefits make it difficult to select plans that work for a patient, much less select the best plan for him or herself.
- 5) It is difficult for patients to resolve problems with their Part D benefit. Part D, Medicare Advantage and CMS call centers do not always give accurate and complete responses needed to resolve problems, leaving patients without adequate resolutions.
- 6) There are co-pay problems in skilled nursing facilities, where patients are told to make copayments.
- 7) Plans change formularies after a patient selects a plan, creating coverage problems for the patient who selected a plan expecting coverage for a specific drug.
- 8) Poor continuity of care when a patient is discharged from an acute hospital on "non-covered" drugs, impacting the patient's drug therapy and health.
- 9) Poor understanding of IV product/coverage/billing by plans (and therefore determining such services are "not covered" with the resultant care problems for patients, or continued hospitalization until the coverage is secured).
- 10) Poor "timely" response by plans to the pharmacy when the law requires in a skilled nursing facility a 1-hour or 4-hour delivery of medication under Title XXII
- 11) Requirements that physicians must do prior authorizations (not allowing the pharmacist to do this, which further delays therapy for patients, and redirects pharmacies to additional phone calls, away from other care functions).
- 12) Drugs on plan formularies that are "not geriatric friendly" per federal and state regulations and guidelines.
- 13) According to an article in the *American Journal of Psychiatry*, 30 percent of dual eligible beneficiaries were denied medication refills and 22 percent had interrupted or discontinued access to medicine; these difficulties led to suicide, hospitalizations and homelessness.

The Honorable Fortney "Pete" Stark
July 26, 2007
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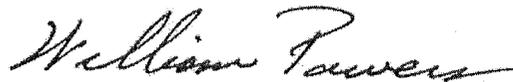
The board is willing to schedule and host a meeting at your convenience and at a location of your choice in California so that interested stakeholders could have the opportunity to provide these concerns directly to you.

The board strongly hopes for changes that will remove barriers that prevent patients from getting the medicine they are entitled to under the Medicare Modernization Plan.

Please advise us if you or your staff would be willing to discuss details for such a meeting in California. To make arrangements or if you have questions, please do not hesitate to contact the board's Executive Officer Virginia Herold (916-574-7911).

Thank you for your consideration of this proposal.

Sincerely,

A handwritten signature in cursive script that reads "William Powers".

William Powers
President
California State Board of Pharmacy

Attachment 2

New Consumer Brochures

Where to find more information

The board's Web site provides consumer education material, application material for licensing, and information for ensuring compliance with California Pharmacy Law. The Web site also provides information on board meetings and critical forums vital to pharmacy services where public comments and input are encouraged. Go to www.pharmacy.ca.gov for materials including:

- Consumer Education Material
- Applications and Forms
- Complaint Resolution process
- Publications and Newsletters
- Pharmacy Law and Regulations
- License Verification
- Licensing Requirements and Renewal Information
- Public board and committee meeting dates, agendas, meeting materials and minutes

Did you know?

Anyone interested in receiving e-mail alerts about updates to the board's Web site can join the board's e-mail notification list. Go to www.pharmacy.ca.gov, click on 'Information For Consumers', then scroll to 'Join our e-mail list.' E-mail alerts provide information regarding:

- Regulations implemented or released for public comment
- Board newsletters when they are published
- Agendas for public meetings when released
- Questions and answers about new laws
- Board actions from board meetings

Consumers and licensees may also call or write to the board:

California State Board of Pharmacy
1625 N. Market Blvd., Suite N-219
Sacramento, CA 95834

(916) 574-7900

September 2007



Healthy Californians

Through Quality Pharmacist's Care



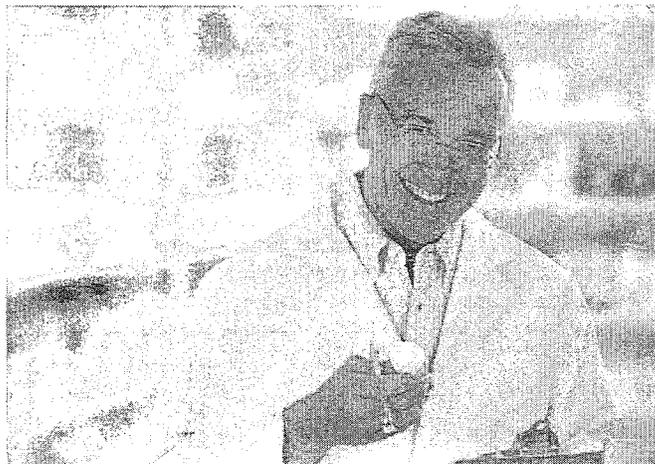
California State Board of Pharmacy

Who we are

The California State Board of Pharmacy (board) serves the public as a consumer protection agency. The board is part of the Department of Consumer Affairs, which is in the executive branch of California's government. The Governor is at the top of the executive branch.

The board consists of 13 members, appointed to four-year terms. Members can serve only two consecutive terms. There are seven pharmacists and six public members appointed to the board. The Governor appoints the seven pharmacists, as well as four of the public members. The Senate Rules Committee and the Speaker of the Assembly each appoint one public member. Public members are individuals who are not licensed by the board.

Members of the board appoint the executive officer, who directs board operations and oversees a staff of more than 55 people. The staff includes over 20 pharmacists who inspect licensed premises and investigate suspected violations of pharmacy law. The board is self-funded through licensing fees, and receives no tax money from the General Revenue Fund of California.



How we protect the public

The board develops and enforces regulations to protect the public from the misuse and diversion of prescription drugs from pharmacies. The board licenses pharmacists, pharmacist interns, pharmacy technicians, and designated representatives (those involved with wholesaling medicine and medical devices, but who do not hold a pharmacist license).

The board also regulates firms that distribute medicine and medical devices in California. These firms include community pharmacies, hospital pharmacies, clinics, out-of-state pharmacies that fill prescriptions and deliver them to patients in California, and wholesalers who ship medicines into California.

To become a licensed pharmacist, an individual must graduate from an accredited pharmacy school, pass two examinations, and complete experience in both community and hospital pharmacies. In addition, continuing education is required for a pharmacist to renew his or her license.

What we do

Under California law, the board's mandate is consumer protection. The board oversees those that compound, dispense, store, ship, or handle prescription drugs and medical devices to patients and practitioners in California. Currently, the board licenses over 100,000 pharmacists, pharmacies, and other individuals and businesses who are involved in these activities. The board sets standards and

Did you know?

Information regarding license status and official actions taken in connection with a licensee, if known, are disclosed to the public upon request. You can obtain:

- Licensee Name
- License Number
- Name of Licensed Facility Owner (including the corporation name and corporate officers) and the Pharmacist-in-Charge
- Address of Record
- Date the original License was issued
- License Expiration Date
- Current License Status
- Letters of Admonishment
- Citations
- Referrals for formal Disciplinary Action
- Accusation/Petition to Revoke Probation
- Board Decisions
- Temporary Restraining Order
- Automatic Suspension Order
- Summary Suspension Order
- Interim Suspension Order
- Penal Code 23 license restrictions

licenses those who comply with these standards to ensure practitioners and businesses possess necessary skills and follow essential components.

The board ensures that pharmacists provide patients with quality pharmacist care when dispensing prescribed medicine, providing information to protect patients to prevent drug misadventures, and taking responsibility for therapeutic outcomes resulting from their decisions.

HOW TO FILE A COMPLAINT

Complaint forms are found at www.pharmacy.ca.gov. The form may be filled out and submitted electronically, or the form can be printed and filled out by hand. The completed form must be sent to the California State Board of Pharmacy, 1625 N. Market Blvd., Suite N-219, Sacramento, CA 95834. An on-line complaint form is also available on the Web site that can be submitted electronically.

WHAT HAPPENS TO MY COMPLAINT?

The board strives to complete most investigations within 120 days. Routine investigations may take up to 90 days, while more complex cases requiring extensive investigation may take longer.

If the complaint is within the board's jurisdiction, the complaint will be referred to staff for mediation or investigation. If the complaint is not within the board's jurisdiction, it may be closed with no action taken or referred to another agency that may have jurisdiction. A complaint could result in disciplinary action being taken against a licensee ranging from a reprimand, a citation and fine, or revocation of the license with loss of the right to practice or operate a pharmacy.

If you write to the board and request information regarding the outcome of a complaint, the board will respond in writing. The following information may be obtained:

- The date the complaint was received by the board
- A summary of the investigation
- The outcome or type of discipline

Formal disciplinary actions are a matter of public record, as are the names of licensees, their license numbers, their address of record, the date the original license was issued, and the current status (active or inactive) of that license.

CALIFORNIA STATE BOARD OF PHARMACY

**FOR MORE INFORMATION ABOUT THE BOARD,
LICENSING, OR THE COMPLAINT PROCESS, YOU MAY:**

VISIT THE BOARD'S WEB SITE AT
WWW.PHARMACY.CA.GOV

WRITE TO THE BOARD AT
1625 N. MARKET BLVD., SUITE N-219
SACRAMENTO, CA 95834

CALL THE BOARD AT
(916) 574-7900

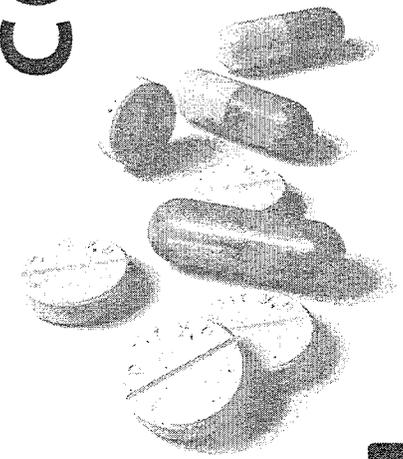


September 2007



STATE OF CALIFORNIA
dca
DEPARTMENT OF CONSUMER AFFAIRS

**DO YOU HAVE A
COMPLAINT?**



California State Board of Pharmacy

COMPLAINT RESOLUTION

A primary way the California State Board of Pharmacy (board) protects the public is through the investigation of consumer inquiries and complaints involving the care patients have received. Errors in filling prescriptions or suspected misconduct by a pharmacist may be violations of pharmacy law, and should be reported, whether or not a patient was harmed. The board does not have jurisdiction over drug prices charged by the pharmacy or prescription billing disputes with insurance carriers.

The board advocates and enforces laws that protect the health and safety of patients, and encourages submission of complaints and inquiries from the public. Each complaint is evaluated to determine if the complaint involves a pharmacist, pharmacy, or firm regulated by the board, and whether the complaint involves a violation of California Pharmacy Law.



WHAT IS PHARMACIST MISCONDUCT?

Examples of misconduct by a pharmacist include (but are not limited to) instances where:

- The pharmacist fails to counsel you about how to take a new prescription medicine (or a prescription with changed instructions) and its possible side effects
- A non-pharmacist counsels you regarding your prescription
- A pharmacist is not present and your prescription is filled by a non-pharmacist
- A pharmacist fails to maintain the confidentiality of your prescription
- A pharmacist appears unable to function safely (due to alcohol or drug abuse)
- The pharmacy is dirty, cluttered, or looks unsanitary
- A pharmacist fails to assist you in obtaining a prescribed drug or device from another pharmacy, when the drug or device is out of stock
- A pharmacist fails to assist you in obtaining a prescribed drug or device from another pharmacy, when the pharmacist refuses to fill the prescription for ethical, moral, or religious reasons



WHAT ARE PRESCRIPTION ERRORS?

Examples of prescription error violations include (but are not limited to) instances where:

- Incorrect information is entered on the label of the prescription container
- A prescription is dispensed with the wrong drug or wrong dosage
- A prescription is refilled without proper authorization from the prescribing physician
- A generic drug is substituted for a brand name drug, without informing the patient of the substitution
- A prescription is filled using drugs whose expiration date has passed

Attachment 3

*Information for Examination
Applicants*

Becoming a Licensed Pharmacist in California

An Insider's View

The California State Board of Pharmacy licenses pharmacists in California. The goal of licensing is consumer protection: the board is required to ensure that before practicing pharmacy, every applicant meets the minimum requirements. Once proof of achievement of the requirements is provided to and approved by the board, the board issues the individual a pharmacist license.

Pharmacy is regulated at the state level, so states have their own licensure requirements, although most states have similar requirements. Each requirement has a purpose. The requirements themselves have their origin in California statutory laws (enacted by the Legislature) or in regulations (rules promulgated by the board).

For many applicants, the process will take four to five months. For others it will take six months, and for a few, longer than six months. Most applicants can take steps to minimize the timeframe required to become licensed to the shorter end of the range. This article describes these steps.

Here are the basic components (note: please use the directions for the online examination application to provide you with the specifics of each component). The more complete your application is when you submit it, the shorter the process will be for you.

I. BECOMING ELIGIBLE TO TAKE THE EXAMINATIONS:

1. EDUCATION: each applicant must be either:
 - A graduate of an ACPE-accredited school of pharmacy, or
 - If a foreign-educated pharmacist, certified by the Foreign Pharmacy Graduate Education Committee.
2. EXPERIENCE: each applicant must provide proof of experience working as an intern pharmacist or if licensed in another state, experience as a pharmacist. Satisfactory evidence of experience must be one of the following:
 - 1,500 hours of intern experience provided on affidavits available from the board if registered in California as an intern.
 - 1,500 hours of intern experience earned as a pharmacist intern in another state – these hours must be certified by the board of pharmacy in the state where the hours were earned.
 - Proof of licensure as a pharmacist in another state for one year – this requires a license certification from the board of pharmacy in the state where the individual is licensed.

3. **CRIMINAL BACKGROUND CHECK:** All pharmacist applicants must undergo a criminal background check by submitting fingerprints for evaluation by the California Department of Justice and Federal Bureau of Investigation. Even if you have previously submitted prints to the California board for an intern or pharmacy technician license, you must submit new prints with the classification of "pharmacist" listed on the fingerprint form. There are two ways to submit fingerprints:
 - If you are located in California, you must submit prints via LiveScan. This is faster, and the California Department of Justice is insistent that LiveScan be used for those residing in California.
 - If you are outside California, request that the board mail you fingerprint cards. You need to submit two cards along with a separate fee (made payable to the Board).
4. **LICENSE VERIFICIATION:** we require a license verification from every state in which you are licensed as a pharmacist. The state boards of pharmacy in the respective states need to provide these certifications.

II. BEING MADE ELIGIBLE FOR THE EXAMINATIONS:

Once the board has a complete application, the board will make you eligible to take the CPJE and NAPLEX exams. We will send you a letter notifying you that you are "eligible," and how to schedule your CPJE and NAPLEX exams. You can take the exams in any order.

- The board does provide some leeway for fingerprint clearances: if we have proof you have submitted prints for a pharmacist license, we will make you eligible without having the background clearances (however, you will not be licensed until we receive the clearances).
- If you passed the NAPLEX after January 1, 2004, you will not need to retake this examination if NABP can transfer the score to California. Contact NABP (www.nabp.net) for more information on how to share prior NAPLEX scores with California.
- Unless we have a quality assurance review (see below) underway for the CPJE, we will mail the scores to you typically within 14 days of when you take the exams.

III. BECOMING LICENSED:

After the board has the two passing scores on the required examinations, the board will send you a green sheet titled "Request for Issuance of Pharmacist License." You will be asked for a license fee and advised of any deficiencies remaining in your application. Typically the only deficiencies at this stage are results to the background clearances. If you believe that you have already corrected the deficiency, use the "Contact Us" feature from the board's Web site to email us or attach a note to the green sheet when you return it to the board.

We try to process these applications very quickly. The fastest way to know you are licensed is to use the license verification feature on the Web site (http://www.pharmacy.ca.gov/verify_lic.htm) and checking your name. Once your name appears as a licensed pharmacist, you are licensed. California law provides that verification of licensure from the Web site is proof you are licensed. You will receive a green, wallet-size license in about 8 weeks (another agency prints and mails these for the board). The large wall license will be mailed within four months.

