Year 4 Evaluation of Use of Selected Psychotherapeutic Drug Profiles in Florida's Developmental Disabilities Home and Community-Based Services Waiver April 2003 – December 2004

March 24, 2006

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Sponsored by the Delmarva Foundation and the State of Florida, Agency for Health Care Administration, Under Contract #M0225, "Statewide Quality Assurance Program for the Florida Home and Community-Based Services Waiver."

Introduction and Objectives

This study is the fourth in a series of annual studies that analyzes pharmacy claims data from the Florida Medical Management Information System (FMMIS) and consumer demographic data from the Department of Children and Families/Agency for Persons with Disabilities (APD), Allocation, Budget and Contract (ABC) Control System ¹ to determine the use of psychotherapeutic medications in Florida's population of persons with developmental disabilities who receive services from the Developmental Disabilities Home and Community Based Services (DD HCBS) Medicaid Waiver. These studies have been conducted as part of the Florida Statewide Quality Assurance Program (FSQAP), a multi-year review of services and outcomes for consumers receiving services under the waiver program. The Delmarva Foundation administers this project through a contract with the Florida Agency for Health Care Administration (AHCA). Medstat is a partner with the Delmarva Foundation, providing data reporting and analytic support for this project through a subcontractual agreement.

The studies in Years 1 and 2 quantified the use of psychotherapeutic medications in the waiver population and identified seven medication profiles for ongoing monitoring that carry increased risk for complications (Appendix A). In October 2003, Medstat and Delmarva began producing quarterly Psychotherapeutic Drug Use Reports for each APD area of DD HCBS waiver eligible persons living in paid residential settings who had pharmacy claims for one or more of the seven medication profiles. These quarterly reports were provided to the Area Medical Case Management Teams to assist them in providing medical oversight for persons in paid residential settings.

The Year 3 psychotherapeutic study narrowed the population studied to persons in paid residential settings who had pharmacy claims for one or more of the seven medication profiles. The study examined results using five quarters (2Q 2003 through 2Q 2004) of APD Area Psychotherapeutic Reports, with the goal of identifying potential trends or changes in psychotherapeutic prescribing patterns over time, both at the state level and across APD areas. Findings from the Year 3 study include:

- The number of consumers in each of the seven medication profiles remained relatively consistent over time.
- Approximately one in five consumers who stayed on a profile for more than two quarters showed evidence of a medication review in the six months following the first appearance of the profile.
- There was considerable variation in drug profiles across APD areas.

This fourth annual psychotherapeutic study updates the profile trends for rates and duration of each drug profile across all seven quarters of analysis data (2Q 2003 through 4Q 2004). The study also follows up on several questions raised by the third report. That report indicated that overall medication review rates for consumers fitting drug profiles were quite low. This study

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¹ The pharmacy claims include the date and quantity dispensed, the National Drug Code (NDC) for the medication prescribed, and the prescribing and dispensing providers. Demographic data about individuals served through the DS HCBS Waiver were available through the ABC database, including primary disability, APD area and residential setting. Consumers with medication reviews were identified using medical claims data in FMMIS. First DataBank® therapeutic classes were used to identify FMMIS pharmacy claims with the drug profiles studied (refer to Appendix A for a complete listing of the medications in each profile).

examines medication review rates in more detail by examining review rates across different characteristics of the population. The third study also indicated more consumers fit the two or more anti-psychotic drug profile than any other profile. Given the large percentage of consumers who fit this profile, this year's study examines prescribing patterns for anti-psychotic drugs by analyzing variations in prescription rates for different anti-psychotic drugs and combinations of drugs across all seven quarters.

Specific goals for this analysis include:

- Update trends pertaining to frequency and duration of drug profiles and further explore differences among the APD areas in psychotherapeutic drug profiles
- Improve the accuracy of identifying consumers in residential settings using a data field recently added to the database and assess the impact on outcomes of changing the data field
- Assess the frequency of medication reviews in more detail overall, by profile, by residential setting, by time period, and by APD area
- Examine prescribing patterns for anti-psychotic drugs in more detail by quarter, by duration of prescription, by profile status, and by dual drug combinations.

Definitions

| Study period | Dates of service from April 1, 2003 through December 31, 2004 Note: Medstat did not receive eligibility data for the October 2004 – December 2004 time period. An analysis of tagging between eligibility and claims data was performed and tagging was extremely high. The impact of the lack of eligibility for 4Q04 is minimal, since this population is highly stable. |
|---------------------------------|--|
| Consumers | Number of consumers is unique within each quarter or profile; if a consumer has more than one profile in a quarter, he/she is counted only once. Likewise, if a consumer is in the same profile for more than one quarter, he/she is counted only once for the overall time period. |
| APD area | If a consumer resides in more than one APD area during the study period, the last APD area in which he/she resides is used for totals over all quarters. |
| Two or more anti- psychotics | Consumers with pharmacy claims for the anti-psychotics Mellaril and Clozaril are included in this profile if they have at least one other antipsychotic medication in a given month (i.e., Clozaril and Abilify). |
| Residential care setting | If a consumer resides in more than one type of residential care setting during the study period, the last setting in which he/she resides is used for totals over all quarters. |

Study Design

Profile Background

In 1998 a group of international experts developed guidelines for anti-seizure and psychotropic medication usage in persons with developmental disabilities and mental health/behavioral problems. This publication, entitled The International Consensus Handbook: Psychotropic Medications and Developmental Disabilities, identified the following multiple medication profiles that could put individuals with developmental disabilities at increased risk for complications and/or decreased quality of life:

- Two or more sedative/hypnotic medications concurrently
- Two or more anti-psychotic medications concurrently
- Two or more selective serotonin reuptake inhibitors (SSRI)
- Phenobarbital while taking another anti-seizure medication. This combination
 presents high potential for side effects and may decrease phenobarbital metabolism
 and the effectiveness of the other medications.

