



The Medicine for People in Need Program: 1999-2007

Overview

The Medicine for People in Need program has focused on medication access issues for uninsured and other vulnerable people in the U.S. since 1999. This California-based program places itself at the intersection of two significant dynamics within the U.S. health care system:

- Goals and activities of multi-national drug companies earning profits from product sales, and
- Goals and activities of local nonprofit and county health department “safety net” clinics caring for low-income people covered by public programs or without insurance.

Among California’s many nonprofit programs working on health care issues, the Medicine for People in Need (Medpin) program is unusual because it was created by settlement of a legal action brought by private attorneys against more than 20 major drug companies. When the parties settled that class action suit, the Oakland, California-based nonprofit Public Health Institute was selected to administer the settlement project. www.phi.org. A new program, later named Medpin, began distributing brand name pharmaceuticals to indigent people in California’s “safety net” clinics. Complementing the settlement-based distribution were a range of technical assistance, policy communications, research, and leadership development projects funded by several California-based philanthropic foundations.

Many leaders in nonprofit health care and in California’s universities contributed their counsel and expertise to help Medpin improve pharmaceutical care for low-income people in California and across the U.S. Medpin activities have included:

- a) Design and operation of a multi-year project viewed as a “model” patient assistance program combining 25 drug companies’ products;
- b) Assistance on eligibility requirements and best use of the federal government’s “340B” drug discount program for safety net providers;
- c) Information workshops and materials on Medicare Part D and its impact on low income people;
- d) Creating credible and independent information on drug selection and purchasing by safety net clinics;
- e) Helping safety net providers understand and use strategies for better value on their drug expenditures, including purchasing group, Preferred Drug List, and generic drug issues;
- f) Encouraging pharmacy student placements and activities within safety net clinics.

History

A “Model PAP” as the Originating Project

Litigation settlement. Medpin started in the late 1990s when the nonprofit Public Health Institute was chosen to administer a multi-million dollar litigation settlement of a private action brought by community pharmacies against many major drug companies.¹ As a result, program staff working with academic advisers and community-based leaders designed a Drug Distribution Project that was the foundation of a larger and broader Medpin program.²

The Drug Distribution Project’s first objective was to implement the litigation settlement with high standards of operational integrity and adherence to the settlement language. With that in mind, Medpin designed and operated an internet- based ordering system that linked \$170 million worth of medications, requested by 200 community clinics, with several hundred brand name products offered by the 25 companies included in the settlement agreement.³ Participating clinics were diverse, including Los Angeles County hospital outpatient clinics, free clinics near the Mexican border, mid-size county health department clinics, tribal organizations, and rural clinics in Northern California.⁴ All clinics used a custom-designed ordering system to request medications, which requests were reviewed and sometimes adjusted by Medpin, then transmitted electronically to each drug company.⁵

¹ Companies participating in the project operating in 1999-2003 were: Abbott Laboratories, American Cyanamid, American Home Products, Boehringer Ingelheim, Bristol Myers Squibb, Burroughs Wellcome, Carter Wallace, Dupont Merck, Eli Lilly, Glaxo, Inc., Hoechst Marion Roussell, Hoffman-LaRoche, Janssen Pharmaceutica, Knoll, Merck & Co. Inc., Novartis, Ortho-McNeil, Pfizer, Rhone-Poulenc Rorer, Schering, G.D. Searle, SmithKline Beecham, Upjohn, Warner Lambert, Zeneca.

² In January 2001 what had previously been the Pharmaceuticals and Indigent Care (PIC) program of the Public Health Institute was renamed Medicine for People in Need. For simplicity, the Medpin name is used throughout this report even when referring to that program’s activities under its earlier name.

³ Encouraging and assisting all safety net clinic participants to use an internet-based information and ordering system in early 2000 was part of Medpin’s overall goal of using multiple strategies to improve knowledge and operations among safety net providers’ pharmacy staff .

⁴ The approximately \$170 million worth of brand name medications offered through the settlement were made available to clinics at no charge. However, each participating clinic was ordering against its credit limit, assigned by Medpin based on that clinic’s most recent numbers of pharmaceutically uninsured patients served. Settlement valuation of products was based on Wholesale Acquisition Cost (WAC) , which was typically a little lower than the Average Wholesale Price (AWP) used as the starting point for much commercial drug pricing at that time, but much higher than the 340B purchase price available to many safety net providers.

⁵ Medpin took responsibility for ensuring that requests for popular drugs did not exceed the supply limits some companies had placed within the settlement. Accordingly, Medpin sometimes needed to adjust clinics’ requests based on a sophisticated allocation system reflecting both the type of health care provider and the amount of indigent care that clinic had recently reported. The Institute for Operations Research and the Management Sciences (INFORMS) selected Medpin’s order system as a finalist for the 2004 Daniel Wagner Prize for Excellence in Operations Research Practice, citing “outstanding work in

Expanding the vision and benefits. In addition to carrying out the settlement's specifically described objectives, Medpin's project also brought larger benefits for California "safety net" health care providers and their vulnerable patients. This was consistent with the overall intent of the settlement, of great interest to community clinic and local health department leaders, and aligned with the participating drug companies' publicly stated interest in helping reduce financial barriers to medication access. To achieve these larger benefits, Medpin developed several activities that were grounded in the settlement project but received additional funding from independent philanthropic foundations.

