05hr_SSC-HCR_Misc_pt31

Details: Medicaid and Health Care Reform. Hearing held in Madison, Wisconsin on August 28, 2006.

(FORM UPDATED: 08/11/2010)

WISCONSIN STATE LEGISLATURE ...
PUBLIC HEARING - COMMITTEE RECORDS

2005-06
(session year)

Senate
(Assembly, Senate or Joint)

Select Committee on Health Care Reform...

COMMITTEE NOTICES ...

- Committee Reports ... **CR**
- Executive Sessions ... **ES**
- Public Hearings ... **PH**

INFORMATION COLLECTED BY COMMITTEE FOR AND AGAINST PROPOSAL

- Appointments ... **Appt** (w/Record of Comm. Proceedings)
- Clearinghouse Rules ... **CRule** (w/Record of Comm. Proceedings)
- Hearing Records ... bills and resolutions (w/Record of Comm. Proceedings)
  (**ab** = Assembly Bill) (**ar** = Assembly Resolution) (**ajr** = Assembly Joint Resolution)
  (**sb** = Senate Bill) (**sr** = Senate Resolution) (**sjr** = Senate Joint Resolution)
- Miscellaneous ... **Misc**

* Contents organized for archiving by: Stefanie Rose (LRB) (August 2012)

Malszycki, Marcie

From: Mike Shattuck [shatt6@fdldotnet.com]
Sent: Monday, August 28, 2006 10:09 PM
To: Roessler, Carol
Subject: Re: Revised Hearing Notice: Senate Select Committee on Health Care Reform

Dear Senator,

I appreciated the opportunity to speak before the committee. I felt badly that I was so rushed. I don't know if I got my points across. I could have told you more.

Anyhow, the article I mentioned that would be worth reading to get a better idea of how drug companies influence health care is www.annals.org/cgi/content/full/145/4/284. The book, "The Truth About the Drug Companies" that I gave is worthwhile reading on this subject also. Could you share this with the other Senators?

I explored the Bid Rx site. This could be helpful to help find the least expensive drugs. I missed the other site that was mentioned. Was it WIO?

Sincerely,
Mike Shattuck

----- Original Message -----
From: Roessler, Carol
To: Mike Shattuck
Sent: Thursday, August 24, 2006 2:20 PM
Subject: RE: Revised Hearing Notice: Senate Select Committee on Health Care Reform

Dear Mike,

Yes, you will be presenting at the hearing on Monday, August 28, 2006. We will have a computer set up for all presenters to use for power point slides.

Thank you and look forward to meeting you.

Sincerely,

CAROL ROESSLER

From: Mike Shattuck [mailto:shatt6@fdldotnet.com]
Sent: Thursday, August 24, 2006 2:16 PM
To: Roessler, Carol
Subject: Re: Revised Hearing Notice: Senate Select Committee on Health Care Reform

I am writing to confirm that I will be presenting before the committee on Monday, Aug. 28th. I would also like to confirm that I will be able to use a projector there for a power point presentation.

Mike Shattuck

----- Original Message -----

Annals of Internal Medicine

Established in 1927 by the American College of Physicians

REVIEW

Narrative Review: The Promotion of Gabapentin: An Analysis of Internal Industry Documents

Michael A. Steinman, MD; Lisa A. Bero, PhD; Mary-Margaret Chren, MD; and C. Seth Landefeld, MD

15 August 2006 | Volume 145 Issue 4 | Pages 284-293

Background: Internal documents from the pharmaceutical industry provide a unique window for understanding the structure and methods of pharmaceutical promotion. Such documents have become available through litigation concerning the promotion of gabapentin (Neurontin, Pfizer, Inc., New York, New York) for off-label uses.

Purpose: To describe how gabapentin was promoted, focusing on the use of medical education, research, and publication.

Data Sources: Court documents available to the public from *United States ex. rel David Franklin vs. Pfizer, Inc., and Parke-Davis, Division of Warner-Lambert Company*, mostly from 1994–1998.

Data Extraction: All documents were reviewed by 1 author, with selected review by coauthors. Marketing strategies and tactics were identified by using an iterative process of review, discussion, and re-review of selected documents.

Data Synthesis: The promotion of gabapentin was a comprehensive and multifaceted process. Advisory boards, consultants meetings, and accredited continuing medical education events organized by third-party vendors were used to deliver promotional messages. These tactics were augmented by the recruitment of local champions and engagement of thought leaders, who could be used to communicate favorable messages about gabapentin to their physician colleagues. Research and scholarship were also used for marketing by encouraging "key customers" to participate in research, using a large study to advance promotional themes and build market share, paying medical communication companies to develop and publish articles about gabapentin for the medical literature, and planning to suppress unfavorable study results.

Limitations: Most available documents were submitted by the plaintiff and may not represent a complete picture of marketing practices.

Conclusion: Activities traditionally considered independent of promotional intent, including continuing medical education and research, were extensively used to promote gabapentin. New strategies are needed to ensure a clear separation between scientific and commercial activity.

■ **Article**

- Table of Contents
- Abstract of this article
- PDF of this article (PDFs free after 6 months)
- Figures/Tables List
- Related articles in Annals
- Articles citing this article
- CME course

■ **Services**

- Send comment/rapid response letter
- Published comments/rapid response letters
- Notify a friend about this article
- Alert me when this article is cited
- Add to Personal Archive
- Download to Citation Manager
- ACP Search

■ **PubMed**

Articles in PubMed by Author:

- Steinman, M. A.
- Landefeld, C. S.
- Related Articles in PubMed
- PubMed Citation
- PubMed

Key Summary Points

Industry promoted gabapentin for on- and off-label uses as part of a comprehensive marketing plan.

Frequent prescribers of anticonvulsant agents, opinion leaders, and local champions of gabapentin were specially targeted for promotion.

Gabapentin was promoted by using education and research, activities not typically recognized as promotional. "Independent" continuing medical education, "peer-to-peer selling" by physician speakers, industry-funded studies, and publications in the medical literature were used to advance marketing goals for the drug.

Recent litigation and congressional inquiry have provided access to pharmaceutical industry documents that shed light on the marketing strategies used to promote drugs (1). One example is the case of gabapentin (Neurontin, Pfizer, Inc., New York, New York). First approved by the U.S. Food and Drug Administration (FDA) in late 1993 for adjunctive treatment of partial complex seizures, by the mid- and late 1990s gabapentin was being widely used for the off-label treatment of pain syndromes and psychiatric conditions (Figure 1) (2–4). Although gabapentin was later approved for the treatment of postherpetic neuralgia, in 2004 the Pfizer subsidiary Warner-Lambert settled litigation and admitted guilt in connection to charges that during the 1990s it violated federal regulations by promoting the drug for pain, psychiatric conditions, migraine, and other unapproved uses (Table 1) (5–7).

View larger version (25K):
[in this window]
[in a new window]

Figure 1. **Prescriptions for gabapentin, by diagnostic category.**

Estimates of diagnosis-linked prescribing provided by Pfizer, Inc. (2–4). Each diagnosis was assigned to a diagnostic category by the authors. *Adjunctive treatment of epilepsy in adults older than age 12 years was the only U.S. Food and Drug Administration–approved use of gabapentin during the time period shown.

View this table:
[in this window]
[in a new window]

Table 1. **Timeline***

Although news articles have described some practices used to market gabapentin (8, 9), to our knowledge there has been little systematic investigation of the overall structure of promotion for this drug. In this paper, we use public documents obtained through litigation to describe how marketing strategies and tactics for gabapentin were developed and used in the mid- and late 1990s. First, we describe the overall organization of marketing efforts, and how certain groups of physicians were targeted as recipients of and vehicles for promotion. Next, we describe specific marketing activities, focusing on how education, research, and other activities not typically considered promotional were used to achieve marketing goals.

Methods

▲ Top
▪ Methods
▼ Discussion
▼ Author & Article Info
▼ References

We reviewed approximately 8000 pages of publicly available documents regarding the case of *United States of America ex. rel David Franklin vs. Pfizer, Inc., and Parke-Davis, Division of Warner-Lambert Company*. Among documents pertinent to this research, two thirds were created between 1994 and 1998 and comprised a mix of internal correspondence and reports; programs, presentations, and transcripts from activities sponsored by Parke-Davis; and correspondence between the drug company and outside vendors and physicians. The remaining pertinent documents included excerpted depositions of Parke-Davis employees and court documents. These documents are now available in a digital archive at http://dida.library.ucsf.edu.

We reviewed documents using the principles of grounded theory, an inductive approach in which source material was used to generate ideas rather than to test a preestablished hypothesis (10). All documents underwent primary review by 1 author, with selected review by the coauthors. First, we cataloged marketing techniques and identified broad themes about marketing strategy for gabapentin. Next, we discussed initial findings and re-reviewed pertinent documents in an iterative process to arrive at the final description and interpretation of marketing techniques and themes. To better understand the role of individuals and organizations discussed in the documents, we obtained supplemental information from the court and through Internet and PubMed searches.

Most data on payments to physicians and organizations were obtained from a payment register compiled by the plaintiff's attorneys from documents supplied by Parke-Davis (4, 11) and augmented with additional information provided to us by those attorneys (for additional detail on analyses of the payment register, see Appendix 1). We also used budget planning documents from 1998 and other years to estimate expenditures for different forms of marketing (12–14).

During the period under review, gabapentin was approved only for the adjunctive treatment of partial seizures in persons older than 12 years of age at dosages up to 1800 mg/d. Thus, for this review, we considered any other indication to be unapproved. In quotations of documents, items in brackets are our addition and represent our best interpretation of abbreviations, phrases, and other data.

This research was approved by the Research and Development Committee of the San Francisco Veterans Affairs Medical Center and the Committee on Human Research at the University of California, San Francisco. The aforementioned archive paid the cost of obtaining and photocopying documents used in this research. No outside source had a role in the mechanisms of document review, presentation of results, or decision to submit the manuscript for publication.

Data Synthesis

Marketing Strategy

Each year, corporate leadership established broad goals ("strategies") for the marketing of gabapentin. Specific programs ("tactics") were then designed to achieve that year's strategic goals (15, 16). For example, planning documents for 1998 show a projected $40 million advertising and promotion budget for gabapentin organized under 4 "topline strategies," further divided into a variety of tactical categories (Table 2) (12, 13). Professional education accounted for half to two thirds of the projected promotional budgets for 1996 through 1998 (12–14).

View this table: [in this window] [in a new window]

Table 2. **Draft Advertising and Promotion Budget for Gabapentin for 1998, by Strategy and Tactical Category***

Parke-Davis identified several groups of physicians for targeted marketing. One such group was physicians who frequently prescribed anticonvulsant agents, categorized by the dollar value of anticonvulsant prescriptions they had the potential to generate (>$300 000 for the highest tier of prescribers) (14, 15, 17–23). Another key group was physicians who had the potential to influence gabapentin use among their colleagues. This included local champions of the drug, who were recruited and trained to serve as speakers in "peer-to-peer selling" programs (19, 24–26), which were noted to be "one of the most effective ways to communicate our message" (19). Another important segment was "thought leaders," "key influencers," and "movers and shakers," influential physicians identified in part by their affiliation with major academic medical centers (12, 13, 18–20, 24, 26–28). For example, in 2 documents Parke-Davis identified 40 potential thought leaders in the northeastern United States, including 26 current or future department chairs, vice chairs, and directors of academic clinical programs or divisions (24, 27). Of these 40 leaders, 35 participated in at least 1 Parke-Davis–sponsored activity, including 14 who requested or were allocated $10 250 to $158 250 in honoraria, research grants, or educational grants between 1993 and 1997 (11).