TIPS for faster and smoother processing, remember:

1. Use one of the processes we suggest for verifying that the board received your application.
2. Status checks are a problem for the board to perform. It diverts limited staff away from processing activities to simply answering a question for someone. We will not generally respond to status inquiries on applications that are less than 60 days old with the board. Instead we direct staff to process applications. Please be patient – and use a technique listed elsewhere in this article to make certain you know we received your application.
3. However, there are times when applicants need to reach us. Use the appropriate email address under “Contact Us” on the Web site. Certainly email the board if it has been more than 60 days, and you have heard nothing from the board -- this is a problem you need to call to our attention. Also, if it has been more than 30 days after you believe your deficiency has been corrected, contact us.
4. If you receive a letter advising you that the board is missing some items (what we call a “deficiency letter”) – this truly means we do not have the listed items. To get through the system faster, you need to provide the item, even if you may think we already have it. So what is most often missing?
 - Transcripts from colleges with the pharmacy degree posted (these must come directly from the school of pharmacy to the board). Oddly, some colleges do not post the PharmD degree to transcripts until 2-3 months after graduation.
 - Fingerprint clearances are sometimes a problem (we run both federal and state background checks). Sometimes we need to ask applicants to resubmit prints because something is preventing the board from receiving the documentation; the board will contact you if additional information is required.
 - Intern hours are missing or less than the 1,500 hours required.
5. Make certain your name matches identically on your government identification, with your social security card and with your name of record that you file with the board (this is the name that will appear on your pharmacist license). Identically means identically (see the board’s Web

- site for more information). Resolving name conflicts is the one area where you should not wait 60 days before resolving the problem.
6. The board periodically conducts quality assurance reviews of the CPJE. When this occurs, no CPJE scores are released until the assessment is completed. The board makes every effort to release scores as soon as we can, but a quality assurance check usually runs 2-3 months or until approximately 400 individuals take the test. We know this is frustrating, but it is necessary. We post this information on the Web site.
 7. Background checks – if you have a prior conviction, you need to disclose it in the required place on the application and describe it fully. (You need to do this if you have reported the conviction on prior applications.) Even if you think a conviction has been expunged or set aside and dismissed, the clearance check usually picks up these records. If you state you have no convictions and yet a background check shows you do, this will become an “enforcement issue.” Enforcement issues will delay the processing of your application or issuance of a license until all enforcement matters are resolved (typically this adds at least two months).

What can you do?

1. Submit as complete an application as you can. This means you should submit in one package:
 - All required application forms
 - The required fee
 - Proof of at least 1,500 hours of intern experience
 - Verifications of pharmacist licensure from all states in which you are licensed
 - LiveScan Receipt showing submission of your fingerprints or if you are out-of-state, enclosing the fingerprint cards and additional processing fee.
2. How to verify the board has received your application:
 - Enclose a self-addressed, stamped post card or simply an envelope addressed to you with your application package. Board staff will mail these to you when the board receives your application -- so you know we have your application.
 - Check to see if the bank has cashed your check. The board cashes all checks it receives very quickly -- within two working days of receipt. If the check has been cashed, we received your application.
3. Contact us if it has been more than 60 days since you submitted your application and you have heard nothing from the board, or more than 30 days since you have taken steps to correct a deficiency and you have had no response from the board.

The board wants all qualified applicants to become licensed as quickly and effortlessly as possible. Use the information above to aid you in getting through the process as expediently as possible.

Attachment 4

*National Council on Patient Information
and Education's
Medication Adherence Report*

EDUCATE *before*
YOU MEDICATE

A stylized black silhouette of a human figure with arms raised, positioned to the right of the main text.

The NCPIE
Coalition—working
together to promote
safe medicine use

Enhancing Prescription Medicine Adherence: A National Action Plan

National Council on Patient Information and Education

August 2007

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National Council on Patient Information and Education
4915 Saint Elmo Avenue
Suite 505
Bethesda, MD 20814-6082
301-656-8565

Printed in the United States of America.

Preface

In the United States and around the world, there is compelling evidence that patients are not taking their medicines as prescribed, resulting in significant consequences. Lack of medication adherence is *America's other drug problem* and leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even death.

Contributing to *America's other drug problem* are numerous behavioral, social, economic, medical, and policy-related factors that must be addressed if medication adherence rates are to improve. This includes lack of awareness among clinicians about basic adherence management principles, poor communication between patients and clinicians, operational aspects of pharmacy and medical practice, and professional barriers. Moreover, adherence improvement is affected by federal policies that provide insufficient funding for adherence-related research and federal and state laws and regulations that impact the availability of compliance assistance programs. All of these problems contribute to a rising tide of poor medication adherence and all must be addressed.

The ramifications of poor prescription medicine adherence affect virtually every aspect of the health care system. Addressing this persistent and pervasive problem cannot wait. Today, extensive research data exist that point to actions that can be taken now to improve adherence education and medication management. Accordingly, the National Council on Patient Information and Education (NCPPIE) -- a non-profit coalition of more than 100 organizations that are working to stimulate and improve communication on the appropriate use of medicines -- convened a group of advisors from leading professional societies, voluntary health organizations, and patient advocacy groups to assess the extent and nature of poor medicine adherence, its health and economic costs, and its underlying factors. These advisors also examined the current state of research funding and educational initiatives around patient adherence to determine where major gaps still exist.

What follows is the result of this review, which focuses specifically on identifying those action steps that can significantly impact medication adherence and can be readily implemented. As such, this report serves as a **blueprint for action** by all stakeholders. To achieve the awareness, behavior changes, and additional resources for research and education that will improve patient medication adherence requires an ongoing partnership through which policymakers, regulators, the public health community, clinicians, the pharmaceutical industry, and patient advocates can share research, resources, and good ideas, while working toward a common goal. It is intended that this report will be a catalyst for this necessary and important collaborative effort.

Project Advisory Team

American Academy of Physician Assistants

Michael Ellwood, MBA, PA-C
Director, Special Projects

American Cancer Society

Len Lichtenfeld, M.D.
Deputy Chief Medical Officer

American College of Physicians Foundation

Ruth M. Parker, M.D.
Special Advisor in Health Literacy to the EVP and CEO

American Diabetes Association

Diane Tuncer
National Director, External Communications

American Heart Association

Penelope Solis, J.D.
Regulatory Relations Manager, Office of Legislative Affairs

Asthma and Allergy Network / Mothers of Asthmatics

Sandra J. Fusco-Walker
Director Government Affairs

National Association of Chain Drug Stores Foundation

Phillip Schneider, M.A.
Vice President, External Relations & Program Development

National Consumers League

Rebecca Burkholder
Director of Health Policy

National Council on Patient Information and Education

Wm. Ray Bullman
Executive Vice President

Deborah Davidson

Membership Director

National Women's Health Resource Center, Inc.

Heidi Rosvold-Brenholtz
Editorial Director and Managing Editor

Executive Summary

At the same time that medical science has made possible new therapies for treating AIDS, cancer, and other once fatal diseases, poor adherence with medication regimens has reached crisis proportions in the United States and around the world.

On a worldwide basis, the World Health Organization (WHO) projects that only about 50 percent of patients typically take their medicines as prescribed. In the U.S., non-adherence affects Americans of all ages, both genders and is just as likely to involve higher-income, well-educated people as those at lower socioeconomic levels. Furthermore, since lack of medication adherence leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even premature death, poor adherence has been estimated to cost approximately \$177 billion annually in total direct and indirect health care costs.

Although the challenge of poor medication adherence has been discussed and debated for at least three decades, these problems have generally been overlooked as a serious public health issue and, as a result, have received little direct, systematic, or sustained intervention. As a consequence, Americans have inadequate knowledge about the significance of medication adherence as a critical element of their improved health. Further, adherence rates suffer from the fragmented approach by which hospitals, health care providers, and other parts of the health delivery system intervene with patients and caregivers to encourage adherence. Consequently, many leading medical societies are now advocating a multidisciplinary approach through coordinated action by health professionals, researchers, health planners and policymakers.

Over a decade ago, the National Council on Patient Information and Education (NCPPIE) recognized the need for such a coordinated approach to improved medication adherence and issued a report

-- *Prescription Medicine Compliance: A Review of the Baseline Knowledge* -- which defined the key factors contributing to poor adherence. Since that time, the National Institutes of Health (NIH) and a number of voluntary health organizations in the U.S. have weighed in with new findings on the importance of adherence for successful treatment. Further elevating the need for action is the WHO, which has called for an initiative to improve worldwide rates of adherence to therapies commonly used in treating chronic conditions, including asthma, diabetes, and hypertension.

Unfortunately, however, these calls for action have yet to be heeded and rates of medicine adherence have not improved. Thus, action is needed now to reduce the adverse health and economic consequences associated with this pervasive problem. While no single strategy will guarantee that patients will fill their prescriptions and take their medicines as prescribed, elevating adherence as a priority issue and promoting best practices, behaviors, and technologies may significantly improve medication adherence in the U.S.

Towards this end, NCPPIE convened a panel of experts to create consensus on ten national priorities that may have the greatest impact on improving the state of patient adherence in the U.S. These recommendations serve as a catalyst for action across the continuum of care -- from diagnosis through treatment and follow-up patient care and monitoring. Ultimately involving the support and active participation of many stakeholders -- the federal government, state and local government agencies, professional societies and health care practitioners, health educators, and patient advocates -- this platform calls for action in the following areas:

1. **Elevate patient adherence as a critical health care issue.**
Medication non-adherence is a problem that applies to all chronic disease states;

affects all demographic and socio-economic strata; diminishes the ability to treat diabetes, heart disease, cancer, asthma, and many other diseases; and results in suffering, sub-optimal utilization of health care resources, and even death. Despite this impact, patient adherence is not on the radar screen of policy makers and many health professionals, which has meant inconsistent government policies and a lack of resources for research, education, and professional development. Until health care policy makers, practitioners and other stakeholders recognize the extent of non-adherence, its cost, and its contribution to negative health outcomes, this problem will not be solved.

2. **Agree on a common adherence terminology that will unite all stakeholders.**

Today, a number of common terms - compliance, adherence, persistence, and concordance -- are used to define the act of seeking medical attention, filling prescriptions and taking medicines appropriately. Because these terms reflect different views about the relationship between the patient and the health care provider, confusion about the language used to describe a patient's medication-taking behavior impedes an informed discussion about compliance issues. Therefore, the public health community should endeavor to reach agreement on standard terminology that will unite stakeholders around the common goal of improving the self-administration of treatments to promote better health outcomes.

3. **Create a public/private partnership to mount a unified national education campaign to make patient adherence a national health priority.**

To motivate patients and practitioners to take steps to improve medication adherence, compelling, actionable messages must be communicated as part of a unified and sustained public education campaign.

A foremost priority is creating the means by which government agencies, professional societies, non-profit consumer groups, and other affected stakeholders can work together to reach public and professional audiences on a sustained basis. Even as NCPIE and various government agencies, professional societies, and voluntary health organizations work to provide information about medication adherence, there needs to be a national clearinghouse, serving as the catalyst and convener so that all stakeholders can speak with one voice about the need for improving patient adherence. NCPIE, a professional society, or academic institution could manage this clearinghouse effectively.

4. **Establish a multidisciplinary approach to adherence education and management.**

There is a growing recognition that a multidisciplinary approach to medication taking behavior is necessary for patient adherence to be sustained. This has led NCPIE to promote a new model -- the "Medicine Education Team" -- in which the patient and all members of the health care team work together to treat the patient's condition, while recognizing the patient's key role at the center of the process. Looking to the future, this approach has potential to improve adherence rates significantly by changing the interaction between patients and clinicians and by engaging all parties throughout the continuum of care.

5. **Immediately implement professional training and increase the funding for professional education on patient medication adherence.**

Today's practitioners need hands-on information about adherence management to use in real-world settings. This need comes at a time when a solid base of research already exists about the steps physicians and other prescribers, pharmacists, nurses, and other health care practitioners can take to help patients improve their medication taking behavior.

Professional societies and recognized medical sub-specialty organizations should immediately apply these research findings into professional education through continuing education courses as well as lecture series on patient adherence issues.

6. Address the barriers to patient adherence for patients with low health literacy.

Low health literacy and limited English proficiency are major barriers to adherence and deserve special consideration. Thus, an important target for patient-tailored interventions is the 90 million Americans who have difficulty reading, understanding and acting upon health information. Accordingly, advocates recommend widespread adoption of existing tools, such as the Rapid Estimate of Adult Literacy in Medicine Revised (REALM-R), validated pictograms designed to convey medicine instructions and specific patient education programs that promote and validate effective oral communication between health care providers and patients supported by provision of adjunctive, useful information in its most useful format to address the patient's individual capabilities.

7. Create the means to share information about best practices in adherence education and management.

Today, stakeholders have access to more than 30 years of research measuring the outcomes and value of adherence interventions. Building on this foundation, a critical next step is for the federal government -- through the Adherence Research Network -- to begin collecting data on best practices in the assessment of patient readiness, medication management and adherence interventions, incentives that produce quality outcomes from adherence interventions, and measurement tools so that this information can be quantified and shared across specialties and health care facilities. Just as federal and state registries collect and share necessary

data on different disease states, a shared knowledge base regarding systems change, new technologies, and model programs for evaluating and educating patients about adherence will significantly improve the standard of adherence education and management.

8. Develop a curriculum on medication adherence for use in medical schools and allied health care institutions.

Lack of awareness among clinicians about basic adherence management principles and their effective application remains a major reason that adherence has not advanced in this country. Changing this situation will require institutionalizing curricula at medical, nursing, pharmacy, and dental schools as well as courses for faculty members that focus on adherence advancement and execution of medication-related problem solving. Moreover, once these courses are developed, it will be important for academic centers to elevate patient adherence as a core competency by mandating that course work in this area be a requirement for graduation.

9. Seek regulatory changes to remove road-blocks for adherence assistance programs.

Improved adherence to medication regimens is predicated in part on supportive government policies. Unfortunately, a number of federal and state laws and policies now limit the availability of adherence assistance programs. Accordingly, limitations to patient communication about medicine adherence in federal and state laws must be identified for lawmakers and regulators to resolve. Key issues to be addressed include clarifying that education and refill reminder communications fall within the scope of the federal anti-kickback statute, and ensuring that federal and state laws related to patient privacy and the use of prescription data are in balance such that they do not unduly limit the ability of pharmacies to communicate with patients about the

importance of adhering to their prescribed therapy.

10. Increase the federal budget and stimulate rigorous research on medication adherence.

Although the National Institutes of Health created the Adherence Research Network to identify research opportunities at its 18 Institutes and Centers, the Network has been inactive since 2002. Moreover, in 2000, when the Network was funding adherence research, the actual NIH dollars earmarked for testing interventions to improve medication-taking behavior was only \$3 million in a budget of nearly \$18 billion. Thus, it will be important for stakeholders to advocate for the Adherence Research Network to be re-invigorated and for NIH to significantly increase the proportion of its research funding to test adherence interventions and measure their effectiveness. Even if NIH triples its 2000 commitment, the small amount spent on patient adherence will still signal that the issue is a critical area for new research efforts.

Everyone in the health care system – from patients and caregivers to health care providers, patient advocates and payors – has a significant role to play in improving prescription medicine adherence. Thus, an agenda that removes the barriers and advances education and information sharing is a critical step to improving the health status of all Americans. Clearly, the time for action is now.