- Developing leadership skills and connections among pharmacy-related safety net clinic staff;
- Designing an internet-based system with a simple user interface supported by behind-the-scenes algorithms reflecting the settlement's complexities;
- Pushing clinic staff to gain familiarity with an internet-based system to receive medications through the project;
- Promoting awareness of ongoing, significant drug discounts available through a relatively new federal program;
- Offering individualized and group technical assistance to help clinics understand and comply with state and federal law regarding dispensing and purchasing medications.

Medpin held two series of regional training workshops throughout California, and three statewide annual conferences. For the initial workshops, another goal was to train clinic staff on an internet-based system at a time (late 1999-early 2000) that some of those people viewed this step as new and intimidating.

Another clearly stated purpose of these gatherings was to develop leadership skills among safety net pharmacists, and to create ongoing connections among the pharmacists and executive staff attending. In 2001 Medpin began a two-pronged professional education and technical assistance plan that combined hard copy materials in a bi-monthly newsletter with regular teleworkshops and website dissemination of materials. These offered participants a chance to reinforce and continue the learning and professional relationships initiated at Medpin's in-person workshops and conferences.

340B Drug Discount Program

Another benefit delivered by Medpin's settlement project was creation of operational infrastructure for ongoing and significant drug discounts through participation in a federal discount program not well known at that time. Enacted by federal law in 1992, this "340B" program allows many county health system and nonprofit community clinics to purchase prescription drugs at discounts averaging roughly 30%- 50%. Even though clinic staff came to Medpin in 2000 to learn about the millions of dollars' worth of brand

the development and implementation of innovative systems for distribution of drugs to uninsured patients." Swaminathan, Ashe, Duke, Maslin, Wilde. "Distributing Scarce Drugs for the Medpin Program," Institute for Operations Research and the Management Sciences (INFORMS), Vol. 34, No. 5, September–October 2004, pp. 353–358.

name drugs available through the settlement project, Medpin always encouraged people to remember that the “free” drug availability would end after several years, while significant 340B discounts were available during the project and after it ended. Medpin promoted awareness of this program throughout California, while helping eligible clinics enroll and meet the federal program requirements.

340B topics were an important part of each Medpin annual conference. In 2005, Medpin worked closely with leaders from the national 340B coalition to jointly develop and present in a Western region location the first version of national 340B conferences that had been happening for eight years in Washington D.C.⁶

Encouraging Longer Range Strategies. Medpin’s technical assistance efforts helped safety net providers with longer range strategies for their medication-related expenditures. A pharmacist with highly successful community clinic experience was brought to Medpin to individually assist many other clinics, which allowed many clinics’ participation in both the litigation settlement project and in the 340B program.

Another specific component of Medpin’s technical assistance related to a California law allowing community clinics a licensing option that does not exist in all states. Under this option, the California Board of Pharmacy licenses clinic dispensaries for drugs purchased or otherwise owned by the clinic. Drugs are dispensed by specified health care professionals, (including physicians, nurses, and pharmacists); and are supervised by a consultant pharmacist required to visit and make reports at least quarterly.⁷ When Medpin started in 1999, few if any of California’s general primary care clinics operated licensed drug dispensaries. During its initial three years, Medpin’s staff pharmacist helped approximately 60 clinics set up and obtain a state license for a drug dispensary, which allowed them to both participate in the settlement project and meet the dispensing requirements for 340B.

Medpin’s pharmacist also helped other safety net pharmacy or dispensary staff use the “educational” portions of the settlement project’s custom-designed order system. This system differed from other known drug order systems because it presented, for each brand-name medication product listed, side-by-side information that included that pharmaceutical product’s approximate 340B price, and whether there was a generic version of that product available. This comparative information reminded the clinic person using the system to think carefully every time a drug was ordered about the best use of a limited supply of “free” medications. Medpin’s design and operation of a patient assistance program with brand-name products from more than 20 companies contrasts clearly with operating procedures for drug company-controlled assistance programs.

Drug Companies’ Assistance Programs

⁶ The 340B coalition includes national organizations representing public and other safety net hospitals, community health centers, family planning clinics, HIV/AIDS programs, and many other safety net provider organizations using 340B discounts to help them serve their low-income patients. For more information on both the annual summer conferences in Washington DC and the annual winter conferences in various Western region locations, www.340bcoalition.org.

⁷ For more information on the laws and best practices of licensed dispensaries in California, see *Providing Consultant Pharmacist Services for Nonprofit Health Clinics: A Training and Resource Manual for Pharmacists and Clinic Administrators*, Dianne Tobias, Medpin/Public Health Institute, 2004.

