Innovative Drug Formulary Management Through Computer-Assisted Protocols

As drug prices continue to rise, one health plan found an effective way to manage the cost of the pharmacy benefit for its patient population.

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Striking a balance between the desire to deliver accessible, high-quality health care and the need to control rapidly escalating costs is a dilemma many decision makers face today. Health maintenance organization (HMO) pharmacy directors, aware that per-member-per-month (PMPM) pharmacy costs are expected to continue to increase, are searching for innovative solutions to reverse this trend. Among the strategies that have been tried across the country to control these costs are capitation, more restrictive closed formularies, and differential copays. Additionally, the use of a health plan's medical and pharmacy data to demonstrate improved patient outcomes is increasingly important to the plan's success. As health plans search for better ways to successfully manage their pharmacy benefits, they are forming new partnerships with vendors. This article describes how one such partnership achieved its goal of better managing pharmacy costs.

Health Plan of the Redwoods (HPR) is a regionally based, independent practice association (IPA) model nonprofit HMO that serves four northern California counties. Founded in 1980 by the local medical association, HPR has since grown to provide health care coverage for more than 86,000 commercial and 10,000 Medicare risk members (as of October 1996). Its current provider network includes more than 1,200 physicians in three IPAs. Almost three-fourths (74%) of its membership is located in Sonoma County and accounts for 34%

of the managed care patients within that county. HPR received one-year accreditation from the National Committee for Quality Assurance (NCQA) in July of 1996 and 1997.

In 1990, HPR began implementing controls to manage spiraling pharmacy benefit costs. HPR had previously tried to limit its open formulary. However, with the continued addition of so many new medications, attempts at managing the open formulary were, by 1995, obviously not working. In order to control drug utilization during the early years, the pharmacy and therapeutics (P&T) committee implemented more than 100 protocols. However, the health plan neither monitored nor enforced these protocols, which were largely ignored by providers.

HPR's drug costs had been escalating at an alarming rate of almost 20% annually. The 1994 commercial PMPM drug costs were projected to increase 38%, from \$13.92 to \$19.32, by 1997 (see Figure 1). HPR did not provide a drug benefit for its Medicare risk members until January 1996.

To control its escalating drug costs, HPR considered several options, including contracting with a pharmacy benefit manager (PBM) and closing its formulary. The pharmacy services manager opposed both concepts and convinced senior management and the board of directors that maintaining local control over the drug benefit would support the regional concept of the health plan's mission; that methods other than a closed formulary were available to control the runaway drug costs and utilization; and

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that a closed formulary would excessively limit drug availability to both providers and patients.

After investigating several methods of formulary management, HPR decided to reinforce several existing programs by reducing maintenance drug quantities, expanding the maximum allowable cost list, increasing generic substitution, and using therapeutic interchange programs.

HPR decided that it would implement a "step therapy" concept to manage the formulary. Using the step therapy formulary option would allow selection of preferred agents, automatic approval of second-level medications when necessary criteria were met, and grandfathering of patients already stabilized on existing therapy. HPR still would be able to control the management of all new therapies.

Instead of a closed formulary, HPR could develop a Preferred Drug List (PDL) to ensure appropriate utilization of medications while allowing prescribing physicians the flexibility to employ other medications when medically necessary. HPR did not want to assume the administrative burden of a manual prior authorization process. They estimated that management of the PDL would require more than 75 step-therapy protocols. HPR thought that at least 50 protocols would require enforcement by computer-based algorithms to eliminate the need for additional HPR staff.

After deciding on step therapy for the bulk of the formulary management, HPR queried several claims processors and PBMs about the feasibility of providing this service. HPR discovered that its existing claims processor, Argus Health Systems Inc., could perform this task at the level required. The other processors had utilized step therapy only to manage a couple of therapeutic classes and never at the level required by HPR.