Parke-Davis also targeted residents; planning documents for the 1998 advertising and promotion budget show allocations of $195 000 to $330 000 for "resident programs," a video case series, and a "CNS [central nervous system] residents course" (13). As described in one report, efforts with residents could be used "to influence physicians from the bottom up" and "to solidify Parke-Davis' role in the resident's mind as he/she evolves into a practicing physician" (24).

Tactics

Continuing Medical Education

"Medical education drives this market!!" noted the author of a Parke-Davis business plan (29). Accordingly, educational activities were used to implement strategic goals for gabapentin (12, 30–32), often through events at which physician speakers could communicate messages about gabapentin directly to their colleagues. Teleconferences linking paid physician moderators with small groups of physicians were a method for reaching prescribers. Although these teleconferences were titled as educational events (33), an internal memo about 1 set of 143 teleconferences on epilepsy management noted that "the key goal of the teleconferences was to increase Neurontin new prescriptions by convincing non-prescribers to begin prescribing and current prescribers to increase their new prescription behavior" (34). In some cases, Parke-Davis helped establish the agenda and was able to surreptitiously monitor teleconferences in progress. In 1 set of 39 calls organized through a medical education and communications company to discuss unapproved uses of gabapentin, an agenda was prepared for physician moderators directing them to discuss such topics as "how Neurontin evolved into a first line therapy option in your practice" (35, 36). In another series of "psychiatry" teleconferences organized through a third-party vendor, senior Parke-Davis employees were invited to participate but told to "instruct the teleconference operator that you should be in LISTEN ONLY mode and your name should NOT be announced during introductions" (capital letters in original) (37). Documents suggest that in some cases moderators were paid $250 to $500 per call and had other financial ties to Parke-Davis (11). For example, each of the 10 moderators from 1 series of calls requested or was allocated between $14 800 to $176 100 for participation in various Parke-Davis–sponsored activities between 1993 and 1997 (11, 33).

Speakers bureaus and related programs were other physician-to-physician activities developed to promote gabapentin (25, 26, 28, 38). Sales employees were encouraged to "expand the speaker base—identify and train strong Neurontin advocates and users to speak locally for Neurontin" (19). Parke-Davis also organized the Merritt-Putnam lecture series to improve "public relations within the neurology community, etc., as well as [to impact] the volume of Neurontin new prescriptions" (26, 28, 38). The speakers bureau for this lecture series included chairs of neurology departments and directors of clinical programs at major teaching hospitals (11, 39). Members of the speakers bureau were invited to special meetings, where, in addition to lectures on the clinical use of gabapentin,

they were updated on promotional strategies for the drug (39, 40).

Many educational events appear to have been sponsored directly by Parke-Davis. However, the company also funded educational programs through "unrestricted educational grants" to medical education and communications companies (hereafter termed "medical education companies"), for-profit businesses that specialize in producing conferences for physicians on behalf of pharmaceutical manufacturers and are often subsidiaries of marketing firms (41–44). Under this "unrestricted" arrangement, Parke-Davis officially relinquished control over program speakers and content. This allowed programs organized by medical education companies to discuss unapproved uses of gabapentin and to grant continuing medical education credit from the Accreditation Council of Continuing Medical Education (ACCME), neither of which is permissible for events directly sponsored by drug companies (45–48).

However, these same medical education companies also worked for Parke-Davis in several other roles, such as organizing teleconferences, coordinating advisory boards and consultants meetings, and conducting tactical planning to promote gabapentin (15, 17, 39, 47, 49–55). Because of these relationships, medical education companies had incentive to develop educational programs that were consistent with Parke-Davis's marketing goals and to control content in a way that reflected favorably on the sponsor (Appendix 2) (56). For example, in 1996, one medical education company prepared a marketing proposal for Parke-Davis outlining 24 tactics to increase gabapentin use shortly after using an unrestricted grant from the drug company to organize a series of study programs on the use of antiepileptic agents for chronic pain (49, 57–59). Although the educational program prepared by this company was accredited by ACCME, Parke-Davis representatives were invited to a curricular development meeting (59), recruited physicians to participate in the course (60), and followed attendance counts at each program meeting (57). These actions were consistent with a Parke-Davis report that described the program as a tactic to support "growth opportunity" in off-label use (32). In another case, another medical education company that organized consultants meetings for Parke-Davis received a grant to assemble and train speakers to deliver grand rounds lectures on anticonvulsant use in nonepileptic conditions at approximately 70 community and teaching hospitals across the northeastern United States (51, 61). Parke-Davis also sought to provide unrestricted educational grants to locally organized symposia at which it expected gabapentin to be favorably discussed (62). One memo recommended the following: "Assist in the organization of a [major university hospital's] pain symposium ... .We will probably write them an unrestricted educational grant to help fund the project. In return, they will discuss the role of Neurontin in neuropathic pain, among other topics. They do have a very favorable outlook toward Neurontin" (63).

Unrestricted grants were used to underwrite other forms of education, including payments to physicians to cover the cost of attending conferences (64). Another grant exceeding $300 000 funded the production, printing, and distribution of 75 000 copies of an epilepsy handbook, with half of this budget allocated to soliciting interest among and delivering books to high prescribers of anticonvulsant agents (65).

Advisory Boards and Consultants Meetings

The stated purpose of advisory boards and consultants meetings was to solicit feedback from physician participants (47, 66). This objective was met at meetings where feedback was requested on clinical trial design (53, 67, 68), educational curriculum development (50, 67), and marketing strategies for gabapentin (14, 54, 67–69). However, other aspects of meetings were conducted in a manner more suggestive of promotional intent. For example, attendees at one consultants meeting were invited largely because of their high rates of anticonvulsant prescribing (17), and sales representatives were given "trending worksheets" to track prescribing behavior before and after the event (70); at the meeting, "participants were delivered a hard-hitting message about Neurontin" (71). Some meetings resembled educational conferences, with dozens of participants and an agenda dominated by lectures from physician "faculty" (17, 52, 71–73). Other meetings seemed to focus on cultivating relationships with thought leaders (26, 69), as in one meeting at which lecture notes for the regional business director notified attendees that "we would like to develop a close business relationship with you" (69).

Participants in advisory boards and consultants meetings received honoraria in addition to paid travel, lodging, and amenities at the resorts and luxury hotels at which such events were held (51, 52, 71–76). In addition, a

number of faculty at these events received thousands of dollars in honoraria and grants from participating in these and other Parke-Davis activities (11, 52, 71, 73). These faculty may have been carefully vetted. As described by a medical education company that organized meetings, "it is [our] policy to complete a literature search to determine who authors favorable articles on the topics outlined" (56). In addition, the company reserved the right in nonaccredited programs "to probe the faculty further to definitively establish presentation content and make the appropriate changes and/or recruit an alternate speaker" (56).

Research Strategy and Publication

Research and publications on gabapentin served as key elements in the marketing strategy for the drug (26). For some clinical uses, such as monotherapy for epilepsy, research was used to support the company's attempt to obtain FDA approval for a new "on-label" indication. However, in other cases Parke-Davis employed a "publication strategy," the goal of which was to use research not as a means to gain FDA approval for new indications but "to disseminate the information as widely as possible through the world's medical literature" (77), generating excitement in the market and stimulating off-label prescribing despite the lack of FDA approval (78, 79). This strategy focused primarily on expanding gabapentin use in neuropathic pain and bipolar disorders, for which detailed decision analyses projected the greatest revenue potential (80–83).

The success of this strategy depended in part on publications being favorable to gabapentin. Some employees of Parke-Davis felt an obligation to publish studies with unfavorable results (80, 84), and in a number of instances such results were published (85–87). However, management expressed concern that negative results could harm promotional efforts (88), and several documents indicate the intention to publish and publicize results only if they reflected favorably on gabapentin (78, 79). As stated in a marketing assessment, "The results of the recommended exploratory trials in neuropathic pain, *if positive*, will be publicized in medical congresses and published" (italics added) (78). Similarly, in discussing 2 nearly identical trials that yielded conflicting results on gabapentin as seizure monotherapy, the "core marketing team" concluded that "the results of [the negative trial] will not be published" (89). (The positive trial was published [90], but we could not locate the negative trial on a PubMed search.)

Beyond publishing its own clinical trials, Parke-Davis expanded the literature on gabapentin by contracting with medical education companies to develop review papers, original articles, and letters to the editor about gabapentin for $13 375 to $18 000 per article, including a $1000 honorarium for the physician or pharmacist author (91–98). For example, one "grant request" from a medical education company to Parke-Davis proposed a series of 12 articles, each with a prespecified topic, target journal, title, and list of potential authors (to be "chosen at the discretion of Parke-Davis") (96). This proposal noted that "all articles submitted will include a consistent message ... with particular interest in proper dosing and titration as well as emerging [off-label] uses," mirroring Parke-Davis promotional goals for the drug (96). In this case Parke-Davis requested that authors prepare articles and submit them for peer review (92, 96). However, in another instance the medical education company offered substantial assistance in the development of manuscripts, reporting in a status report that "at [the author's] request, we did an extensive literature search and submitted selected articles to him for reference ... . We have offered him help in identifying and collecting his appropriate cases, analyzing data, writing a manuscript, or whatever he needs" (91). Among 7 published articles that we matched to sponsorship by a medical education company, 4 had favorable conclusions about gabapentin (99–102), and the other 3 adopted a neutral tone (103–105). Article sponsorship was often not disclosed, with 6 of 7 articles not acknowledging receipt of an honorarium from the medical education company (although 1 of these acknowledged support from Parke-Davis) (99–105). In 5 of 7 articles, the author identified by the medical education company had received funds from Parke-Davis for speaking engagements, consultants meetings, or other activities (11).

Engaging physicians in the research process had potential benefits for Parke-Davis beyond the publications themselves, providing an opportunity to engage thought leaders, reward key physician customers, or influence prescribing (20, 50, 67, 106–108). Marketing strategy documents stated that "the list of key influencers should be ... kept aware of the availability of research opportunities in clinical trials" (24) and recommended the "funding of smaller studies ... with our key customers for investigation of Neurontin and pain" (29). Among the 40 thought leaders described, 5 requested or were allocated research funding ranging from $32 000 to $75 000 per person

(11, 24, 27).

