Appendix C-1

Summary Report Effect of Second Opinion Review on Attention Deficit Hyperactivity Disorder (ADHD) Medication Prescribing in a Medicaid Insured Population

SUMMARY REPORT
EFFECT OF SECOND OPINION REVIEW ON ATTENTION DEFICIT HYPERACTIVITY DISORDER (ADHD) MEDICATION PRESCRIBING IN A MEDICAID INSURED POPULATION

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This report details record review activity and outcomes of a second opinion review process on ADHD medications including all stimulants and atomoxetine in Washington State Medicaid insured children and adolescents. This report is a contractual responsibility which summarizes the activities and outcomes of the review process with emphasis on the period since Seattle Children's Hospital (formerly Children's Hospital and Regional Medical Center) entered into a contract with the Department of Social and Health Services from March of 2008 through December 2008.

Washington State Medicaid has developed safety parameters for ADHD medications based on a process involving clinicians, community providers, consumer advocates and industry, which began in 2004, when the state Medicaid convened a mental health drug work group to discuss issues related to implementation of a preferred drug program, and make recommendations to improve quality and safety. Attendees included primary care physicians and child and adolescent psychiatrists, university researchers, drug company representatives, advocate groups, and Medicaid staff. The group developed a set of safety guidelines based on published scientific literature and utilization data such that when thresholds were exceeded, a second opinion record review would be required. The thresholds included age (< 5 years old), combination medication use greater than 30 days (≥2 ADHD drugs), and high doses (amphetamines or dexmethylphenidate >60 mg/day, methylphenidate or atomoxetine > 120mg/day; for newer brand named preparations Daytrana >30 mg/day or Vyvanse >70 mg/day). These guidelines served as the basis for second opinions and were discussed with the work group as new drugs came on the market.

First-time prescriptions exceeding the thresholds were not filled pending a record review. Prescribers were asked to send clinical records to Medicaid which forwarded to contracted second opinion centers. Second opinions decisions were based on the appropriate diagnosis and clinical justification contained in the medical chart notes and on an ADHD work sheet asking the prescribers for their prescribing rationale. Additional information was obtained via phone consultation between the second opinion physician and prescriber.

Washington Medicaid initially contracted with three children's medical centers in Seattle, Tacoma, and Spokane, and their child and adolescent psychiatrists or developmental pediatricians to conduct second opinions via record reviews. In many cases, the second opinion provider and the prescriber had a phone consultation when a question arose from the record review concerning a change in medication. While the thresholds were generally adhered to by the reviewers providing the second opinion, it was understood that clinical judgment and well documented symptom relief as well as safety would confirm the medical necessity for stimulant use in the very young, at high doses, and/or with long term combination use.

In the first phase of data collection from May 2006 to April 2006 information was obtained from the Washington State Medicaid payment system, which contains patient information used to characterize utilization, demographics, and costs. Data on second opinion outcomes were obtained through collection of the ADHD worksheets with the prescribing rationale and second opinion physician's outcomes (approval, denial and alternatives). Average daily costs (ADC) were calculated based on the prescribed dose, frequency noted on the prescription, and unit cost paid to pharmacies that included federal rebates.

Results from the review from inception in May 2006 to April 2008 were that 5.35% of ADHD prescriptions exceeded safety thresholds with a 3.0% change in the population stemming from 1032 second opinions requests. Of those, 576 (56%) resulted in a prescription adjustment. Of the prescriptions adjusted, 322 (37%) were from primary care physicians, 86 (28%) were from psychiatrists, 54 (38%) were from nurse practitioners (ARNP), and 21 (38%) were from physician assistants. Second opinions reduced utilization in children less than five (23%), use of high dose (53%) and use of combinations (44%) when the pre and post periods were compared. The review process resulted in a savings of $1.2 million with 798 fewer patients exceeding safety thresholds, a 10:1 return over administrative costs.

Washington States Medicaid enrolls ~960,000 clients with 60% in managed care and 40% fee-for-service program (FEE-FOR-SERVICE). The majority of children are in managed care programs (80%); however, many of the children with the most severe mental health issues are enrolled in FEE-FOR-SERVICE (e.g. foster care, SSI, and developmental disability). At the beginning of the Second Opinion program in 2006 there were 135,501 children

enrolled. In the population of ADHD medication users, 1,317 (19.1%) were less than age five years, 788 (3.5%) had more than one ADHD medication prescribed, and 285 (4.6%) were on doses above our safety thresholds, including 7 children less than age 5 years on higher doses.

