

Rx Clinical Improvement Team

Phase 1 Final Report - April 2006

I. Background

The mission of the Puget Sound Health Alliance (the Alliance) is to coalesce leadership among purchasers (employers and unions), physicians, hospitals, consumers, health plans, and others to design and implement an innovative, high quality, and affordable health care system in the Puget Sound region. In June 2005, the Alliance Board of Directors agreed to focus the Alliance's initial efforts on four health conditions: heart disease, diabetes, back pain, and depression. The Rx Clinical Improvement Team was subsequently created by the Quality Improvement Committee (QIC) of the Alliance as a fifth area of initial focus, in response to generally accepted indications that pharmacy presents an immense opportunity for the Alliance to quickly improve quality and reduce costs. The Alliance Board approved the QIC's recommendation to establish the Rx CIT during its November 2005 meeting and the first meeting was held in January 2006. The Rx CIT has met a total of four times and this report documents the first set of recommendations (Phase I). The Rx CIT will continue to meet and develop additional recommendations throughout 2006.

The purpose of the Rx Clinical Improvement Team is to:

- Provide guidance and technical expertise to the Alliance Quality Improvement Committee (QIC) and the Alliance Board on issues related to prescription drugs.
- Make recommendations for high impact improvements that can be implemented rapidly and easily regarding the use of prescription drugs. This may include the following recommendations: prescribing guidelines and standards, performance metrics, measurement approaches, monitoring, and implementation strategies related to quality improvement and cost management for prescription drugs.
- Focus on generic drugs as well as high cost medications, high volume medications, medications with extreme variability in prescribing patterns, and other topics of interest identified by the team.
- Identify the highest priorities that provide quick impacts for change. Focus on the highest cost reduction or quality improvement opportunities that are easy to implement.

Functions of the Rx Clinical Improvement Team

The Rx CIT was asked to perform the following functions:

- Identify drugs or prescribing patterns where there is strong evidence of widespread overuse, under-use, or misuse of prescription drugs.
- Recommend prioritized opportunities for change that achieve significant improvements in quality or reductions in costs (ideally, both).
- Advise the QIC and the Board on methodologies and implementation strategies to align financial and quality improvement incentives for prescription drugs for providers, patients, health plans, and purchasers.
- Identify barriers to making the recommended changes and develop recommendations for overcoming those barriers that are actionable and timely.

Structure

A team of fourteen local experts in pharmacy, benefits design and purchasing issues was established in January, 2006, as the Alliance Rx CIT. Appendix 1 provides a list of the Rx CIT members. The team has completed its initial phase of work through the course of four meetings and has developed three high priority recommendations. The team will continue to meet over the next six to eight months to address additional opportunities to improve quality and reduce pharmacy costs.

II. Phase I Recommendations

1. Increase Use of Lower Cost Generic¹ Drugs

Background: Local provider and health plan representatives informally estimate that a 1% increase in generic fill rates results in an approximate 1% to 2% reduction in overall prescription drug costs. According to Haas et al. (2005), if a generic drug had been substituted for all corresponding name-brand outpatient medications when at least one generic alternative was available in the year 2000, there would have been an estimated \$5.9 billion in national savings (for adults younger than 65) and an estimated \$2.9 billion in national savings for adults age 65 and older.² Experts believe there is substantial opportunity for cost reduction through generic substitution, specifically in at least four major therapeutic drug classes. Currently, the

¹ According to the Food and Drug Administration's Center for Drug Evaluation and Research, "a generic drug is identical, or bioequivalent to a brand name drug in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. Although generic drugs are chemically identical to their branded counterparts, they are typically sold at substantial discounts from the branded price. According to the Congressional Budget Office, generic drugs save consumers an estimated \$8 to \$10 billion a year at retail pharmacies."

² Jennifer S. Haas et al., "Potential Savings from Substituting Generic Drugs for Brand-Name Drugs: Medical Expenditure Panel Survey, 1997-2000," *Annals of Internal Medicine* 142, 11 (June 2005): 891-897.

average generic fill rate for all medications is estimated to be 50% - 55% nationally, with some local high performers averaging 70% or better. The term “generic fill rate” refers to the percentage of prescriptions filled using a generic drug, not to the prescribing rate of generic drugs. Most providers will sign a prescription on the line “substitution permitted” which allows the pharmacist to substitute generic for brand name when it exists. Although the generic fill rate averages 50% - 55%, some providers’ rates remain well below these averages, indicating an opportunity to improve generic fill rates across the provider and pharmacist community. In addition, several popular brand drugs are scheduled to transition to generic status as drug company patent protections expire this year, providing another related immediate opportunity to increase generic fill rates. The Washington Post recently reported that an unprecedented \$60 billion to \$70 billion a year in brand-name drugs will come off patient over the next four years (examples cited were Zocor, Zoloft, Pravachol, and Ambien).³