As the Drug Distribution Project came to an end in 2003, participating clinic administrators and pharmacy directors celebrated its accomplishments in direct assistance (distributing no-cost medications) plus many types of technical assistance. In addition, this project offered a more effective and cost-efficient model for a “patient assistance” program than the diverse efforts directly controlled by the same drug companies whose products had been distributed through the Project. Although drug company programs had a target population and stated goals similar to Medpin’s project, the clinics helping uninsured patients reported strongly preferring the Medpin project based on user simplicity and predictability--notwithstanding the settlement project’s caps on availability of some popular medications. Recognizing the importance of these clinic users’ concerns, Medpin responded with both research and advocacy.

Research. Using case study interviews followed by telephone surveys of clinics in California and four other states, Medpin’s Project Director and two academic researchers examined drug company patient assistance programs from the perspective of safety net clinics with large numbers of patients eligible for these company programs.⁸ Prior to publication of this study, policy leaders and the general public knew about drug company assistance programs based solely on personal anecdotes and public statements by those drug companies or their trade association PhRMA. These statements would typically be reminders that such programs existed, or would focus on the estimated market value of drugs donated and the “number of people helped;” they offered no information on how accessible the programs were or how much time patients spent trying to understand and navigate them.⁹

Medpin’s research confirmed that safety net clinic staff found short-term value in at least some companies’ “free drug” programs. At the same time, clinics reported using a significant amount of clinic staff or consultant resources to help their patients effectively use those company programs. Clinics also strongly encouraged drug companies to move beyond the highly fragmented, uncoordinated, and transient patchwork of assistance programs into something with more uniform and predictable processing requirements, and operations more appropriate to a highly transient group of people who may have little or no ability to navigate application steps explained in English.

Advocacy. An additional issue that emerged from Medpin’s five-state study was of particular concern to California clinics. Data collected suggested that during the study period, an uninsured patient in California was significantly less likely to be receiving medication assistance from drug company programs than an uninsured patient in any of the other states surveyed. One explanation for this finding was that California safety net clinics had been using the Medpin settlement project to help their patients instead of the drug company controlled programs also in effect at that time. As safety net clinics saw the end of the Medpin project approaching, it was sobering to know that the drug

⁸ Survey results and analysis published at *American Journal of Health-Systems Pharmacy*—Vol 62 Apr 1, 2005.

⁹ Pharmaceutical Research & Manufacturers of America, www.phrma.org. See also the PhRMA-supported www.pparx.org.

companies who had been participating in that project were likely to be unprepared for a sudden surge of California patients needing medication assistance.

Medpin and its safety net and academic partners, looking ahead to the mid-2003 end of the settlement project, initiated several efforts to continue and build on that project's accomplishments. One such effort was an invitation to each of the project's participating drug companies to voluntarily continue at least some of the cost-effective, coordinated and expenditure-capped approaches that had operated so well throughout California under Medpin.

Another effort was the letters sent by Medpin's Director plus leaders of eleven regional or statewide safety net provider associations to the CEOs of each participating drug company requesting that they agree to five commitments that would continue after the settlement ended. Each company's CEO was asked to release figures on the total annual value and number of outpatient prescriptions that company had provided at no charge to California patients during the settlement project, and to commit to providing uninsured Californians during the next three years the same annual amount of product "expenditures" that the company's own program plus Medpin's program had been annually offering in the past. In addition, the letters asked each CEO to release to an appropriate public agency or independent nonprofit organization sufficient information to verify that company's success in meeting the previously described commitments to continue the same level medication assistance.¹⁰

Drug companies' lack of response was notable. The most proactive response came from one large company whose vice president organized a conference call with Medpin staff and advisers, and then began to regularly report its California patient assistance accomplishments to Medpin.¹¹ Another company explored the idea of Medpin operating at least some of its patient assistance programs in California.¹² However, all the other companies provided minimal or no response.

Despite this lack of response, Medpin's request that drug companies report to "an appropriate public agency" information on their assistance efforts was given some life in language contained in several key pieces of California legislation during 2004-5, and in the California Discount Prescription Drug Program law enacted in 2006.¹³ While the

¹⁰ The remaining requests in this letter were for commitments to help medically and financially vulnerable Californians fill their prescriptions regardless of age or Medicare eligibility status, and to send an appropriate company representative each year to meet and discuss with California's safety net leadership the successes and challenges in providing effective and cost-efficient assistance.

¹¹ The company that responded was Merck. If at least a few other companies had made a similar offer, Medpin planned to start developing and disseminating information on program activities across companies. However, this did not happen because no other companies offered to do what Merck did.

¹² This company, which was one of the smaller ones, decided after further reflection that it wanted to use a program administrator with more auditing capacity than Medpin possessed.

¹³ AB 2911, which was enacted as Chapter 619, Statutes of 2006, added Section 130530 to the California Health & Safety Code, which now states in part: (e) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the [California Department of Health Care Services] shall require drug manufacturers to provide the department annually with all of the following information: (1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year. (2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

existence of drug company “patient assistance” programs continues to be proudly announced through television ads, special websites, attractive brochures, and bus tours, California may be the only state with a law requiring even this modest amount of company reporting on their patient assistance programs’ specific accomplishments.