Argus is an independent prescription claims processor based in Kansas City, Missouri. Argus provides prescription drug management systems and services to HMOs, preferred provider organizations, insurance companies,

Figure 1. Projected PMPM Impact

and other managed health care companies. In support of its customers, Argus edits for more than 275,000 unique benefit plans that cover 20 million lives. Since its inception in 1986, Argus has become one of the largest processors of prescription claims in the United States, handling more than 150 million claims in 1997.

Argus offered HPR an extensive array of point-of-service drug utilization review (DUR) edits, including the therapy protocol algorithms that HPR was looking for. The protocol algorithms included therapy/time interval, dose/time interval, quantity/time interval, initial dose, prerequisite step therapy, and preclusive step therapy.

The customer could customize each type of protocol logic. HPR's objective—to change prescribing habits for each therapeutic class in its PDL—could be enforced using the Argus prerequisite step-therapy protocols (see Figure 2). These prerequisite step-therapy protocols would require a defined use of HPR's first-line agents before allowing patients to receive second-line therapy. Protocol rules would be specific down to each individual drug level, and messages sent to the pharmacy network would be customized to the protocol type. The Argus protocols would screen for prior use of a drug and grandfather it when found, thus creating another layer of automatic preauthorization.

Figure 2. Process to Implement Step Therapy

- P&T committee reviewed and selected preferred drugs and step-therapy criteria
- Reviewed by >100 network providers
- Established 52 step-therapy protocols
- Published and notified all providers and members
- 3-month transition from 7/1/96 through 9/30/96
- Implement 10/1/96
- Monitor and track with Argus support

Source: Health Plan of the Redwoods/Argus Health Systems

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Argus also offered an online *ad hoc* query tool called RxFocus, which would allow HPR to monitor the impact of its proposed program. This Argus tool could measure the effectiveness of HPR's program in the following ways:

- ▲ allow HPR to develop customized queries at the desktop and receive answers within minutes;
- ▲ allow HPR to measure changes in utilization, cost reduction, and market share shifts; and
- ▲ allow HPR to perform cost savings analysis.

The first and most important step in this development process was deciding which therapeutic classes required computer-assisted protocols. Argus and HPR discussed those they knew had both the highest utilization and the greatest potential to affect costs. The ultimate objective, of course, was not to increase the point-of-service denials but rather to enforce behavior changes.

The next step was deciding (per drug) how much first-line therapy within a specified retrospective search would be required before allowing access to second-level therapy. After that, Argus programmed the protocols so that from July 1, 1996 through September 30, 1996, HPR network pharmacies received messages alerting them that prior therapy by a first-line agent was required. After October 1, 1996, Argus changed the protocols so that a message still was sent to the pharmacy but the claim was denied if the system found no history of a member's necessary first-line agent.

HPR's P&T committee reviewed and selected the preferred drugs and the customized step-therapy criteria. More than 350 drugs were made available at first level and another 300 at second level, while 40 were placed on prior authorization only.

▲ The preferred first-level therapies were those medications approved as standard of practice by the medical community for most medical needs. No authorization was required to dispense these medications.

▲ Second-level medications were those drugs the P&T committee considered necessary only if first-line agents were ineffective or the patient had other medical conditions that ruled out utilization of a first-line agent.

▲ The 40 prior authorization medications were listed under a separate "prior authorization required" level when the P&T committee felt stricter controls or monitoring were needed. Patient safety, inappropriate utilization, and severe potential for abuse were factors considered in determining whether to exclude these drugs from the step-care therapy process.

HPR's P&T committee decided that only patients taking angiotensin converting enzyme (ACE) inhibitors, histamine H₂ antagonists (H₂RAs), and lipid-lowering statins would be required to change therapies. The Argus computer protocols grandfathered in all other classes of maintenance drugs.

The PDL draft was submitted to more than 100 HPR network providers, including pharmacists, primary care physicians, and medical specialists for suggestions and comments. Included in this initial review were the suggested criteria for second-level drug usage. Second-level agents could be used only if first-level medications were not effective or the patient had developed adverse effects.