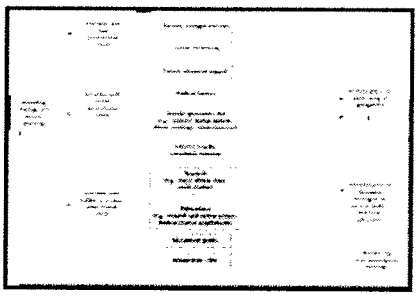
One notable example of the confluence between promotion and research was STEPS (Study of Neurontin: Titration to Effectiveness and Profile of Safety), an uncontrolled open-label study in which physicians were instructed to begin adjunctive gabapentin therapy in their patients with epilepsy and to keep increasing the dose until their patients were seizure-free, or until a maximum dosage of 3600 mg/d (twice the maximum FDA-approved limit) was achieved (109). More than 700 physicians were enlisted to participate, enrolling an average of 3 patients each (with a $300 payment for each patient enrolled) (109–111). The published report of the study stated that it "examined the effectiveness of gabapentin" in this dose range (109). However, company documents described the goal of the study as to "teach physicians to titrate Neurontin to clinical effect" (112) and "to give neurologists the opportunity to titrate to higher doses (>1800 mg) when needed" (16), central promotional goals at the time (30, 69). Described as a "key activity" for the implementation and support of marketing goals, "indicators of success" for the study included increases in market share and use of higher doses of gabapentin (16, 30). At least 6 of 9 authors of the published report had substantial financial relationships with Parke-Davis; they had participated in a total of 263 activities sponsored by Parke-Davis between 1993 and 1997, with requested or allocated payments ranging from $11 450 to $69 000 per author (11, 109).

Discussion

▲ Top
▲ Methods
▪ Discussion
▼ Author & Article Info
▼ References

During the mid- to late 1990s, Parke-Davis used a comprehensive campaign to promote prescribing of gabapentin. Research, publications, and educational programs (including "independent" events) were used as marketing opportunities, augmented by opinion leaders and local physician champions to engage their physician colleagues. Since the promotional intent of these activities may not have been widely recognized, their impact on physicians was probably greater than interactions with known commercial intent, which are typically approached with greater skepticism (42, 43, 113–115).

While the limited nature of our source material precludes a definitive understanding of marketing practices, we hypothesize a model for the marketing of gabapentin that incorporates our findings (Figure 2). In this model, activities with clear promotional intent are known to originate from a pharmaceutical manufacturer and to serve a commercial purpose (thereby disclosing potential commercial bias). In other activities, the promotional underpinnings may be partially obscured (for example, where funding is known to originate from a drug company, but where the stated purpose of the event is education) or largely obscured (for example, "independent" activities delivered through a third party, or funding for research and publication). Many such activities rely on physician-to-physician communication, in which opinion leaders and local advocates are engaged with speaking, research, and educational opportunities and in turn may communicate favorable messages about the drug to their colleagues.



View larger version (25K):
[in this window]
[in a new window]

Figure 2. **Framework for gabapentin marketing.**

In this model, marketing strategy and tactical planning allocate resources to different types of activities. Activities are divided into 3 categories according to the extent to which their promotional intent is generally known to physicians (for example, in directly sponsored continuing medical education [*CME*], the pharmaceutical company is known to be the direct source of funding, but because the event is framed as an educational program, its promotional intent may be obscured). Each of these activities can directly influence prescribing by practicing physicians. In addition, activities in the lower half of the

figure can also influence prescribing through physician-to-physician communication, in which opinion leaders and local gabapentin champions are directly or indirectly engaged to communicate favorable messages about gabapentin to their colleagues. Physician prescribing patterns and other outcomes are then monitored to assess the effectiveness of marketing tactics, which influences future marketing planning decisions. For the sake of simplicity, other relationships are not shown in this diagram. For example, many marketing tactics can work synergistically, such as the use of research findings to promote gabapentin in CME settings.

Our work has several limitations. First, our research was limited to publicly available documents, many of which were submitted by the plaintiff to support allegations of off-label marketing; as a result the view of company practices and decision making is incomplete. Second, we could not determine the frequency of specific activities, nor in most cases confirm that planned activities and payments were executed. Third, this report is based on primary document review by 1 investigator and collaborative interpretation of the authors, 3 of whom were unpaid expert witnesses in the litigation that yielded the documents. The reproducibility of our findings has not been established. Fourth, we reviewed the marketing practices for a single drug made by a single company, and we do not know the extent to which these techniques were used in the marketing of other products made by Parke-Davis or by other pharmaceutical firms. Finally, the litigation focused not on marketing activities themselves but on whether these activities were used to promote unapproved uses (5, 6). Thus, although certain activities, such as ghostwriting, violated prevailing ethical norms, many appear to have been legal (or in a broad "gray zone" of legality) when or if used solely to promote FDA-approved indications for gabapentin (48, 116, 117).

There is widespread agreement that commercial interests should not influence the clinical decisions that physicians make on behalf of their patients. As a result, a complex system has evolved to help manage these conflicts, focused primarily on disclosure and self-regulation by physicians, professional organizations, and the pharmaceutical industry. These efforts have been largely ineffective (118, 119), and the techniques used to promote gabapentin illustrate how commercial interests can intrude into the practice of medicine in both visible and hidden ways. Incremental efforts to strengthen the existing patchwork of guidelines are unlikely to be sufficient in an environment where marketing is so deeply embedded and where the borders between research, education, and promotion are more porous than is commonly recognized. New strategies are needed, including rigorous regulatory oversight, strict sequestration of commercial and scientific activities, and a fundamental internal reevaluation of the interactions between individual physicians, professional organizations, and industry (42, 120–124).

Appendix 1: Analysis of the Payment Register

Web-Only

The payment register was assembled by the plaintiff's attorneys by using data from documents provided by Parke-Davis, in most cases covering 1993–1997. It was organized by individual physicians or institutions, with each payment to that individual, or activity attended by that individual without evidence of payment, appearing as a separate line in the spreadsheet. We used this register to assess payments to physicians of interest whom we identified by name in other court documents, such as physicians targeted as "thought leaders," or physicians who moderated teleconferences on behalf of Parke-Davis. For each physician of interest, 1 of the authors reviewed all line-item entries for that physician to eliminate duplicate entries. Then, on the basis of limited descriptive information for each line item, funds were classified as "requested" (for example, a letter from a physician requesting grant support) or "allocated" (for example, an agenda for an upcoming event with a notation of expected payment). In the absence of contrary evidence, most payments under $2000 were considered

"allocated" since they usually appeared to be honoraria. However, in most cases we could not definitively confirm that physicians participated in or received payment for the listed activity.

Appendix 2: Control of Content in an "Independent" Program: A Case Study Web-Only

In a letter from the medical education and communications company Proworx to Parke-Davis (56), the author describes working with Parke-Davis on an upcoming satellite symposium at the American Diabetes Association annual meeting. When employees at Proworx became concerned about possible "negative" content at their program, they took corrective action (surnames have been removed in the reproduction of this letter):

> When Proworx finally received each of the abstracts [for talks by two speakers] within the week prior to the actual program, they were immediately forwarded to both Vic and Allen [Parke-Davis marketing employees] for their comments. Upon receipt of Dr. B's abstract, Vic called Bina [a project director at Proworx] to express his concerns. However, Bina had already contacted [the accrediting institution] to establish what could be done, within the accreditation guidelines, to address these concerns. At that point, Dr. B. was contacted and told that the accrediting institution had asked that she revise her abstract to remove any specific product information that she could not provide references for. She then revised her abstract and faxed it back again for our review. Lisa, the copy writer for the Parke-Davis account, was then contacted and asked to make any further revisions.
>
> Although the abstract had been revised, there were still concerns on Proworx's and Vic's part in regard to Dr. B's presentation. Her abstract illustrated that [she] was clearly not planning on presenting what had originally been agreed upon. Therefore, Proworx immediately looked at what possible options were available, aside from canceling her talk, to counteract a possible 'negative' presentation. [The accrediting institution] was contacted to address accreditation issues and the CDM [Cline, Davis & Mann, an advertising firm that was the corporate parent of Proworx] account team met with Bina to identify what key issues needed to be presented to give attendees a 'positive message' to go away with.
>
> At this point, Proworx requested that Dr. B. forward a copy of her slides for our review. Upon review, we determined that the slides did not include any specific negative information in regard to Neurontin or anticonvulsants as a whole, and that we should concentrate on creating a setting in which she would have no choice but to address the issue she had originally agreed to present. Therefore, when meeting with the CDM account team, pre-written questions were developed to address any issues that were not mentioned in Dr. B's presentation, as well as questions counteracting negative comments ... .
>
> It was then decided that the best option, while not crossing over [American Council of Graduate Medical Education] guidelines, was to present questions at the Q & A session, which would take place immediately following her presentation. This did indeed lead Dr. B. to address some of the positive aspects of anticonvulsants and of Neurontin ... .
>
> If this had not been an accredited program, Proworx would have been able to probe the faculty further to definitively establish program content and make the appropriate changes and/or recruit an alternative speaker.

Author and Article Information

From San Francisco Veterans Affairs Medical Center and University of California, Top

San Francisco, San Francisco, California.

▲ Methods
▲ Discussion
▪ Author & Article Info
▼ References

Acknowledgment: The authors thank Elizabeth Boyd, PhD, for her careful review of the manuscript.

Grant Support: By a Veterans Affairs Health Services Research & Development Research Career Development Award (Dr. Steinman); by grants from the California Tobacco-Related Disease Research Programs (13RT-0108) (Dr. Bero), the National Institute of Arthritis and Musculoskeletal and Skin Disease (AR02203) (Dr. Chren), the National Institute on Aging (AG00912), and the John A. Hartford Foundation (2003–0244) (Dr. Landefeld); and by the Health Services Research Enhancement Award Program at the San Francisco Veterans Affairs Medical Center.

Potential Financial Conflicts of Interest: Drs. Steinman, Chren, and Landefeld served as unpaid expert witnesses for the plaintiff in the lawsuit that generated these documents (*United States of America ex. rel. David Franklin vs. Pfizer, Inc., and Parke-Davis, Division of Warner-Lambert Company*). Dr. Bero was not involved in this or any other legal action involving Pfizer or Parke-Davis. Seed funding for an online searchable archive of documents from the gabapentin litigation (http://dida.library.ucsf.edu) was provided by a gift from Thomas Greene, lawyer for the whistleblower plaintiff in this litigation, to the University of California Board of Regents. Drs. Steinman and Landefeld participated in the creation and development of the archive, including solicitation of start-up funding from Mr. Greene. The cost of obtaining and photocopying documents used in this research was paid by the archive, which incorporated these documents into the collection.

Requests for Single Reprints: Michael A. Steinman, MD, San Francisco Veterans Affairs Medical Center, 4150 Clement Street, Box 181G, San Francisco, CA 94121; e-mail, mike.steinman@ucsf.edu .

Current Author Addresses: Drs. Steinman and Landefeld: San Francisco Veterans Affairs Medical Center, 4150 Clement Street, Box 181G, San Francisco, CA 94121.

Dr. Bero: University of California, San Francisco, 3333 California Street, Suite 420, Box 0613, San Francisco, CA 94143.

Dr. Chren: San Francisco Veterans Affairs Medical Center, 4150 Clement Street, Box 151R, San Francisco, CA 94121.