A California Safety Net Purchasing Alliance

In addition to moving toward greater transparency and efficiency in assistance programs, in January 2002 Medpin also began moving toward a complementary goal. The nonprofit and public agency providers participating in Medpin’s drug distribution project started dreaming of the possibility of leveraging their pharmaceutical purchasing power. They hoped to build on the relationships and momentum already in place to bring together nearly 1,000 outpatient safety net clinics in California, including those owned by a county hospital or health system, and those that were part of a nonprofit organization such as a community health center. Although these outpatient clinics were spending a total of \$250 million annually on pharmaceutical purchases, only the very largest of them had anywhere near the staff resources and purchasing power to reduce their costs through pharmacy and therapeutics committees, preferred drug list development, advanced information services, and group purchasing.

With this in mind, Medpin and its health care and academic partners moved to plan a new project with two goals:

- Use the combined purchasing power of California safety net providers to gain lower drug prices or related benefits for all of them;
- Use a small part of funds flowing through this new purchasing alliance as ongoing financing for the kinds of drug information and technical assistance activities that Medpin had been offering thanks to more temporary funding sources. This second goal was sometimes described as creating a nonprofit pharmacy benefits management company operated by and for the benefit of California safety net providers.

Working with several outside consultants, Medpin developed a plan for a statewide drug purchasing alliance that would negotiate on behalf of all its California members able to purchase through 340B. Smaller organizations (community clinics and smaller county health programs) were excited by this chance to benefit from the purchasing power of larger purchasers, most notably California’s largest county health systems. Larger safety net purchasers were agreeable to having smaller county or community providers benefit from their purchasing power, so long as there was no financial downside for them.

In addition, all of the safety net clinic physicians and pharmacists working together through Medpin looked forward to further developing the working relationships that had been fostered during Medpin’s initial project among clinic staff and faculty and students from two major California pharmacy schools—University of California, San Francisco and University of Southern California. These academic relationships offered independent and expert sources of drug information to safety net pharmacists and physicians who

would otherwise be relying more on drug company sales people and company-affiliated information.

A new public benefit corporation called the Safety Net Provider Purchasing Alliance (“the Alliance”) was created in late 2003, and the Alliance’s Pharmacy & Therapeutic Committee began meeting regularly to develop information materials and purchaser data, and to generally prepare to begin purchasing. Despite the extensive preparations and groundwork created for the Alliance, it was never able to begin purchasing, and later was dissolved.

The reasons for the Alliance faltering were complex. One reason was new thinking behind the 340B “prime vendor” program; another was the federal prohibition on hospitals getting 340B discounts while using a group purchasing organization other than the federal 340B prime vendor.¹⁴ As a result, California’s new multi-provider type purchasing alliance, including a statewide Pharmacy & Therapeutics Committee and newly created nonprofit organization and advisory board, could only operate with approval from HealthCare Purchasing Partners International (HPPI), which took over 340B Prime Vendor management in the midst of California’s efforts to launch its drug purchasing Alliance¹⁵ After many months of waiting for action, the Alliance’s safety net provider leaders and the philanthropic foundation financing its preparations came to understand that the federal government and its contractor did not support California’s model of grouping one state’s county hospital, county health system, and community clinic purchasers. No other state or region has launched a similarly ambitious regional grouping of hospital and non-hospital 340B purchasers since California’s statewide Alliance was ended.

A California Safety Net PBM?

Many safety net providers were dismayed to learn that California’s purchasing alliance would not proceed. However, the physicians and pharmacists who had been working together toward the Alliance wanted to build on the interdisciplinary and inter-organizational relationships that had been developing through Medpin. The same philanthropic foundation that had funded feasibility analysis and implementation planning for the Alliance agreed to one year’s financial support of a new, more limited venture called California Safety Net Alliance for Pharmacy & Therapeutics Support (Cal SNAPTS).

The main purpose of Cal SNAPTS was to further the partnerships between pharmacy faculty and safety net professionals who had started working together through Medpin, creating information materials and dissemination activities useful to pharmacy and therapeutics (P&T) committees and others in safety net clinics throughout the state.

¹⁴ This is often referred to as the “GPO exclusion.” Because the Alliance aimed to build on relationships developed among hospital and non-hospital safety net providers through their work with Medpin, it had a different model than an existing, national 340B purchasing group created by the Texas Association of Community Health Centers (TACHC). This “340Better” purchasing group excluded hospitals and therefore was not affected by the “GPO exclusion.” www.tachc.org

¹⁵ HPPI was part of VHA and University HealthSystem Consortium (UHC), based in Irving, Texas. <https://www.340bvp.com/public/news/archive/PVPPress101204.pdf>.