Internal medicine specialist and P&T committee Chairman Tim Gieseke, M.D., stated, "I am quite pleased with the way the physician community provided input into the development process and [with] their quick acceptance of the PDL."

After the network physician review process was completed for the PDL, HPR worked with Argus to establish 52 different computer-assisted step-therapy protocols. Argus named the protocols by the specific therapeutic class of the medications and assigned rules at the product ingredient level. The length of the prerequisite therapy and the retrospective search criteria required were customized for each therapeutic class of medications. When a claim was submitted for

processing, the Argus computer system would check the patient's utilization of the first-level medication within the required time period. If found, the Argus computer system would then automatically authorize the filling of the second-level medication, even if previously filled at another pharmacy.

HPR then implemented a project team at the health plan level to communicate the formulary changes to those affected. It included representatives from marketing, member services, professional services, communications, customer relations, contracting, and pharmacy services. The project team developed a communication plan to convey these formulary changes to:

- ▲ the four major HPR customers;
- ▲ individual physician providers and IPAs;
- ▲ individual network pharmacy providers and pharmacy chain administrators;
- ▲ members;
- ▲ brokers; and
- ▲ major employer groups.

HPR used multiple communication methods including newsletters, meetings, and presentations. They communicated with physicians and pharmacy providers four times and with members three times. The members received brochures describing their prescription drug coverage and the new "Preferred Drug List."

Community pharmacist Zachary Contreras, R.Ph., stated, "The step-therapy process requires physicians to think about what they are prescribing instead of just using the newest, most expensive products. This process helps to reduce costs for the plan, pharmacy, and member, yet allows access to those drugs for the complex patient."

Finally, HPR rolled out the PDL in a soft-edit mode for the three-month period of July through September 1996, allowing physicians a grace period during which claims would not be denied if step-therapy criteria were not met.

Once the three-month implementa-

tion phase was completed, HPR could begin measuring the results of the PDL program. HPR routinely performed claim-trending analysis, cost-saving analysis, and market-share-shift documentation. RxFocus allowed HPR to access, develop, and produce reports online to monitor the performance of its step-therapy protocols. On a monthly basis, HPR measured various parameters including percentage of first-line agent utilization, generic utilization, and average ingredient cost.

The dramatic success of the PDL and the computer-assisted protocols soon were apparent. Although HPR had projected a 20% increase in trended year-end drug costs PMPM for 1996, they actually experienced a 9% decrease within six months of implementing the Argus computer-assisted step therapy. The RxFocus reports HPR generated for that six-month period demonstrated the following:

- ▲ Generic utilization increased from 45% to 51%.
- ▲ Average dollars paid per claim decreased from \$29.24 to \$26.95.
- ▲ Only 14% of all prescriptions were required at the second level, with utilization of the first-level medications leveling out at 86%.
- ▲ The Argus automatic step-therapy process handled 94% of all second-level overrides, with only 6% requiring a manual override. This automatic pre-authorization process allowed the health plan to manually process less than 1% of all prescription drug claims.

Dan Sloan, HPR's chief financial officer, stated: "By mid-1996, with an average annual Rx cost increase nearing 20% in a market anticipating flat or slightly reduced premium renewals, HPR's pharmacy management was indeed challenged. Enabled with effective use of available technology, they successfully implemented the step-therapy approach, reducing HPR's Rx costs to competitive levels while minimizing the legitimate concerns of all HPR's constituents."