An important distinction is the difference between generic and therapeutic substitution. The main distinction is that a generic drug is chemically identical to the brand name drug for which it is being substituted, while a therapeutic substitution is a drug within the same class but not chemically identical. Statins (such as Zocor and Lipitor) provide a good example of therapeutic substitution. The different statins are not chemically identical, but work in similar ways to achieve the same effect. Often times the pharmacist has to make a therapeutic substitution (because of formulary requirements, etc.). Therapeutic substitutions could be a name-brand for a name-brand change, or could be a generic for a brand name substitution. Therapeutic substitution may create added opportunities for cost savings when a therapeutic substitution is appropriate for the patient. A recent study by Meissner et al. (2006) looked at the impact of a statin therapeutic interchange on drug costs and medical management costs for over 3,000 patients. From the year prior to the intervention to the year post-intervention, the authors concluded that the net statin expenditure decreased by 33%.⁴

Recommendations: In response to these opportunities, the Rx CIT recommends the following position statements:

- A. The Puget Sound Health Alliance will develop focused educational campaigns for providers and patients/employees to increase overall generic fill rates by 3% per year, on average, for the next two years. Providers’ fill rates for generic drugs that are below an average of 50%

³ Marc Kaufman, “Why You Can’t Get Generic,” The Washington Post National Weekly Edition, February 13-19, 2006, p. 20.

⁴ Brian Meissner et al., “Drug and Medical Cost Effects of a Drug Formulary Change With Therapeutic Interchange for Statin Drugs in a Multistate Managed Medicaid Organization,” Journal of Managed Care Pharmacy 12, 4, (May 2006), 331-339.

are expected to increase their generic fill rates by more than 3% while those above 50% are expected to experience slower rates of change.

B. The Alliance will develop and focus its educational campaigns around five therapeutic drug classes, as follows:

- Statins (cholesterol lowering agents)
- SSRIs (antidepressants)
- PPIs (proton pump inhibitors or gastric acid secretion reducers)
- NSAIDs (non-steroidal anti-inflammatory drugs)
- Antibiotics (the issue here is not generic substitution but rather eliminating the inappropriate prescribing of antibiotics)

The first four drug classes listed above focus primarily on cost reduction opportunities through generic substitution of equally effective lower cost generics for brand name drugs. The focus on antibiotics reflects continuation of recent national and local campaigns to increase awareness of over-utilization and inappropriate prescribing of antibiotics that adversely affect patient care quality. Also note that SSRIs will be a specific focus of recommendations currently being developed by the Depression CIT.

Strategies: To increase substitution of lower cost, chemically identical and equally effective generics, the Alliance should adopt the following strategies:

A. The Alliance should develop a “consumer-centric” approach for promoting generics within the five major drug classes to enable consumers to become a significant change agent for increasing the fill rate of generics. Information should be included that identifies and compares generic alternatives to specific brand names in each class of drugs, including cost, quality and known outcomes. The comparative information should be focused on available, evidence-based research.

Statistics indicate that use of generics increases adherence rates among consumers, due most likely to the lower copay for generic drugs. A recent study by the RAND Corporation (2006) found that reducing copayments for patients on cholesterol-lowering medication lowered the rates of hospitalizations (357 fewer hospitalizations annually per 1000 high-risk patients) because these patients were 6-10% more likely to fully comply with their doctors’ orders to take their medication.⁵ Higher priced drugs, typically brand name drugs, have lower adherence rates as patients try to extend a 30-, 60- or 90-day supply over a longer period. When this happens, over time, the efficacy of the higher priced drugs diminishes due to less frequent than prescribed use, worsening patient outcomes and increasing the overall cost of care.

⁵ Dana P. Goldman et al., “Varying Pharmacy Benefits With Clinical Status: The Case of Cholesterol-lowering Therapy,” *American Journal of Managed Care* 12, 1 (January 2006), 21-27.

- B. The Alliance should identify, as part of its overall focus on re-aligning performance incentives, opportunities for improvement where benefit designs create inadvertent incentives that discourage the use of generic drugs or lower cost therapeutic substitutions. The Alliance recommends benefit design improvements for features such as consumer cost-sharing, co-pays for generic vs. brand name drugs, and coverage for specific medications available over-the-counter (OTC) without a prescription to remove disincentives for generic use.

The Alliance agrees with the Washington State Medical Association that “[f]inancial incentives should not be placed on physicians to prescribe the lower cost drug as this creates a moral hazard potentially injurious to patients’ trust in their physicians.”⁶ Therefore, the Alliance does not recommend a payment model in which providers are offered financial incentives to change patients from brand to generics.

It will also be important as part of this effort to increase awareness among purchasers and health plans about the cost implications of benefit package designs that could be improved to eliminate current disincentives to the use of generic drugs.