Several profiles were added to these four. Clozaril was added as a new profile after the first year. Lithium and Mellaril were included in the first study even though they were not part of the Consensus recommendations.

- Clozaril (generic name clozapine). Clozaril is an atypical anti-psychotic used for the treatment of schizophrenia. This drug should be the last choice for treatment of this condition because it can:
 - 1) lower the seizure threshold;
 - 2) cause Neuroleptic Malignant Syndrome (fever, respiratory distress, tachycardia, convulsions, diaphoresis, hypertension, hypotension, pallor, tiredness; and
 - 3) cause agranulocytosis, a potentially lethal disorder of the white blood cells.

Because of the risk of agranulocytosis, anyone who takes Clozaril is required to have a complete blood count (CBC) once a week for the first six months at the initiation, biweekly thereafter and weekly for the four weeks following discontinuation.

- Lithium. Lithium is most often used for the treatment of manic/depressive (bipolar) and depressive disorders. Lithium levels should be monitored every three months and a periodic EKG obtained for consumers over age 40 or with cardiac involvement.
- Mellaril (greater than 25 mg). Mellaril (generic name thioridazine) is a typical antipsychotic. According to a warning posted on the U.S. Food and Drug Administration (FDA) website, it should be reserved for use in the treatment of schizophrenic

patients who fail to show an acceptable response to adequate courses of treatment with other anti-psychotic drugs because it:

- 1) prolongs the QTc² interval, in a dose related manner, and has been associated with life-threatening arrythmias and sudden death;
- 2) is contraindicated with fluvoxamine (Luvox), propanolol (Inderal) and fluoxetine (Prozac); and
- 3) can cause Neuroleptic Malignant Syndrome (see *Clozaril* above).

Consumers with this profile should have an annual EKG and monitoring of serum potassium and magnesium.

Population Characteristics

Based on demographic information available in FMMIS and the ABC databases, two demographic characteristics were used to define the population for the analyses:

- Developmental Disabilities Home and Community Based Services Medicaid Waiver
- Residential Setting

Analyses include claims data only for persons who receive services from the Developmental Disabilities Home and Community Based Services Medicaid Waiver and reside in a paid residential setting. Except where otherwise noted, consumers living in the family home and independent/supported living arrangements were excluded from analyses³. Past quarterly APD area Psychotherapeutic Reports have used the REC_SETT field from the ABC database to identify a consumer's recommended *residential setting*. Residential settings were grouped into the following broad categories for analyses (refer to Appendix B for a complete listing of the settings included in each category):

- Small Group Home
- Large Group Home
- Foster Home
- All Other

A new field, SBPG_C1, was added recently to the ABC database, which reflects more accurately where the consumer actually resides. The SBPG_C1 field was used to identify *residential setting* in all analyses for this study⁴.

² The QTc is a measure of the time between the beginning of the Q wave and the end of the T wave in the heart's electrical cycle, correcting for heart rate.

³ Consumers living in the family home or an independent/supported living arrangement are excluded from analyses because they are not required to receive an annual medication review. Consumers living in paid residential settings are required to receive an annual medication review.

⁴ Analyses assessing the impact of the new, as compared to old, measure for place of residence on the characteristics of consumers included in analyses show that using the new measure has a minimal impact on the number of consumers fitting each drug profile who are included in the analyses.

Results

<u>Updated Psychotherapeutic Drug Profile Trends</u>

Frequency of Psychotherapeutic Profiles by Quarter

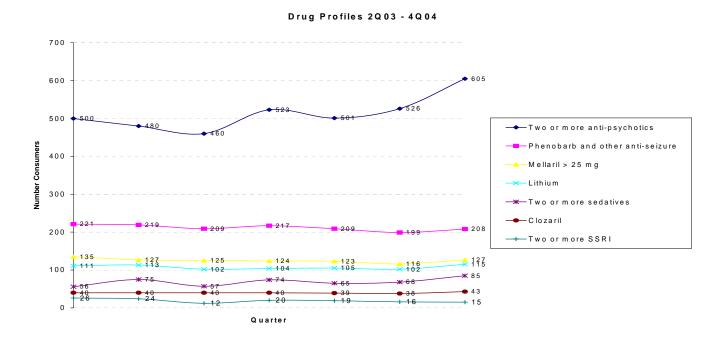
The overall number of unique consumers with profiles per quarter has increased since the beginning of the study period in 2Q 2003, from 950 consumers to 1,065 consumers in 4Q 2004 (Table A). In addition, the number of consumers who fit the Two or More Anti-Psychotics drug profile has increased during the course of this study. The number who fit the Mellaril and Phenobarbital and Other Anti-Seizure profiles has shown a moderate decline while the number who fit Two or More Sedatives has fluctuated up and down over the total period. The other drug profiles show relatively stable trends from 2Q 2003 to 4Q 2004.

Table A
Unique Consumers by Psychotherapeutic Drug Profiles by Quarter

| DRUG PROFILES | 2Q03 | 3Q03 | 4Q03 | 1Q04 | 2Q04 | 3Q04 | 4Q04 |
|---|------|------|------|------|------|------|-------|
| Two or more anti-psychotics | 500 | 480 | 460 | 523 | 501 | 526 | 605 |
| Phenobarb and other anti-seizure | 221 | 219 | 209 | 217 | 209 | 199 | 208 |
| Mellaril > 25 mg | 135 | 127 | 125 | 124 | 123 | 116 | 127 |
| Lithium | 111 | 113 | 102 | 104 | 105 | 102 | 115 |
| Two or more sedatives | 56 | 75 | 57 | 74 | 65 | 68 | 85 |
| Clozaril | 40 | 40 | 40 | 40 | 39 | 38 | 43 |
| Two or more SSRI | 26 | 24 | 12 | 20 | 19 | 16 | 15 |
| Total Unique Consumers With Profiles | 950 | 941 | 893 | 973 | 940 | 952 | 1,065 |

Figure 1 shows a graphical representation of the number of consumers by psychotherapeutic drug profile by quarter.