Observers sometimes commented on the similarities and differences between a large, commercial pharmacy benefits management (PBM) company's typical drug information and negotiation activities, compared to Cal SNAPTS.¹⁶ The important differences were that

- Cal SNAPTS included safety net physicians and pharmacists who had credibility with and knowledge about their safety net colleagues,
- Cal SNAPTS benefited greatly from the expertise of faculty and advanced students from two major California pharmacy schools, and
- Cal SNAPTS received no funding from either the providers using its materials and teleworkshops, or from the drug companies whose products were the subject of Cal SNAPTS drug monographs.¹⁷

During its final months, Cal SNAPTS was able to behave somewhat like a “nonprofit PBM” when it received funds for a new project to promote generic drug use among safety net clinics. This new High Value Medications project was funded through a litigation settlement by the California Attorney General involving the PBM now called Medco Health. Drawing on materials developed by CalSNAPTS, this 2007 project supported use of cost-effective generic drugs.¹⁸

Federally-supported project and pharmacy schools connect with safety net clinics

Although Medpin's initial years included direct technical assistance to clinics seeking pharmacy-related knowledge and advice, that model shifted in subsequent years. Now both a federally-funded program in Washington DC, and pharmacy schools throughout California plus some in other states, are bringing financial and human resources to this kind of technical assistance.

The federally-funded Pharmacy Services Support Center (PSSC) was established in 2002 to assist Health Resources and Services Administration grantees optimize the value of the 340B Program, and to provide clinically and cost effective pharmacy services that improve medication use and advance patient care.¹⁹ At the same time that the PSSC began developing national pharmacy information materials and activities similar to Medpin's initial efforts, Medpin sought to expand its network of California pharmacy school faculty and students who could help reach out to local safety net providers.

¹⁶ Pharmacy benefits management companies (PBMs) are hired by health plans to manage their pharmacy-related costs. PBMs also receive rebates from the drug companies, which rebates may or may not be passed on to the PBM's client health plans.

¹⁷ Cal SNAPTS information materials were available at no charge through the Medpin website for two years, but have been removed because they are not being updated to reflect any new information that may emerge about existing drug products or the availability of new products.

¹⁸ This topic had been part of Medpin's earlier trainings and order system that encouraged clinics to save their project “credit” for use in securing brand name drugs without a generic equivalent, which allowed their pharmacy's direct expenditures to favor lower-priced generic drugs. However, this was the first time Medpin was able to offer what was, in effect, a generic drug PAP.

¹⁹ <http://pssc.aphanet.org/> Based at the American Pharmacists' Association in Washington DC, the PSSC is sometimes described by the director of the Office of Pharmacy Affairs as one leg in the “three legged stool” representing that federal government office's relationship with the 340B Prime Vendor Program and the PSSC.

In September 2006, Medpin convened a summit of faculty from each of California's schools of pharmacy plus selected leaders from groups of community clinics. This summit was the first time that all seven of California's pharmacy schools had sent one or more faculty members to jointly discuss mutual interests and community service opportunities for their faculty and students involving safety net clinics. That gathering was a predecessor for several subsequent projects involving all of California's pharmacy schools and their efforts to reach low-income patients.²⁰

Part D

Medicare's new Part D coverage has brought significant federal involvement in helping low-income people eligible for Medicare. For two years prior to the 2006 start of actual drug coverage, CMS offered Medicare-approved Drug Discount Cards. Amidst the scramble to decide what these new cards did or did not accomplish, Medpin tried to remind policy makers and safety net providers of the bigger drug pricing picture. Medpin compared prices for top selling drugs through those cards with prices through major sources in Canada, through California's SB 393 program, and through the federal 340B program. Medpin's reports included equal numbers of brand name and generic drugs, effectively reminding people to look at the actual price and not just at a discount off of a high starting price.

The initial months of actual Part D coverage 2006 brought widespread chaos and concern among safety net providers and their low-income patients. The confusion and implementation glitches hit hardest at low-income people who had their drug coverage through Medicaid, because that drug coverage ended on January 1, 2006 when it was automatically transferred to enrollment in one of the lower cost Part D Prescription Drug Plans. As a result, a highly vulnerable group of people was the first to experience a major new program's inevitable confusion and problems.

To help California safety net providers sort through the emerging information and confusion, Medpin and the Lifelong Medical Care community health center partnered in late 2005 and early 2006 to present a series of teleworkshops and special written materials, all tailored for and presented by pharmacy-related staff in safety net clinics. A year later, a similar partnership presented information to safety net clinics as they helped patients with the first annual reenrollment period. People who made presentations and took questions during these teleworkshops included state and federal health officials, public interest attorneys, and physicians and pharmacists working in safety net clinics with many Medicare patients.

For people who had been receiving help through drug companies' PAPs, that assistance ended or changed significantly as a result of legal concerns that accompanied Part D's influx of federal funding. In December 2005, Medpin worked with the Association of Clinicians for the Underserved, National Association of Free Clinics, Free Clinics of the Great Lakes Region, Public Hospital Pharmacy Coalition, MedBank of Maryland, Senior PHARMAssist, Volunteers in Health Care, and National Association of Community

²⁰ One post-summit project involving all California pharmacy school faculty and students reaching out to underserved people is training pharmacy students to counsel Medicare Part D beneficiaries. <http://www.partnersind.com>.