References

▲ Top
▲ Methods
▲ Discussion
▲ Author & Article Info
▪ References

1. Waxman HA. Memorandum to Democratic Members of House Government Reform Committee: The Marketing of Vioxx to Physicians. 5 May 2005.Accessed at http://www.democrats.reform.house.gov/documents/20050505114932-41272.pdf on 5 May 2005.

2. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39 (D. Mass. 2001), Exhibit 136. [Estimates of gabapentin uses, by diagnosis.]

3. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39 (D. Mass. 2001), Exhibit 134. Responses and Objections of Defendant Pfizer Inc to Relator David Franklin's Second Set of Interrogatories [and attachments]; 11 October 2002:WL38831-WL39121.

4. *United States ex rel. Franklin v. Parke-Davis*, 147 F. Supp.2d 39 (D. Mass. 2001), Affidavit of Ilyas J. Rona in Support of Relator's Opposition to Defendant's Motion for Summary Judgment. 21 May 2003.

5. U.S. Department of Justice. Warner-Lambert to pay $430 million to resolve criminal & civil health care liability


FORWARD

Malszycki, Marcie

From: Sara Finger [sara.finger@wiawh.org]
Sent: Monday, August 28, 2006 3:39 PM
To: Sen.Roessler
Subject: Dental Access for Pregnant Women

Hello Senator Roessler.

After attending the Health Care Reform Committee Hearing today, I wanted to follow up and send you some information regarding the link between periodontal disease and low birth weight babies.

Oral Health: Many risk factors contribute to mothers having premature, low birth weight babies. Mounting evidence suggests pregnant women who have periodontal disease may be as much as seven times more likely to have a baby that is premature.

For more information on this important public health issue, please link to:
National Healthy Mothers, Healthy Babies Coalition http://www.hmhb.org/oralhealth.html
American Academy of Periodontology http://www.perio.org/consumer/pregnancy.htm
Women's Health Oral Resource Guide http://www.mchoralhealth.org/PDFs/WomensResourceGuide.pdf

If there's any other information or resources I can provide, you please don't hesitate to ask.

Thank you for your efforts to address health care reform in Wisconsin.
Sara Finger

Wisconsin Alliance for Women's Health
P.O. Box 1726 | Madison, WI | 53701-1726
[p] 608.251.0139 | 866.399.WAWH | [f] 608.256.3004
www.supportwomenshealth.org


FORWARD

Malszycki, Marcie

From: Sweet, Richard
Sent: Friday, September 08, 2006 3:38 PM
To: 'BHCGSW'
Cc: Rose, Laura; Malszycki, Marcie
Subject: FW: Pharmacy lock-in

Attachments: lock-in.doc

Diane,

I heard back from DHFS on your lock-in question. They cited s. HFS 104.02(5) as the authority for locking in MA recipients to a particular pharmacy. That section discusses limiting or terminating benefits in cases of abuse or misuse (defined similarly as in the SeniorCare abuse or misuse rule shown in the Word document below), but isn't as specific on use of the lock-in itself. For example, it doesn't include a provision that allows DHFS to pick the pharmacy if the recipient doesn't do so within 15 days.

I've pasted in s. HFS 104.02(5) below.

Dick

HFS 104.02 (5) NOT TO ABUSE OR MISUSE THE MA CARD OR BENEFITS. If a recipient abuses or misuses the MA card or benefits in any manner, the department or agency, as appropriate, may limit or terminate benefits. For purposes of this subsection,"abuses or misuses" includes, but is not limited to, any of the following actions:

(a) Altering or duplicating the MA card in any manner;

(b) Permitting the use of the MA card by any unauthorized individual for the purpose of obtaining health care through MA;

(c) Using an MA card that belongs to another recipient;

(d) Using the MA card to obtain any covered service for another individual;

(e) Duplicating or altering prescriptions;

(f) Knowingly misrepresenting material facts as to medical symptoms for the purpose of obtaining any covered service;

(g) Knowingly furnishing incorrect eligibility status or other information to a provider;

(h) Knowingly furnishing false information to a provider in connection with health care previously rendered which the recipient has obtained and for which MA has been billed;

(i) Knowingly obtaining health care in excess of established program limitations, or knowingly obtaining health care which is clearly not medically necessary;

(j) Knowingly obtaining duplicate services from more than one provider for the same health care condition, excluding confirmation of diagnosis or a second opinion on surgery; or

(k) Otherwise obtaining health care by false pretenses.

From: Sweet, Richard
Sent: Tuesday, August 22, 2006 9:46 AM
To: 'BHCGSW'
Cc: Rose, Laura
Subject: Pharmacy lock-in

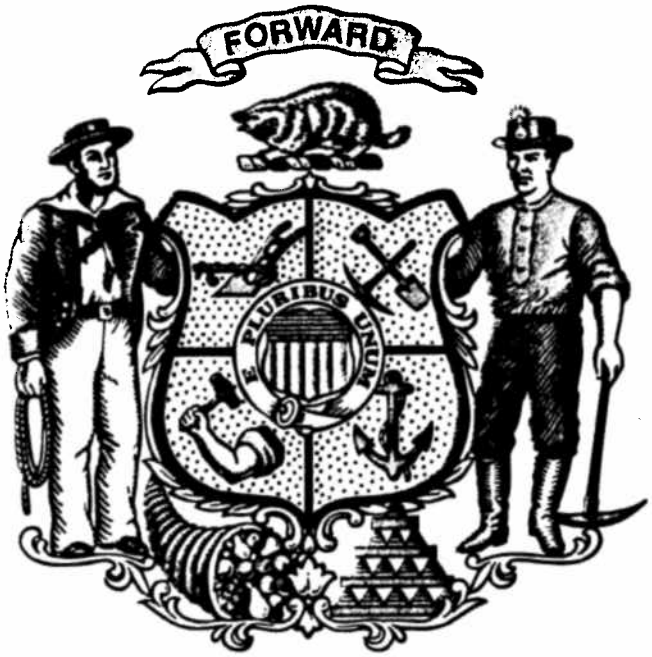
Dianne,

I'm back from vacation. Hope your meeting went well last week.

I've started looking at the pharmacy lock-in rules that we discussed the previous week. I found fairly detailed rules about pharmacy lock-in for SeniorCare (copy attached), but didn't find anything similar for family MA. (This issue wouldn't relate to elderly or disabled MA recipients since they now get their drugs under Medicare Part D). I contacted DHFS and will let you know when I hear back from them.

lock-in.doc (34 KB)

Dick Sweet
Richard Sweet
Senior Staff Attorney
Wisconsin Legislative Council
(608)266-2982
richard.sweet@legis.state.wi.us


FORWARD
E PLURIBUS UNUM

Wisconsin Chapter
American College of
Emergency Physicians

September 12, 2006

SEP 15 2006

The Honorable Alberta Darling
The Honorable Carol Roessler
Senate Select Committee on Health Care Reform
Wisconsin State Senate
P.O. Box 7882
Madison, WI 53707-7882

Dear Senators Darling and Roessler:

We want to thank you for inviting Wisconsin's emergency physicians to share our experience and views as your committee tackles the complex issues associated with reforming Wisconsin's health care system, including the Medicaid program. After listening to the testimony at the hearing on August 28, it seems obvious that while there are significant challenges facing us, many groups and individuals also are interested in rolling up their sleeves to implement solutions. You can count the Wisconsin Chapter of the American College of Emergency Physicians (WACEP) among them.

Please consider the following observations regarding the issues brought out at the hearing:

- Emergency departments provide an *essential public service*. The federal EMTALA law mandates that all patients be seen and evaluated by a physician regardless of their insurance status or ability to pay. Because of this unique standing in the health care system, it is vital that emergency medical services be appropriately supported so they remain available to all of our citizens.

- The Medicaid system is *grossly underfunded*, and fees for physicians are an embarrassment. Something has to change when a doctor spends 3 ½ hours with a critically ill patient and is paid less than $27. A hair stylist's fee is higher! Doctors cannot make up in volume with insured and private pay patients what they are losing on Medicaid cases. Moreover, is it really fair to impose a "hidden tax" on insured patients to cover the cost of Medicaid deficiencies?

- Exceedingly low Medicaid fees are a significant factor in lack of "on-call" coverage in the emergency department by specialists. They are reluctant to or simply unable to respond when their compensation likely will be very low or non-existent. This problem affects everybody, not just Medicaid beneficiaries, when orthopaedic surgeons, cardiologists or other specialists can't be found to treat patients in the emergency department.

- Medicaid fees for EMTALA-related services provided in the emergency department should be set on a par with the *Medicare* fee schedule. This certainly is justified due to the federal rules which apply to emergency medical services. By plugging this financial hole, the state would do a lot to maintain the financial viability of emergency departments and to encourage "on-call" specialty coverage.

- We believe there is great potential in the proposition that better access to primary and preventative care will improve health overall and also can save money in the long run. Emergency physicians strongly support these efforts and look forward to participating in development of these plans.

Administrative Office: **10 W. Phillip Rd., Suite 120, Vernon Hills, IL 60061-1730**
Phone: **(800) 798-4911 ❖ *Fax:*** **(847) 680-1682 ❖ *Email:*** **WACEP@aol.com ❖ *Internet:*** **www.wacep.org**

- Creating a "medical home" for Medicaid patients, as suggested by one witness, makes a lot of sense. We believe that this idea, coupled with case managers who are accessible "24/7," would be a huge improvement overall.

- Because of a lack of access to reliable information, emergency physicians may not be aware of recent tests, prescriptions for medicine, allergies, chronic conditions or visits to other doctors. Establishing a database encompassing all Medicaid beneficiaries with basic information about each person's contact with the health care system will reduce or eliminate unnecessary tests, as well as save substantial money while enabling doctors to provide better care.

- Emergency physicians often spend an inordinate amount of time calling around to find follow-up or specialty care for emergency department patients. It is not unusual to call five or more doctors, hospitals or clinics before locating a willing referral for a Medicaid patient. A database of primary care and specialty physicians who are able and willing to accept these patients – with the additional assistance of case managers – would result in much greater efficiencies, thus freeing more time for direct patient care by the emergency doctor.

- Changing behavior is not easy, and we must be cognizant of unintended consequences. While we work to make primary care more accessible and try to encourage Medicaid patients to utilize these services when needed and appropriate, it is critical that we avoid creating *new* problems by establishing artificial barriers to care which is available in the emergency department, whether or not the condition is an emergency. It is better for a patient to get the medical care they need when they need it – even in the emergency department – than to not get it at all, possibly ending up with a much more serious (and costly) medical condition.

Seeing is believing, and nothing substitutes for personal experience. Several legislators already have participated in our "job shadowing" program by spending some time in an emergency department with one of our chapter members. We would like to extend an invitation to you to do the same at your convenience. Please contact our executive director, Rich Paul (800/798-4911; email: WACEP@aol.com) to learn more.