Figure 1 – Unique Consumers by Psychotherapeutic Drug Profile by Quarter



Frequency of Consumers with Psychotherapeutic Profiles

As shown in Table B below, there were 2,016 unique consumers with drug profiles during the seven quarters of analysis. The Two or More Anti-Psychotics drug profile is the most common drug profile (n = 1,065) among consumers in the residential setting, followed by Phenobarbital and Other Anti-Seizure (n = 265).

Looking at the percentage change between 4Q03 and 4Q04, the Two or More Anti-Psychotics drug profile increased significantly (+ 31.5%), while the number of consumers matching the Phenobarbital and Other Anti-Seizure drug profile decreased slightly (- 0.5%). There was also a dramatic percentage change in the number of consumers who fit the Two or More Sedatives drug profile (+ 49.1%) between 4Q 2003 and 4Q 2004. However, the emphasis on the increase should be tempered by a recognition that the number of consumers who fit this profile shows a great deal of fluctuation from quarter to quarter, as shown in Table A. The magnitude of the percentage change is in large part a result of the small number of consumers who fit this profile⁵.

⁵ Changes to very small numbers will produce a very large percentage change. For example, a change from 1 to 2 consumers is a 100% increase even though the increase involves only one person. Compare this to a change from

500 to 501 consumers. This also involves an increase of only one person, but it is a .2% increase.

Table B
Unique Consumers with Profiles Statewide between 2Q 2003 and 4Q 2004

| DRUG PROFILES | Total Unique Consumers w/Profile | Average Quarters Per Consumer | % Change, 4Q04 over 4Q03 |
|----------------------------------|---|-------------------------------------|--------------------------------|
| Two or more anti-psychotics | 1,065 | 3.4 | 31.5% |
| Phenobarb and other anti-seizure | 265 | 5.6 | -0.5% |
| Mellaril > 25 mg | 175 | 5.0 | 1.6% |
| Lithium | 154 | 4.9 | 12.7% |
| Two or more sedatives | 214 | 2.2 | 49.1% |
| Clozaril | 48 | 5.8 | 7.5% |
| Two or more SSRI | 95 | 1.4 | 25.0% |
| Total Number | 2016 | | |

On average, consumers tend to fit the Clozaril drug profile for the longest time period (5.8 quarters of the 7 quarters studied) and the Two or More SSRI drug profile for the shortest time period (1.4 quarters). Consumers' use of two or more sedatives concurrently also tends to be short in duration (2.2 quarters).

Distribution Patterns of Consumers by # of Quarters fitting Psychotherapeutic Profile

Table D displays the number of consumers fitting each profile over the seven quarters, by the number of quarters they matched the profile.

Table D
Number of Consumers on Psychotherapeutic Profiles
by Number of Quarters fitting Drug Profile

| Drug Profiles | 1 | 2 | 3 | 4 | 5 | 6 | 7 | Totals |
|----------------------------------|-----|-----|----|----|----|----|-----|--------|
| Two or more SSRI | 73 | 16 | 3 | 1 | 0 | 0 | 2 | 95 |
| Two or more sedatives | 118 | 37 | 15 | 12 | 8 | 13 | 11 | 214 |
| Two or more anti-psychotics | 374 | 156 | 98 | 74 | 67 | 88 | 208 | 1065 |
| Lithium | 26 | 15 | 12 | 8 | 4 | 15 | 74 | 154 |
| Mellaril > 25 mg | 31 | 13 | 8 | 11 | 13 | 6 | 93 | 175 |
| Phenobarb and other anti-seizure | 30 | 12 | 12 | 15 | 10 | 20 | 166 | 265 |
| Clozaril | 6 | 2 | 1 | 0 | 0 | 6 | 33 | 48 |

Looking at the psychotherapeutic profiles for all seven quarters, there were only 48 persons on Clozaril. Of these, 33 (68.8%) were on Clozaril for all seven quarters (see Figure 2 for the percentage distributions). In comparison, 1,065 persons were on Two or More Anti-Psychotics, with the largest percentage of persons fitting this profile for only one quarter (35.1%). However, there was also a sizeable group that fit this profile longer-term (approximately one in five consumers with this profile fit the profile for seven quarters).

Figure 2 graphically illustrates the duration that consumers fit each profile. Figure 2 shows that a small percentage of consumers fit the Two or More SSRI or Two or More Sedatives drug profiles for an extended period of time. However, we do see a slightly larger percentage of the population (approximately 15%) who fit the Two or More Sedatives drug profile for over a year.

Figure 2
Percent of Consumers who fit a Drug Profile by the Number of Quarters Fitting a Drug Profile

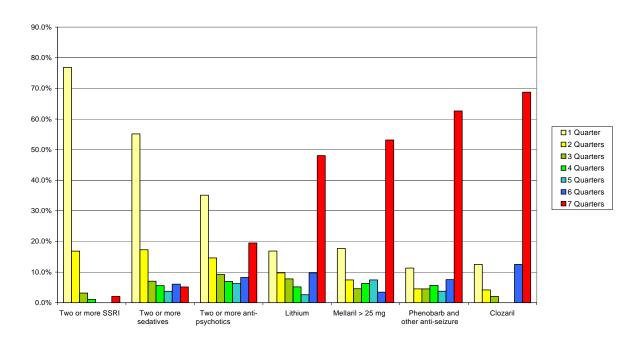


Figure 2 clearly shows that consumers tend to fit the following profiles for shorter periods of time (1 – 2 quarters): Two or More SSRI, Two or More Sedatives and Two or More Anti-Psychotics. In contrast, consumers tend to fit the Lithium, Mellaril >25 mg, Phenobarbital and Other Anti-Seizure, and Clozaril drug profiles for longer periods of time (over a year). The long duration associated with the Phenobarb and other Anti-Seizure profile may result from a seizure disorder diagnosis among consumers since individuals diagnosed with a seizure disorder usually require lifetime usage of an anti-seizure medication. Similarly, the length of duration for the Lithium, Mellaril, and Clozaril profiles could result from the difficulty of switching an individual to one of the newer psychotherapeutic medications once the person has taken one of the older psychotherapeutic medications like Lithium, Mellaril, or Clozaril for an extended period.