Health Centers to develop and send jointly signed letters to the CEO of each major drug company. Each of these letters acknowledged that Medicare Part D “changes the legal and financial landscape of medication access for drug companies” and requested that company “to join us soon in considering and discussing some specific ideas for adapting your PAP program to the new Part D environment.”²¹

Policy Analysis and Communications

Throughout its technical assistance and direct service activities, Medpin staff and advisors regularly stepped back to consider the state and federal policy and program implementation issues underlying clinics’ pharmacy challenges. On some of these issues, it seemed useful for Medpin to become involved in some way. One example already mentioned was the impact of Part D’s launch on low-income, Medicare-eligible individuals, both those in California who had been receiving drug coverage through Medi-Cal (California’s Medicaid program), and those throughout the U.S. who had been receiving medications through drug company PAPs.

Medpin’s grounding in California safety net providers’ experiences, plus the logistical challenges of involvement in federal matters unfolding many miles away, meant that most of Medpin’s policy-related activities were focused on its home state. The earliest example of direct interaction with government laws and programs was the close working relationship Medpin developed with California’s Board of Pharmacy, which contributed materials and staff time to Medpin’s 2000 series of regional sessions to help clinics understand and comply with state law regarding licensing of clinic dispensaries. One policy-related result of this relationship was Medpin’s sponsorship in 2001 of California legislation that specifically allowed 340B-eligible clinics unable to operate their own pharmacy to contract with community pharmacies to dispense drugs purchased by the clinic at 340B discounted prices.²²

California Legislative and Ballot Initiative Developments. Medpin developed and disseminated periodic informational updates on relevant California legislation. Most notably, Medpin developed an in-depth analysis of two 2005 ballot initiatives that were the result of several different high-profile bills that had been highly discussed and

²¹ The specific steps requested by this ad hoc national coalition of nonprofits in December 2005 were the following:

- (1) Refrain from implementing any PAP-related changes regarding Part D until after the end of the initial enrollment period, now set at May 15, 2006 (this is particularly important given the Social Security Administration’s backlog in processing low income subsidy applications); and
- (2) Commit to working with our group, CMS and the OIG over the next several months in an effort to create a workable option for providing medication “outside the Part D benefit” and to explore models of “independent, *bona fide* charities” that might be appropriate for taking on some PAP-like activities for eligible Medicare beneficiaries.

²² Senate Bill 340, Chapter 631, Statutes of 2001, authored by Senator Jackie Speier. This bill added Sections 4052.5 and 4126 to the California Business and Professions Code. As a side note, it is not a coincidence that the legislation to expand 340B dispensing options was called SB 340--thanks to Senate staff member Michael Ashcraft, MD, and his idea of taking steps to get an appropriate number for that bill.

debated throughout the previous two years.²³ One of these voter initiatives (“Cal Rx”) was promoted by the drug industry and groups supported by drug companies, and based on legislation previously supported by the Governor but unable to gain legislative approval. The other (“Cal Rx Plus”) was promoted by a labor-consumer coalition and based on legislation previously passed by the Legislature but vetoed by the Governor.

The two measures both had complicated language, combined with strong similarities in their titles and their aim of creating a state-administered discount program for low-income people. This alone pointed to the expectation of great public confusion, while record-breaking spending by the drug industry supported outreach and advertising campaigns with brief messages aimed at the general public.²⁴ Both measures failed to win voter approval.

The key difference between the two ballot measures arose from the same question that had run through earlier legislative debates: should the state health department have an option to create incentives/penalties aimed at encouraging/pushing drug companies to offer specified levels of discounts to uninsured patients? And more specifically, was it appropriate to involve Medi-Cal’s prior authorization process as a potential “hammer” to help bring lower drug prices to people expected to benefit from a state program helping people whose incomes were limited, but above the Medi-Cal cutoff?

In addition to the campaign expenditures directly connected with the ballot initiative campaigns happening throughout 2005, PhRMA was taking other steps that reminded people of their “voluntary” approach toward reducing financial barriers to medications. PhRMA launched a national effort called Partnership for Prescription Assistance while also tweaking that program and website to create something it called Rx Help for Californians.²⁵ Both of these appeared to be part of a larger effort to remind elected officials and the general public of PAPs as examples of voluntary programs that address the same concerns as other options, for example, greater access to Canadian pharmacies, state government involvement in drug discount programs, and federal government involvement in Part D price negotiations. PhRMA CEO Billy Tauzin, speaking of PhRMA’s Partnership for Prescription Assistance, was quoted in an April 2005 news article as follows.

This is going to be very expensive for the companies, but they’re willing to make this commitment to save the free-market system in America. The reason why PhRMA supports the free-market system is that it’s the last

²³ *The California Debate: Competing Drug Discount Programs for Millions of Residents*, Public Health Institute, September 2005.

²⁴ See, for example, “Ad Watch: Drug firms criticize Prop. 79 scenarios,” *Sacramento Bee*, September 19, 2005.