WACEP's members are totally committed to helping the committee sort through these issues as it develops concrete proposals to improve our state's health care system. A substantial amount of study already has gone into some of these subjects, especially emergency medical care. It's not an exaggeration to say that there *is a crisis in the emergency room,* and so it is imperative that actions be taken soon to keep the health care safety net in place before it starts to unravel.

Thank you for your dedication and efforts in this regard. The leadership of this committee undoubtedly will play a critical role in providing quality health care to all of our citizens when they need it. Please feel free to call on us to assist in meeting this goal.

Sincerely,

Christine Duranceau, MD
President

cc: Committee members

APF Health & Human Services

Modernizing Medicaid: Bureaucracy "Out" - Flexibility "In"

By Christie Raniszewski Herrera

At the end of every calendar year, pop culture mavens review the year's trends and declare which styles are "in" or "out." Similarly, the beginning of 2006 has signaled a brave new world for Medicaid reform. And thanks to new federal provisions governing the Medicaid program, bureaucracy is "out"—and consumer choice, flexibility, and sustainable spending are all the rage.

Medicaid Reaches the Breaking Point

Skyrocketing Medicaid costs are reaching a budgetary breaking point. In fiscal year 2004, total federal and state Medicaid expenditures reached more than $288 billion.[1] Medicaid also accounted for 16.9% of state-level expenditures, which is more than spending on higher education, transportation, and all other forms of public assistance combined.[2] The Congressional Budget Office projects that total Medicaid spending will increase by an average of 8.4% annually, rising to $392 billion in 2015.[3]

In many states, Medicaid spending growth poses a real threat to other funding priorities, such as K-12 education or law enforcement. Perversely, however, many states create their own spending problems by milking the Federal Medical Assistance Percentage, otherwise known as "FMAP" or the "federal match." The federal government pays for more than half of all Medicaid spending using the FMAP, so for every dollar states spend on Medicaid, the feds chip in at least one dollar in matching funds. The average FMAP is 57%. That means that for every dollar states spend on Medicaid, they yield approximately $2.46 in total Medicaid benefits.

For some state lawmakers, cutting Medicaid spending means that they will potentially turn down "free" federal dollars. But all taxpayers (including many Medicaid recipients) pay federal, state, and local taxes—and when states attempt to game the federal match, all taxpayers are worse off because of it. Expanding Medicaid eligibility is another common tactic of states attempting to draw down "free" federal dollars. So much for the Medicaid "safety net"—coverage for optional services and populations is now the rule, not the exception. Only 39% of Medicaid spending is now spent on mandatory coverage.[4]

Unsustainable Medicaid spending growth can only spell trouble for state taxpayers. What's worse, unpredict-

Christie Raniszewski Herrera is the Health and Human Services Task Force Director at the American Legislative Exchange Council.

able spending and Medicaid eligibility expansion could also affect the long-term health of the truly needy. Faced with tax increases, service cuts, or eligibility reductions, 49 states and the District of Columbia have implemented superficial Medicaid cost containment actions with little success.[5]

Out with the Old: Waivers and Demonstrations

Several states are completely overhauling their Medicaid programs to eliminate perverse incentives in the current Medicaid structure, limit Medicaid's unsustainable growth, and lead beneficiaries to self-sufficiency and better health. These "consumer-directed" approaches will allow Medicaid beneficiaries to own a fixed amount to pay for a benefit plan of their choice, or they could opt-out of Medicaid altogether and purchase health insurance through an employer.

Florida became the first state to implement such reforms in two test counties in June, as its "Empowered Care" waiver [6] was approved by the Centers for Medicare & Medicaid Services (CMS) and the Florida Legislature last fall. Under the plan, insurance companies will compete in a "Medicaid marketplace" and offer varying benefit packages that specialize in certain health needs. The plan will also allow beneficiaries to opt-out of Medicaid and purchase health insurance through their employer, as well as earn extra money in "enhanced benefit accounts" by participating in healthy practices.

At press time, the Oklahoma Legislature also sent House Bill 2842—otherwise known as the Medicaid Reform Act of 2006—to Governor Brad Henry's desk. Like Florida's "Empowered Care" waiver, House Bill 2842 authorizes the Oklahoma Health Care Authority—the state agency charged with administering the Medicaid program—to petition the federal government for a waiver allowing beneficiaries to own a risk-adjusted "personal health account" to purchase a competitive benefits package or opt-out of Medicaid altogether and purchase health insurance through an employer. The legislation would provide for the establishment of an electronic prescription system and a provider database to track utilization of Medicaid services; appropriate $93 million to fully reimburse doctors and hospitals for the costs of serving Medicaid patients; and eliminate some costly state-mandated benefits from the Medicaid program.

Both Florida and Oklahoma structured their Medicaid reform legislation based on what's known as a "Section 1115" research and demonstration waiver granted by CMS. This waiver process—established by Section 1115 of the Social Security Act—allows the U.S. Secretary of Health and Human Services to authorize experimental, pilot, or demonstration projects that exist in promoting objectives of the Medicaid program.[7] States submitting a Section 1115 waiver proposal are required to enter into a five-step negotiating process with CMS, and the lengthy waiver application—Florida's clocked in at 119 pages—must outline a number of benchmarks and implementation time frames.

More than $100 billion of Medicaid spending is currently delivered through waivers and demonstrations, including Section 1115 waivers. But even CMS admits that its own Medicaid waiver process stifles state innovation:

> "The very nature of a waiver, candidly stated, is to demonstrate more modern approaches than those contained in the outdated rules of title XIX [of the Social Security Act, which established the Medicaid program]. But even with the success of waivers and demonstrations, they can be cumbersome to administer. Waiver and demonstration programs must show that they meet a variety of budget neutrality and cost-effectiveness tests, necessitating detailed analyses and lengthy discussions with the Federal government while putting States at risk for expenditures beyond predetermined spending ceilings."[8]

In with the New: The Deficit Reduction Act

Enter the federal Deficit Reduction Act of 2005 (DRA)[9], which was signed into law in February. The goal of this federal legislation is to reduce Medicaid spending by $4.8 billion over the next five years and $26.1 billion over the next ten years. To get there, the DRA implements a number of tiny—but important—first steps that reduce the perverse financial incentives plaguing the Medicaid program.

Cost Sharing

One of Medicaid's biggest flaws is that it looks nothing like private health insurance—recipients rarely pay premiums or copays. Critics of market-based Medicaid reform claim that cost sharing creates "barriers to coverage" resulting in underutilization of services and worsening health outcomes. But the famous RAND Health Insurance Experiment found that cost sharing not only reduces spending—it also found that, with the exception of blood pressure control, there were no significant health differences between those who had free care and those who participated in cost sharing.[10]

Based on income, the DRA will allow states the flexibility to charge premiums and copayments for up to 20% of the cost of medical care, and it will allow higher copayments for non-emergency services rendered in an emergency room. Total cost sharing will not exceed five percent of a family's income.

Long-Term Care

Questionable eligibility exemptions often make Medicaid the long-term care insurer of first resort, not last resort. In fact, a recent National Bureau of Economic Research study found that entitlement programs discourage between 66% and 90% of seniors from purchasing long-term care insurance.[11] According to Center for Long-Term Care Reform President and ALEC HHS Task Force Advisor Stephen Moses:

> "Consider home equity, seniors' largest asset. According to The National Council on the Aging, 81% of America's 13.2 million householders aged 62 and over own their own homes, and 74% own their homes free and clear. Altogether, seniors possess nearly $2 trillion worth of home equity. Yet, by the time they apply for Medicaid, few own their homes. Are they giving the homes away to their grown-up children or other relatives? Such a transfer of assets carries no legal penalty as long as it is done at least three years and a day before applying for Medicaid.
>
> "That's just one of hundreds of eligibility 'loopholes' that allow individuals, especially those advised by Medicaid planning attorneys, to qualify for Medicaid

> long-term care benefits without spending down their own wealth for care. If you doubt this, try an Internet search for 'Medicaid planning' and read some of the sales pitches on the more than six million hits. You'll learn how to purchase noncountable assets, buy and give away a string of luxury cars without penalty, hide wealth in exempt annuities, sell your ailing parent a 'life-care contract,' even buy a farm or business—all for the express purpose of 'impoverishing' yourself or a loved one artificially and qualifying for Medicaid long-term care benefits."[12]

By cracking down on these abuses, the DRA will encourage seniors to take steps in financing their own medical expenses when possible. Among other provisions, the DRA puts a $500,000 cap on the previously-unlimited amount of home equity an individual can possess before applying for Medicaid. The legislation also increases the "look back" period for Medicaid-qualifying asset transfers from three to five years, and it counts some previously-exempt "impoverishments"—including some life estates, promissory notes, mortgages, and certain annuities—as penalizable assets. In addition, the DRA eliminates the popular "half a loaf" Medicaid planning strategy—in which a person transfers half of their assets and keeps the other half to pay for the cost of long-term care during the penalty period—by moving the penalty period from the start of the asset transfer to the date of the Medicaid application.

The DRA also includes a number of provisions[13] that transform Medicaid long-term care from an institutionally-driven system to one that reflects the dignity of individuals that may not want or need institutional care. First, the DRA allows states to offer home and community-based services (HCBS) as an "optional benefit" rather than requiring states to undergo the time-consuming waiver process. Beneficiaries will be provided individualized care plans and may be offered the option of self-directing their care—and the federal government will give an increased FMAP percentage for each person that states transition from an institution to the community. The move will not only make Medicaid long-term care more "person-centered," but it's also expected to save taxpayer dollars. According to CMS, between 1999 and 2002 the average nursing home payment increased 13%, but the average cost per participant in an HCBS waiver increased by just 2.2%.[14]

Modernizing Medicaid: The "Roadmap to Reform"

Perhaps the most easily-implemented of the DRA provisions makes it effortless for states to improve and expand coverage for acute care needs. While long-term care accounts for over 70% of all Medicaid spending,[15] the aforementioned explosion in Medicaid eligibility has made non-disabled adults the fastest-growing Medicaid population. Between 1999 and 2003, while total Medicaid eligibles grew 35%, non-disabled adult eligibles grew by almost 70%.[16]

Released as one of two "Roadmaps to Medicaid Reform,"[17] CMS announced in April that states can overhaul Medicaid benefit packages and coordination of care without seeking an onerous federal waiver of Medicaid rules. Instead, CMS will provide pre-formed

State Plan Amendments (SPAs) on which states can check a few boxes and fill in a few blanks in order to amend their basic Medicaid "state plan," or blueprint. By moving from the waiver process to SPAs, the DRA gives states greater control over their Medicaid programs in a number of areas.

Benefit Flexibility and Medicaid Opt-Out

Medicaid is largely perceived as a one-size-fits-all system in which rigid benefits are not tailored to meet individual needs. But thanks to the DRA, states no longer have to standardize coverage across Medicaid populations and across the state. Instead, they can provide "benchmark benefits" that look like coverage in the private sector. This benchmark approach grants states flexibility in extending four types of coverage to Medicaid beneficiaries: Blue Cross/Blue Shield standard coverage offered to federal employees; standard coverage offered to employees in that state; coverage by the largest commercial health maintenance organization in that state; or federally-approved coverage providing appropriate care for the population served. CMS hopes that disease management "wrap around" benefits will complement the benchmark plans and cut costs.