In the period between May 2006 to April 2008, out of 19,444 ADHD prescription requests, 1032 (5.3%) exceeded the age, dose, or combination thresholds. In 456 (44%) expert second opinion reviews the initial treatments were continued. The remaining 576 (56%) had prescriptions adjusted including lowering dosages, discontinuing the ADHD medication in younger children, and/or simplifying combination therapy to mono-therapy. In 276 cases, (27%) the prescriber adjusted the prescription request when the records were requested, and a peer review was not performed. In 154 (15%) cases the providers did not respond to a record request, and Medicaid authorized the previous prescription that was within the safety parameters (i.e. the previous ADHD drug prescription met safety criteria whereas the new prescription exceeded the threshold). In 108 (10%) the prescription was not indicated based on the second opinion, and in 38 (4%) of clients were no longer eligible for Medicaid coverage (i.e. the patient moved, family switched to other insurance, or no longer financially qualified for Medicaid) during the second opinion process.

We evaluated prescription histories for patients whom providers did not respond to a record request and who wrote a prescription exceeding the safety thresholds to determine whether patient had unintended outcomes related to prescription disruptions. In all but 8 patients (0.8%) the pharmacy system recorded continuation of an ADHD drug below the thresholds. In those 8 patients, we noted an atypical anti-psychotic (AAP) was prescribed within 60 days of the second opinion record request and no previous history of AAP use. We recorded no unplanned psychiatric hospitalizations and only one ER visit resulted from a medication lapse were noted in a claims review for clients exceeding the thresholds. Finally, we examined legal actions as a consequence of medication changes. In Medicaid a client may challenge any medication denial via an administrative appeal in a Fair Hearing. We recorded 33 requests for a fair hearing, two of which heard by an administrative law judge, and in each case the agency's denial was supported.

We evaluated overall cost and utilization outcomes for ADHD prescription requests as well as those exceeding the safety thresholds in the pre and post periods of our second opinion process. In Medicaid, overall users of stimulants

decreased by 2.2% while the overall costs increased $3.02 million (16.5%) from the pre (2004-6) to the post periods (2007-8). In the population exceeding the threshold there were 798 fewer users with a difference in overall expenses of $1,185,401 comparing pre and post periods. The expert opinion costs were $118,125, at $225 per review, resulting in a return on investment of 10:1. Overall, the per-user-per-month (PMPM) costs increased from $222 to $252 (13.5%). There was a consistent trend toward fewer users of stimulants above the thresholds high doses and combination therapies between the pre and post periods. Patients in the foster care programs exceeding the thresholds had similar reductions in users while overall utilization of stimulants increased.

In an effort to optimize the second opinion review process and to improve reliability in March 2008 the contract was shifted to a single site with reviews done by child and adolescent psychiatrists at Seattle Children's Hospital all of whom are on the faculty in the Division of Child and Adolescent Psychiatry, Department of Psychiatry and Behavioral Sciences, University of Washington School of Medicine.

During the period from March 1, 2008 to December 1, 2008 there were a total of 199 reviews. Of those, there was a recommendation for no change in drug therapy in 165 reviews. In 30 reviews there was a recommendation for a change in ADHD medication therapy treatment. In 4 cases there was a recommendation for a direct clinical consultation with a direct examination of the child and family. (Table I)

In the period of March 1, 2008 to December 1, 2008 the review group met monthly to promote quality control and reliability in the review process. To improve the specificity of the review process and to enhance relationships with providers a decision was made to have direct discussion by phone between providers and reviewers for every review if possible. Case reviews conducted by one of the reviewing child and adolescent psychiatrists were brought to the review team's monthly meeting for purposes of promoting optimal, uniform and reliable review of cases. In these monthly meetings there also were several recommendations to streamline the review process and to respond to comments and concerns expressed by community providers. Refinements were made in some of the individual standards which led to reviews. For example, in cases in which a provider chose to prescribe more than one ADHD medication class at once a process was developed whereby a provider could provide in writing a rationale for that clinical recommendation including documenting that a child had had individual monotherapy trials of each of the

two stimulant classes (amphetamine and methylphenidate) as well as atomoxetine, which were not of benefit to the child. In those instances the request would be authorized without a formal review.

Other recommendations from the second opinion review group to DSHS were to be as responsive in timely a fashion as possible to provider and patient concerns implementing as quickly as possible the recommendations of the review process.