Introduction

There is much to celebrate about the improved health status of many Americans. Smoking rates have dropped significantly, infant mortality has declined and there have been major advancements in treatments for serious diseases that once devastated the lives of millions. This includes more than 300 new drugs, biologics and vaccines approved by the U.S. Food and Drug Administration (FDA) since 1993 to prevent and treat over 150 medical conditions.⁽¹⁾

While we recognize such progress, now is the time to be even more mindful of the public health problems we have yet to solve. One of these persistent challenges is improving patient “compliance” (or “adherence”) – defined as the extent to which patients take medications as prescribed by their health care providers.⁽²⁾ At the same time that medical science has made possible new therapies for treating AIDS, cancer, and other once fatal diseases, poor adherence with medication regimens has reached crisis proportions in the United States and around the world. According to the World Health Organization (WHO), only about 50 percent of patients typically take their medicines as prescribed.⁽³⁾ For this reason, WHO calls poor adherence rates “a worldwide problem of striking magnitude”⁽³⁾ and has published an evidence-based guide for health care providers, health care managers, and policymakers to improve strategies of medication adherence.⁽²⁾

Looking specifically at lack of medication adherence in the U.S., a recent survey reported that nearly three out of every four American consumers report not always taking their prescription medicine as directed.⁽⁴⁾ Commissioned by the National Community Pharmacists Association (NCPA), this survey also found a major disconnect between consumers’ beliefs and their behaviors when it comes to taking medicines correctly. Some of the findings of the survey include:

- + Almost half of those polled (49 percent) said they had forgotten to take a prescribed medicine;
- + Nearly one-third (31 percent) had not filled a prescription they were given;
- + Nearly three out of 10 (29 percent) had stopped taking a medicine before the supply ran out; and
- + Almost one-quarter (24 percent) had taken less than the recommended dosage.

While disturbing, these statistics only begin to demonstrate the magnitude and scope of poor adherence in the U.S. Lack of adherence affects Americans of all ages and both genders, but is of particular concern among those aged 65 and over who, because they have more long-term, chronic illnesses, now buy 30 percent of all prescription medicines⁽⁵⁾ and often combine multiple medications over the course of a day. Regardless of age and sex, poor medication adherence is also just as likely to involve higher-income, well-educated people as those at lower socioeconomic levels.⁽²⁾ As a result, poor medication adherence has been estimated to cost approximately \$177 billion annually in total direct and indirect health care costs.⁽⁶⁾

Adherence rates are typically higher in patients with acute conditions, as compared to those with chronic conditions, with adherence dropping most dramatically after the first six months of therapy.⁽²⁾ The problem is especially grave for such patients with chronic conditions requiring long-term or lifelong therapy, because poor medication adherence leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and premature death.⁽³⁾ Lack of adherence also increases the risk of developing a resistance to needed therapies (e.g., with antibiotic therapy), more intense relapses, and withdrawal (e.g., with thyroid hormone replacement therapy)

and rebound effects (e.g., with hypertension and depression therapy) when medication is interrupted.⁽³⁾ Because of this impact, adherence has been called “the key mediator between medical practice and patient outcomes.”⁽⁷⁾

A TIME FOR ACTION

Although the challenge of poor medication adherence has been discussed and debated for at least three decades, these problems have generally been overlooked as a major health care priority. Compounding the situation, adherence problems have been exacerbated by the fragmented approach by which hospitals, health care providers, and other parts of the health delivery system intervene with patients and caregivers to encourage adherence. Consequently, many leading medical societies are now advocating a multidisciplinary approach through coordinated action by health professionals, researchers, health planners and policymakers.

Over a decade ago, the National Council on Patient Information and Education (NCPIE) recognized the need for such a coordinated approach to improved medication adherence and issued a report -- *Prescription Medicine Compliance: A Review of the Baseline Knowledge*⁽⁸⁾ -- which defined the key factors contributing to poor adherence. The report further outlined strategies that could be implemented by health care professionals, patients and caregivers and health care systems, including these key strategies recommended for health care providers:

- + Using a verbal discussion reinforced with appropriately designed written materials to help the patient understand the medical condition, the need for the treatment, and the value of the treatment;
- + Offering verbal counseling from both the prescribing health care provider and the pharmacist that the prescription should be filled and taken as prescribed. While written instruction sheets can reinforce these instructions, they should never be used as a substitute for counseling;
- + Providing useful written information in “patient language” that clearly explains

how the patient can correctly manage his/her medications. This information includes details on how to administer the medication, the exact time the medicine should be taken and why, how long to take the medicine, recognition and management steps for common side effects, special precautions, and how to monitor the progress of the therapy;

- + Making patients aware of the various medication adherence aids and devices available, such as dosing reminders, pill boxes and refill reminder programs;
- + Monitoring patient adherence with every visit to the prescribing health care provider or pharmacist; and
- + Instructing patients and caregivers on home monitoring activities (such as home blood pressure monitoring) and home monitoring records that should be maintained for use during future medical and pharmacy visits.

Since the NCPIE report was published, the National Institutes of Health (NIH) and a number of voluntary health organizations focusing on the major chronic diseases affecting Americans today -- asthma, cancer, cardiovascular disease, diabetes and mental illness -- have weighed in with new findings on the importance of adherence for successful treatment. The consensus of these groups is that interventions that improve patient adherence improve health status and reduce health care costs. As stated in *The Multilevel Compliance Challenge*, a paper by the American Heart Association:

“Maximum use of strategies to enhance compliance must be made. Application of these strategies is particularly important now, when there is great pressure to decrease costs and improve quality and patient outcomes.”⁽⁹⁾

Further elevating the need for action is the World Health Organization (WHO), which has called for an initiative to improve worldwide rates of adherence to therapies commonly used in treating chronic conditions, including asthma, diabetes, and hypertension. In a 2003 report entitled *Adherence*

to *Long-Term Therapies: Evidence for Action*, WHO defined poor medication adherence as a critical issue for global public health, and identified five broad dimensions affecting adherence that need to be addressed by health managers and policymakers:⁽³⁾

1. social and economic factors;
2. health system and health care team-related factors;
3. therapy-related factors;
4. condition-related factors; and
5. patient-related factors.

To bring about needed change, the WHO report called for a multidisciplinary approach toward adherence that includes patient-tailored interventions and training in adherence management for health professionals. This approach was also addressed in a 2005 review article by researchers Lars Osterberg, M.D., and Terrence Blaschke, M.D. published in the *New England Journal of Medicine* where the authors identified 12 major predictors associated with poor adherence -- from the side effects of treatment to the patient's belief in the benefit of the medicine.⁽²⁾ (See Table 1; page 29) Noting that race, sex, and socioeconomic status have not been consistently associated with levels of adherence,⁽²⁾ the authors conclude that poor adherence should always be considered when a patient's condition is not responding to therapy. Accordingly, the authors recommend that physicians ask a series of non-judgmental questions of their patients designed to facilitate the identification of poor adherence and enlist ancillary health care providers, such as pharmacists, behavioral specialists, and nursing staff to improve adherence.⁽²⁾

Another major development since the publication of NCPIE's report is new technology that makes available a number of useful mechanisms for fostering adherence. For example, patients can receive pharmaceutical information and refill reminders via letter, fax, telephone, e-mail and pager messages. There are also electronic reminder devices, which can be programmed for multiple

daily alarms and may permit the user to record brief dosing instructions. Moreover, a number of medication organizers now incorporate electronic alarms to alert patients when doses are due.

Despite such developments, adherence rates have not changed significantly since NCPIE issued its recommendations over a decade ago, demonstrating that an intensified, sustained focus on adherence improvement among all stakeholders is essential to reduce the adverse health and economic consequences associated with this pervasive problem. While no single strategy will guarantee that patients will fill their prescriptions and take their medicines as prescribed, elevating adherence as a priority issue and promoting best practices, behaviors, and technologies may significantly improve medication adherence in the U.S.

This report, therefore, is intended as a renewed nationwide call to action. Based on an analysis of research to date, it examines the current state of patient adherence and trends that may lead to improved medication use. This report also offers realistic goals for improving medication adherence through patient information and education, health professional intervention, and supportive government policies.

Prescription Medicine Adherence: A Fresh Look at a Persistent and Complex Problem

Even as the issue of taking medicines as prescribed is getting increased attention within the public health community, the multi-faceted nature of poor adherence has significantly clouded the debate. The following is a look at the current state of patient adherence and the factors contributing to this complex problem.

LACK OF A STANDARD DEFINITION AND CONSISTENT TERMINOLOGY LIMITS CONSENSUS

Even though there is a growing recognition about the need for improvements in medication adherence, progress has been hampered by a lack of consistent terminology. Today, a number of common terms are used to define the act of seeking medical attention, filling prescriptions, and taking medicines appropriately. All have their supporters and detractors and all reflect different views about the relationship between the patient and the health care provider.

In its 1995 report, NCPIE defined adherence as following a medicine treatment plan developed and agreed on by the patient and his/her health professional(s). Originally, NCPIE used the term “compliance” because historically, it is the term most widely used in medical indices. First appearing in the medical literature in the 1950’s, the term “compliance” came into popular use following the 1976 publication of the proceedings of the first major academic symposium on the subject.⁽¹⁰⁾ As originally defined, “compliance” was intended to describe “the extent to which patients’ behaviors coincide with the health care providers’ medical or health advice.”

Yet to many researchers, “compliance” connotes a passive role for the patient and appears to blame and stigmatizes the patient’s independent judgment

as deviant behavior. Thus, many stakeholders prefer the term “adherence,” which implies a more collaborative relationship between patients and clinicians and is more respectful of the role that patients can play in their own treatment decisions. Thus, the NCPIE definition proposed in 1995 was intended to encompass the concept of adherence, including two-way communication, patient-centered treatment planning, and agreement upon the medication and dosing requirements.

The term “persistence” has also entered the lexicon and is intended to address the treatment continuum, beginning with having the prescription filled and continuing with taking and refilling the medicine for as long as necessary. However, in the view of some researchers, the term “adherence” is more comprehensive and reflects both taking the medicine as directed (compliance) and continuing to take the medication for the duration required (persistence).

Another term now being used is “concordance,” which is intended to convey an active partnership between the patient and the health care professional. Developed by the Royal Pharmaceutical Society of Great Britain, the concept suggests that the clinician and patient find areas of health belief that are shared and then build on these beliefs to improve patient outcomes.⁽¹¹⁾ However, this term has also been challenged as being more inspirational than what is possible in promoting better medication taking by patients.

Despite the increased use of “persistence,” and “concordance,” many researchers now use the terms “compliance” and “adherence” interchangeably. However, since “concordance” is being increasingly used in Europe, an important priority for the global public health community is to agree on a standard definition that will unite all stakeholders around the common goal of improving the self-administration of treatments to promote better health outcomes. For the purposes of this report, NCPIE has adopted

the term “adherence” because the term supports a patient-centered approach to improving how patients seek information, fill their prescriptions and take their medicines as prescribed.

THE EXTENT OF THE PROBLEM

Agreeing on a standard definition for patient adherence also requires an up-to-date assessment of the problem, which today rivals many disease states in terms of prevalence, human suffering, and health care costs. From a public health perspective, poor adherence is nothing short of a crisis.

Although the problem varies by condition and the types of drugs prescribed, it is significant, not only in the U.S. but around the world. According to research findings:

- + Between 12 percent and 20 percent of patients take other people’s medicines;⁽¹¹⁾
- + In developed countries like the U.S., adherence among patients with chronic conditions averages only 50 percent;⁽³⁾
- + Other studies show that about one-third of patients fully comply with recommended treatment while another third sometimes comply and one-third never comply;⁽¹²⁾
- + The World Health Organization reports that only about 43 percent of patients in developed nations take their medicines as prescribed to treat asthma and between 40 percent and 70 percent follow the doctor’s orders to treat depression;⁽³⁾
- + Although hypertension increases the risk of ischemic heart disease three- to four-fold and increases the overall cardiovascular risk by two- to three-fold, just 51 percent of patients take their prescribed doses of drugs to manage this condition;⁽¹³⁾
- + Among 17,000 U.S. patients prescribed beta blocker drugs following a heart attack, a major study conducted by Duke University Medical Center reported that only 45 percent regularly took these medications during the first year after

leaving the hospital, with the biggest drop in adherence occurring during the initial months after hospital discharge;⁽¹³⁾

- + Less than 2 percent of adults with diabetes perform the full level of care, which includes self-monitoring of blood glucose and dietary restrictions as well as medication use, that is recommended by the American Diabetes Association;⁽¹⁴⁾
- + Although adherence with short-term therapy is generally considered to be higher than for long-term treatments, rapid declines occur even in the first ten days of use;⁽¹⁵⁾ and
- + Even among health care professionals, self-reported adherence with prescribed therapies averaged only 79 percent in one study.⁽¹⁶⁾

Researchers have found that even the potential for serious harm may not be enough to motivate patients to take their medicines appropriately. In one study, only 42 percent of glaucoma patients met minimal criteria for adherence after having been told they would go blind if they did not comply. Among patients who already had gone blind in one eye, adherence rates rose only to 58 percent.⁽¹⁷⁾ Another study of renal transplant patients facing organ rejection or even death from poor adherence with immunosuppressant therapy found that 18 percent of patients were not taking their medicine as prescribed.⁽¹⁸⁾

SPECIAL POPULATIONS AT RISK

Of special concern to the public health community is poor adherence among people aged 65 and over, who tend to have more long-term, chronic illnesses--such as arthritis, diabetes, high blood pressure, and heart disease-- and therefore, take more different medications as they age. According to one study, people aged 75 years and older take an average of 7.9 drugs per day.⁽¹¹⁾ Other studies have shown that between 40 percent and 75 percent of older people do not take their medications at the right time or in the right amount⁽¹⁹⁾ due to such complicating factors as having multiple health problems requiring treatment,

needing multiple medications, being seen by multiple prescribers, and having physical and cognitive challenges that may impact medication use.

The impact of poor adherence is also a serious problem among the medically underserved -- those Americans of all ethnic backgrounds who are poor, lack health insurance, or otherwise have inadequate access to high-quality health care. According to the third National Healthcare Disparities Report (NHDR) issued in 2005 by the Agency for Healthcare Research and Quality (AHRQ), health care disparities by race and ethnicity remain prevalent in the U.S. and are significantly correlated with health literacy -- the ability of an individual to access, understand and use health-related information and services to make appropriate health decisions -- among the underserved. The Office of the U.S. Surgeon General estimates that more than 90 million Americans cannot understand basic health information,⁽²⁰⁾ which costs the health system billions of dollars each year due to misdirected or misunderstood medical advice.

Children and teenagers are also an at-risk group, especially when it comes to adherence to treatments for asthma, one of the most common chronic diseases of childhood.⁽²¹⁾ Research shows that adherence to prescribed pulmonary medication may be as low as 30 percent in adolescents,⁽²⁾ leading to uncontrolled asthma. A number of factors related to children's experiences taking medicines during their formative years affect future rates of compliance. These factors include parents not adequately monitoring their children's use of medicines, poor parental adherence to treatment regimens, and lack of school education about medicine use.

PAYING THE PRICE FOR POOR ADHERENCE

Who is paying the price for the epidemic of poor medication adherence? We all are -- and the costs are substantial. Researchers have calculated that non-adherence costs the U.S. health care system about \$100 billion annually,^(22, 23, 24) including approximately \$47 billion each year for drug-related hospitalizations.⁽²⁵⁾ Moreover, not taking medicines as prescribed has been associated with as many as 40

percent of admissions to nursing homes⁽²⁶⁾ and with an additional \$2,000 a year per patient in medical costs for visits to physicians' offices.⁽²⁶⁾ The total direct and indirect costs to U.S. society from prescription drug non-adherence are about \$177 billion annually.⁽²⁷⁾

Employers also pay a high price for employees' non-adherence to prescribed medical treatments, both in terms of reduced productivity and absenteeism, and in higher costs for private or managed care health insurance benefits. With prescription drugs representing the fastest-growing cost component for most health plans (climbing at more than 17 percent annually),⁽²⁸⁾ employers are increasingly requiring that covered members and their families assume a greater percent of their cost.