DRA provisions will also permit families—often split between Medicaid, the State Children's Health Insurance Program (SCHIP), and private coverage—to be together in the same Medicaid plan with one set of providers, helping to ease the eventual transition from public to private coverage. Additionally, SPAs can now authorize states to use Medicaid and/or SCHIP to pay insurance premiums for employer-sponsored insurance.

Health Opportunity Accounts

The most exciting DRA provision is the five-year, ten-state Health Opportunity Accounts (HOA) demonstration program, which is designed to combine the success of Health Savings Accounts (HSAs) and Health Reimbursement Accounts. Under the demonstration, states can enroll some of their Medicaid beneficiaries into an HSA-like account funded with a risk-adjusted amount based on health needs. According to CMS, 10 demonstrations will be approved to operate for five years, after which an SPA can make HOAs a permanent part of a state's Medicaid program.

Free-Market Medicaid Reform: Trends for 2006

Since passage of the DRA in February, several states have publicly announced intentions to reform their Medicaid programs using the law's provisions.

Although South Carolina Governor Mark Sanford initially submitted a Section 1115 Medicaid waiver last year, he announced in February that part of his "Healthy Connections" plan will proceed without a waiver.[18] South Carolina is applying to be part of the HOA demonstration program, which Sanford expects to have in place by January 2007. Sanford's original "Healthy Connections" plan would have allowed all Medicaid beneficiaries to own a risk-adjusted "personal health account" to directly pay for medical expenses, join a managed care plan, or buy employer-sponsored insurance.[19]

In May, Kentucky became the first state in the nation to target benefits to different Medicaid populations under DRA provisions.[20] Under the plan, en-

titled "KyHealthChoices,"[21] Kentucky will transition most of its 700,000 Medicaid beneficiaries to one of four managed care plans: the "Family Choices" program to serve healthy children, the "Comprehensive Choices" and "Optimum Choices" programs to serve individuals with more complex needs, and the "Global Choices" program to serve other vulnerable populations. Medicaid enrollees will be able to "opt-out" for employer-sponsored coverage and also earn "Get Healthy" benefits—such as dental/vision coverage, nutritional counseling, and smoking cessation programs—which will provide incentives toward healthy lifestyles. Beneficiaries will also be required to make copayments on certain prescriptions and medical services, with maximum out-of-pocket costs totaling $450.

Similarly, West Virginia became the second state to change their Medicaid program as part of the DRA.[22] About 160,000 non-disabled, non-elderly Medicaid enrollees will soon have the option of choosing two benefit packages there. The first option is a basic plan that mirrors the current Medicaid benefits package, and the second option includes an enhanced package with current Medicaid benefits and "Healthy Rewards Account" credits to be used for tobacco cessation, nutritional education, diabetes care, chemical dependency/mental health services, skilled nursing care, and orthotics/prosthetics. To qualify for the enhanced package, enrollees must sign a "personal responsibility contract" that they will comply with all recommended medical treatment and wellness behaviors. Beneficiaries who do not sign a contract or undergo certain wellness activities will lose access to the enhanced package.[23]

Idaho recently became the third state to have Medicaid benefits overhauled as allowed by the DRA. Under the plan,[24] Idaho will offer three targeted benefit packages. For healthy children and adults, the "Benchmark Basic" plan will cover Early, Periodic Screening, Diagnostic and Treatment (EPSDT) for children and include most traditional Medicaid benefits except for long-term care, organ transplants, and intensive mental health treatment. The "Enhanced Benchmark" plan will serve the elderly and disabled and include all traditional Medicaid benefits, including long-term and institutional care. The "Coordinated Benchmark" plan will serve dual-eligibles—in other words, Medicaid enrollees who are also eligible for Medicare. All three of the packages will include "preventive health assistance" to help the obese, smokers, and other high-risk groups toward wellness.

Conclusion

Thanks to the Deficit Reduction Act, market-based Medicaid reform is taking shape in Florida, Oklahoma, South Carolina, Kentucky, West Virginia, and Idaho. Let's hope that patient empowerment, free markets, and stabilized Medicaid spending won't go out of style anytime soon.

Endnotes

[1] Henry J. Kaiser Family Foundation. "Total Medicaid Spending, FY 2004": www.statehealthfacts.org. (Author's note: FY 2004 is the most recent year for which complete Medicaid spending data is available.)

[2] Henry J. Kaiser Family Foundation. "Distribution of State General Fund Expenditures (in millions), SFY 2004": www.statehealthfacts.org.

[3] Congressional Budget Office. *The Budget and Economic Outlook: Fiscal Years 2006 to 2015.* January 25, 2005.

[4] Graham, John R. "How Many Governors Does It Take to Reform Medicaid?," Pacific Research Institute Health Policy Prescriptions Vol. 3, No.1, August 2005: http://www.pacificresearch.org/pub/hpp/2005/hpp_08-05.html.

[5] Henry J. Kaiser Family Foundation. "Medicaid Cost Containment Actions Taken by States, FY 2006": www.statehealthfacts.org.

[6] Author's note: For more information on Florida's "Empowered Care" Medicaid reform plan, see: Raniszewski Herrera, Christie. "The Free Market Road to Medicaid Reform," *ALEC Policy Forum*, Fall 2005. You may also visit Florida's Agency for Health Care Administration website at http://ahca.myflorida.com/Medicaid/medicaid_reform/index.shtml.

[7] Author's note: For more information on the Section 1115 waiver process, as well as other waivers and demonstrations not mentioned here, visit CMS' website at http://www.cms.hhs.gov.

[8] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. *Roadmap to Medicaid Reform: New Options to Improve and Expand Insurance Coverage for Acute Care Needs*, April 18, 2006.

[9] Author's note: For full text of the Deficit Reduction Act of 2005, see U.S. SB 1932: http://thomas.loc.gov/cgi-bin/query/C?c109:./temp/~c109K7Ge4R.

[10] Keeler, Emmett B. "Effects of Cost Sharing on Use of Medical Services and Health," *The Journal of Medical Practice* Management, Summer 1992: http://www.rand.org/publications/RP/RP1114/RP1114.pdf.

[11] Jonathan Skinner et. al. "The Efficiency of Medicare," National Bureau of Economic Research Working Paper No. 8395, July 2001: http://www.nber.org/papers/w8395.

[12] Moses, Stephen A. "Welfare for the Well-to-Do," *Wall Street Journal*, December 17, 2005.

[13] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. *Roadmap for Medicaid Reform: New Options to Support Individuals with Disabilities and Long-Term Care Needs*, April 18, 2006.

[14] *Ibid.*

[15] The Kaiser Commission on Medicaid and the Uninsured. "The Medicaid Program at a Glance," Medicaid Facts, January 2004: http://www.kff.org/medicaid/upload/The-Medicaid-Program-at-a-Glance-January-2004-Fact-Sheet.pdf.

[16] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. *Roadmap to Medicaid Reform: New Options to Improve and Expand Insurance Coverage for Acute Care Needs*, April 18, 2006.

[17] *Ibid.*

[18] Smith, Bruce. "Sanford: Congress Clears Way for Medicaid Overhaul," Associated Press, February 2, 2006.

[19] Author's note: For more information on South Carolina's "Healthy Connections" Medicaid reform plan, visit http://www.dhhs.state.sc.us/dhhsnew/HealthyConnections/schcnov.pdf.

[20] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. "HHS Approves Historic Medicaid Reform Plans for Kentucky," May 3, 2006.

[21] Author's note: For more information on Kentucky's "KyHealthChoices" Medicaid reform plan, visit http://www.chfs.ky.gov/dms/kyhealthchoices.htm.

[22] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. "HHS Approves Innovative Medicaid Reform in West Virginia," May 3, 2006.

[23] Author's Note: For more information about West Virginia's Medicaid reform plan, visit http://www.wvdhhr.org/bms/.

[24] U.S. Department of Health and Human Services, Centers for Medicare & Medicaid Services. "HHS Approves Historic Medicaid Reform Plans in Idaho," May 25, 2006. (Author's note: For more information about Idaho's Medicaid reform plan, visit http://www.healthandwelfare.idaho.gov/site/3629/default.aspx.)

The I

W

Price controls
From biblical tin
world have tried t
form or another
commonality of
price control reg
comprehensive
Reagan once s
problem that go
worse. The U.S
1970s was und
government-imp
the domestic pr
Indeed, when I
policy soon after
domestic produ
and rejuvenated
it is somewha
companies were
following petro
year. Hurricane
Rita, devastate
most intensiv
production in the
hampered by a
domestic prod
capacity, short-t
only to be expec
economy.

But that reali
companies fallin
worst affliction
criticism of the

Sally M
International
Legi


FORWARD
E PLURIBUS UNUM

Horan
Consulting

Medicaid Reform Task Force Report

November 2006

Wisconsin Academy of Family Physicians

142 North Main Street • Thiensville, WI 53092
Phone: (262) 512-0606 • Fax: (262) 242-1862
E-mail: academy@wafp.org • Web Site: www.wafp.org

Executive Summary

The Medicaid Reform Task Force has examined the current state of Medicaid in Wisconsin and the attempts from other states to address reform. **As a result of these efforts the Task Force has identified a number of key elements that should be included in any reform effort.** These elements are summarized below.

Recommended Components in any Medicaid Reform Effort:

1. **Primary Care must be at the center of the Medicaid system. Research shows that there is better overall quality and lower overall costs when Primary Care is at the center of the system.** (See Starfield Report in Appendix).

2. **Primary Care Physicians should be partners in assuring that Quality Initiatives, Health Promotion, and Health Prevention are assured for their Medicaid population.**

3. **There must be incentives for creating a medical home for Medicaid patients, through Primary Care Physicians. The** North Carolina experience validates that continuity of care for Medicaid patients decreases costs and increases quality:
   - **There must be incentives for family physicians to provide timely and comprehensive services to the Medicaid population.**
   - **There must be increased co-pays for non-emergent ER services and self-referrals to specialists.**
   - **Care management (disease management) must be integrated into the care delivery model. There must be tools and programs to help Primary Care Physicians improve care and decrease costs for the most costly disease entities and most vulnerable patients.**

4. **There must be increased reimbursement for Primary Care Physicians in providing better access and coordination of care to reduce hospitalization and ER costs.** Starfield et al showed that Primary Care provides better quality at lower cost:
   - **There must be incentives for physicians to remain in the Medicaid program.**
   - **Primary Care Physicians must agree to provide services in a timely, comprehensive and cost-effective manner.**
   - **The Medicaid program should expect a decrease in Emergency Room utilization due to improved access to Primary Care Physicians.**

5. **There must be improvement in the provision of prescription drugs to Medicaid patients:**
    - **There must be improved formulary information available to Primary Care Physicians.**
    - **The Medicaid program must maintain an adequate formulary for physicians to use.**
    - **There should be competitive contracting for prescription drugs.**
    - **There should be increased co-payments for non-allowed drugs.**

6. **A provision for cost-based reimbursement should be available for large Medicaid providers.** This will allow Primary Care providers who care for large numbers of Medicaid patients to make a better living by decreasing their liability burden and covering expenses:
    - **Consideration should be given to FQHC reimbursement for any providers with a caseload of 25% or higher Medicaid patients.**
    - **Consideration should be given to replicating the FQHC type medical liability coverage for any providers with a caseload of 25% or higher Medicaid patients.**

7. **All Medicaid patients must have Advanced Directives. This will decrease the amount of futile care at the end of life.**

Introduction

The Great Debate
The high cost of Medicaid puts it in the eye of a storm.