In 2008, an anonymous questionnaire was created by the second opinion review team to review provider experience with the review process and was sent by mail to each of the 156 prescribers who had a second opinion review conducted in the period of March 2008 to December 2008 asking whether the ADHD medication second opinion program had a clear purpose, if the reviewers were clear in their opinions, and if customer services were timely and convenient. The respondents indicated that the second opinion program had a clear purpose (87%), the reviewers were clear in their opinions (95%), and customer services timely and convenient (87%). No untoward patient outcomes were reported. (Table II)

Members of the review group were instrumental in the development of the next phase of the psychotropic medication practice for Medicaid insured children and adolescents in the state of Washington with the extension of the review process to include all other psychotropic medications including atypical antipsychotic medications, mood stabilizers, antidepressant medications and anxiolytic medications. As was described above with regard to the process employed to set standards with regard to ADHD medication this was an iterative process which reviewed best practices in each of the medication groups identify optimal dosing strategies stratified by age. Decisions were made with regard to how many psychotropic medications could be prescribed concomitantly before a review was put into a place. The following criteria were established as a result.

Reviews will occur:

(1) if two or more antipsychotic medications were concomitantly prescribed for longer than 60 days

(2) If three or more concomitant mood stabilizers were prescribed for a mental health diagnosis after 60 days

(3) If five or more psychotropic medications were prescribed concomitantly after 60 days

(4) There were established for dosing of atypical antipsychotic medications, stratified by age

Subsequent to the creation of these standards, the second opinion review team was instrumental in the development of a community questionnaire which was sent to all of the Child and Adolescent Psychiatrists in the state of Washington as well as all of the Registered Nurse Practitioners with expertise and credentials allowing them to prescribe psychotropic medications to children and adolescents asking them to comment upon the standards established for the next phase of the review process. In general, as reflected in Table III, there was agreement with the criteria, although that was not uniform.

SUMMARY:

We describe a statewide effort to monitor safety threshold in ADHD medication prescriptions in a Medicaid population. Our findings indicate that administrative processes can coexist and balance the risks of overuse with the benefits of unique prescribing circumstances. Community providers, drug companies and the medical associations generally supported the program, providing letters of support for second opinions to the agency prior to program start. The program was developed in a transparent manner with all interested stakeholders invited to program development discussion. Reviews were done by community experts rather than within the Medicaid program.

Statewide, approximately 5 % of prescriptions exceeded safety thresholds. Since inception of the review process, a substantial percentage (56%) were revised based on the second opinion process, either by expert review or attention to the safety thresholds. This continued in the current reporting period of March 1 through December 1, 2008. A very small number, with minimal to no clinical relevance, of unintended consequences (i.e. medication disruption) were noted using our claims system. We found that both PCP and mental health professionals prescribed above thresholds. Across prescriber types the second opinion process found some prescriptions not medically indicated, with mental health professionals having a lower rate of reversals. Experience overtime was that the percentage of cases in which medications was changed as a result of the formal review process was fairly consistent, with changes in medication required between May 2006 and March 2008 by virtue of the formal review in 19% versus 16 % in the period of March to December 2008. The overall rate of prescription adjustment of 56% was the result of the entirety of the review process. For example 27% of prescribers adjusted doses after they were notified that a review was required and records were requested, without a formal second opinion review.

During the program development, prescribing data were shared with a group of community mental health professionals, psychiatrists and advocates in a mental health workgroup, which allowed a consensus for thresholds and the process of second opinions to unfold. Program data were shared throughout the program life cycle. Program issues were dealt with using the advisory committee, second opinion experts and community input. Although opinions concerning where to set safety thresholds varied widely, the research literature helped forge a consensus in the group. Although mental health professionals were less likely than primary care providers to have an ADHD prescription reversed by a second opinion the attribution of care, regional variation, and co-morbidity issues makes it difficult to determine absolute rates of variation between mental health and primary care providers.

In the analysis of cost and utilization trends the program appeared to decrease the number of prescriptions over the safety thresholds. This resulted in cost savings that were ten-fold the administrative costs for the second opinion program. We also evaluated and found little evidence that providers were bypassing the second opinion processes such as by prescribing atypical anti-psychotics for treatment of ADHD.

There were many hurdles implementing the second opinion program. First, pharmacy systems have difficulty recognizing differing utilization programs (e.g. differing prior authorization criteria in health plans) especially ones requiring the prescriber to submit clinical documentation prior to the pharmacist dispensing the medication. Second, this program was often confused with other prior authorization programs used by Medicaid contracted health plans with differing formularies from the FEE-FOR-SERVICE preferred drug list. Some of this was due to state administrative rules, coverage and coordination of medical benefits between contracted health plans, FEE-FOR-SERVICE rules, and the contracted mental health programs. In addition, there were large hurdles to ensure optimal customer service and turn around times from a program requiring second opinion experts to conduct reviews in a timely manner. These have been, and continue to be, efforts to improve and streamline this process.