Although the economic cost associated with poor adherence is already staggeringly high, the World Health Organization predicts that this problem will only grow as the burden of chronic diseases increases worldwide.⁽³⁾ As policymakers consider ways to address the escalating costs of health care in the U.S., it is critical that the agenda include the pressing issue of improving patient adherence with medication regimens. Mounting evidence shows that better adherence leads to improved clinical outcomes and reduced costs.⁽²⁹⁾ Based on a meta-analysis of 63 studies involving more than 19,000 patients, higher adherence was found to reduce the risk for a poor treatment outcome by 26 percent.⁽³⁰⁾ Other data associate patient self-management and adherence programs with a reduction in the number of patients being hospitalized, days in the hospital, and outpatient visits. The data suggest a cost to savings ratio of approximately 1:10 in some cases, with the results continuing over several years.⁽³¹⁾

As Americans age, an increasing number are prescribed multiple medications for multiple chronic conditions. As a result, new strategies to enhance prescription medicine adherence are needed. While new interventions are not cost-free, improving adherence is likely to increase the cost effectiveness of health interventions, thereby reducing the burden of chronic illness. The investment of time and resources to improve patient adherence will likely more than pay for itself through improved health status and reduced utilization and costs.

What Is Behind Poor Adherence: Factors That Contribute to the Problem

Poor adherence encompasses much more than patients not taking their medicines as directed. Numerous behavioral, social, economic, medical, and policy-related factors contribute to the problem and must be addressed if adherence rates are to improve.⁽³⁾

To understand the interplay of these issues, the research community has categorized the factors underlying non-adherence as medication-related, patient-related, prescriber-related, and pharmacy-related. Additionally, federal and state government policies can also serve as impediments to adherence improvement. The following describes these factors and the challenges they represent.

MEDICATION-RELATED FACTORS

For many patients, one of the biggest stumbling blocks to taking their medicines is the complexity of the regimen. Studies find that patients on once-daily regimens are much more likely to comply than patients who are required to take their medicine(s) multiple times each day.⁽³²⁾

Conversely, the number of medications a person takes has a negative impact on adherence. In any given week, four out of five U.S. adults will use prescription medicines, over-the-counter (OTC) drugs, or dietary and herbal supplements and nearly one-third will take five or more different medications.⁽³³⁾ Of special concern are adults aged 65 and older, who take more prescription and OTC medicines than any other age group.⁽³⁴⁾ According to a 2001 survey of older Americans conducted by the American Society of Health-System Pharmacists (ASHP), 82 percent of patients over age 65 take at least one prescription medicine, more than half (54 percent) take three or four prescription medicines, and as many as a third (33 percent) take eight or more prescription medicines to treat their health conditions.⁽³⁵⁾ Adherence also decreases when patients are asked to master a specific technique in

order to take their medication, such as using devices to test blood levels as part of a treatment protocol, using inhalers, or self-administering injections.⁽³⁶⁾

Compounding the problem, many patients -- and especially older adults -- are being seen by more than one physician or other prescriber, and each may be prescribing medications for a specific condition. Unless there is a primary care provider who coordinates these medication regimens, the number of different medicines the patient takes each day may limit adherence while also increasing the risk of medication errors and harmful drug interactions.

Beyond the complexity of the regimen, concern about medication side effects remains a powerful barrier to patient adherence. In a 2005 survey of 2,507 adults conducted by Harris Interactive, nearly half of the respondents (45 percent) reported not taking their medicines due to concerns about side effects.⁽³⁷⁾ Conversely, when medications such as antidepressants and corticosteroids are slow to produce intended effects, patients may believe the medication is not working and discontinue use.⁽³⁸⁾

Addressing these medication-related factors will require better communication between the patient and his/her prescriber about what to expect from treatment and about the patient's medication challenges (including the number of medicines being taken, worries about side effects and how to administer and monitor the medicine). Through high-quality, two-way discussions, clinicians will be able to identify and discontinue unnecessary medications, simplify dosing regimens, and address other medication-related issues that make adherence difficult.

PATIENT-RELATED FACTORS

Patients ultimately are in control of whether, how safely and how appropriately they take their

medicines. For example, a common reason why patients don't take their medicines is simply forgetfulness.⁽³⁹⁾ Another significant barrier is the inability to understand and act on instructions for taking the medication. In fact, a study found that 60 percent or more of patients being followed could not correctly report what their physicians told them about medication use 10 to 80 minutes after receiving the information.⁽⁴⁰⁾

While problems such as these are significant, public health officials are increasingly concerned about patients and especially those with chronic conditions requiring long-term therapy, such as asthma, diabetes, and hypertension, who make a conscious choice not to fill the prescription, not to take their medicine as prescribed, or to discontinue therapy. Influencing these decisions are a number of factors related to the patient's experiences, perceptions, and understanding about his or her disease. These include:⁽⁴¹⁾

1. Perceptions about the nature and severity of their illness;
2. Denial of illness and the need to take medicines;
3. The assumption that once the symptoms improve or the person "feels better," he or she can discontinue use of the medication;
4. Limited appreciation about the value of medicines when properly used;
5. Beliefs about the effectiveness of the treatment;
6. Acceptance of taking medications for preventive purposes and for symptomless conditions (e.g. statins to lower blood cholesterol levels);
7. Worries about the social stigma associated with taking medicines;
8. Fear of side effects or concern about becoming drug dependent;
9. Fear of needles and the need for self-injections;

10. Lack of confidence in the ability to follow the medication regimen;
11. Media influence regarding safety or risk issues associated with particular medicines; and
12. Lack of positive motivations and incentives to make necessary changes in behavior.

Along with these attitudes and beliefs, the duration of the course of therapy also contributes to whether and how patients take their medicines.⁽³⁶⁾ Adherence rates have been found to decline over time when patients are treated for chronic conditions.⁽²⁹⁾

Moreover, for many Americans, the high cost of medications is a barrier to medication use.⁽³⁶⁾ In a 2004 study of nearly 14,000 Medicare enrollees, 29 percent of disabled people and 13 percent of seniors reported skipping doses or not filling a prescription because of cost.⁽⁴²⁾ Limited access to health care services, lack of financial resources, and burdensome work schedules are also associated with poor adherence to medication regimens.⁽²⁾

Compounding these problems is the impact of low health literacy and limited English language proficiency, which greatly affect the ability of patients to read, understand, and act on health information about medication use. According to published studies, 45 percent of the adult population (90 million people) have literacy skills at or below the eighth grade reading level, making it difficult for these individuals to read health information, understand basic medical instructions and adhere to medication regimens.⁽⁴³⁾ In one study involving patients over age 60 who were treated at two public hospitals, 81 percent could not read or understand basic materials, such as prescription labels.⁽⁴³⁾ A 2006 study, published in the *Annals of Internal Medicine* found that low-literacy patients have difficulty understanding basic information regarding medication dosage. While over 70 percent of the respondents correctly stated instructions about taking two pills twice a day, only one-third (34.7 percent) could demonstrate the correct number of pills to be taken daily.⁽⁴⁴⁾

Further, studies have found that people with low health literacy or limited English language proficiency are often ashamed to get help with medical instructions,⁽⁴⁵⁾ which increases the likelihood that they will not be able to follow their treatment regimens. As a result, the U.S. Surgeon General, the National Quality Forum, and other stakeholders have called for immediate action to improve adherence among these sizeable vulnerable populations.

PRESCRIBER-RELATED FACTORS

In 1995, NCPIC identified the lack of awareness of basic compliance management principles among some clinicians as a major causal factor for prescription non-adherence. More than a decade later, this appears to remain the case. According to a 2004 telephone survey conducted by the Food and Drug Administration (FDA), only 66 percent of consumers polled reported receiving instructions from their physician about how often to take a new medication and only 64 percent were told how much to take.⁽⁴⁶⁾ The survey also examined the receipt of medicine information at the pharmacy. Here, the figures dropped considerably, to 31 percent (how often to take) and 29 percent (how much to take) respectively.⁽⁴⁶⁾

Why is this the case? One reason is that clinicians tend to overestimate the extent of their patients' ability to adhere to a medication regimen and the patient's actual adherence level. In one study of 10 family physicians who had known many of their patients for more than five years, researchers found that only 10 percent of the physicians' estimates of adherence with digoxin therapy were accurate when compared with information from a pill count and serum digoxin concentration measurements.⁽²⁹⁾ Earlier studies reported that health professionals overstate the adherence of their patients by as much as 50 percent.⁽⁴⁷⁾

At the same time, the WHO report attributes lack of adequate medication counseling to the outdated belief that adherence is solely the patient's responsibility.⁽³⁾ Practical issues such as lack of time and lack of financial reimbursement for education

and counseling also represent persistent barriers to health care provider adherence interventions.⁽⁴⁸⁾

Besides these practical issues is the factor of trust between the clinician and the patient. According to a study recently reported in the *Archives of Internal Medicine*, when physician trust levels are low, patients are more likely to forego the use of medications.⁽⁴⁹⁾ This study suggests that clinicians need to encourage adherence through behaviors designed to improve patient trust. Further, a meta-analysis of 21 studies assessing the quality of physician-patient communication found that the quality of communication both in the history-taking segment of the visit and during discussion of the management plan significantly improved patient health outcomes.⁽⁵⁰⁾

Finally, there is the pervasive problem of poor communication between the clinician and the patient. Because this lack of effective communication can lead to medication errors and non-adherence, the Institute of Medicine (IOM) in its landmark 1999 report – *To Err is Human; Building a Safer Health System* – called on clinicians to educate their patients about the medications they are taking, why they are taking them, what the medications look like, what time patients should take their medicines, potential side effects, what to do if a patient experiences side effects, and what regular testing is necessary.⁽⁵¹⁾ Osterberg and Blaschke also present a range of communications-based strategies for improving medication adherence in their review article, *Adherence to Medication*, published in the August 4, 2005 issue of the *New England Journal of Medicine*.⁽²⁾ (See Table 2; page 30 of this report).

PHARMACY-RELATED FACTORS

Because pharmacists have direct and frequent contact both with prescribers and patients, research suggests that community-based pharmacists can play a unique role in promoting medication adherence.^(3,16) For example, a study examining the interaction of 78 ambulatory care clinical pharmacists with 523 patients treated at selected Veterans Affairs medical centers over the course of a year found that pharmacists were responsible

for adjusting patients' drug regimens as well as identifying and preventing drug-related problems.⁽⁵²⁾

Also demonstrating the ability of community-based pharmacists to increase medication adherence is the recent Federal Study of Adherence to Medications in the Elderly (FAME) conducted among military health care beneficiaries aged 65 years or older who were prescribed at least four chronic medications a day. Designed to assess the efficacy of a comprehensive pharmacy care program, this multi-phase study examined the impact of patient education and the use of an adherence aid (medications custom packaged in blister packs), finding that the program increased medication adherence and persistence, whereas discontinuation of the program was associated with decreased medication adherence and persistence.⁽⁵³⁾ Findings from the FAME study call for greater emphasis within health care delivery systems and policy organizations on the development and promotion of clinical programs to enhance medication adherence particularly among the at-risk elderly population.

Despite these research findings, however, four categories of pharmacy-related barriers to improved patient adherence remain and must be addressed. Broadly defined, these categories are: the attitudes of patients and pharmacists, the knowledge level of pharmacists, the operational aspects of the pharmacy practice, and professional barriers.⁽⁴¹⁾

In its 1995 report, NCPPIE identified many attitudinal barriers that contribute to the poor adherence, including the perceptions of patients, caregivers, and other health care providers about the expertise of pharmacists and the pharmacist's willingness to tailor education and counseling to the needs of the patient. Moreover, pharmacists' own views about their role in medication adherence can be a factor. Many pharmacists are accustomed to a paternalistic relationship where the pharmacist tells the patient what to do and the patient is expected to follow those instructions.⁽²⁶⁾ Further complicating the situation for pharmacists is identifying potential adherence problems when medication regimens can be complex and then applying complex technical information to practice situations.⁽²⁶⁾

Beyond these issues, NCPPIE has noted functional and professional barriers that can significantly impact the ability of pharmacists to engage in adherence education and counseling. Functional barriers can include space limitations, time constraints, the lack of resources, and the lack of management support to counsel patients on medication adherence.⁽⁵⁵⁾ Moreover, thousands of pharmacies must divert time and cannot efficiently fill prescriptions because information needed to obtain reimbursement frequently does not appear on a patient's drug benefit card. As a consequence, thousands of hours are occupied calling employers or insurance companies to obtain this information.⁽⁵⁶⁾ Reimbursement for counseling patients has not kept pace with the pharmacy profession's attempts to obtain this payment, although the Medicare prescription drug benefit plan affords opportunities due to requirements for medication therapy management programs (MTMP) for specific enrollees.

Professional barriers also arise from a lack of consensus within the pharmacy community about the role of pharmacists in health care delivery. To gain this consensus, national pharmacy organizations have endorsed the concept of "pharmaceutical care,"⁽⁵⁷⁾ a maturation of pharmacy as a clinical profession, with pharmacists cooperating directly with other professionals and the patient in designing, implementing and monitoring a therapeutic plan. This approach requires a knowledgeable frontline staff supported by managers, other pharmacists and effective work systems.

GOVERNMENT IMPEDIMENTS

The pharmaceutical care model advanced by the pharmacy community is predicated on supportive government policies. However, a number of federal and state laws, as currently interpreted, may actually impede the availability of adherence assistance programs.

One such impediment is the federal anti-kickback statute containing rules that cover businesses reimbursed by Medicare, Medicaid or other federally funded health care programs. This statute is so

broadly written that many types of health care practices and business relationships designed to increase patient adherence may theoretically be subject to criminal prosecution under the statute.

To help address this problem, the Office of the Inspector General (OIG) within the Department of Health and Human Services (HHS) issued regulations granting “safe harbor” protections to certain types of health care practices and business arrangements.¹ However, because OIG’s regulations don’t specifically cover patient education, medication refill reminder programs and other pharmacy-based adherence messaging programs, the result has been a reduced use of adherence messaging programs. In an abundance of caution, some refill reminder programs now exclude any patients who participate in any federal health care program (e.g., Medicare, Medicaid, TRICARE).²

Another impediment to pharmacy adherence assistance programs involves federal and state medical privacy requirements. At the federal level, there is the “Privacy Rule,”³ a set of federal medical privacy regulations issued to implement the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Although these rules permit health care providers to carry out “treatment” functions, including refill reminders and other adherence messaging programs, without first obtaining the patient’s written permission,⁴ some privacy advocates object to these provisions.

With these concerns in mind, the National Consumers League (NCL) created voluntary performance-based Best Practice Principles that build on the requirements contained in the HIPAA privacy rule.⁽⁵⁸⁾ Developed by a Working Group of representatives from public interest groups, health professional societies, the consumer/privacy movement, pharmacy industry trade groups, pharmacy vendors, retail chains, and the pharmaceutical industry, the Best Practices

Principles are intended to bridge the gap between the protections afforded by HIPAA and fair information practices that define the degree of control that consumers should have over the ways their health information is used. Accordingly, the Best Practices Principles include:⁽⁵⁸⁾

- + Ensuring that a pharmacy’s Notice of Privacy Practices can be easily understood;
- + Providing patients with a description of pharmacy messaging programs;
- + Providing an opportunity to opt out of the pharmacy messaging programs;
- + Ensuring that opt-out mechanisms function properly;
- + Identifying sponsorship;
- + Disclosing limitations of materials as a source of health care information;
- + Providing information that is clear and reliable;
- + Endeavoring to use discretion in communicating about sensitive subjects;
- + Ensuring that persistence and adherence messages are written in a manner consistent with available data about the characteristics of effective messaging; and
- + Engaging in messaging about alternative and/or adjunctive therapies only when there is a clear potential benefit to patients.

Even with these voluntary principles, however, HIPAA does not preempt state law, which is why a number of states have enacted, or are considering, legislation to restrict the ability of pharmacies to conduct adherence messaging programs. As with the federal anti-kickback statute, the unintended consequence of some of these state laws is uncertainty about which types of medical information require patient authorization and which do not. For example,

¹ 42 C.F.R. Part 1001.