Medication Reviews

Medication Review Rate by Psychotherapeutic Profile

According to the requirements listed in the Developmental Disabilities Waiver Services Coverage and Limitations Handbook under Medication Review, the Waiver Support Coordinator (WSC) should request a medication review by a pharmacist for consumers in residential settings.

The Year 3 study found that a pharmacist's medication review was conducted for 17 percent of the consumers with a profile within six months after the time the specified drug(s) was dispensed.

Because medication reviews are required annually for the individuals in paid residential settings, the current analysis assessed the percentage of consumers in residential settings with psychotherapeutic drug profiles in calendar year (CY) 2004 who received a medication review (Table F). Overall, 26 percent of consumers with profiles in paid residential settings in that year had a medication review.

Table F
Medication Review Rate by Psychotherapeutic Profile
for Consumers with Drug Profiles in Paid Residential Settings in CY2004

| Review Rate by Profile | Consumers with Psychotherapeutic Profiles | Consumers with Medication Reviews | % of Consumers with Profile who had Medication Review |
|----------------------------------|---|--------------------------------------|---|
| Two or more anti-psychotics | 881 | 228 | 25.9% |
| Phenobarb and other anti-seizure | 243 | 56 | 23.0% |
| Mellaril > 25 mg | 154 | 50 | 32.5% |
| Lithium | 133 | 37 | 27.8% |
| Two or more sedatives | 170 | 34 | 20.0% |
| Clozaril | 46 | 24 | 52.2% |
| Two or more SSRI | 56 | 12 | 21.4% |
| Total | 1,683 | 441 | 26.2% |

Consumers fitting the Clozaril Drug Profile had the highest percentage of medication reviews during calendar year 2004, at 52.2 percent (Table F). Consumers fitting the Two or More Sedatives Drug Profile had the lowest rate of medication reviews during 2004, with a 20 percent compliance rate.

Medication Review Rate by Setting

For this year's study, we examined the frequency of medication reviews for all consumers with a pharmacy claim across all residential settings, including Family Home and Independent/Supported Living. For the entire population, the percentage of consumers with at least one medication review across all seven quarters of analysis was 21.1 percent, with the average for the paid residential care setting being slightly higher at 28.9 percent. Small Group Homes had the highest medication review rate -- 31.1 percent of consumers across all seven quarters. Among consumers in the Family Home setting, for which medication reviews are not required, 14.3 percent had a review during the seven-quarter period.

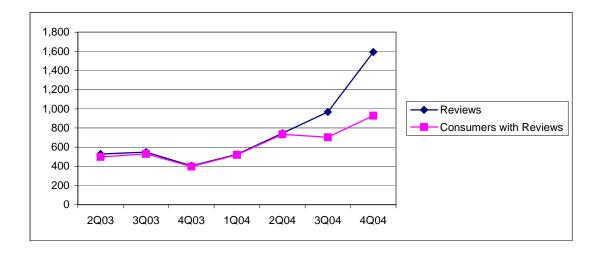
Table G
Medication Review Rate by Setting for All Consumers with a Pharmacy Claim

| Setting | Consumers w Pharmacy Claims during CY2004 | Consumers w Medication Reviews during CY2004 | % of Consumers with Pharmacy Claim who had Medication Review during CY2004 | Consumers w Medication Reviews in all 7 quarters | % Consumers with Medication Reviews in all 7 quarters |
|------------------------------|--|---|--|---|---|
| Independent/Supported Living | 1,772 | 350 | 19.8% | 456 | 25.7% |
| Family Home | 6,923 | 788 | 11.4% | 989 | 14.3% |
| Foster Home | 315 | 57 | 18.1% | 81 | 25.7% |
| Small Group Home | 3,305 | 809 | 24.5% | 1,028 | 31.1% |
| Large Group Home | 1,136 | 231 | 20.3% | 301 | 26.5% |
| All Other | 380 | 64 | 16.8% | 73 | 19.2% |
| Paid Residential Total | 5,136 | 1,161 | 22.6% | 1,483 | 28.9% |
| Total | 13,831 | 2,299 | 16.6% | 2,928 | 21.1% |

Medication Reviews for All Residential Settings by Quarter

Figure 3 shows that through 2Q04, the number of medication reviews stayed fairly constant. Between 4Q03 and 4Q04, medication reviews nearly quadrupled (from 405 medication reviews to 1,593 medication reviews), but this was largely due to an increase in the number of reviews per consumer, not the number of consumers with reviews.

Figure 3
Number of Medication Reviews and Consumers with Reviews by Quarter for Consumers with a Pharmacy Claim in All Residential Settings



In addition, Table H indicates the average number of medication reviews per consumer increased substantially in 3Q04 and 4Q04, to 1.38 and 1.71 respectively, with an average rate of 1.56.

Table H
Number of Medication Reviews and Consumers with Reviews by Quarter
for Consumers with a Pharmacy Claim in All Residential Settings

| Quarter | Medication Reviews | Consumers with Medication Reviews ⁶ | Average Reviews per Consumer |
|---------|-----------------------|---|------------------------------------|
| 2Q03 | 528 | 498 | 1.06 |
| 3Q03 | 549 | 530 | 1.04 |
| 4Q03 | 405 | 399 | 1.02 |
| 1Q04 | 525 | 520 | 1.01 |
| 2Q04 | 746 | 734 | 1.02 |
| 3Q04 | 968 | 704 | 1.38 |
| 4Q04 | 1,593 | 930 | 1.71 |
| Totals | 5,314 | 4,315 | 1.56 |

Distribution of Consumers by Number of Medication Reviews

Of all the consumers with a medication review in the past seven quarters (Table I), 57 percent had one medication review. Of the 43 percent who had multiple medication reviews, less than 1.5 percent of consumers had four or more medication reviews between April 1, 2003, and December 31, 2004.