- C. The Alliance should develop and disseminate to providers a list of “first choice” drugs available in generic form in the first four therapeutic classes above (where appropriate), including over-the-counter alternatives, for use in step therapy. Step therapy is a means by which lower cost medications are prescribed initially and other drug options are considered only if the patient does not respond as indicated. A recent study by Dunn et al. (2006) concluded that an intervention requiring use of a generic antidepressant prior to use of a brand-name resulted in a cost savings of 9.0% (over \$1.8 million) for the entire class of antidepressants in the first year of the intervention.⁷

Potential Barriers to This Change: Many consumers believe that generics are less effective and/or more difficult to use. Some consumers are more savvy, and since most plans already have differential co-pays for brand vs. generic, these patients are more likely to ask for generics if the incentives are structured properly. Consumers are also less tolerant of generics that must be taken more often than brand named drugs. The Alliance needs to exercise caution in its endorsement of *specific* generic substitutions. Generics must be comparable to brand drugs in cost and effectiveness and they need to be easy to administer.

⁶ Letter from Peter Dunbar, MD, WSMA President, to Ron Sims, Alliance Board Chair, dated May 4, 2006.

⁷ Jeffrey D. Dunn et al., “Utilization and Drug Cost Outcomes of a Step-Therapy Edit for Generic Antidepressants in an HMO in an Integrated Health System” 12, 4 (May 2006), 294-302.

Another barrier to change is use of the term “generics” which includes generally negative connotations for consumers. The Alliance may want to consider using other descriptors to describe generics such as chemically equivalent substitution, or lower cost substitution. The Alliance needs to assure that its message regarding generics is clear, consistent, and succinct. If there are too many messages or changing messages, consumers and providers will quickly lose interest.

A pay-for-performance strategy may be difficult to implement. Stronger interest – including a source of funding - must be developed among health plans and purchasers to support this strategy. Payment methods, such as withholds with a bonus at the end of the year, are primitive and need more development and testing before being recommended on a wide scale.

In addition, there are operational issues to overcome. One pharmacy benefit management company represented on the Rx CIT implemented a similar pay-for-performance program and experienced or tracked potential problems. Problems included:

- billings for generic substitution that did not actually occur
- providers who intentionally prescribed a higher cost drug, then switched to a lower cost generic drug purely to take advantage of the new reimbursement stream
- patients who switched to a generic without positive results then needed to switch back, thereby increasing the overall cost to health plans when they were billed for a substitution fee that otherwise would not have been necessary
- benefit designs that already incentivized use of generics now paid more under the pay-for-performance strategy, without necessarily seeing a commensurate return on investment compared to that of brand name formularies
- purchasers and health plans may be reluctant to change benefits for a variety of reasons, even if cost savings are a likely result

Many of these problems can be overcome through a strong audit function to monitor provider and patient compliance - however, this function can be both costly and complex to administer.

There is also a need to differentiate between prescribing patterns and dispensing patterns when measuring generic fill rates. Clinics and providers should not be held accountable for improving generic fill rates when a pharmacy ignores a “substitution permitted” prescription for a generic and dispenses a brand name drug instead, or when benefit design is a barrier to the patient in using a generic. Providers often sign “substitution permitted,” for a

brand name drug, which allows for a chemically identical generic substitution. The pharmacist is not legally obliged to offer a lower cost generic if the provider writes for a brand name, but they often do. Encouraging providers to always use the generic name to ensure that it is chosen might be the most effective strategy. If the generic name is written with “substitution permitted” it is unlikely the pharmacist will substitute a more expensive brand name.

Another barrier with over-the-counter drugs (OTCs) in step therapy programs is that if OTCs are not covered under the benefit, the patient or member may be required to pay more for the OTC than the copayment for a name brand drug. Thus patients are incented to use the benefit and only pay the copay. Benefit design becomes very important in this strategy.

2. Consumer Education About Generic Drugs

Background: Many patients/consumers lack a basic understanding of their medications and are not well informed about the availability of lower cost generic alternatives and therapeutic substitutions. There are also many negative myths about generics which have created a need to mitigate inaccurate concerns about inferior quality and safety. At the same time, pharmaceutical companies maintain a substantial financial advantage from the promotion of brand name drugs. Drug advertising is effective, which is why the pharmaceutical industry spends about \$21 billion to market their drugs. About 90% of that is spent on promotions for doctors, including distribution of free samples.⁸ This needs to be countered with increased information on generics as well as dissemination of information on medication management in general. Trust and credibility are consumer issues which have created the need to establish a reliable, accurate, and objective source of drug information.

Recommendation: In response to these concerns, the Rx CIT recommends that the Puget Sound Health Alliance develop a patient education program that emphasizes the quality and safety of generic drug usage and promotes a consistent, clear and focused message about the quality and cost effectiveness of generic alternatives and also therapeutic substitution.