² To the extent that the antikickback statute discourages refill reminders and other compliance programs, its effect is somewhat at odds with the Medicare Modernization Act, which required that, every Part D benefit plan implement medication management therapy programs (MTMPs). MTMPs are designed to optimize the therapeutic outcome of drug treatment for certain beneficiaries through education and management programs. Improved medication compliance and adherence is a key part of a successful MTMP.

³ Pub. L. No. 104-191.

⁴ 45 C.F.R. § 164.506(a) and (c).

the California Confidentiality of Medical Information Act (CMIA) provides (in relevant part):

Except to the extent expressly authorized by the patient . . . no provider of health care . . . shall intentionally share, sell, use for marketing, or otherwise use any medical information for any purpose not necessary to provide health care services to the patient.⁵

When read literally, the CMIA seems to prohibit adherence-messaging programs without specific authorization, when in fact, the Act views these programs as “necessary to provide health care services” and exempts this requirement. The CMIA also exempts the authorization requirement for adherence communications that address a “chronic and seriously debilitating or life-threatening condition” if certain conditions are satisfied.⁶ But since there is uncertainty as to how state regulators could interpret these provisions, many pharmacies and pharmaceutical manufacturers have opted not to run adherence programs in California, or run them on a limited basis. The consequence is that adherence communications for medications for diabetes, osteoporosis, asthma, hypertension and heart attack and stroke prevention now being provided in other states are, in some cases, being withheld from Californians. The same situation could result if a number of state bodies enact legislation that broadly prohibit the use of prescription drug information for commercial purposes, including pharmacy-based programs funded through third parties.

LIMITED FEDERAL SUPPORT FOR ADHERENCE RESEARCH

Besides federal and state laws and policies that impact the availability of adherence assistance programs, insufficient federal funding for adherence research is another impediment to improving medication use. Although created the Adherence Research Network to identify research opportunities at its 18 Institutes and Centers, the Network has been inactive since 2002. Moreover, in 2000, when the Network was funding adherence research, the actual NIH dollars earmarked

for testing interventions to improve medication-taking behavior was only \$3 million in a budget of nearly \$18 billion.⁽⁵⁹⁾ The overall NIH budget in 2000 was \$17.8 billion.

Such paucity in adherence research funding has implications for public policy, as policymakers look to researchers to help determine priorities for the medical community. While NIH dollars are being spent on patient adherence as it applies to treating specific disease states, very little is actually going into testing interventions and measuring their effectiveness. Thus, a key goal will be to re-invigorate the Adherence Research Network while increasing substantially the level of NIH funding for research to test adherence interventions and measure their effectiveness.

Kripalani, Yao, and Haynes (Interventions to Enhance Medication Adherence in Chronic Medical Conditions) point out key limitations and challenges for future adherence research, noting that because most of the available literature does not separate out the effects of the individual components of multifaceted interventions, it is not possible to draw definitive conclusions about which features of combined interventions are most beneficial.⁽⁶⁰⁾ Additional research, the authors note, is needed to clarify which features are most responsible for changes in adherence and clinical outcomes, with the caveat that individual components may not prove powerful enough to show important effects.

Future studies should also examine the effect of varying the intensity of interventions to determine dose response relationships. Such findings would have important implications for health systems considering the implementation of patient adherence programs on a large scale. Investigations should be conducted with clinically meaningful outcomes as the primary end points and be sufficiently powered to detect a difference in these measures. Most important, future research should seek to understand the determinants of adherence behavior and to develop and test innovative ways to help people adhere to prescribed medication regimens, rather than persisting with existing approaches.⁽⁶⁰⁾

¹ Cal. Civ. Code § 56.10(d), as amended by A.B. 715.

² Cal. Civ. Code § 56.05(f)(3).

Strategies for Improving Patient Adherence

How do we change behavior? How can we motivate patients with chronic illnesses to take steps that will keep their diseases from progressing? How can we engage health professionals to intervene with patients and their caregivers about the need to take medicines as directed -- sometimes for life? And how can we elevate the subject of prescription medicine adherence, an issue to which Americans have been largely indifferent, to one that is both compelling and actionable by all affected stakeholders?

These are the challenges facing the U.S. health system at a time when lack of patient adherence to medication regimens, especially for the treatment of chronic conditions, leads to unnecessary disease progression, disease complications, reduced functional abilities, a lower quality of life, and even death. To address this serious problem, a range of strategies must be used to target the underlying causes of poor adherence and to make the relevance of taking medicines as prescribed meaningful to all stakeholders -- patients, caregivers, clinicians, payors, public health advocates, and policymakers. But this does not mean starting from scratch: extensive research exists that provides insights into effective approaches to improve adherence to therapeutic regimens.

RECOGNIZING THE DISEASE CHARACTERISTICS OF NONCOMPLIANCE

The 1994 report *Noncompliance With Medications: An Economic Tragedy With Important Implications for Health Care Reform* introduced the concept that non-adherence is a disease because the problem shares many features of a medical disorder, including:⁽²²⁾

- + Non-adherence can lead to increased morbidity and mortality;

- + The problem can be assessed and monitored;
- + Effective interventions have been identified;
- + Triage is needed to identify those patients at greatest risk of non-adherence; and
- + Non-adherence is a public health problem for which prevention is an important goal.

In light of these similarities, approaching non-adherence as a disease could be an important step towards increasing the extent to which patients take their medications as prescribed by their health care provider(s). With implications for research, health policy, and the day-to-day practice of medicine and pharmacy, widespread recognition of the disease characteristics of non-compliance would put the issue into a new perspective that would help gain the attention, focus and sustained commitment that this problem deserves.

INCREASING PUBLIC AWARENESS THROUGH EDUCATION

To motivate patients to adhere to their medication regimens, the American public must first recognize the role each person plays in taking their medications as prescribed or in making sure that a loved one does so. Simply put, the American public needs increased education about medication adherence that captures their attention, increases their understanding, and enhances their motivation to take their prescribed medication in the recommended way.

To achieve these goals, specialists in medication use advocate mounting a sustained, national public education campaign to provide patients and caregivers with meaningful information about adherence that they can incorporate into their daily lives. Ultimately, enlisting the support and participation of many stakeholders -- including the public health community, physicians and other

prescribers, nurses, pharmacists, the pharmaceutical industry, government, private payors, and consumer organizations – such a campaign must elevate adherence as a health priority and utilize multiple information channels to engage the public on a sustained basis. Only by making the public aware of the role individuals play in the management of their own health conditions will we empower people to ask questions about their medicines, fill their prescriptions, and follow their treatment regimens as recommended.

PATIENT INFORMATION STRATEGIES

As noted by the American Heart Association, the rationale for enhancing adherence is based on the premise that the patient will get well or stay well if the physician, other health care providers, and the health care organization make appropriate recommendations, providing the patient has the requisite knowledge, motivation, skills, and resources to follow the recommendations. Specifically, the American Society of Consultant Pharmacists states that patients need to know:⁽⁶¹⁾

- + What condition the medicine was prescribed to treat.
- + What the medicine is, why it is needed and how it works in the body.
- + Why the medicine was selected.
- + The dosage schedule and related instructions about how to take the medicine (before eating, with food, etc).
- + Whether the medicine will work safely with other medicines being taken (both prescription and nonprescription medicines).
- + What to do if doses are missed or delayed.
- + The common adverse effects that may occur and what to do about them.
- + How to monitor whether the medicine is having its intended effect (are lab tests or blood work necessary; if so, how often).

- + Serious adverse effects to look out for and what to do if they occur.
- + What action to take when the prescription is about to run out.

In the outpatient setting, the primary opportunities for providing this information to the patient occur in discussions when the prescriber writes the prescription and when the patient fills the prescription at the pharmacy. Visiting nurses in the home setting also have an opportunity for such dialogue with patients. During these discussions, research has found that relaying the most important information first, repeating key points, and having patients restate key instructions increase patient understanding.⁽⁶²⁾ Moreover, data show that providing patients with information about possible adverse effects does not appear to decrease adherence.⁽⁶³⁾

Besides providing basic information about how to take the medication correctly, an important reason for clinicians to educate patients about their medication regimens is to address common misperceptions that lead to non-adherence. This may include the perception that the medication can be stopped when the condition improves or that the medicine is only needed when there are symptoms. Moreover, studies demonstrate the benefits of improved adherence when patients are encouraged to ask questions and share information. This process is built upon the Health Belief Model, one of the most widely used conceptual frameworks in health behavior, which suggests that people's beliefs guide their understanding of and response to their diseases.⁽²⁶⁾

However, since studies find patients forget more than half of the information from a verbal explanation immediately after they hear it,⁽¹⁷⁾ health care providers should welcome patients who bring a partner or caregiver as a "second set of ears," and should ask patients to repeat instructions and encourage note taking during the oral discussion. Complementing these actions, providing written information about the medication has been shown to improve patients' knowledge and decrease medication errors. A 2007 study conducted by researchers at the Arnold & Marie Schwartz

College of Pharmacy and Health Sciences, Long Island University, found that approximately two-thirds of surveyed patients reported reading the non-manufacturer developed consumer medicine information (CMI) leaflets about new medications provided by pharmacies.⁽⁶⁴⁾ Accordingly, the study recommends that pharmacists should encourage patients to read the CMI leaflet and promote it as a useful resource, although this information should be used in conjunction with, but not as a substitute for, oral discussions.⁽⁶⁰⁾

In the case of teaching complex medication-taking techniques, such as using a metered dose inhaler or administering an injection, oral and written information will not suffice. Here, patients need a health care provider to walk them through the process in easy steps and to observe while the patient repeats the procedures. The health care provider is then able to answer questions, point out any problems with the patient's technique and work with the patient to repeat the procedure until the problems are resolved.

While all these strategies are helpful in promoting patient adherence, how the information is conveyed also matters greatly to how patients ultimately respond. For example, a 2006 study conducted for the American College of Physicians (ACP) Foundation and reported in the *Annals of Internal Medicine*⁽⁶⁵⁾ found that a major barrier to patient adherence is patient understanding of prescription drug labels, including the format, content, and use of medical jargon. Because this problem is especially acute among those with lower literacy (eighth grade level or below) and patients taking multiple prescription drugs, the ACP Foundation has launched a Prescription Medication Labeling project to address the problems associated with poor health communication.

A key strategy of the Prescription Medication Labeling project is the use of patient-centered counseling, an approach that focuses not only on the content of the information but also on the tone used by health professionals. As detailed in the 1995 NCPIE report, patient adherence improves when professionals:⁽³⁶⁾

- + Are warm and caring and respect the patient's concerns,
- + Talk to patients directly about the need for adherence,
- + Probe patients about their medicine taking habits and health beliefs,
- + Obtain agreement from the patient on the specifics of the regimen, including the medical treatment goals,
- + Communicate the benefits and risks of treatment in an understandable way that fosters the perception that the patient has made an informed choice about his or her care, and
- + Probe for and help resolve patient concerns upfront so they do not become hidden reasons for non-adherence.

BEHAVIORAL REINFORCEMENT AND PATIENT SUPPORT

Especially in chronic disease management, where medication is required on a continuing basis, adherence with medication regimens involves a change in behavior on the part of the patient.⁽⁶⁶⁾ In some cases, patients may need to take specific medications every day at a set time. Adherence also requires that patients remember to get their prescriptions refilled and to incorporate their medication taking into their daily schedules and lifestyle.

Because these actions require diligence, adherence can be viewed as a continuum, with most patients starting as very diligent and declining over time. Adherence has also been shown to decline between visits to the physician/clinic.⁽³⁾ That is why regular interaction between patients and health providers is so important for improving medication use.

Recognizing these challenges, adherence researchers stress the importance of tailoring the medication regimen to the patient's daily schedule and lifestyle, such as:

- + Decreasing the number of daily doses to once or twice a day;^(17,36)
- + Eliminating unnecessary or redundant medications or using combination products when possible;
- + Changing the route of administration, such as using oral medications or transdermal patches; and
- + Decreasing the overall cost of the medication regimen if affordability is a barrier to compliance.

Additionally, long-term adherence requires behavioral reinforcement and patient support strategies throughout the continuum of care. Providing cues to patients -- through medication packaging that helps patients chart and remember to take each dose and through tools such as medication organizers and reminder charts -- have been shown to improve adherence. A personal medication chart encourages the patient to keep a list of all the prescription and over-the-counter medications used, including recording how much to take, when and how to use the medicine, why to use the medicine, and the name of the prescriber.

Another approach that has produced measurable outcomes is direct-to-patient adherence programs, such as arranging supportive home visits by health care providers or encouraging the patient to establish a buddy system with a friend who also takes daily medication. In a meta-analysis of 153 studies assessing the effectiveness of different adherence interventions, those that combined educational and behavioral approaches were more successful than single-focused interventions.⁽⁶⁷⁾

Along with these strategies, specialists in the field are advocating for broader awareness and adoption of new technologies that make it possible to engage patients more effectively about medication adherence. For example, prescribers can use email to communicate directly with patients who are encouraged to ask questions electronically. Pharmacies can use adherence-messaging programs to reach patients using letters, newsletters, brochures, telephone calls, e-mails, faxes and even pagers. These programs can be triggered by

automated pharmacy dispensing records, based on estimates of when the patient may run out of the medication. These communications not only remind the patient to refill the prescription but also emphasize the importance of following their health care provider's instructions and keeping follow-up visits.

Other technological innovations that have the potential to improve medication adherence include electronic reminder devices and automated medication dispensers. For example, electronic pillboxes are available that can be programmed to light up when a dose is due. Also in development is new technology that allows a microchip to be embedded in the packaging to monitor the dates and times when the package is opened, allowing pharmacies to scan the information and plot out patients' medication taking patterns.

STRATEGIES DIRECTED AT HEALTH PROFESSIONALS

Although ultimately patients must make the decision to fill their prescriptions and take their medicines as prescribed, improved adherence requires the successful interplay between the patient and those involved in managing his/her care -- the physician, physician assistant, nurse or nurse practitioner, and pharmacist. This partnership is the principle behind patient-centered medicine,⁽⁶⁸⁾ where clinicians cooperate directly with the patient in designing, implementing and monitoring a therapeutic plan.

Shifting to a patient-centered approach, however, requires that health care providers have the knowledge to educate and counsel about medication adherence. As a result, specialists advocate starting with increased training of prescribers, nurses and pharmacists to improve their adherence-related skills.⁽⁶⁸⁾ Currently, courses in patient education and adherence promotion are incorporated into the curriculum of many nursing and pharmacy schools, but there are major gaps, especially in the training of medical students. It is not surprising then that even among health care

professionals, studies find that lack of medication adherence is a problem.⁽¹⁶⁾

To fill this troubling education gap will require developing a curriculum that will allow medical, nursing and pharmacy students to conceptualize and execute responsible medication-related problem-solving on behalf of individual patients. Curricula should be designed to produce graduates with sufficient knowledge and skills to provide patients with adherence education and counseling competency. Expanding the core competencies of clinicians also requires a significant investment in expanding professional education through courses provided by recognized medical sub-specialty and allied health organizations as well as lecture series on patient adherence.