Table I
Distribution of Consumers with Medication Reviews
by Number of Medication Reviews for Consumers with a Pharmacy Claim in
All Residential Settings from April 2003 to December 2004

| # of Medication Reviews during last 7 quarters | Consumers with Reviews | % of Total Consumers |
|--|------------------------|-------------------------|
| 1 | 1,938 | 57.0% |
| 2 | 1,071 | 31.5% |
| 3 | 341 | 10.0% |
| 4 | 45 | 1.3% |
| 5 | 5 | 0.1% |
| 6 | 1 | 0.0% |
| Totals | 3,401 | 100% |

Medication Review Rate by APD Area

Looking at the medication review rate by APD Area in 2004, APD Area 12 is performing the best with a rate of 46.3 percent (see Table J). APD Areas 3 and 4 follow with medication review

⁶ Individuals with a medication review in more than one quarter are counted multiple times in the total number of consumers with medication reviews.

rates of 39.1 percent and 29.6 percent respectively. APD Areas 1, 9 and 10 have the lowest rates of medication reviews in 2004 at 2.7 percent, 3.4 percent and 3.5 percent.

Table J
Consumers with Medication Reviews by APD area for Consumers with a
Pharmacy Claim in All Residential Settings
For CY2004

| | | | | | % Consumers with Medication Reviews that had |
|----------|------------------------------------|---|-----------------------------|---|--|
| APD area | All Psychotropic Consumers 2004 | Consumers with Medication Reviews | Total Medication Reviews | % Consumers with Medication Reviews | multiple Medication Reviews |
| 1 | 708 | 19 | 22 | 2.7% | 13.6% |
| 2 | 1,071 | 153 | 193 | 14.3% | 20.7% |
| 3 | 686 | 268 | 454 | 39.1% | 41.0% |
| 4 | 1,080 | 320 | 429 | 29.6% | 25.4% |
| 7 | 1,311 | 220 | 305 | 16.8% | 27.9% |
| 8 | 436 | 123 | 164 | 28.2% | 25.0% |
| 9 | 716 | 24 | 39 | 3.4% | 38.5% |
| 10 | 1,155 | 41 | 78 | 3.5% | 47.4% |
| 11 | 2,005 | 293 | 477 | 14.6% | 38.6% |
| 12 | 441 | 204 | 279 | 46.3% | 26.9% |
| 13 | 738 | 106 | 141 | 14.4% | 24.8% |
| 14 | 473 | 135 | 193 | 28.5% | 30.1% |
| 15 | 465 | 70 | 99 | 15.1% | 29.3% |
| 23 | 2,478 | 324 | 419 | 13.1% | 22.7% |
| Total | 13,763 | 2,300 | 3,292 | 16.7% | 30.1% |

The number of consumers with multiple medication reviews varies widely from 13.6 percent in APD area 1 to 47.4 percent in APD area 10, with an average of 30.1 percent of all consumers receiving more than one medication review in 2004.

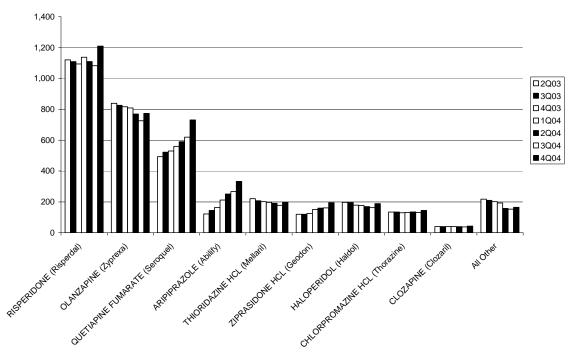
Prescribing Patterns for Anti-Psychotics

Prescribing Patterns for Anti-Psychotics by Quarter for Consumers in Paid Residential Settings

There was an increase in 4Q 2004 in the number of all anti-psychotic drugs prescribed. The newer drugs – Abilify, Seroquel and to a lesser degree, Geoden are being prescribed more often to consumers in the residential setting. Abilify, first approved in 2002, was approved in November 2004 for Acute Bipolar Mania. In addition, Seroquel was approved for Acute Bipolar Mania in January 2004 and Bipolar Disorder in August 2004.

Figure 4
Number of Drug Prescriptions for Paid Residential Consumers by Quarter

Residential recipients prescribed by quarter



Older drugs, such as Zyprexa, Risperdal, Haldol and Mellaril, were decreasing in frequency over 2003 and 2004, but showed an increase as well in 4Q 2004.

The decrease in the All Other category is primarily due to Mesoridazine, Besylate and Serentil being prescribed less often after the July 2000 warning from the FDA that Serentil was a last defense drug for schizophrenia, because of heart complications. Serentil (generic name: Mesoridazine Besylate) was prescribed until 2Q 2004, then had nearly no prescriptions for this drug during 3Q 2004 and 4Q2004.