Strategies: To promote the substitution of lower cost, chemically equivalent and equally effective generic drugs and therapeutic substitutions, the Alliance should implement a consumer education program utilizing the following strategies:

- A. The Alliance should enlist the help and financial support of generic drug manufacturers to adapt and disseminate consumer education materials that identify and compare generic drugs to specific brand name drugs on

⁸ Troyen A. Brennan et al., “Health Industry Practices that Create Conflicts of Interest: A Policy Proposal for Academic Medical Centers.” *Journal of the American Medical Association*, 295, 4 (January 25, 2006) 429-433.

cost, efficacy, safety, and quality. To build trust in the Alliance's education strategy, initially select one of the targeted areas for generic substitution (preferably either PPIs or Statins) and roll out that promotional campaign first.

- B. To accelerate speed to market and to reduce development costs for these educational campaigns, the Alliance should base its promotional / educational campaign on materials and tools currently available through the Federal Drug Administration, the State Pharmacy and Therapeutics (P&T) Committee, and other entities with similar programs - such as Minnesota Blue Cross Blue Shield (BCBS) - and then tailor the messages through engagement of a professional marketing firm.
- C. The Alliance will distribute the information to consumers through the Alliance website, through participating organization's work places, and through providers' offices.
- D. As high volume brand name drugs no longer are protected under patents, the Alliance should stage educational campaigns to promote transition to generic equivalents.
- E. The Alliance should recommend (and post on its website) web-based tools that consumers and providers can use to help evaluate and compare outpatient prescription options. To the extent that reputable "low-tech" methods (i.e., non-computer based) are available for consumers to access information on medication options, these should be promoted as well, where it is cost-effective to do so.
- F. As was noted under recommendation #1, the Alliance needs to assure that its consumer education messages regarding generics are clear, consistent, and succinct. If there are too many messages or changing messages, consumers and providers will quickly lose interest. As well, education should center on the point that generic prescription drugs are chemically identical to brand name prescription drugs (as opposed to other generic products, such as household items that may sacrifice quality for cost).
- G. In developing recommendations on performance incentives, the Alliance should link incentives (for example, pay for performance) to physicians' and pharmacists' efforts to improve quality, not cut costs.

Barriers to This Change: The Alliance needs to recognize that many purchasers, including some of its participating organizations, have designed their formulary and cost structure to include higher cost brand name drugs as an employee recruitment and retention strategy. At the same time, health plans view their formulary and drug benefit designs as a competitive strategy to garner larger numbers of enrollees. Any patient education campaign designed

to improve quality and lower prescription drug costs for consumers will need to equitably address potential issues raised by purchasers and health plans.

Trust and credibility will be important to consumers who have access to a wide range of diverse perspectives on generics and brand name drugs. To successfully lower drug costs and improve quality, the patient education program must build/maintain consumer trust by assuring the accuracy of information, citing evidence-based research, and using programs that are already trusted and in place (such as the FDA, State P&T Committee, etc) to minimize the effect of counter-responses from the pharmaceutical industry.

3. Eliminate Drug Detailing and Free Samples

Background: The Puget Sound Health Alliance recognizes the important role that pharmaceutical companies play in the areas of research, drug development, education, and possibly even distribution of free samples when distributed to patients without the financial means to otherwise purchase needed medications. As noted earlier, the pharmaceutical industry spends in excess of \$18 billion a year on marketing directly to physicians, including distribution of free samples. It is the job of pharmaceutical and sales representatives to sell specific products, not necessarily to provide unbiased information on the efficacy and availability of the range of drugs available in the market, including generic equivalents which often cost substantially less for both the patient and payer. There are other, and potentially better, ways to get evidence-based information to physicians about the availability and efficacy of drugs, e.g., “The Medical Letter”, FDA Center for Drug Evaluation and Research, State and other Pharmacy and Therapeutics Committees, etc. These sources of information are more reliably unbiased in presenting evidence based information on the range of drugs available.

Likewise, the pharmaceutical industry spends billions of dollars annually on the distribution of free brand samples to physician practices because samples are an effective promotional tool. The Puget Sound Health Alliance recognizes the important role that pharmaceutical samples play in practice locations where under- or uninsured patients are predominant. The Alliance acknowledges that, in these instances, the continued use of pharmaceutical samples may be necessary in the absence of larger, systemic changes that improve the coverage and financing of health care, including medications. However, it must be noted that the use of samples can result in patients receiving medications that are more expensive (than generic equivalents) and/or less efficacious. Furthermore, many practices do not keep proper track of what samples are given to whom, complicating medication management and degrading the overall quality of care.

The Puget Sound Health Alliance is committed to supporting the practice of medicine in the best interest of patients and on the basis of the best available evidence, rather than on the basis of advertising or promotion.

The Quality Improvement Committee (QIC) of the Alliance requested that the Rx CIT consider and adopt recommendations related to pharmaceutical and sales representatives in practice locations and the use of pharmaceutical samples. The initial language for these recommendations was developed by staff at the direction of the QIC, then discussed and modified by the Rx CIT. The recommendations below present the result of that Rx CIT discussion. Final recommendations from the CIT are presented in Appendices 4 and 5.