At the same time, improving the ability of patients to adhere to their therapy regimens necessitates an expanded role for pharmacists, who are among the most accessible members of the health care team once medication therapy is initiated.⁽³⁾ There is also growing evidence that pharmacy-based interventions are effective in improving drug therapy results. For example, in a study where pharmacists provided adherence counseling to patients with high blood cholesterol, medication adherence improved from a national average of 40 percent to 90 percent.⁽⁶⁹⁾

To capitalize on the role of pharmacists as the nexus for conducting adherence interventions, the pharmacy community has been working to implement collaborative drug therapy management (CDTM) through which pharmacists and physicians voluntarily enter into agreements to jointly manage a patient's drug therapy.⁽⁷⁰⁾ Currently, 40 states have specific laws that allow CDTM and others are developing or reviewing proposed legislation to enable CDTM for improved disease and drug therapy management.⁽⁵⁶⁾

At the same time, more initiatives like the "Asheville Project," the longest-running test using pharmacist interventions to improve patient adherence with diabetes and asthma regimens, are needed to improve health outcomes.⁽⁷¹⁾ Featuring patient counseling, the Asheville Project

provides pharmacists with intensive training in managing the target disease and then pays them for monthly consultations with patients, during which they encourage those patients to adhere to the recommended lifestyle changes and prescribed medication regimen. Currently, the American Pharmacists Association (APhA) Foundation has launched the Diabetes Ten City Challenge modeled after the Asheville Project to improve medication adherence among people with diabetes.⁽⁷²⁾ This demonstrates that matching patients with specially trained pharmacists is a useful strategy to help patients learn how to manage their disease more effectively while lowering the costs of health care.

Pharmacists should also take advantage of advances within the practice that make patient adherence efforts more effective. This includes designating areas within the pharmacy that are conducive to patient counseling and undertaking such activities as monitoring blood pressure, blood glucose levels and other patient screening activities. Further, adherence technologies now make it possible for pharmacists to conduct direct-to-patient counseling programs tailored to the needs of patients who have been prescribed medication in virtually every therapeutic class. These programs can be implemented in various forms, including education and reminder letters, e-mail messages, newsletters, brochures, and phone calls.

THE NEED FOR A MULTIDISCIPLINARY APPROACH TO IMPROVE ADHERENCE

If the goal of medication adherence is to improve the outcome for each patient through the correct use of prescribed medicines, then what is ultimately needed is a multidisciplinary approach to adherence management whereby the patient and all members of the health care team work together to cure the patient's illness, provide symptom relief, or arrest the disease process. This approach is intended to convey a respect for the goals of both the patient and the health professional, and envisions patients and clinicians engaging in a productive discussion about medication regimens.

The idea of a multidisciplinary team is the concept behind the term “concordance” advanced by the Royal Pharmaceutical Society of Great Britain⁽¹¹⁾ and other European bodies, and behind the term “pharmaceutical care,”⁽⁵⁷⁾ which has gained traction within the U.S. Regardless of the term, the underlying premise is what NCPPIE calls the “Medication Education Team,” a model of open communication and shared responsibilities in which physicians and other prescribers, nurses, pharmacists and other providers communicate with patients at every “teachable medicine moment,” making communication a two-way street, listening to the patients as well as talking to them about their medicine use. Since the 1980s, NCPPIE has advocated for the formation of a “Medicine Education Team” for every patient, so each individual is fully informed about each medicine he/she is taking, has the instructions for taking these medicines properly, and knows the medication risks to avoid.

Recognizing that many interventions have been shown to be effective in improving adherence rates, the World Health Organization (WHO) report specifically calls on health professionals, researchers, health planners and policymakers to implement a multidisciplinary approach to adherence education and management.⁽³⁾ This has led to the creation of a special Task Force on Medicines Partnership in the United Kingdom.⁽⁷³⁾ In the United States, pharmacy researchers are also examining ways to demonstrate the benefits of pharmacy-based adherence intervention services. What is needed now is for leading physician, nursing, and pharmacy organizations to embrace NCPPIE’s concept of the Medicine Education Team, resulting in its widespread adoption in clinical settings.

THE NEED FOR SUPPORTIVE GOVERNMENT POLICIES

At a time when the number of prescriptions dispensed in the U.S. is expected to grow to 4.5 billion by 2010,⁽⁷⁴⁾ enabling pharmacists to use the most modern technologies to conduct adherence assistance programs would seem obvious.

However, as noted previously, there are a variety of impediments, including limitations by a number of federal and state laws. An immediate need is to resolve ambiguities about whether sponsored programs fall within the scope of the federal anti-kickback statute, and to ensure that federal and state medical privacy laws make clear that pharmacies may communicate with patients about the importance of adherence to prescribed courses of therapy, as long as such compliance programs address privacy-related concerns.

THE NEED FOR RESEARCH SUPPORT AND RESEARCH RIGOR

With the astonishing advances in medical therapeutics during the past two decades, one would think that studies about the nature of non-adherence and the effectiveness of strategies to help patients overcome it would flourish. On the contrary, the literature concerning interventions to improve adherence with medications remains far from robust. Compared with the many thousands of trials for individual drugs and treatments, only a few relatively rigorous trials of adherence interventions exist and these studies provide limited information about how medication adherence can be improved consistently using the resources usually available in the clinical settings.⁽⁷⁵⁾

At the same time, there has been inadequate funding from the NIH for research on the causes of non-adherence and the interventions needed to improve adherence across types of health-care professions, settings, interventions, and persons of varying educational, economic, and ethnic backgrounds. Policymakers must re-examine how research on patient adherence is addressed within NIH with the goal of significantly increasing funding for research on interventions to improve adherence. While the creation of the Adherence Research Network is a good start, now is the time to invest in adherence research to identify behaviorally sound multi-focal interventions across diseases and in different service delivery environments.

Advancing Adherence: A National Action Agenda

10 PRIORITIES FOR ACTION

Mounting evidence shows that poor medication adherence is pervasive and costly. The problem affects all ages, both genders and people of all socioeconomic levels. Non-adherence is particularly important for patients with chronic conditions as it leads to unnecessary disease complications, reduced functional abilities, a lower quality of life and too often, premature death.

Because of the nature and extent of this challenge, NCPIE has described non-adherence as America's "other drug problem." NCPIE, along with NIH, WHO, and numerous voluntary health and professional societies around the world, has contributed a new understanding about the importance of adherence for successful treatment. The consensus of all stakeholders is that interventions that improve patient adherence enhance health status and reduce health care costs.

But this consensus is only the beginning of what is needed to address the problem of patient nonadherence. Adherence problems have been generally overlooked as a serious public health issue and, as a result, have received little direct, systematic, or sustained intervention. Moreover, Americans have inadequate knowledge about the significance of medication adherence as a critical element of their improved health. Thus, a major, sustained public education effort is required to educate people before they become ill, to prepare them to respond positively to adherence information when faced with a condition requiring medication.

Because the stakes are so high, NCPIE has become a convener and catalyst for promoting a dialogue on new ways to advance patient medication adherence across the continuum of care -- from diagnosis through treatment and follow-up patient care and monitoring. Accordingly, NCPIE convened a panel

of experts to create consensus on ten national priorities that may have the greatest impact on improving the state of patient adherence in the U.S. Ultimately involving the support and active participation of many stakeholders -- the federal government, state and local government agencies, professional societies and health care practitioners, health educators, and patient advocates -- this platform calls for action in the following areas:

1. Elevate patient adherence as a critical health care issue.

Medication non-adherence is a problem that applies to all chronic disease states; affects all demographic and socio-economic strata; diminishes the ability to treat diabetes, heart disease, cancer, asthma, and many other diseases; and results in suffering, death, and sub-optimal utilization of health care resources. Despite this impact, patient adherence is not on the radar screen of policy makers and many health professionals, which has meant inconsistent government policies and a lack of resources for research, education, and professional development. Until health care policy makers, practitioners and other stakeholders recognize the extent of non-adherence, its cost, and its contribution to negative health outcomes, this problem will not be solved.

2. Agree on a common adherence terminology that will unite all stakeholders.

Today, a number of common terms -- compliance, adherence, persistence, and concordance -- are used to define the act of seeking medical attention, filling prescriptions and taking medicines appropriately. Because these terms reflect different views about the relationship between the patient and the health care provider, confusion about the language

used to describe a patient's medication-taking behavior impedes an informed discussion about compliance issues. Therefore, the public health community should endeavor to reach agreement on standard terminology that will unite stakeholders around the common goal of improving the self-administration of treatments to promote better health outcomes.

3. **Create a public/private partnership to mount a unified national education campaign to make patient adherence a national health priority.**

To motivate patients and practitioners to take steps to improve medication adherence, there must be compelling and actionable messages as part of a unified and sustained public education campaign. A foremost priority is creating the means by which government agencies, professional societies, non-profit consumer groups, voluntary health organizations and industry sectors can work together to reach public and professional audiences on a sustained basis. Although NCPIE and a number of government agencies, professional societies and voluntary health organizations are promoting information about medication adherence, there also needs to be a national clearinghouse, serving as the catalyst and convener so that all stakeholders can speak with one voice about the need for improving patient adherence. NCPIE, a professional society, or an academic institution could manage this clearinghouse effectively.

4. **Establish a multidisciplinary approach to compliance education and management.**

There is a growing recognition that a multidisciplinary approach to medication taking behavior is necessary for patient adherence to be sustained. This has led NCPIE to promote -- the "Medication Education Team" -- in which the patient and all members of the patient's health care team work together to treat the patient's condition, while recognizing the patient's

key role at the center of the process. Looking to the future, this model has the potential to improve adherence rates significantly by changing the interaction between patients and clinicians and by engaging all parties throughout the continuum of care.

5. **Immediately implement professional training and increase the funding for professional education on patient medication adherence.**

Today's practitioners need hands-on information about adherence management to use in real-world settings. This need comes at a time when a solid base of research already exists about the steps physicians and other prescribers, pharmacists, and other health care practitioners can take to help patients improve their medication taking behavior. Professional societies and recognized medical sub-specialty organizations should immediately apply these research findings into professional education through continuing education courses as well as lecture series on patient adherence issues.

6. **Address the barriers to patient adherence for patients with low health literacy.**

Low health literacy and limited English proficiency are major barriers to adherence and deserve special consideration. Thus, an important target for patient-tailored interventions are the 90 million Americans who have difficulty reading, understanding and acting upon health information. Accordingly, advocates recommend widespread adoption of existing tools, such as the Rapid Estimate of Adult Literacy in Medicine Revised (REALM-R), validated pictograms designed to convey medication instructions, and specific patient education programs that promote and validate effective oral communication between health care providers and patients supported by the provision of adjunctive useful information in its most useful

format to address the patient's individual capabilities.

7. Create the means to share information about best practices in adherence education and management.

Today, stakeholders have access to more than 30 years of research measuring the outcomes and value of adherence interventions. Building on this foundation, a critical next step is for the federal government -- through the Adherence Research Network -- to begin collecting data on best practices in the assessment of patient readiness, medication management and adherence interventions, incentives that produce quality outcomes from adherence interventions, and measurement tools so that this information can be quantified and shared across specialties and health care facilities. Just as federal and state registries collect and share necessary data on different disease states, a shared knowledge base regarding systems change, new technologies, and model programs for evaluating and educating patients about adherence will significantly improve the standard of compliance education and management.

8. Develop a curriculum on medication adherence for use in medical schools and allied health care institutions.

Lack of awareness among clinicians about basic adherence management principles remains a major reason that adherence has not advanced in this country. To change this situation will require institutionalizing a curriculum at medical, nursing, pharmacy and dental schools as well as courses for faculty members that focus on the adherence advancement and execution of medication-related problem solving. Moreover, once these courses are developed, it will be important for academic centers to elevate patient adherence as a core competency by mandating that course work in this area be a requirement for graduation.

9. Seek regulatory changes to remove road-blocks for adherence assistance programs.

Improved adherence to medication regimens is predicated on supportive government policies. Unfortunately, a number of federal and state laws and policies now limit the availability of adherence assistance programs. Accordingly, language in these federal and state laws that limits communications to patients about medication adherence must be identified for lawmakers and regulators to resolve. Key issues to be addressed include clarifying that education and refill reminder communications fall within the scope of the federal anti-kickback statute, and ensuring that federal and state laws related to patient privacy and the use of prescription data do not unduly limit the ability of pharmacies to communicate with patients about the importance of adhering to their prescribed courses of therapy.

10. Increase the federal budget and stimulate rigorous research on medication adherence.

Although the National Institutes of Health has put in place the Adherence Research Network to identify research opportunities at its 18 Institutes and Centers, the actual NIH dollars earmarked for testing interventions to improve medication taking behavior was only \$3 million in a budget of nearly \$18 billion in 2000, the latest date available. Thus, it will be important for stakeholders to advocate for NIH to significantly increase the proportion of its research funding to test adherence interventions and measure their effectiveness. Even if NIH triples its 2000 commitment, the small amount spent on patient adherence will still signal that the issue is a critical area for new research efforts.

THE TIME IS NOW

Creating a public policy agenda that elevates patient non-adherence as a priority concern is essential to reduce the adverse health outcomes and economic consequences associated with this pervasive problem. Improving how and when patients take their medicines is a complex challenge, requiring changes in the knowledge, attitudes, and skills of patients, health professionals, and policy-makers alike. While no single strategy will guarantee that patients fill their prescriptions and take their medicines as prescribed, it is hoped that the priorities identified in this report will serve as a catalyst for action and offer realistic goals for improving the standard of medication adherence through research, education, and policy changes.

Now is the time to improve patient care, recognizing the importance of medication adherence, and providing the resources and attention that are required.

Table 1

MAJOR PREDICTORS OF POOR ADHERENCE TO MEDICATION ACCORDING TO STUDIES OF PREDICTORS

Predictor:	Presence of psychological problems, particularly depression
Study:	vanServelien et al., Ammassari et al., Stilley et al.
Predictor:	Presence of cognitive impairment
Study:	Stilley et al., Kino et al.
Predictor:	Treatment of asymptomatic disease
Study:	Sewitch et al.
Predictor:	Inadequate follow-up or discharge planning.
Study:	Sewitch et al., Lacro et al.
Predictor:	Side effects of medication
Study:	van Servellen et al.
Predictor:	Patient's lack of belief in benefit of treatment
Study:	Okuno et al., Lacro et al.
Predictor:	Patient's lack of insight into the illness
Study:	Lacro et al., Perkins
Predictor:	Poor provider-patient relationship
Study:	Okuno et al., Lacro et al.
Predictor:	Presence of barriers to care or medications
Study:	van Servellen et al., Perkins
Predictor:	Missed appointments
Study:	Servellen et al., Farley et al.
Predictor:	Complexity of treatment
Study:	Ammassari et al
Predictor:	Cost of medication, copayment, or both
Study:	Balkrishnan, Ellis et al.

(Source: N Engl J Med 353:5 www.nejm.org August 4, 2005, page 491)

Table 2

STRATEGIES FOR IMPROVING ADHERENCE TO A MEDICATION REGIMEN*

- + Identify poor adherence
 - Look for markers of nonadherence: missed appointments (“no-shows”)
 - Lack of response to medication, missed refills
 - Ask about barriers to adherence without being confrontational
- + Emphasize the value of the regimen and the effect of adherence
- + Elicit patient’s feelings about his or her ability to follow the regimen, and if necessary, design supports to promote adherence
- + Provide simple, clear instructions and simplify the regimen as much as possible
- + Encourage the use of a medication-taking system
- + Listen to the patient, and customize the regimen in accordance with the patient’s wishes
- + Obtain the help from family members, friends, and community services when needed
- + Reinforce desirable behavior and results when appropriate
- + Consider more “forgiving”** medications when adherence appears unlikely
 - Medications with long half-lives
 - Depot (extended-release) medications
 - Transdermal medications

* Information in this table was adapted from Osterberg and Rudd (Osterberg, LG, Rudd, P. Medication Adherence for Antihypertensive Therapy. In: Oparil S, Weber MA, eds. Hypertension: a comparison to Brenner and Rector’s The Kidney. 2nd ed. Philadelphia: Elsevier Mosby, 2005:848

** Forgiving medications are drugs whose efficacy will not be affected by delayed or missed doses.

(Source: N Engl J Med 353:5 www.nejm.org August 4, 2005, page 493)

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Attachment 5

Public Outreach Activities



California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

September 7, 2007

To: Communication and Public Education Committee

Subject: Update on the Board's Public Outreach Activities

Public and licensee outreach activities performed since the June report to the committee include:

- Board Member Goldenberg provided information about the board's citation and fine program to the Pharmacists Professional Society of San Fernando Valley on June 24.
- Board Member Ravnar provided information about medication errors as part of panel discussion with Lyle Bootman and Michael Cohen hosted by *Drug Topics* in concert with the American Society of Health Systems Pharmacists annual meeting in San Francisco on June 26.
- Supervising Inspector Nurse met with visiting dignitaries from Australia who were interested in learning about California's controlled substances requirements.
- Supervising Inspector Judi Nurse provided information about the Veterinary Food Animal Drug Retailer program to a group of food animal veterinarians on August 23.
- Public Outreach Coordinator Karen Abbe staffed an information booth for the Department of Consumer Affairs and the board at the California State Fair on August 31.
- Supervising Inspector Ming provided information about pharmacy law to the Indian Pharmacist Association on September 15.
- Supervising Inspector Nurse spoke about California's pedigree requirements at LogiPharma's annual conference in Philadelphia on September 17.
- Analyst Sue Durst staffed an information booth on September 17 at the Senior Fraud Fest event at the South San Francisco Conference Center.
- Analyst Karen Abbe staffed an information booth at a health fair at the Siskiyou County Fairgrounds on September 22.
- Executive Officer Herold and AG Liaison Room spoke at the Healthcare Distribution Management Association's two-day conference, California Pedigree: Preparing for Implementation on September 27.
- Executive Officer Herold and Supervising Inspector Nurse spoke at EPCglobal's annual US Exposition on California's pedigree requirements in Chicago on October 3.