The claims data do not address other unintended outcomes including patient expectations, provider time for phone calls, and the added complexity to an already over burdened public medical system. New contracts and payments to the prescribers seeking a second opinion are planned to hopefully reduce these issues. As prescriptions were changed without second opinion review we do not know the clinical circumstances or the rationale for the small number of cases in which ADHD medications over one of the thresholds were discontinued and an atypical

antipsychotic medication was prescribed. The program was limited to the fee-for-service Medicaid population, albeit this population had all the foster care children and most of the disabled child population.

CONCLUSIONS:

A statewide second opinion process reduced outlier ADHD medication practices and was cost effective. The Washington Medicaid second opinion program reduced combination ADHD therapies, dosing above recommended clinical and FDA standards, and stimulant prescriptions to clients younger than 5 years old. In addition, the administrative controls and second opinions gave the community some insight on prescription practices and how to reduce prescribing variance. The second opinion program high-lighted a large amount of prescription variation in the foster care population. Subsequent analysis has shown regional prescribing variation in prescribing. Further analysis and meetings with the community are ongoing to understand the differing prescribing practices. These data help guide future efforts to improve quality of care and reduce variation in prescribing practices. The second opinion program has shown that public agencies can work closely with communities to mix safety controls and provider autonomy. Closer inspection of programs and research on client outcomes beyond specific drug classes are needed including prescribing variation, use of other drugs, accuracy of diagnosis, and outcomes beyond the medical claims system.

To this end, the program has demonstrated a proof of concept such that legislative action now allows these administrative controls be extended to children prescribed atypical anti-psychotics and to measure multiple outcomes. This statute requires Medicaid and a university to measure not only prescription outcomes but also long term outcomes (e.g. symptom reduction, permanency of placement for youth in foster care, school performance, graduation rates, juvenile justice activity, and overall health benefits). The next phase of second opinion reviews of psychotropic medication prescription, including atypical antipsychotic medications, in Washington State Medicaid insured children and adolescents will formally begin in March, 2009.

To date we strongly believe that the standards set and effects of the second opinion review have resulted in safer and more effective care for Medicaid insured children with ADHD treated with medication. It is anticipated that the

next phase, extending to all psychotropic medication, will further promote adherence to evidenced based practice and improve safety and effectiveness of treatment of vulnerable children with mental health disorders.

Table I

Medication Reviews Completed from March, 1 2008 – December, 1 2008

Total Reviews=199

Reviews resulting in a recommendation for no change in drug therapy	Reviews resulting in a recommendation for a change in drug therapy	Reviews completed resulting in a recommendation for a clinical consultation
165	30	4

Table II

ADHD Drug Utilization Review Program Survey Results

N= 23

Question	Yes	No	No Response
Was the purpose of the review clear prior to the review?	20	3	0
If no, was it made clear by the reviewer?	5	0	18
Was scheduling the review timely and convenient?	20	3	0
Was the reviewer's final opinion explained clearly?	22	1	0
How useful was the review process?	5	4	14
To what extent do you agree with the following statements:			
It is important for 2nd opinion reviews to be conducted to promote adherence to the best practice parameters	6	3	14
It is important that efforts are taken to reduce variance in prescribing practices for mental health medications in WA	7	3	13

Table III
Survey Results of Clinician Reactions to Proposed Broader Psychotropic Medication Standards

N=161 distributed; 33 responses

Threshold for 2nd opinion review

Questions	Strongly Agree	Agree	No Response	Disagree	Strongly Disagree
Absence of any DSM-IV diagnosis in the child's claim record	20	6	2	2	2
Five or more psychotropic medications prescribed concomitantly after 60 days	14	13	2	1	3
Two or more concomitant medications after 60 days	8	8	6	5	5
Three or more concomitant stabilizer medications for a mental health diagnosis	16	9	5	0	3
The prescribed psychotropic medication is not consistent with appropriate care for the patient's diagnosed mental disorder or with documented target symptoms usually associated with a therapeutic response to the medication prescribed	11	14	6	0	2
Psychotropic poly-pharmacy for a given mental disorder is prescribed before utilizing psychotropic mono-therapy as new start noted from pharmacy claims data	12	9	5	5	2
Psychotropic medications prescribed for children of very young age, including children receiving an antipsychotic less than five years of age	12	13	4	0	3
	Yes	No			
I agree with the thresholds shown below regarding acceptable does by patient age range	18	13			
I feel that treatment guidelines developed by the Pediatric Advisory Group were generally followed by prescribers in WA, then care for children in our state overall will be improved	6	3	7	9	8