Recommendation: In response to these concerns, the Rx CIT recommended, after extended discussion, that the Alliance adopt the following “position statements” on pharmaceutical and sales representatives and the use of free brand samples in practice locations:

- A. “The Puget Sound Health Alliance strongly recommends that providers and provider groups not meet with pharmaceutical and sales representatives in practice locations. The Puget Sound Health Alliance encourages providers to adopt policies that significantly limit or eliminate access of pharmaceutical and sales representatives in clinic or hospital locations. This limitation of access should include distribution of food and gifts, drug promotional materials, and pre-printed prescription pads.”

The Alliance agrees with the Washington State Medical Association that the final decision on whether or not to restrict or prohibit pharmaceutical representatives from a physician’s office is ultimately up to the discretion of each clinic, hospital, or other medical facility. The Alliance - as a regional coalition of physicians, hospitals, employers and other purchasers, consumers, and health plans – is making a strong recommendation that providers and provider groups not meet with pharmaceutical and sales representatives in practice locations.

- “B. The Puget Sound Health Alliance strongly recommends that providers and provider groups not accept or distribute pharmaceutical samples in their practices.”

There was not complete consensus among RX clinical improvement team members for these recommendations. Several CIT members suggested allowing the use of sampling that supports a value-based approach to providing care. One team member noted that value-based can be challenging to define, however, since “a system that simply looks at unit cost is too narrow, and risks the appearance of providing value, yet it does not consider all costs, such as other health care costs beyond pharmacy, as well as key employer-related costs

(e.g., productivity, absenteeism, presenteeism, short-term disability, long-term disability, and worker's compensation).”⁹

The same CIT member noted that “[w]hile this type of solution may work for a large integrated delivery system or medical group, it may not be the answer in all settings. All of us must agree that this issue is more complex than this type of answer would suggest.”

Subsequent to the preparation of this report in draft form, the QIC reviewed the initial Rx CIT recommendations. After discussion, the QIC took the position that (1) the suggested language regarding pharmaceutical representatives in practice locations was appropriate and reflected their position, and (2) the suggested language above regarding use of samples in practice locations was not strong enough. On this second item, staff was asked to re-draft the position statement to include stronger language prohibiting the use of all samples. This revised language (shown above) was adopted by the Rx CIT by a vote of 8-1 at the May 4, 2006 meeting.

Comments from the Alliance Consumer Advisory Group and others were also considered on both of these recommendations, and the CIT endorsed numerous changes to the draft.

Strategy: The Alliance will work with providers, medical societies and specialty societies in the five-county area to promote these changes. The Alliance will facilitate the sharing of information (e.g., examples of organizational policy) from local health care organizations that have already successfully taken steps to constrain pharmaceutical companies’ in-clinic marketing tactics and eliminate distribution of free brand name drug samples.

Barriers to This Change: The Alliance recognizes that the pharmaceutical industry spends billions of dollars each year on drug detailing and free samples to physicians, and that this expenditure clearly has a positive return on investment. Pharmaceutical industry participants in the Alliance will undoubtedly be dissatisfied with the position recommended.

Those health care providers in the five-county area who are part of the community “safety net”, who provide a significant proportion of the care for the under- or uninsured people, may be unsupportive of a move to eliminate the use of free brand samples from their practice, because they believe that this is the only way that some patients are able to receive medication.

Physicians and other health care providers in small to mid-size practices rely heavily on pharmaceutical representatives for information on medications,

⁹ Letter from Steve Hall, Director, Employer Market, West, Johnson & Johnson Health Care Systems Inc. to the Rx Clinical Improvement Team, dated April 26, 2006.

insofar as they do not have the advantage of in-house pharmacist consultants or P&T committees. These providers may feel that they do not have sufficient time to avail themselves routinely of unbiased, evidence based information available through other means.

III. Additional Areas of Interest for the Rx CIT

The Rx CIT was created with an expectation that it would complete its work in three meetings over a two month period. However, members of the Rx CIT unanimously agreed that there are a sufficient number of topics of interest with potential for positive impact that they would like to continue their work through the remainder of 2006. One such area in which the CIT has already begun discussions is the area of financial incentives for providers to perform patient medication audits. The CIT's preliminary direction in this area is summarized below, but the team has not made specific recommendations yet. A number of other topics have also been briefly explored, but require more in-depth consideration. These other areas are also noted below and represent the ongoing scope of work for the Rx CIT.