Prescribing Rate of Anti-Psychotics by Quarter

Table L Number of Paid Residential Consumers with a Prescription for an Anti-Psychotic

| | 2Q03 | 3Q03 | 4Q03 | 1Q04 | 2Q04 | 3Q04 | 4Q04 |
|--------------------------------|-------|-------|-------|-------|-------|-------|-------|
| RISPERIDONE (Risperdal) | 1,121 | 1,109 | 1,094 | 1,138 | 1,110 | 1,083 | 1,210 |
| OLANZAPINE (Zyprexa) | 839 | 826 | 817 | 809 | 770 | 726 | 774 |
| QUETIAPINE FUMARATE (Seroquel) | 493 | 522 | 530 | 560 | 590 | 620 | 731 |
| ARIPIPRAZOLE (Abilify) | 122 | 145 | 164 | 212 | 251 | 267 | 333 |
| THIORIDAZINE HCL (Mellaril) | 221 | 208 | 202 | 197 | 191 | 178 | 198 |
| ZIPRASIDONE HCL (Geodon) | 120 | 120 | 126 | 151 | 160 | 161 | 195 |
| HALOPERIDOL (Haldol) | 197 | 196 | 179 | 177 | 170 | 163 | 189 |
| CHLORPROMAZINE HCL (Thorazine) | 134 | 134 | 130 | 132 | 135 | 132 | 145 |
| CLOZAPINE (Clozaril) | 40 | 40 | 40 | 40 | 39 | 38 | 43 |
| All Other | 218 | 210 | 202 | 193 | 158 | 153 | 165 |

Of the top Anti-Psychotic drugs prescribed, Risperdal is prescribed most frequently across all quarters of analysis, followed by Zyprexa, and Seroquel. Clozaril shows the smallest number of prescriptions across all quarters.

Concurrent Anti-Psychotic Drug Use

Table M Concurrent Anti-Psychotic Drug Use for Paid Residential Consumers

| | | 2Q 2003 | | 4Q 2004 | | | |
|------------------------|---------------------------|--|---|---------------------------|--|---|--|
| Generic Drug Name | All residential consumers | Consumers with 2+ anti- psychotics | % of consumers using with other antipsychotic | All residential consumers | Consumers with 2+ anti- psychotics | % of consumers using with other antipsychotic | |
| RISPERIDONE | 1,121 | 215 | 19.2% | 1,210 | 267 | 22.1% | |
| QUETIAPINE FUMARATE | 493 | 182 | 36.9% | 731 | 261 | 35.7% | |
| OLANZAPINE | 839 | 205 | 24.4% | 774 | 196 | 25.3% | |
| ARIPIPRAZOLE | 122 | 73 | 59.8% | 333 | 132 | 39.6% | |
| HALOPERIDOL | 197 | 98 | 49.7% | 189 | 119 | 63.0% | |
| ZIPRASIDONE HCL | 120 | 53 | 44.2% | 195 | 89 | 45.6% | |
| CHLORPROMAZINE HCL | 134 | 72 | 53.7% | 145 | 76 | 52.4% | |
| THIORIDAZINE HCL | 221 | 64 | 29.0% | 198 | 59 | 29.8% | |
| HALOPERIDOL DECANOATE | 28 | 17 | 60.7% | 33 | 25 | 75.8% | |
| FLUPHENAZINE HCL | 45 | 25 | 55.6% | 36 | 16 | 44.4% | |
| PERPHENAZINE | 32 | 16 | 50.0% | 28 | 13 | 46.4% | |
| CLOZAPINE | 40 | 15 | 37.5% | 43 | 13 | 30.2% | |
| THIOTHIXENE | 27 | 10 | 37.0% | 22 | 12 | 54.5% | |
| FLUPHENAZINE DECANOATE | 13 | 10 | 76.9% | 10 | 9 | 90.0% | |
| HALOPERIDOL LACTATE | 7 | 5 | 71.4% | 11 | 8 | 72.7% | |
| TRIFLUOPERAZINE HCL | 16 | 6 | 37.5% | 9 | 7 | 77.8% | |
| LOXAPINE SUCCINATE | 10 | 5 | 50.0% | 8 | 6 | 75.0% | |
| ZIPRASIDONE MESYLATE | 0 | 0 | 0.0% | 2 | 2 | 100.0% | |
| PIMOZIDE | 2 | 2 | 100.0% | 5 | | 20.0% | |
| MOLINDONE HCL | 1 | 0 | 0.0% | 0 | 0 | 0.0% | |
| MESORIDAZINE BESYLATE | 37 | 14 | 37.8% | 1 | 0 | 0.0% | |

Both of the consumers taking Pimozide are also taking another anti-psychotic in conjunction with this drug. Fluphenazine Decanoate and Haloperidol Lactate consumers also show a high percentage (76.9% and 71.4% respectively) of additional anti-psychotic use, although all three of these drugs are taken by a small numbers of consumers. Molindone HCL (0.0%) (but this is only one person) and Risperidone (19.2%) show low concurrent anti-psychotic use.

Table N
Most Frequent Drug Combinations – 2Q03

| Top 15 combinations | 2Q03 | Consumers | % of Total |
|-------------------------------------|---------------------|-----------|------------|
| OLANZAPINE | RISPERIDONE | 45 | 9.0% |
| QUETIAPINE FUMARATE | RISPERIDONE | 45 | 9.0% |
| OLANZAPINE | QUETIAPINE FUMARATE | 31 | 6.2% |
| OLANZAPINE | THIORIDAZINE HCL | 26 | 5.2% |
| HALOPERIDOL | RISPERIDONE | 25 | 5.0% |
| CHLORPROMAZINE HCL | RISPERIDONE | 20 | 4.0% |
| CHLORPROMAZINE HCL | OLANZAPINE | 19 | 3.8% |
| RISPERIDONE | THIORIDAZINE HCL | 16 | 3.2% |
| ARIPIPRAZOLE | QUETIAPINE FUMARATE | 14 | 2.8% |
| HALOPERIDOL | QUETIAPINE FUMARATE | 14 | 2.8% |
| ARIPIPRAZOLE | OLANZAPINE | 11 | 2.2% |
| HALOPERIDOL | OLANZAPINE | 11 | 2.2% |
| CHLORPROMAZINE HCL | QUETIAPINE FUMARATE | 9 | 1.8% |
| ARIPIPRAZOLE | HALOPERIDOL | 8 | 1.6% |
| ARIPIPRAZOLE | RISPERIDONE | 8 | 1.6% |
| FLUPHENAZINE HCL | QUETIAPINE FUMARATE | 8 | 1.6% |
| Total Members with multiple anti-ps | 500 | | |

At the beginning of this study period, the two most common anti-psychotic drug combinations were Olanzapine – Risperidone and Quetiapine Fumarate – Risperidone, each accounting for nine percent of the consumers on two or more anti-psychotics.