- President Powers spoke to the Renaissance Society (a group of highly involved seniors) on October 5 about pedigree issues, purchasing drugs online and other consumer issues involving pharmacy.
- Public Outreach Coordinator Abbe and Associate Analyst Sue Durst staffed a booth at the 22nd Annual Marin County Senior Information Fair on October 10 (both had high praise for this event).
- Executive Officer Herold Nurse will speak about California's electronic pedigree requirements along with EPCglobal at CSHP's Seminar on October 20 in Palm Springs.
- The board will staff an information booth at the CSHP's Seminar on October 19 and 20.

Attachment 6

*Meeting Summary of the
Communication and Public Education
Committee Meeting
of September 14, 2007*



California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE MINUTES

Date: September 14, 2007

Location: Department of Consumer Affairs
First Floor Hearing Room
1625 N. Market Boulevard
Sacramento, CA 95834

Board Members Present: Ken Schell, PharmD, Chairperson
Susan L. Ravnan, PharmD
Andrea Zinder, Public Member
Henry Hough, Public Member

Staff Present: Virginia Herold, Executive Officer
Anne Sodergren, Legislation and Regulation Manager
Karen Abbe, Public and Licensee Education Analyst

Call to Order

Chairperson Schell called the meeting to order at 2:03 p.m. He recognized Dr. Marcus Ravnan who was in attendance.

Dr. Schell noted that the board recognizes pharmacists with 50 years of licensure, and a pin is presented to those pharmacists who reach that milestone and attend a board meeting to be formally recognized. The board has a new 50-year pin, and Dr. Schell stated that the new pin is very well designed.

1. Consumer Fact Sheet Series with UCSF's Center for Consumer Self Care

Dr. Schell advised that the meeting materials contained the background information on this topic. Dr. Soller, who had been heading up the consumer fact sheet series with UCSF's Center for Consumer Self Care, was unable to attend this committee meeting.

Dr. Schell stated that he and Executive Officer Herold went to UCSF on August 9th to speak with Dr. Soller about the fact sheet series. During that meeting, Dr. Soller reaffirmed that UCSF could not continue participation in the project without funding. UCSF offered to produce 16 additional consumer fact sheets for a stipend of \$25,000.

Ms. Herold said that the board could consider redirecting money to do this project. However, four inspectors and one supervising inspector will be hired this year, and once those positions are filled, it's unlikely there will be a surplus to draw from for this project.

Ms. Zinder commented that her understanding was that Dr. Soller had been hands-on for this project, and she was concerned that the board would not be able to find another person of his caliber. She added that if we paid Dr. Soller, we could continue with this project.

Dr. Schell responded that he agreed with Ms. Zinder about her concern to maintain a high level of quality. If we could work something out financially with UCSF, that would be fine, and he understood that they could not continue to provide free services. He advised that he and Board Member Ravnan agreed to contact other pharmacy schools to learn if they were interested in having their interns develop fact sheets in conjunction with the board.

Dr. Ravnan stated that she contacted Touro and UOP on the matter. Touro said they were on board, and would love to have their students develop fact sheets.

Dr. Schell added that he spoke to UCSD's School of Pharmacy. Their students may be able to produce the fact sheet as part of their course work. He encouraged spreading the project among more than one school. He offered to write a formal letter to UCSD about what we're looking for. He will bring up these ideas at the October 2007 Board Meeting.

Mr. Hough said he thought it was a wonderful thing for students to get involved with this project because it's an educational opportunity, as well as a benefit to consumers. He also thought that competition is a good thing, so maybe an award could be made to a pharmacy intern for the best fact sheet. He also encouraged Dr. Ravnan to bring students into the project through her role at North State University.

Dr. Schell agreed that a competition is a fabulous idea. At the October 2007 Board Meeting, he will present the idea of a self-care pamphlet of the year.

Ms. Herold added that we owe the students a general template so they can format the fact sheets around that template. We would also require annotated versions of the fact sheets so that the board would know the origin of the statistics and other information provided on each fact sheet. Footnotes are particularly important when quoting statistics. We need to keep up due diligence to be sure the information we put out is accurate.

Dr. Ravnar suggested that one fact sheet should be able to be put out every other month. Each fact sheet should have specific criteria. The board could choose the best consumer fact sheet from those submitted for consideration. An alternative to contracting with UCSF would be to use a special service that produces this type of information, which would be less expensive than the quote provided by Dr. Soller.

Dr. Schell said that at the next board meeting, we would advise that we have not shut the door on UCSF, but the committee is pursuing other schools of pharmacy to participate in the project. He asked if there were any other questions on the matter. There were none.

2. Update Report on *The Script*

Dr. Schell advised that the next issue of *The Script* is planned for publication and distribution in January 2008. The focus of this issue will be on new laws, questions and answers about pharmacy practice asked of the board, and new regulation requirements. The issue will also include detailed information about e-pedigree implementation and the board's forthcoming fee increases.

Dr. Ravnar asked about an item in *The Script* relating to a pharmacist-in-charge (PIC). She asked what a PIC should do if he or she is on a leave of absence for a week or a month. Should there be an interim PIC?

Ms. Herold responded that for a week's absence, the PIC would be considered "on vacation." For a one-week period, the PIC is still responsible for activities in the pharmacy. If a PIC is absent longer period of time, for example for a month or months, an interim PIC should probably be on board.

Dr. Schell asked if there was any guidance for a leave of absence that was longer than one month.

Ms. Herold responded that professional judgment should prevail.

Dr. Ravnar asked if there is a board form for a PIC to fill out.

Ms. Herold said these questions should be run as a Q&A in *The Script*. She said that a PIC may not be in the pharmacy every day, but the PIC is still responsible for the pharmacy.

Dr. Schell asked about separate DEA numbers. He asked whether each practitioner had to have their own DEA number, or if they could they fall under the same DEA number as the facility.

Ms. Herold suggested we ask DEA that question because it's a DEA technical issue.

Ms. Herold responded that she would ask *The Script* Editor Hope Tamraz to look into it.

Dr. Schell suggested that legislation affecting how consumers dispose of medications should be put in a future issue of *The Script*.

Ms. Herold added that that is a major consumer issue, and legislation has been passed that is on the Governor's desk to create parameters for drug take-back programs.

Dr. Schell emphasized that he is concerned about consumers dropping off medicines in grocery stores, which will create a challenge in controlling particular items.

3. Development of New Consumer Brochures

Dr. Schell summarized the background information provided in the meeting materials regarding new consumer brochures. He said that the public would be well served by the recent updates made to the board's outreach materials.

Ms. Abbe emphasized that comments about the board's outreach material are encouraged. She added that the board's motto "Be Aware and Take Care" should be more prominent on the brochures, and there should be a consistent theme and format in the materials. Minimal printing of the brochures will be done as additional revisions are made.

Ms. Zinder noted an error in a text box in the brochure relating to buying drugs from foreign countries. The wording in the text box is truncated in the middle of a sentence.

Ms. Abbe said that that error would be corrected.

Ms. Herold added that we need to warn patients about counterfeit drugs obtained from unauthorized Internet pharmacies, so Ms. Abbe should add information about counterfeit drugs to that brochure.

Mr. Hough asked who establishes the standards and criteria for brochures in various languages. He asked if the language translations are based on the percentage of our population.

Ms. Herold added a past member of the board had a primary role to represent various minorities. That member said he wanted to represent the perspective of other minorities. Since that time, the board has typically translated materials into Spanish, Chinese, and Vietnamese. The board has also had the Notice to Consumers poster translated into seven different languages, including Russian. Materials must be consistent with DCA and vetted through translators. There are expenses involved, so we have to look at whether people are requesting the material in other languages.

Mr. Hough emphasized that we must bear in mind that English is our main language.

Dr. Schell suggested we either set a comment period, or change the brochures the next time we go to press.

Ms. Herold added that it is beneficial to periodically review these materials. We will incorporate the changes prior to each printing, unless there is an obvious error.

Dr. Ravnan noted that the draft fact sheet called the Traveling Medicine Chest contained an error. Senakot is used to relieve constipation, not diarrhea.

Ms. Herold noted that Ms. Abbe drafted two fact sheets relating to becoming a licensed pharmacist in California. The drafts will be reviewed. In the meantime, please refer to Ms. Herold's draft article entitled, "Becoming a Licensed Pharmacist in California" contained in the meeting materials. She wants applicants to know up front that the process can take 4-5 months.

Dr. Schell suggested that the information be mailed to students of pharmacy and residency programs because they really don't understand the system. We cannot change our process so that residencies can get their candidates starting on certain dates. He supports investing the time to put this information together.

Ms. Herold responded that we will convert this information into something attractive.

4. Update on Proposed Forum on Medicare Part D Plans

Dr. Schell summarized the information in the meeting materials.

Since 2005, the board has been working with stakeholders to aid patients in receiving benefits under the federal Medicare Modernization Act, and specifically the Medicare Part D plans implemented in January 2006. The board has held six public forums over the last one and one-half years to discuss difficulties patients and providers are having with the plans, in hopes of finding resolutions. However, any structural changes to the program need to be made at the federal level.

At the April 2007 Board Meeting, the board directed staff to seek a public forum, in conjunction with a member of the California Congressional Delegation, perhaps Pete Stark or Nancy Pelosi. The goal would be to discuss implementation issues impacting patient safety that warrant legislative correction.

Since the July 2007 Board Meeting, Board President Powers and Ms. Herold have been in contact with Congressman Pete Stark. The result was Congressman Stark's assessment that the White House would not make any modifications to the program, so holding a forum would not be productive. He encouraged the board to continue with its outreach activities, and to consider holding similar discussions with other state boards of pharmacy.

Dr. Schell commented that the board should consider how much of its resources it can devote to this issue. We have made our best effort, but we haven't heard from our two senators on the issue. He suggested that because next year is an election year, we could consider making a push for the issue at that time.

Dr. Ravnan stated that the Partners in D Program have a grant to do 3-year study, but she hopes it will be ongoing. There are a couple of schools involved, including UOP. During the Medicare Part D enrollment period, faculty and students will be out in the public helping patients pick a program to enroll in. Patients can contact them later for help in navigating the programs, staying out of the gap, and looking at costs.

Dr. Ravnan said students in a course at UOP will have extensive training in Medicare and the Part D program. It will be a whole outreach program. When the students leave college, it's hoped that they can continue to use it in their practice.

Ms. Zinder asked for clarification as to whether the outreach would be limited to helping patients select the best PDP, or whether it would also help them once they run into problems with a plan that they're enrolled in.

Dr. Ravnan said it will be both. Patients can call to make an appointment to talk to someone if they are having problems with the plan they have enrolled in.

Ms. Ravnan stated that UOP will participate in AARP events coming up, and they will go other places where seniors are. They are looking at different ways to conduct the outreach effort.

Ms. Herold noted that Board Member Goldenberg suggested that pharmacists provide a "mock bill" when filling prescriptions covered under Part D. The mock bill would show the value of the service, and patients will appreciate the value provided by the pharmacist. The mock bill would demonstrate that the patient is not being charged for the full value of the medicine, but this is what the value is. Other professionals are not giving away free services, so this would be a way to recognize the value of the service provided by pharmacists.

Dr. Schell added that patients sometimes downplay the value of a service that they think is free. A mock bill would add value to the service provided by the pharmacist.

Ms. Herold added that Congressman Stark made it clear that he's done everything he could do at this point. His involvement now could bring partisanship to the issue. Congressman Stark sees the board as having credibility on the issue, and he encouraged us to work with other boards of pharmacy on the issue.

5. Medication Compliance Report by the National Council on Patient Information and Education

Dr. Schell noted that patients might not get better if they don't take the medicine as prescribed. He referred to the five items provided in the meeting materials relating to medication compliance.

- Enhancing Prescription Medicine Adherence: A National Action Plan – from the National Council on Patient Information and Education (NCPPIE), this publication identifies action steps that can significantly impact medication adherence
- 'Take as Directed' a lot easier with these new tools – from DrugTopics.com, this article looks at new ways to increase medication compliance
- America's Other Drug Problem, Poor Medication Adherence – from PharmacyFoundation.org, this article references the NCPPIE report and looks at ways to increase medication adherence
- Millions of Patients Not Taking Prescription Drugs Properly, Report Says – from kaisernetnetwork.org, this article references the NCPPIE report and other articles in the media relating to medication compliance
- Medication Adherence – from *Pharmacist's Letter*, this article relates to medication adherence

Mr. Hough commented that he had heard of this problem before, and he has great difficulty with irresponsible patients. His own experience is that he has been taking blood pressure medication since 1981, and other medications in conjunction, and he takes them habitually. He considers it like brushing teeth, and he questions whether we also need to educate people on teeth brushing.

Mr. Hough added that there's a limit, and we shouldn't pamper people, especially seniors. Patients who are mentally disabled and need help are one thing. We can publish materials and do surveys, but patients still have responsibility to take their medicines as directed.

Dr. Schell stated that he has trouble with his own family members in taking medications as directed. He added that it's like leading a horse to water.

Ms. Herold added that these issues are part of NCPPIE's national agenda. There are literacy issues that affect compliance. In addition, container labeling could cross into the issue of compliance.

6. Board of Pharmacy Web Site Redesign

Dr. Schell summarized the information in the meeting materials. The Governor's Office has directed all state agencies to have a state-standardized Web site by November 1, 2007. Two board staff have been working part time on this project.

Ms. Herold added that she met with the two staff working part-time on the Web site project, and the redesign is 60% complete. She wants the redesign in place no later than November 1, 2007.

7. Miscellaneous Consumer Issues/Articles in the Media

Dr. Schell noted that there are some compelling articles contained in the meeting materials. There are also copies of other items, like the letter to the FDA from Stanley Miller dated May 15, 2007. In his letter, Mr. Miller suggested the country of manufacture be added to the label. A response from the FDA was sent to Mr. Miller dated June 12, 2007, and a subsequent letter to the board was mailed about June 28, 2007.

Ms. Zinder asked whether the country of origin for a medication can be identified.

Ms. Herold responded that medication can be manufactured in different countries in FDA-licensed facilities.

Ms. Zinder asked if brand names can be produced in more than one country.

Dr. Schell responded, yes.

Ms. Herold stated that the chain of distribution will show who manufactured the drug but not necessarily where it was manufactured. Pedigree will help resolve questions about where a drug has been, and which wholesalers have owned it. The pedigree will show that they accepted a product.