1. Give Providers Incentives to Perform Patient Medication Audits

Background: Many patients currently take multiple prescriptions without adequate oversight from their providers. In many instances there are multiple providers prescribing medications for various conditions, none of which have adequate knowledge of other providers' prescribing activities for the same patient. Until a shared electronic medical record or other Rx-specific system with interoperability is established, there is no mechanism within the current system to access the data necessary to electronically perform medication oversight functions. In addition, there is currently no additional payment to cover the cost of these activities. This has created a need to better manage patient medications through regular physician audits of medications. A medication audit is a review of all of an individual patient's medications by a physician, or a pharmacist, or another health professional. A program to promote medication audits will:

- Improve patient outcomes
- Identify opportunities for lower cost generic or therapeutic substitution
- Reduce the potential for adverse drug reactions
- Reduce the frequency of drug duplication and/or contra-indications
- Mitigate over-utilization problems
- Reduce costs
- Decrease the potential for medical errors

Preliminary Recommendation: At the time of this report, the Rx CIT has not yet concluded its development of specific recommendations. Therefore, additional work is needed by the Rx to finalize these *draft* position statements (offered here as a “status report” of the work completed to date by the CIT):

- A. The Puget Sound Health Alliance should actively promote the value of medication audits to physicians, pharmacists, payers, and patients.
- B. The Alliance should demonstrate to payers and purchasers the potential return on investment for adding medication audits to their pharmacy benefit design, including payment to cover physicians’ and pharmacists’ time to perform such audits.
- C. Through patient/consumer educational materials, the Alliance should promote the availability and increased patient safety of scheduling periodic medication audits with their physician or pharmacist.
- D. The Alliance should disseminate information on use of multiple drugs (polypharmacy) with the intent of increasing consumer knowledge about medications as well as promoting the related concept of consumers taking greater responsibility for their health and their health care decisions.

Preliminary Thoughts on Strategies: An initial strategy for jump starting medication audits is to promote, through consumer education, a “brown bag” poly-pharmacy program for patients with multiple medications and conditions. Patients would be encouraged to bring their medications to their next physician visit, where they could discuss duplications, contra-indications, over- or under-utilization, adverse reactions, and opportunities for generic substitution. This potentially could be billed under current payment systems as a “preventive medicine” visit, although it might require benefit modifications since some benefit plans limit preventive visits to one a year. The structure of the physician office visit would be different but the billing would be the same. A team approach could be endorsed that would bring patient, doctor, and (if readily available) a pharmacist into the brown bag visit/consultation.

The underlying assumption is that medication audits will reduce costs. However, there is no data to support or refute this assumption at this time. To demonstrate the value of medication audits to patients, payers and purchasers, it may be necessary to conduct a pilot test and complete an analysis of the potential return on investment. In the absence of such data, purchasers and plans are likely to be reluctant to adopt this approach on a widespread basis. A pilot project could be designed to perform medication audits through which data are gathered on:

- The frequency of generic substitution opportunities to lower drug costs
- Calculation of the potential cost reduction to both the consumer and the health plan if generic substitution occurs

- Frequency of drug duplication and/or contra-indications
- Over-utilization
- Under-utilization
- Lack of adherence to recommended dosages and the patient's reason for non-compliance

Data from the pilot project would provide the basis to support or refute the value of medication audits by physicians or pharmacists. Additional data, including generic drug costs compared to brand name drug costs, would need to be collected and analyzed as well as cost information about added physician visits and avoided medical costs that resulted from reductions in drug duplication, contra-indications, and over- or under-utilization.

Implementation of medication audits provides a near term opportunity to improve patient safety and to reduce costs - while at the same time positioning providers for a more robust medication therapy management (MTM) program similar to that proposed under Medicare Part D. Rather than embracing MTM now, experts agree that more information is needed and this will be forthcoming as CMS moves forward with its efforts. This information will provide more credible evidence as to whether or not MTM provides value and whether or not the Alliance should further examine the value of endorsing such a program for non-Medicare beneficiaries.¹⁰

Barriers to Change: Currently, there is little or no data available to support or dispute the contention that medication audits provide value. Without credible and objective data, the Alliance will have little or no basis to influence payers and purchasers to reimburse or to incent providers to engage in these activities. Without such data, there is no mechanism to calculate the potential financial impact of both direct costs through payment for these activities as well as potential cost savings through generic substitution, improved patient safety, improved adherence, and reduction in over- or under-utilization, duplication, and contra-indications.

2. Other Area of Interest – Next Steps

In addition to the area of patient medication audits, the Rx CIT has identified eleven other areas of interest that represent potential opportunities to reduce pharmacy costs and to improve quality. The CIT has agreed to continue working on these opportunities and to provide the Alliance with additional recommendations for improvement. In addition to finalizing its recommendations on medication audits, the next set of high priorities includes:

¹⁰ A source of additional information on the Medicare Part D MTM program is <http://courses.washington.edu/pharm560/CRPC/Medication%20Therapy%20Manage.pdf>

- Promote drugs with proven value (evidence-based medicine) through formulary re-design and cost-sharing incentives for patients to purchase drugs that have value and disincentives to purchase drugs with less or uncertain value.
- Reduce drug costs and increase access to drugs at the best possible prices (with pooled purchasing identified as a possible strategy to achieve these results).
- Target for intervention specific high-volume or high-cost drugs that have a high incidence of over-utilization.