Figure 3. Current PMPM Impact

More than any other class of drugs in the PDL, the antibiotics generated the most questions and concerns from providers during the first quarter of the step-therapy process. These antibiotic step-therapy protocols were the most restrictive protocols in the PDL. Patients had to have failed on the generic narrow-spectrum agents within the past three months in order to access the newer broad-spectrum and extended-action antibiotics. This step-therapy process reduced the utilization of fluoroquinolones and betalactamase resistant agents by more than 50%, and newer macrolides by more than 75%, with substantial cost savings to the health plan. Because of the initial concerns expressed by providers about the restrictive nature of the antibiotic protocols, HPR scrutinized the medical utilization costs for patients with sinusitis, pneumonia, and bronchitis diagnoses, comparing the November/December 1995 and November/December 1996 time periods. No apparent impact was found on inpatient PMPM as a result of the increased use of first-line therapy antibiotics. ER/outpatient, M.D. office, and total medical PMPM costs even decreased slightly (see Figure 3), indicating that the antibiotic restrictions

caused no adverse medical effect.

The use of the computer-assisted step-therapy protocols demonstrated the ability to reduce financial and administrative costs without interfering with the quality of care. Furthermore, the use of these step-therapy protocols allowed HPR to document the increased use of first-line medications. Because of their ability to increase the market share of first-line agents, HPR was able to renegotiate with pharmaceutical manufacturers and reduce the number of drug rebate contracts from 53 to 12.

The pharmacy services department easily managed administration of the 12 remaining contracts. Their data analyst developed a customized report template in RxFocus, which pulled the documentation required by the pharmaceutical manufacturers on a quarterly basis. Then the pharmacy services administrative assistant mailed the RxFocus reports with a cover letter to the manufacturers. Within the first quarter of using these computer-assisted protocols, HPR had more than tripled the return on the remaining contracts.

Despite some customer satisfaction issues due to the reduction in drug accessibility and to switching from the open formulary, when open enrollment

for many groups occurred five months after the protocols were implemented, HPR actually demonstrated a small net gain in members.

HPR CEO John Baxter said, "To deliver superior value to our members at a reasonable cost, HPR needed a new approach to managing our pharmacy benefit, one that gave members access to more costly drugs when needed, yet encouraged the use of more cost-effective products when possible. The PDL program met that goal."

Provider education now is the main area of focus for HPR. The company has added a clinical pharmacist to work more closely with physicians. Because the prerequisite step-therapy protocols gave HPR the ability to monitor compliance with second-level medications, the HPR clinical pharmacist can provide education to physicians regarding noncompliant patients. The clinical staff also is responsible for the development of criteria and guidelines that coincide with the current PDL. Obviously, this is a collaborative process involving as much physician input as possible. The long-term goal of

HPR's pharmacy services department is to become a clinical resource for the physician community it serves.

HPR's 1998 goals include reviewing all step-therapy protocols to determine cost effectiveness and the impact on medical costs. Because some claims are still being denied at the pharmacy level due to the failure to meet criteria for second-level drug access, HPR's pharmacy services department will focus on trending those denials by physician and drug. This will enable HPR to interact more specifically with the provider and determine whether any step-therapy criteria need to be revised.

Fifteen months after the implementation of the PDL step-therapy process, the health plan continues to show a reduction in drug costs compared to the previous year. Commercial and Medicare risk year-to-date figures for the first four months of HPR's fiscal year (July-October 1997) show a \$1.32 PMPM reduction compared to the same period the previous year. The amount paid per prescription for 1997 dropped from \$27.47 to \$25.73 for the commercial population and from \$19.91 to \$16.20

for the Medicare risk population. No changes were made to the patients' copayments during this process.

HPR Chief Medical Officer Ed Martin, M.D., concurs that "HPR needed to manage its pharmacy costs but did not want to create major barriers for clinical decision making. The step-therapy program allowed us to contribute objective decision criteria to initial therapy while giving the clinician the flexibility to make changes based on the patient's response. The program improved the delivery of health care for patients and physicians."

In summary, the partnership between HPR and Argus provided a mechanism to control pharmacy benefit costs while implementing effective quality control measures. HPR had to balance the need to reduce costs with the demand of the marketplace for access to appropriate medications. HPR and Argus worked together to design and implement an effective PDL program. It truly was a collaboration of efforts between HPR, Argus, and the community of health care providers that made this a successful program.

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