²⁵ PhRMA’s national website www.pparx.org was given a state-specific look for California and other selected states starting in 2005. See for example www.rxhelpforca.org, which was developed and promoted during 2005, and the more recent California Partnership for Access to Treatment, www.caaccess.org.

bastion that rewards innovation. But we realize that if we're going to retain that system, we can't leave people out simply because they're impoverished.²⁶

In an interesting coincidence, an article Medpin had been working on for several years appeared in a national peer-reviewed journal in April 2005, just when PhRMA was making significant new efforts to focus public attention on PAPs. The published article was based on a multi-state survey of safety net providers' experiences with PAPs, included specific suggestions for improving PAP design, and names of companies whose programs were reported by the responding safety net clinics as used most often or least often because of their difficulty.²⁷

Medi-Cal's Drug List. Great attention was given during the ballot initiative discussions to the question of how the state decides which drugs do or do not appear on Medi-Cal's Contract Drug List (CDL). This was because pharmaceutical products included in the CDL typically have no prior authorization requirement, so are more likely to be prescribed for Medi-Cal patients. However, few people were aware of Medi-Cal's Contract Drug Advisory Committee (MCDAC) and its connection to the CDL's development process.²⁸ Because many of California's safety net clinics serve a mix of uninsured and Medi-Cal patients, the health care professionals from those clinics had great interest in getting more information on and access to the process of deciding which drugs go onto the CDL, and how to move that list toward greater similarity with the other drug lists used at those clinics.²⁹

When Medpin established its statewide P&T support committee, it also worked with Medi-Cal to nominate health care professionals for positions on MCDAC. As a result, three physicians and one pharmacist with current safety net clinic or hospital experience were appointed by the department director in August 2005 to the committee, joining the two pharmacists and Medi-Cal staff physician who were the existing committee members. Unfortunately, initial excitement among the safety net community about the potential for greater communication and cooperation between its health care professionals and Medi-Cal staff lasted for two meetings in 2005, after which time the MCDAC never met again. California safety net clinics continue to hope for a better fit between Medi-Cal prescribing incentives associated with the CDL and their own determination of the most cost-effective drugs for their uninsured patients.

Medpin Partners and Financial Supporters

Medpin was able to accomplish all that it did with a remarkably small number of staff and limited financial resources only because of the many individuals who generously

²⁶ Kevin Freking, *Drug firms launch \$10 million ad campaign*, THE ASSOCIATED PRESS, April 5, 2005, available at http://archive.mail-list.com/hbv_research/msg07894.html (last visited Sept. 13, 2005).

²⁷ Duke K, Raube K, Lipton H. "Patient Assistance Programs: Assessment of and use by safety net clinics," *Am J Health-System Pharm*, Vol 62, April 1, 2005.

²⁸ California Welfare & Institutions Code Section 14105.4 requires the California Department of Health Care Services to "appoint a Medi-Cal Contract Drug Advisory Committee for the purpose of providing scientific and medical analysis on drugs contained on the list of contract drugs."

²⁹ Revenues from the supplemental rebates associated with the state's CDL go to the state, not to any of the providers whose Medi-Cal patients' prescriptions are governed by the CDL.

joined and supported Medpin’s efforts. Attached to this report are names of some of the people who donated their time and expertise toward the shared goals of helping vulnerable people get better access to appropriate medications.

In addition, Medpin is proud to acknowledge the following sources of direct financial support and in-kind support.

- Two litigation settlement funds, as described earlier in this report.
- Three independent philanthropic foundations in California: The California Endowment, the California HealthCare Foundation, and The California Wellness Foundation.
- Kaiser Permanente Community Benefits program.
- The federally funded Pharmacy Services Support Center.
- In-kind donations of time and expertise from California pharmacy and medical school faculty and law students.
- In-kind donations of time and experiential learning from pharmacists and other health care professionals in California.
- Partnerships with California-based associations of safety net providers or pharmacists, and with nonprofit organizations based in other states and Washington D.C.

Some lessons and observations from Medpin’s eight years

1. **It is very difficult for individual safety net clinics to move beyond a short-term perspective on increasing the value of their pharmacy-related expenditures.** Constant financial pressures in the back office, vulnerable patients crowded into the waiting rooms, staff turnover, and limited resources all undermine a single clinic’s ability to take a larger look at its pharmacy spending and efforts. This is why sources of “free” prescription drugs—through drug samples, drug company controlled assistance programs, or a program by an independent nonprofit such as Medpin—are so attractive to these nonprofit clinics. This is also why it is important for an outside organization to support and advise these clinics about pharmacy management strategies that bring value in a larger context.
2. **The history of the California Discount Prescription Drug Program holds sobering lessons for larger health care reform in California and beyond.** California’s several years of high-profile legislative efforts, followed by confusing and expensive ballot initiative campaigns, ultimately resulted in bipartisan enactment of the California Discount Prescription Drug Program of 2006. However, that law failed to include any funding, and we’re still waiting to see if anything comes from all the campaign money and political negotiating invested in creating that program. Given this state’s huge budget shortfall, chances are not good for implementation of a meaningful drug discount state program anytime soon. The implications of this story are sobering for people expecting that powerful stakeholder groups will reach agreement on larger health care reform.