Medicaid officials celebrated the program's 40th anniversary in July. With the federal government drowning in debt and states just emerging from a recession, the program is at the center of a national debate over how to cut costs while maintaining the safety net for roughly 58 million Americans including the disabled, low-income children and their parents, pregnant women, and seniors.

Even though Medicaid growth rates have slowed in the past year or two, the economy has improved and states have taken some steps to control costs, **Medicaid spending is now more than 21 percent of total state budgets**. Overall, the price tag was $329 billion last year, of which the federal government paid 57 percent. Spending growth is likely to be 7.7 percent per year over the next decade, according to Congressional Budget Office. Virginia Governor Mark Warner told the National Governors Association in July 2005, "Medicaid could actually bankrupt every state in the country before 2020 unless we can get a handle on it."

Dramatic changes in some states' Medicaid programs have already taken place, and more are inevitable in the near future. Commissions and study groups are pursuing broad-scale reform. At the federal level, the Health and Human Service Commission on Medicaid Reform submitted a report with ideas for the future of the Medicaid program. It also fulfilled its charge to carve $10 billion out of the Medicaid bill over the next five years, submitting recommendations for $11 billion in savings. It suggested such cost controls as new formulas for prescription drug reimbursement, tiered drug co-payments for Medicaid recipients and barriers to families who siphon off elderly relatives' assets in order to qualify them for Medicaid-reimbursed long-term care. Several months before, the National Governors Association issued a report recommending some of the same ideas plus a number of others. The NGA also called for more flexibility for state officials to balance the delivery of quality health care with the need to tame costs.

The Challenge of Change
Medicaid's relentless growth is its weakness - and its strength.

In Medicaid's happier days, a mere six or seven years ago, budget-flush states gave the program a jolt. They increased income levels for eligibility, cut the red tape that had restrained sign-ups and searched for citizens who were qualified for the program but had not applied. In the State Children's Health Insurance Program, six million uninsured children who were not eligible for Medicaid were awarded a Medicaid-like package of health care coverage. The uninsured rate among low-income children dropped by a third between 1997 and 2003, despite the onset of a recession in 2001.

Health care itself has become so costly. While inflation was in the 1.5 to 3.3 percent range from 2000 to 2003, health care spending went on a wild ride: prescription drug costs rose 17.1 percent annually and inpatient hospital costs went up 11 percent a year. During the first few years of this decade, the

economy slid into a downturn, causing Medicaid caseloads to grow. In the past five years, they have increased by 40 percent.

State revenues have not been able to keep pace with Medicaid's unremitting growth, and the federal government, with fiscal problems of its own, has grown ever more unhappy about footing its open-ended share of the bill. Medicaid's mission, meanwhile, is formidable. It finances not only acute care for low-income families but also long-term care and support for individuals with disabilities. Even more challenging is the demographic future. **The number of elderly Americans is growing steadily, increasing demand for expensive services such as nursing home beds, other long-term care facilities or home-based care.** Already, **about one-third of Medicaid's budget goes to long-term care.** There is pressure from all levels of government to rethink all aspects of the program. The program is not fiscally sustainable, and things are not likely to get better without intervention.

Balancing the Books

There is, of course, a profound connection between money and care. When it comes to reimbursing its medical providers, for instance, **Medicaid is stingier than either Medicare or commercial insurance.** Compensation cuts have become one of the most expedient means for saving dollars.

By low-balling compensation, however, the program ends up reducing the number of providers willing to take care of Medicaid patients. According to the California Health Care Foundation, only about half of California physicians participate in Medi-Cal, and the number is shrinking. A focus group of Medicaid participants with disabilities reported some difficulty in locating providers willing to accept Medi-Cal, particularly specialists.

The negative cause and effect between low reimbursement rates and declining access to physicians for Medicaid patients is clear. For many of the fiscal fixes for Medicaid's problems, the unintended consequences of change may be harder to see. **The nation's health care system is often likened to a balloon: squeeze one part of it and another portion expands. This is true in Medicaid as well. Reduce the number of asthmatics who receive preventive treatment through Medicaid, and the same people may wind up in Emergency Rooms for far more expensive care.** There is also a relationship between Medicaid and private insurance. Forty-two percent of the cost of treating uninsured patients is shifted to private insurance, according to a 2004 report issued by the Urban Institute. That can and does raise private insurance rates. Partners Health-Care, a major academic health system in Boston, reports that Medicaid cuts in Massachusetts have required it to raise charges to commercial health plans by 4 percent.

There's a vicious cycle here. **When health insurance costs increase, private coverage tends to fall, Medicaid absorbs some of those who lose coverage, and the ranks of the uninsured grow.** But if insurance picks up only 42 percent of the cost of treating the uninsured, where does the other 58 percent come from? The individuals themselves pay about a quarter of it. The remainder mostly comes from the states and the federal government, who pony up money for hospitals that provide a significant amount of charity care.

In the final analysis, as much as cuts in Medicaid may seem like real savings for the states and federal government, the bills for uncompensated health care do not go away. They are paid by

average Americans and by a variety of state and federal programs. The illusion of real savings comes because those expenses don't flow through just one program and aren't easily tracked.

Questioning Value

Although evaluations of Medicaid programs are plentiful, there are enormous holes in the kind of analytic information policy makers need to make positive change. Relatively few public dollars are spent on determining which treatments work best and how to encourage their use. Often, Medicaid's practices are driven by what is cheapest or easiest, what is politically acceptable and what has been done before rather than through a determination of what is most effective.

Even when pilot programs are successful, follow-up on those successes is often shortchanged, so good ideas aren't replicated as much as they should be. The federal government has focused relatively little analytic attention on Medicaid, given the size of the program. "Compare the literature and resources going into Medicare versus those going into Medicaid," says Andy Schneider, a former congressional aide who is currently a Medicaid consultant. "There's just not an investment in Medicaid." Consider this: The Centers for Medicare & Medicaid Services (CMS) will pay up to 90 percent of any costs required to streamline or to improve claims management. Yet a number of states haven't taken advantage of what would seem to be a golden opportunity. Why? "Even finding just the 10 percent is expensive," says South Carolina Medicaid director Robert Kerr.

An Age-old Problem

So far, states have relied much more on cuts in services for the relatively healthy and young adult beneficiaries rather than for the aged or those with disabilities. Politically, it's easier. It's also an illusion. Senior citizens and people with disabilities make up 25 percent of the Medicaid population but consume 70 percent of the costs.

Clearly, any attempt to constrain Medicaid's growth and spending has to address the elderly and disabled, a tricky task since both groups have strong advocacy networks. "You can't balance your budget for this program on the backs of welfare recipients," Smith says. "There just aren't enough of them, and they are not very expensive people to serve."

A major component of spending for the disabled and elderly has been institutional costs for long-term care. But there is a large group of elderly and disabled patients that live outside of long-term care institutions, and 40 percent of the spending for this group has been on hospital care. More than half of the individuals were hospitalized within the previous year. Other big expenditures were for home health care, at 24 percent of spending, and prescription drugs, at 18 percent.

"If, at age 85, you have the good judgment to pass from this earth in an explosion of acute care services, Medicare will be perfectly willing to pay $100,000 to a hospital in a non-means tested program, with modest cost sharing," says James Tallon Jr., chair of the Kaiser Commission on Medicaid and the Uninsured. "God forbid that you choose dementia as the route of departure." In that case, Tallon notes, you kick into a national policy that worries about whether you should pay the cost of care out of your reverse mortgage, or whether the state can go after your assets or how much cost sharing the state can get out of you. "That doesn't make any sense as a national policy," Tallon says.

Federal Tension

The two programs, (Medicaid and Medicare) may not play well together, but neither do the states and their Medicaid partners, the feds. There is an increasing tension between the two. Governors are eager to see Medicare pick up more of the bill for older Americans. At the same time, the federal government is concerned about the ways in which states have amplified their efforts to "maximize federal dollars." In 2004, for instance, 34 states, up from 10 in 2002, used contingency fee consultants to help increase federal Medicaid reimbursements. According to the Government Accountability Office, Georgia paid a consultant $82 million between 2000 and 2004 to generate $1.5 billion in new federal Medicaid dollars.

Some of the efforts to get a federal match for state expenditures are based on logic that aligns with the current nature of state responsibilities. Bruce Vladeck, who ran the Medicaid and Medicare programs from 1993 to 1997, notes that the big growth areas in the Medicaid program in the 1990s "were in services for the mentally ill, the retarded and AIDS patients. Historically, the states did take care of a lot of those problems on their own." There are also a variety of complicated but legal financing arrangements that states have used to attract additional federal matching dollars. "Neither the feds nor the states have invested in running these programs well," says Schneider.

Perhaps the biggest bone of contention is over waivers, the exemptions from established law that the states need in order to experiment with their Medicaid programs. Waivers can take years to win approval from CMS. But even more to the point, advocates for Medicaid beneficiaries are concerned that waivers may not effectively balance cost savings with the need to retain quality and access. For example, they may include limits on the number of people served, which can result in long waiting lists for valuable services.

Meanwhile, governors complain that for some ideas that have already been tested, there shouldn't be a requirement to get a waiver from federal rules. For instance, states are still required to get waivers to provide long-term care in-home or community-based settings as an alternative to a nursing home. The rule persists, even though a million people already get their care this way and federal officials say they believe home and community care hold the potential for great success. [1]

[1] Pew Center on States. <http://www.pewcenteronstates.com>


FORWARD
E PLURIBUS UNUM

Milwaukee Journal Sentinel August 11, 2006

Mon.

State health plan rebounds in 2006

High-risk insurer estimates $14.4 million profit after 2005 loss

By GUY BOULTON
gboulton@journalsentinel.com

The state's health plan for people who can't buy insurance in the private market because of serious health problems rebounded strongly in its 2006 fiscal year after posting a sharp loss in 2005.

The Health Insurance Risk-Sharing Plan, which insures about 18,650 people in Wisconsin, reported a loss of $7.6 million for its fiscal year ended June 30, 2005, according to an audit released Thursday by the Legislative Audit Bureau. The loss stemmed partly from an unexpectedly large increase in medical claims.

But unaudited results for the 2006 fiscal year show a strong turnaround, with the plan tentatively reporting a profit of $14.4 million.

Oversight of the health plan, which is funded by premiums and a tax on the state's health insurance companies, was given to a quasi-private, non-profit corporation on July 1.

"I inherited a health plan that is in a good financial position," said Amie Goldman, the new chief executive of the Health Insurance Risk-Sharing Plan Authority.