Top 15 Drug Combinations at the End of Analysis

Table O
Most Frequent Drug Combinations – 4Q04

| Top 15 combinations | 4Q04 | Consumers | % of Total |
|---------------------|---------------------|-----------|------------|
| QUETIAPINE FUMARATE | RISPERIDONE | 67 | 11.1% |
| OLANZAPINE | QUETIAPINE FUMARATE | 45 | 7.4% |
| ARIPIPRAZOLE | RISPERIDONE | 33 | 5.5% |
| OLANZAPINE | RISPERIDONE | 33 | 5.5% |
| HALOPERIDOL | QUETIAPINE FUMARATE | 29 | 4.8% |
| ARIPIPRAZOLE | QUETIAPINE FUMARATE | 28 | 4.6% |
| HALOPERIDOL | RISPERIDONE | 25 | 4.1% |
| CHLORPROMAZINE HCL | RISPERIDONE | 21 | 3.5% |
| ARIPIPRAZOLE | OLANZAPINE | 20 | 3.3% |
| QUETIAPINE FUMARATE | ZIPRASIDONE HCL | 18 | 3.0% |
| OLANZAPINE | THIORIDAZINE HCL | 17 | 2.8% |
| CHLORPROMAZINE HCL | OLANZAPINE | 16 | 2.6% |
| RISPERIDONE | THIORIDAZINE HCL | 16 | 2.6% |
| RISPERIDONE | ZIPRASIDONE HCL | 16 | 2.6% |
| HALOPERIDOL | OLANZAPINE | 13 | 2.1% |

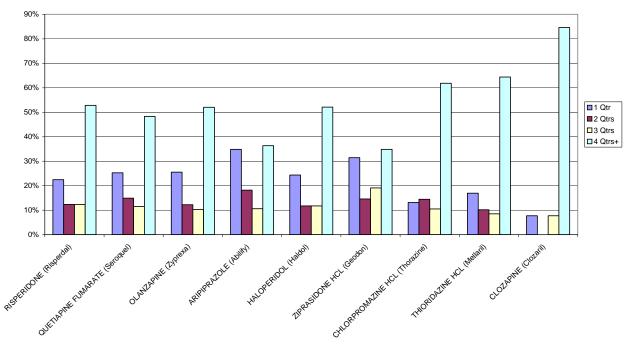
| CHLORPROMAZINE HCL | QUETIAPINE FUMARATE | 10 | 1.7% |
|---|---------------------|-----|------|
| Total Members with multiple anti-psychotics | | 605 | |

The second and third most frequent drug combinations in 2Q 2003 moved up to first and second in 4Q 2004. The combination of Quetiapine Fumarate – Risperidone became the top prescribed combination of anti-psychotics, accounting for 11.1 percent of all consumer combinations. Use of the Olanzapine – Risperidone combination decreased to 5.5 percent, whereas the combination of Olanzapine – Quetiapine Fumarate increased to 7.4 percent among all consumers.

Duration of Anti-Psychotic Drug Prescriptions for Drugs taken Concurrently with Other Anti-Psychotics in 4004

Figure 5 shows the number of quarters a drug is prescribed when the drug is taken concurrently with any other anti-psychotic drug.

Figure 5
Anti-Psychotic Drugs by Number of Quarters Prescribed for Drugs used
Concurrent with another Anti-Psychotic in 4Q04



Prescriptions lasting four or more quarters are most common for every drug in 4Q04. However, Abilify and Geodon have almost as many prescriptions lasting only a quarter as they do four or more quarters. Prescriptions for Clozaril concurrent with another anti-psychotic show the highest percent lasting four or more quarters (85%). Prescriptions for Geodon concurrent with another anti-psychotic show the lowest percent lasting four or more quarters (35%). Prescriptions for Abilify concurrent with another anti-psychotic show the highest percent lasting only a quarter (35%). Abilify is a newer drug which could account for the shorter duration, however further investigation would need to be done to determine if this fully explains this trend.

Duration of Anti-Psychotic Prescriptions for Consumers on More than One Anti-Psychotic Drug

Table P Prescribing Patterns by Duration of Prescription

| % of Consumers prescribed | 1 Qtr | 2 Qtrs | 3 Qtrs | 4 Qtrs+ |
|--------------------------------|-------|--------|--------|---------|
| RISPERIDONE (Risperdal) | 22% | 12% | 12% | 53% |
| QUETIAPINE FUMARATE (Seroquel) | 25% | 15% | 11% | 48% |
| OLANZAPINE (Zyprexa) | 26% | 12% | 10% | 52% |
| ARIPIPRAZOLE (Abilify) | 35% | 18% | 11% | 36% |
| HALOPERIDOL (Haldol) | 24% | 12% | 12% | 52% |
| ZIPRASIDONE HCL (Geodon) | 31% | 15% | 19% | 35% |
| CHLORPROMAZINE HCL (Thorazine) | 13% | 14% | 11% | 62% |
| THIORIDAZINE HCL (Mellaril) | 17% | 10% | 8% | 64% |
| CLOZAPINE (Clozaril) | 8% | 0% | 8% | 85% |

The prescriptions for the majority of the drugs (six out of nine) lasted for four or more quarters. For consumers on Abilify and Geodon, prescribing patterns are somewhat equally distributed among number of quarters that consumers are prescribed these drugs. Most consumers on Clozapine however, take this medication for more than four quarters. Thioridazine HCl has a similar trend to Clozapine, just not as pronounced.