Additional areas of interest that may also be addressed over time include:

- Develop a “drug of first choice” approach for common conditions
- Reduce unnecessary variation across provider prescribing patterns
- Link electronic medical records (EMRs) to prescribing in ambulatory settings
- Assess/monitor adverse drug reactions
- Improve patient safety
- Expand use of technology
- Recommend a uniform/standardized core formulary or set of standards on formulary design to reduce confusion for providers
- Promote transparency across Pharmacy Benefit Managers (PBMs)
- Consider productivity as part of the cost equation

Please refer to Appendix 3 for a more detailed listing of these topics and potential change strategies that could be considered.

Appendix 1
Rx Clinical Improvement Team Members

Name	Title	Affiliation
Dr. Jim Carlson	Director of Clinical Pharmacy Services	Group Health Cooperative
Mr. Steven Hall	Director, Employer Market West	Johnson & Johnson
Mr. Ray Hanley	Sr. Prescription Program Manager	Health Care Authority
Dr. David Lorber	Vice President, Clinical Affairs	Caremark
Ms. Sepi Soleimanpour	District Pharmacy Supervisor	Walgreens
Dr. Andy Stergachis	Professor, Department of Epidemiology & Adjunct Professor of Pharmacy	University of Washington
Ms. SuAnn Stone	Director, Pharmacy Services	Regence BlueShield
Dr. Sean Sullivan	Professor, Pharmacy & Health Services	University of Washington
Ms. Yvonne Tate	Director, Human Resources	City of Bellevue
Dr. Michael Tronolone	Medical Director	Polyclinic
Dr. John Verrilli	Physician, General Internal Medicine	Minor & James Medical
Dr. Dave West	Chief of Pharmacy	Swedish Medical Center
Ms. Jennifer Wilson-Norton	Pharmacy Director	The Everett Clinic
Dr. Ed Wong	Director of Pharmacy	Premera
Dr. Art Zoloth	Vice President	Northwest Pharmacy

Appendix 2 Alliance Rx CIT Staff and Consultants

Name	Alliance Affiliation	Email
Michelle Vest	Lead Consultant, Phase I Rx CIT	michelle@westcoastconsulting.net
Susie Dade	Quality Improvement Director	sdade@pugetsoundhealthalliance.org
Lance Heineccius	Program Director	lance@pugetsoundhealthalliance.org
Jane Keary	Research Staff	jkeary@pugetsoundhealthalliance.org
Kaj Trapp	Committee Coordinator	ktrapp@pugetsoundhealthalliance.org

Appendix 3

Other Opportunities for Change and Potential Change Strategies Identified by the Rx CIT During Their Initial Meetings

1. Reduce the cost of drugs

- a. Limit promotional activities direct to prescribers
- b. Focus on what consumers are willing to pay rather than industry pricing strategies
- c. Promote new drugs that are cost neutral
- d. Develop "step-wise" approach for the introduction of new drugs

2. Reduce unnecessary variation in prescribing patterns

- a. Profile physicians, broadly, not at the patient level
- b. Establish protocol-driven prescribing standards for specific disease conditions
- c. Pool purchasing information from private and public sectors.
- d. Establish purchasing standards
- e. Base purchasing decisions on evidence/research rather than marketing/advertising

3. Identify and reduce over and under utilization

- a. Reimburse physicians for managing patient medications
- b. Create registries to track adherence
- c. Create tool kits for medication therapy management

4. Link EMRs to prescribing within the ambulatory setting

- a. Expand upon the Everett Clinic model
- b. Jump start the EMR - PSHA Phase II opportunity

5. Assess/monitor adverse drug reactions (ADRs)

- a. Evaluate hospital admissions for drug interactions and ADRs
- b. Develop electronic tool to monitor ADRs

6. Improve patient safety

- a. Eliminate inappropriate off-label use of drugs
- b. Monitor experimentation
- c. Reduce inappropriate usage that is not evidence based

7. Expand use of technology

- a. Promote better technologies for physicians to evaluate drugs at point of care
- b. Deploy low tech methods to assist patients in taking greater responsibility for their drug purchasing decisions.
- c. Use hand held devices to identify top Rx interactions

8. Develop a uniform or basic core formulary that all plans must offer

- a. Emphasize generics and lowest cost, equally effective drugs in each class
- b. Allow different dosage options, trial usage to test effectiveness, include OTCs
- c. Emphasize value (cost and effectiveness)
- d. Establish a single data repository for real time access

9. Promote price transparency across pharmacy benefit managers (PBMs)

Other Rx-Related Ideas and Problem Areas that the Rx CIT Might Explore

Employment of evidence-based principles by all insurers and groups

- New drugs come at a high cost, are highly promoted by the industry, and often have no additional value over products (brand or generic) currently available. Physicians make prescribing decisions that are not always based on evidence (Vioxx being the most visible). Medical literature quality is inconsistent; editors and reviewers can lack critical appraisal skills.