The health plan, commonly known as HIRSP, previously was overseen by the state Department of Health and Family Services.

HIRSP, one of the largest health plans of its kind in the country, is often the only affordable insurance available to people with pre-existing medical conditions, such as heart problems, cancer and diabetes.

It had revenue of $125.2 million for 2005, up from $116 million the year before.

Health insurance companies paid $32.4 million to offset the plan's cost in 2005, according to the audit released Thursday.

That cost is borne largely by small businesses. Most employers with several hundred employees now self-insure and are exempt from the tax.

Employers that self-insure pay most of the health costs for their employees but contract with health insurers or other companies to administer their health plans.

Part of HIRSP's $7.6 million loss in 2005 stemmed from the plan's decision to apply $3.9 million of its accumulated assets to offset projected expenses. But the plan also reported a steep loss, despite receiving $2.2 million in federal funds.

The most recent year was a different story, with a new estimate on projected costs contributing to the $14.4 million profit. That enabled HIRSP to keep rate increases for its two main health plans to 5% on average for the year starting July 1, Goldman said. The plan had raised rates 15% the previous year.

HIRSP now charges premiums that are roughly 149% of what a healthy person would pay for a comparable plan. That puts the cost beyond the reach of many people. Rates vary across the state, but a man in Milwaukee who is 60 to 64 years old would pay $14,424 a year — about $1,200 a month — for the basic plan.

Enrollment in HIRSP more than doubled from fiscal 1998 to fiscal 2005. It fell by 735 people in the most recent year.

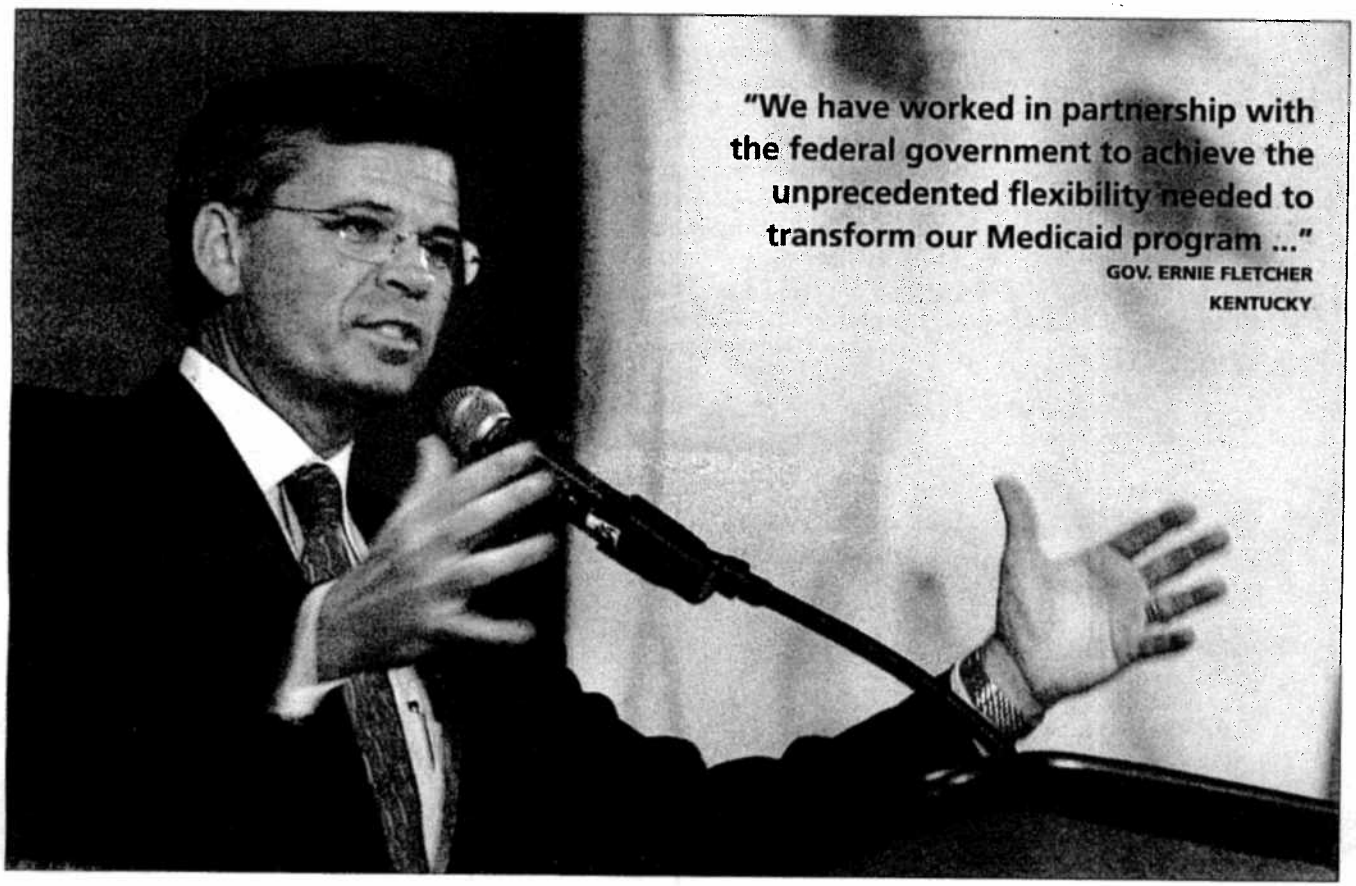
Much of the drop was in the plan for people who are under 65 but eligible for Medicare because they are disabled. That plan pays expenses not covered by Medicare. HIRSP attributes the drop to Medicare's addition of a prescription drug benefit.


FORWARD

Health Care News

Nov

Kentucky First State to Implement New Medicaid Reform Plan



By Christie Raniszewski Herrera

In early May, Kentucky became the first state to redesign its Medicaid benefits under provisions in the federal Deficit Reduction Act of 2005 (DRA), signed by President George W. Bush in February.

Under the plan, known as KyHealth Choices, Kentucky will transition most of its 700,000 Medicaid beneficiaries into one of four benefit packages customized for different beneficiary groups. Beneficiaries will be required to make co-payments on certain prescriptions and medical services, with annual out-of-pocket spending capped at $450.

Immediately after its passage on May 3, the new benefit design was implemented in all areas of Kentucky except Jefferson County, where 135,000 beneficiaries already participate in Passport, an existing Medicaid managed care demonstration project.

"We have worked in partnership with the federal government to achieve the unprecedented flexibility needed to transform our Medicaid program," Kentucky Gov. Ernie Fletcher (R) said in a May 3 statement, "[and] we are leading the

KENTUCKY p. 6

Kentucky

Continued from page 1

Kentucky Gov. Ernie Fletcher said his state's new Medicaid plan is "leading the way for the national transformation of Medicaid."

way for the national transformation of Medicaid as the first state to put a program such as this in place under the new Deficit Reduction Act."

Waiver Process Simplified

Several states, including Florida and South Carolina, have petitioned the federal government for market-based "waivers" of federal Medicaid rules. Traditionally, states submitting Medicaid waiver proposals are required to enter into a five-step negotiating process with the Centers for Medicare and Medicaid Services (CMS)—the federal agency charged with administering the Medicaid program—and outline benchmarks and implementation timeframes. More than $100 billion of Medicaid spending is currently delivered through waivers and demonstrations.

But thanks to provisions in the DRA, CMS announced in April that states can overhaul their Medicaid benefit packages without seeking a federal waiver of Medicaid rules. Instead, CMS will provide preprinted State Plan Amendments (SPAs) through which states can complete a standardized form and amend their Medicaid "state plan."

"The fact is that the Deficit Reduction Act shows that our elected representatives and the federal government have listened and recognized the needs of state Medicaid programs," Kentucky Health and Family Services Cabinet Secretary Mark D. Birdwhistell said in a May 3 statement.

Budget Was Strained

Policy experts say Medicaid's skyrocketing expenditures have reached the breaking point in Kentucky's budget, and reforms were needed to change the way the state finances and delivers the Medicaid program.

"If we didn't get our arms around reducing the cost of Medicaid in the near future, it would have consumed the entire Kentucky budget," said Chris Derry, president of the Bluegrass Institute for Public Policy Solutions, a think tank based in Kentucky, "because there are more people on Medicaid in Kentucky than in the K-12 education system."

Under KyHealth Choices, Kentucky will enroll each of its Medicaid beneficiaries in one of four specialized managed care plans: the "Family Choices" program to serve healthy children, the "Comprehensive Choices" program to serve the elderly and brain-injured who require nursing care, the "Optimum Choices" program to serve the mentally and developmentally disabled, and the "Global Choices" program to serve the general Medicaid population. The plan also will allow beneficiaries to opt out of Medicaid and purchase health insurance though their employers.

"This plan allows flexibility because Kentucky's [previous] Medicaid system was one-size-fits-all, and everyone doesn't need everything Medicaid has to offer," said state Sen. Richard "Dick" Roeding (R-Lakeside Park), who supports the plan. "Those that need a full suite of Medicaid services will still get them, and with reform, we will teach all Medicaid recipients to be better, more responsible health consumers."

Cost-Sharing Added

In addition to customized benefits packages, Kentucky Medicaid enrollees will get enhanced disease-management benefits and earn "Get Healthy" credits such as dental and vision coverage, nutritional counseling, and smoking cessation programs that will provide incentives toward healthy lifestyles.

The plan's most controversial provision imposes income-based co-payments on certain medical services and prescriptions, with maximum annual out-of-pocket costs totaling $450. The plan also limits some beneficiaries to four prescriptions per month, with exemptions for chronic disease management.

"If we didn't get our arms around reducing the cost of Medicaid in the near future, it would have consumed the entire Kentucky budget, because there are more people on Medicaid in Kentucky than in the K-12 education system."
CHRIS DERRY
PRESIDENT
BLUEGRASS INSTITUTE FOR PUBLIC POLICY SOLUTIONS

Roeding explained the changes will give Medicaid beneficiaries a stake in their own health spending and help preserve the program for future generations.

"Without this plan, Kentucky would have to raise taxes or cut benefits to pay for its bloated Medicaid program," Roeding said. "Through reform, we are trying to continue to serve Kentucky's needy without cutting benefits."

Further Reforms Sought

Derry denounced critics' claims that Kentucky's market-oriented reform will cause a "race-to-the-bottom" of higher costs and worsening health outcomes.

"For the first time in a generation, we have people [on Medicare] questioning the cost and quality of their medical care," Derry said, "and under market reforms, the ultimate beneficiary will be the Medicaid consumer."

Roeding agreed KyHealth Choices is a "good first step," but said he thinks Kentucky would benefit from even more comprehensive market-based reforms.

"I would hope that our reform plan would spur more private-sector involvement in the Medicaid program," Roeding said. "That's because the private-sector health care industry has always done it so much better than the bloated, out-of-control Medicaid bureaucracy."

Christie Raniszewski Herrera (**christie@alec.org**) *is director of the Health and Human Services Task Force at the American Legislative Exchange Council.*