3. **It's challenging for any group to walk a middle path between the interests of drug companies, and the interests of safety net providers and their patients.**

The primary goals and activities of multi-national drug companies that earn profits from product sales are not the same as the primary goals and activities of local nonprofit and county health department "safety net" clinics that care for low-income people. Sometimes the interests of all these groups converge, but when they do not, it's difficult for one organization to work with all parties.

It is challenging for any group to accept drug company funding or similar assistance while staying independent of pressure--however subtle or self-generated--to avoid ruffling their funders' feathers. Medpin was fortunate to start with major funding and program elements coming from drug companies, but indirectly through a court-supervised litigation settlement.

4. **There is confusion about the goals of shareholder-owned drug companies as they relate to uninsured patients.**

Sometimes drug companies, and sometimes policymakers or nonprofit organizations, behave as if drug companies are nonprofit organizations providing charitable services, instead of companies that must answer to shareholders looking for financial return. This confusion creates unrealistic expectations of drug companies when the public relies on them to voluntarily assist non-paying customers/patients.

5. **Adding litigation settlement program design and funding possibilities can help bring a nonprofit organization new dimensions of freedom.**

Both of the litigation settlement projects that came to Medpin brought highly desirable program elements and funding that could then attract additional philanthropic funding, allowing complementary programs and goals.

6. **There has too often been a focus more on discounts from drug "prices" than on the actual price of pharmaceutical care.**

Much public discussion has focused on arguments about the level of discount from a drug's "price." This happened, for example, during negotiations for what became California's Discount Prescription Drug Program, and during national discussions about the prices of drugs from Canadian pharmacies. These discussions about brand name drugs' discount levels took place despite availability of many generic drugs whose full retail price was lower than chemical or therapeutically equivalent brand name drugs after a discount. Only now, when there are increased numbers of generic drugs similar or identical to popular products that were recently brand name, are non-pharmacists starting to look at a broader range of pharmaceutical products when considering medication affordability.

7. **Pharmacists are evolving from product dispensers to clinicians who can be and often are part of the health care team.**

As prescription drugs become an increasingly important but complex part of health care, physicians and other prescribers need expert information that is independent from drug companies. Pharmacists from the providers' own organization, or from an independent

outside group, should be used more often as a resource on medication safety and effectiveness issues, and on new drug products.

- 8. Prescription drug issues for safety net providers have become increasingly focused on people and programs in Washington DC.** During Medpin's initial eight years, activities of significant interest to safety net pharmacy providers have become increasingly national in funding and control. One obvious example is the creation of a Medicare outpatient drug benefit, which has had major and mixed impact on local safety net providers.

Another example is the growing participation levels and federal focus of the 340B control. This program, overseen by the federal Office of Pharmacy Affairs, is enrolling increasing numbers of providers into a single, federal 340B Prime Vendor Program that negotiates with drug companies and uses a portion of drug purchase payments to support its work. As for pharmacy-related information and technical assistance support to these providers, the federally-funded Pharmacy Services Support Center is replacing some of what would have been previously offered by independent nonprofits such as the former Volunteers in Health Care/RxAssist (based in Rhode Island) and Medpin (based in California). Other information and technical assistance is provided through national membership organizations that come together in a Washington DC-based 340B Coalition. In addition, PhRMA's Partnership for Prescription Assistance (PPA Rx) provides strong national support and direction for its promotion of public awareness in communities across the U.S. of drug companies' patient assistance programs.

- 9. Public agency and nonprofit safety net payers and providers should move toward a more "evidence-based" approach to prescribing incentives.** Drug effectiveness and safety issues, in addition to the pricing issues referenced above, suggest that independent evaluation of drug information is a worthwhile investment for public agency payers and nonprofit safety net providers. Medpin's relationship building between safety net providers and major pharmacy schools was one example of this effort. Another, ongoing resource available nationally is the Drug Effectiveness Review Project of the Oregon Health Sciences University.³⁰

- 10. Effective health care should integrate medications into a larger array of health services, and integrate health services into a larger view of the public's health.** For everyone, but especially for low income people coming to safety net providers, pharmaceutical care should be only one part of effective medical care. In the same way, medical care spending and attention should be put into a larger framework of topics not typically considered medical, or even "health" related. Recent writing by Californians such as Michael Pollan, Steve Schroeder, Dick Jackson, and other thoughtful observers move us to pay more attention to our food, the built environment of our communities, tobacco use, and other factors whose combined power to help or hurt our health status is greater than the impact of medical care. How ironic it would be if we in the U.S. achieve access to appropriate medication at affordable prices for everyone, but see growing

³⁰ <http://www.ohsu.edu/drugeffectiveness/>

numbers of people eating “food-like substances” instead of authentic food, smoking cigarettes, and living in communities designed more for cars than humans. Those are all big issues, but it’s helpful to step back sometimes and acknowledge this bigger picture of “health.”

More information

For more information on Medpin and many of the issues and documents referenced in this story, visit the Medpin website at www.medpin.org.

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Medpin Program Director, 1999-2007*

Attachment: Medpin Partners and Supporters: 1999-2007