Persistency/compliance by patients

- Patients not taking medications as directed by their provider.
- Patients either not getting the expected result or not getting the medication requested

Medication safety

- Post marketing surveillance is weak
- Most adverse events are not known until a medication has been on the market for approximately seven years

Information transparency for patients

- Patients are not aware of pricing differences for different medications within a class, the reasons a medication is not on a formulary, side effects of various products used for the same medical reason(s).
- Patients are more likely to hear marketing sound bites from manufacturers than plans
- Evidence-based information needs to be shared with patients to improve their understanding of the rationale for generic and therapeutic substitution

Pricing transparency for groups

- Education of groups/group administrators/benefit committees to improve understanding of how spread pricing, lowest net cost, rebate guarantees, generic utilization, and administrative fees by PBMs obfuscate the real cost of drugs.

Appendix 4

Puget Sound Health Alliance Statement Adopted by the Rx CIT on May 4, 2006 Regarding Pharmaceutical and Sales Representatives in Practice Locations

The Puget Sound Health Alliance strongly recommends that providers and provider groups not meet with pharmaceutical and sales representatives in practice locations. The Puget Sound Health Alliance encourages providers to adopt policies that significantly limit or eliminate access of pharmaceutical and sales representatives in clinic or hospital locations. This limitation of access should include distribution of food, gifts, branded office supplies, drug promotional materials, and pre-printed prescription pads.

Supporting Statement:

The Puget Sound Health Alliance recognizes the important role that pharmaceutical companies play in the areas of research, drug development, and education. It is the intent of the Alliance to partner closely with pharmaceutical companies, along with its other constituents in the health plan, provider and purchaser communities, when that partnership supports the Alliance's overall goals of improving quality and reducing health care costs in the 5-county area of Puget Sound.

The Puget Sound Health Alliance is committed to supporting the practice of medicine in the best interest of patients and on the basis of the best available evidence regarding the wide range of available options, rather than on the basis of research presented with the ultimate goal of sales or promotion of a specific drug. The pharmaceutical industry estimates that it spends in excess of \$5 billion a year on marketing directly to physicians. Generally, it is the job of pharmaceutical and sales representatives to market specific products, not necessarily to provide unbiased information on the efficacy and availability of the full range of drugs available in the market, including generic equivalents (when available) which often cost substantially less for both the patient and payer. There are other ways to get evidence-based information to physicians about the availability and efficacy of drugs, e.g., The Medical Letter, FDA Center for Drug Evaluation and Research, Pharmacy and Therapeutics Committees in clinics and at the State level, etc.

Therefore, it is the position of the Puget Sound Health Alliance that the presence of pharmaceutical and sales representatives in practice locations with direct contact with physicians runs counter to the goals of improving quality and reducing health care costs.

Note: The above recommendation was subsequently revised by the QIC based on recommendations from the Alliance Consumer Advisory Group to make the terminology more understandable to the average consumer. The substance of the recommendation was not changed. The revised version of the recommendation was sent to the Board for approval on May 30, 2006.

Appendix 5

Puget Sound Health Alliance Statement Adopted by the Rx CIT on May 4, 2006 Regarding Use of Pharmaceutical Samples in Practice Locations

The Puget Sound Health Alliance strongly recommends that providers and provider groups not utilize pharmaceutical samples in their practices.

Background Statement:

Typically, pharmaceutical samples are distributed to patients directly by providers within the context of an office visit, rather than through a formal dispensing process. Handing out samples of medications degrades overall quality of care by not allowing for proper documentation and tracking of medications being taken by each patient and the related safety checks (e.g., to protect against drug interactions, follow-up in the event of a drug recall, etc). Distributing samples directly from the provider's office removes the pharmacist from the medication management process which often includes patient education about side effects and possible interaction with other medications being taken by the patient. The availability of samples can put providers in a difficult position where they may feel pressured to provide a sample medication that would not normally be the first choice for a given patient, simply because the drug sample is free to the patient. As well, when used inappropriately, the use of brand samples may result in patients receiving medications that are more expensive than a generic equivalent that is just as effective.

In clinics and other practice settings which serve low-income patients for whom the cost of pharmaceuticals is a significant barrier, the practice of distributing drug samples still risks lower quality care. Instead, the Alliance encourages alternative methods of addressing the cost of prescription drugs, such as streamlining and expanding programs that provide free or reduced-price generic and brand-name medications, via a prescription as determined by the provider, and through a formal dispensing process to patients who qualify based on income.

The Puget Sound Health Alliance is committed to supporting the highest quality in medical practice. Therefore, it is the position of the Puget Sound Health Alliance that physicians and physician groups not utilize pharmaceutical samples in their practices.

Note: The above recommendation was subsequently revised by the QIC based on recommendations from the Alliance Consumer Advisory Group to make the terminology more understandable to the average consumer. The substance of the recommendation was not changed. The revised version of the recommendation was sent to the Board for approval on May 30, 2006.