Dr. Schell also noted an article in the meeting materials referring to the FDA's reversal of its long-standing opposition to establishing a behind-the-counter class of non-prescription drugs. He added that this would create some opportunities for the board in public safety. Creating a separate class may force California to look at its laws.

Dr. Schell asked if there any other items to discuss or bring to the attention of the committee regarding consumer issue or articles in the media.

Ms. Zinder said she wanted to comment on an issue of consumer outreach. She went to her neighborhood Rite Aid and saw 15 different over-the-counter products for an illness. She said all the products treated the same symptoms, but each were slightly different. She asked whether we should help guide consumers.

Dr. Ravnan said consumers should talk to their pharmacists.

Dr. Schell said he had been cautioned by attorneys not to advise consumers in the product aisles. If he were to give advice, he would suggest getting the product with the least number of drugs which will give you the result you want.

Dr. Ravnan stated that she tries to educate people to look for a particular ingredient in a product. For example, look for a suppressant if you have a cough.

Dr. Schell warned that you don't always want to suppress a cough.

Dr. Ravnan said we're getting into the practice of medicine.

Ms. Herold said we could say that certain active ingredients do this, and talk to a pharmacist or your health care providers. We could make a list of common symptoms and common elements to treat those symptoms.

Ms. Zinder suggested putting this topic on the long list of fact sheets to be developed.

Ms. Herold added that it may be helpful during the cold season.

8. Update on the Board's Public Outreach Activities

Dr. Schell referred to the list of public and licensee outreach activities that have been performed since June 2007. He noted that there were several outreach activities in the last quarter. The information in the meeting materials also noted several future outreach events that board members and staff will be participating in.

Dr. Schell said that board members and staff should advise Ms. Herold that they are providing outreach, and the lists of activities are provided to the full board.

Adjournment

There being no additional business, Chairperson Schell adjourned the meeting at 3:24 p.m.

Attachment 7

*First Quarterly Update on the
Committee's Goals for 2007-08*

COMMUNICATION AND PUBLIC EDUCATION COMMITTEE

Goal 4: Provide relevant information to consumers and licensees.

Outcome: Improved consumer awareness and licensee knowledge.

Objective 4.1	Develop a minimum of 10 communication venues to the public by June 30, 2011.
Measure:	Number of communication venues developed to the public.
Tasks:	<ol style="list-style-type: none"> 1. Assess the effectiveness of the board's educational materials and outreach: survey consumers to identify whether board-produced materials are valued and what new materials are desired. <ul style="list-style-type: none"> <i>Sept. 2006: Committee begins review of consumer outreach.</i> <i>Dec. 2006: Staff conducts assessment of the board's consumer outreach written materials. Material is identified for revision and update, future development, or evaluation for continued need.</i> <i>Jan. 2007: Drafts of board informational brochure and complaint process brochures are updated; brochures will undergo review.</i> <i>April 2007: Drafts of board informational brochure and complaint process brochures are provided to the Department of Consumer Affairs for review.</i> <i>June 2007: Committee reviews Department of Consumer Affairs prepared brochures and recommends board produce its own versions.</i> <i>Sept. 2007: Board publishes new board brochure and complaint brochure.</i> 2. Restructure the board's Web site to make it more user friendly. <ul style="list-style-type: none"> <i>July 2006: Web site modified to contain lists of disciplinary actions finalized each quarter and permit online access to public documents regarding board disciplinary actions taken against a licensee.</i> <i>March 2007: Web site modified by adding 14 links to obtain various information regarding Medication Safety and Drug Interactions.</i> <i>Web site modified by adding 7 links to obtain information from FDA regarding Medications and Medical Devices.</i> <i>March 2007: Work initiated on the latest State Web site design to be in place by November 2007.</i> <i>June 2007: Work progressing for timely completion by November 1, 2007.</i> <i>Oct. 2007: Work nearly completed on Website.</i> 3. Work with the California Health Communication Partnership on integrated public information campaigns on health-care topics. <ul style="list-style-type: none"> <i>Sept. 2006: Committee continues collaboration with the partnership whose fall campaign is screening for prostate and breast cancer. Plans underway to work to promote generic drugs in the future.</i> <i>April 2007: Summary provided of the Fall 2006 campaign to raise awareness about breast cancer screening and prostate cancer screening. No recent meetings of the partnership have occurred.</i>

4. Continue collaboration with UCSF's Center for Consumer Self Care for pharmacist interns to develop consumer fact sheets on health topics.
 - Sept. 2006: Nine previously developed fact sheets are sent to a translation service to develop Spanish, Chinese, and Vietnamese versions of these materials. Four new fact sheets developed and undergoing review by the board.*
 - April 2007: Four draft fact sheets are still under review and the committee receives three new fact sheets. The committee determines that the board will expand the project beyond the Center for Consumer Self Care to include students from other Schools of Pharmacy.*
 - Sept. 2007: Discussion with UCSF lead to request for funding to continue project. Meanwhile board seeks to establish intern projects with other schools of pharmacy.*

5. Develop a Notice to Consumers to comply with requirements of AB 2583 (Nation, Chapter 487, Statutes of 2006) on patients' rights to secure legitimately prescribed medication from pharmacies.
 - Sept. 2006: Governor signs AB 2583.*
 - Oct. 2006: Committee advances draft regulation text for comment at the October Board Meeting. Board votes to create a second Notice to Consumers poster vs. adding additional language to current poster.*
 - Jan. 2007: Committee refines language to be advanced to the board. Board reviews, modifies, and sets for regulation notice the proposed language for a second Notice to Consumers poster.*
 - April 2007: Board reviews comments submitted in rulemaking process to adopt this regulation change, and plans to renotice amended language for a new rulemaking process.*
 - July 2007: New "Notice to Consumers" approved by board; rulemaking file submitted to Administration for approval.*

6. Evaluate the practice of pill splitting as a consumer protection issue.
 - Jan. 2007: Board holds discussion of pill splitting issues during Board Meeting.*
 - March 2007: Legislation and Regulation Committee and Communication and Public Education Committee continue discussion of pill splitting.*
 - April 2007: Board hears discussion of pill splitting.*
 - June 2007: Communication and Public Education Committee discussed proposed consumer fact sheet on pill splitting.*
 - July 2007: The Script newsletter contains an article for pharmacists on pill splitting.*
 - Sept. 2007: Consumer Fact Sheet completed.*

7. Evaluate the SCR 49 Medication Errors Report for implementation.
 - March 2007: Communication and Public Education Committee reviews SCR 49 report.*
 - April 2007: Board presentation of the SCR 49 report by former board member Sandra Bauer.*
 - Oct. 2007: SB 472 enacted to require the board to standardize container labels into a patient friendly format by 2011.*

Objective 4.2	Develop 10 communication venues to licensees by June 30, 2011.
Measure:	Number of communication venues developed to licensees.
Tasks:	<ol style="list-style-type: none"> <li data-bbox="365 210 1523 462">1. Publish The Script two times annually. <ul style="list-style-type: none"> <li data-bbox="430 241 1523 304"><i>Sept. 2006: The Script published, placed online and mailed to pharmacies and wholesalers.</i> <li data-bbox="430 315 1523 378"><i>Jan. 2007: The Script published, placed online and mailed to pharmacies and wholesalers.</i> <li data-bbox="430 388 1523 451"><i>July 2007: The Script published, placed online and mailed to pharmacies and wholesalers.</i> <li data-bbox="365 472 1523 1959">2. Develop board-sponsored continuing education programs in pharmacy law and coordinate presentation at local and annual professional association meetings throughout California. <ul style="list-style-type: none"> <li data-bbox="430 577 1523 640"><i>1st Qtr 06/07: Board supervising inspectors present five CE programs on pharmacy law and the Board of Pharmacy to pharmacist associations statewide.</i> <li data-bbox="430 651 1523 756"><i>Sept. 2006: Supervising Inspector Ming provides information on pharmacy law to 80 pharmacists and pharmacy technicians at a San Mateo Pharmacist Association.</i> <i>Supervising Inspector Ratcliff provides information on pharmacy law to the Sacramento Valley Society of Health System Pharmacists.</i> <li data-bbox="430 766 1523 829"><i>Oct. 2006: Interim Executive Officer Herold presents Legislation and Regulation update at CSHP's Annual Seminar. Board also staffs information booth for licensees.</i> <li data-bbox="430 840 1523 945"><i>Nov. 2006: Board Member Goldenberg speaks at the California Association of Health Facilities Convention in Palm Springs.</i> <i>Supervising Inspector Ming provides information on pharmacy law to UCSD students.</i> <li data-bbox="430 955 1523 1018"><i>Jan. 2007: Supervising Inspector Ming provides information on pharmacy law to the Indian Pharmacist Association.</i> <li data-bbox="430 1029 1523 1092"><i>Feb. 2007: Executive Officer Herold provides information about the board at the CPhA's annual meeting.</i> <li data-bbox="430 1102 1523 1165"><i>Feb. 2007: Board Member Hiura provides information about pharmacy law to pharmacists at a Korean pharmacist association meeting.</i> <li data-bbox="430 1176 1523 1281"><i>March 2007: Supervising Inspector Nurse presents California's Electronic Pedigree requirements to the Generic Pharmaceutical Manufacturers Association annual meeting in Phoenix.</i> <li data-bbox="430 1291 1523 1354"><i>March 2007: Supervising Inspector Ratcliff provides information about pharmacy law and the board to 80 UCSF students.</i> <li data-bbox="430 1365 1523 1428"><i>March 2007: Former Board Member John Jones provides a law update to Western University students.</i> <li data-bbox="430 1438 1523 1543"><i>April 2007: Supervising inspectors and board members provide information about pharmacy law and board programs to pharmacists at Anaheim Memorial Hospital, to the Diablo Valley Pharmacists Association Meeting and the San Diego Pharmacists Association.</i> <li data-bbox="430 1554 1523 1659"><i>May 2007: Staff and board members provide information about pharmacy law and board programs to Loma Linda and University of the Pacific School of Pharmacy graduating students, and to Sutter Hospitals' pharmacists.</i> <li data-bbox="430 1669 1523 1732"><i>June 2007: Board member provides information about the board's citation and fine program to the Pharmacists Professional Society of San Fernando Valley.</i> <li data-bbox="430 1743 1523 1806"><i>Aug. 2007: Staff provide information about the Veterinary Food Animal Drug Retailer program to a group of food animal veterinarians.</i>

Sept. 2007: Staff provide information about pharmacy law to the Indian Pharmacist Association.

3. **Maintain important and timely licensee information on Web site.**

*1st Qtr 06/07: Added 50-year pharmacist recognition pages as a special feature.
Updated license totals.
Added enforcement actions for effective dates between April 1 and June 30, 2005.
Changed definitions on license lookup to clarify license status.
Posted board and committee meeting agendas and materials.
Sent out subscriber alert notifications to the board's e-mail notification list, including two drug recalls.*

*2nd Qtr 06/07: Unveiled new Web site of the board, and created new Web links.
Revised and added new fax and contact information to speed communication with appropriate enforcement and licensing staff.
Updated listing of 50 year pharmacists.
Added frequently asked questions on emerging contraception.
Updated listing of enforcement actions taken.
Reviewed and updated board member biographies.
Made corrections to the board's online lawbook.
Added all agendas, meeting packets and minutes for board and committee meetings.
Sent out nine subscriber alerts for important information added to the board's Web site.*

*3rd Qtr 06/07: Completed updates to website to comply with SB 796.
Updated copyright year.
Updated links referring to California's and the governor's web pages.
Added information about the denial of a registration or license.
Added information about the new CPJE vendor.
Added inspector and supervising inspector exam information.
Revised information on our Contact Us page.
Updated applications on the website to include mandatory reporting information.
Updated public disclosure through Web Lookup to include discipline taken after January 2002.
Updated listing of 50-year pharmacists.
Added enforcement actions for effective dates between January 1 and March 30, 2007.
Posted board and committee meeting agendas and materials.
Sent out 19 subscriber alert notifications to the board's e-mail notification list.*

	<p><i>4th Qtr 06/07: Created a page dedicated to drug alerts and recalls. Updated exam information to reflect the new vendor. Added the new self-assessment forms for Community and Hospital Pharmacies. Added the self-assessment form for Wholesalers. Updated the lawbook with an updated, book marked version for easier usability. Updated DEA links. Added enforcement actions for the effective dates between April 1 and June 30, 2007. Posted board and committee meeting agendas and materials. Sent out 20 subscriber alert notifications to the board's email notification list.</i></p> <p><i>1st Qtr 07/08: Added information about NAPLEX being suspended. Added the latest issue of The Script. Added information about Heat Preparedness. Updated fingerprint fees. Updated regrade information. Updated information about the release of CPJE results. Added information about pill-splitting. Updated information on our Contact Us page. Sent out 8 subscriber alert notifications to the board's e-mail notification list. Posted board and committee meeting agendas and materials. Verified that minutes are included for each of the past meetings listed on the website.</i></p>
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Objective 4.3	Participate in 12 forums, conferences and public education events annually.
Measure:	Number of forums participated.
Tasks:	<p>1. Participate in forums, conferences and educational fairs.</p> <p>Sept. 2006: <i>Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Logi-Pharma's Annual Convention in Austin TX.</i></p> <p>Oct. 2006: <i>Board hosts the three-day NABP Districts 7 & 8 Meeting. Topics include the FDA's pedigree requirements, the DEA's pseudoephedrine requirements, divergent intern requirements from state to state, and development of ethics programs for health professionals. Supervising Inspector Nurse provides presentations to national EPCglobal Convention (a standards setting organization) in Los Angeles on California's e-pedigree requirements for prescription drugs. Board staffs information booth at San Mateo Senior Fest where 600 people attend.</i></p> <p>Dec. 2006: <i>Inspector Barnard and Public and Licensee Education Analyst Abbe staff information booth at the Sacramento AARP-sponsored Ask A Pharmacist event.</i></p> <p>Jan. 2007: <i>Supervising Inspector Nurse provides presentation on California's e-pedigree requirements at Secure Pharma 2007, the supply chain security conference in Philadelphia.</i></p> <p>Feb. 2007: <i>The board hosts an information booth for two days at CPhA's annual meeting.</i></p> <p>March 2007: <i>Inspector Wong and Analyst Abbe staff information booth at the 2007 Consumer Protection Day forum in San Diego.</i></p> <p>April 2007: <i>Presentation on being a pharmacist at a career day presentation in Southern California.</i></p> <p>May 2007: <i>The board staffed a public information booth at the Family Safety and Health Expo at Safetyville in Sacramento, at the Sacramento Chapter of the American Diabetes Association Health Fair. Also provided information about California's electronic pedigree requirements for prescription medicine to a full session at the National Association of Boards of Pharmacy annual meeting.</i></p> <p>June 2007: <i>Board Member participated in panel discussion that will be released as a web cast on prescription errors with Lyle Bootman and Michael Cohen hosted by Drug Topics.</i></p> <p>July 2007: <i>Staff met with visiting dignitaries from Australia who were interested in learning about California's controlled substances requirements.</i></p> <p>Aug. 2007: <i>The board staffed a public information booth at the California State Fair.</i></p> <p>Sept. 2007: <i>Major presentation made on California's standards to LogiPharma in Philadelphia. The board staffed a public information booth at the Senior Fraud Fest event. The board staffed a public information booth at the Siskiyou County Fairgrounds. Major presentation made on California's standards at HDMA's conference.</i></p>

	<p><i>Oct. 2007: Major presentation made on California's standards to EPCglobal representatives.</i></p> <p><i>Board Member spoke to the Renaissance Society about pedigree issues, purchasing drugs online and other consumer issues involving pharmacy.</i></p> <p><i>The board staffed a public information booth at the Annual Marin County Senior Information Fair.</i></p> <p><i>Major presentation made by the board and EPCglobal on California's standards at the SCHP's Seminar.</i></p> <p><i>The board staffed a public information booth at CSHP's Seminar.</i></p>
	