Summary of Findings

<u>Updated Psychotherapeutic Drug Profile Trends</u>

- The Two or More Anti-Psychotic Drug Profile is the most common drug profile.
- There has been an increase over the course of the study in the number of consumers on the Two or More Anti-Psychotic drug profile.
- While the number of consumers who take Clozaril or Lithium is relatively low, consumers tend to take these drugs for long periods of time.
- The duration that consumers fit selected psychotherapeutic drug profiles varied greatly across the seven quarters in this study, with consumers fitting Two or More SSRI for an average of 1.4 quarters, while consumers on Clozaril tended to fit this drug profile for an average of 5.8 quarters.
- Thirty-five percent of all consumers who fit the Two or More Anti-Psychotic drug profile fit the profile for only one quarter.

Medication Reviews

- The Clozaril drug profile has the highest rate of medication reviews.
- Overall, the Medication Review rate for all settings is 21.1 percent, with paid residential settings showing a slightly higher than average review rate of 28.9 percent.
- The number of Medication Reviews per consumer with reviews increased significantly in 3Q 2004 and 4Q 2004.
- The majority (57.1%) of all consumers with Medication Reviews had only one review in the seven quarters of analysis.
- APD area 12 exhibited the highest Medication Review rate with 46.3 percent.

Prescribing Patterns for Anti-Psychotic Drugs

- Overall drug usage increased in 4Q 2004.
- Risperadal is the most common Anti-Psychotic drug prescribed in all quarters.
- The drugs that comprised the Two or More Anti-Psychotic drug profile shifted a little from the beginning to the end of the study period.
- The duration of the use of Anti-Psychotics varies. For consumers on Clozapine, they are typically on this drug for more than four quarters. For Risperdal and Seroquel, the number of consumers on these drugs is evenly distributed across all quarters of analysis.

Discussion and Recommendations

The results of this study indicate the Two or More Anti-Psychotic profile is the most frequent among consumers, and that, along with other drug profiles (except Two or More SSRI), it has been increasing in frequency over the course of the study. APD area variation in rates of occurrence for the different profiles has the potential to reveal details of the underlying dynamics behind rates of occurrence and increasing rates of occurrence for the different profiles. Given the frequency of the Two or More Anti-Psychotics among consumers, further examination of the dynamics driving its frequency, and increasing frequency over the course of this study, is warranted.

• We recommend analysis of the variation in frequency of the Two or More Anti-Psychotic drug profile by APD area. To determine whether variation by area is due to unique

clusters of consumers in specific areas or distinct prescribing practices, we suggest an analysis of disability code and diagnosis by area and an analysis of provider-specific prescribing practices by areas.

Results from the analysis of prescribing patterns for each Anti-Psychotic drug have shown that three drugs – Risperidone, Olanzapine, and Quietiapine Fumarate – have much higher prescription rates than any other drug over the course of the study. These same three drugs also comprise the top three most common drug combinations at the beginning of the study, and the top two and fourth most common drug combinations at the end of the study.

• We recommend analysis of whether specific anti-psychotic drugs tend to be prescribed for particular disabilities and/or diagnoses, and whether these disabilities or diagnoses cluster by APD area. We also recommend analysis of provider-specific prescribing practices for each anti-psychotic drug by area.

We have shown that some drug profiles have a high rate of occurrence among paid residential consumers while others occur less frequently. Among profiles that occur less frequently, most tend to involve a lengthy duration of use. Both frequency and duration of use indicate the importance of regular monitoring of consumers' health for potential medical complications. Results have also shown this mandate is not being met. Only about a quarter of consumers with drug profiles have received a medication review within the 2004 calendar year. While medication review rates vary by profile, place of residence, and APD area, most consumers are not receiving regular medication reviews. It is critical the low rate of medication reviews be addressed.

- We recommend analysis of the claims data to determine whether the Best Practice Protocol for Medication Reviews implemented in August/September of 2004 has improved medication review rates. Analyses should include an examination of actual use of medication reviews before and after implementation of the protocol as well as an examination of where medication reviews are, and are not, being completed. APD area variation in rates of medication reviews suggests geographical differences in access to providers may be a contributing factor. Thus, analyses should also consider the availability of providers qualified to perform medication reviews in each area.
- We recommend analysis of the claims data in conjunction with the demographic data to examine the impact of drug profiles on consumers' well-being. Specifically, we suggest analyzing the impact of drug profiles on consumers' physical capabilities, behavior, and health.

⁷ The Best Practice Protocol for Medication Reviews refers to a number of documents that outline a set of practices to be carried out by waiver support coordinators, pharmacists, and physicians that are designed to ensure that consumers receive annual medication reviews, pharmacists receive necessary documents to complete the medication review, and consumers receive any necessary follow-up exams with physicians. The documents were disseminated to waiver support coordinators in August and September of 2004.

Appendix A

For the Psychotherapeutic Study we identified (profiled) consumers with drug claims for at least one of the following seven medications or groups of medications:

- 1. Clozaril
- 2. Lithium (includes CIBALTH, ESKALITH, LITHOBID)
- 3. Mellaril > 25 mg
- 4. Phenobarb and other anti-seizure

| OTHER ANTI-SEIZURE | | | |
|--------------------|------------------|-----------|--|
| BUTISOL SODIUM | FELBATOL | | |
| CARBATROL | GABITRIL | PRIMIDONE | |
| CELONTIN KAPSEALS | KEPPRA | RIVOTRIL | |
| CLONAPAM | KLONOPIN | SECONAL | |
| CLONAZEPAM | LAMICTAL | TEGRETOL | |
| DEPAKENE | MEBARAL | TOPAMAX | |
| DEPAKOTE | MYSOLINE | TRILEPTAL | |
| DILANTIN | NEURONTIN | ZARONTIN | |
| EPITOL | PEGANONE | ZONEGRAN | |

5. Two or More Antipsychotic

| ANTI-PSYCHOTICS | | | |
|-----------------|-----------|-----------|--|
| Typical | | Atypical | |
| ABILIFY | PERMITIL | CLOZARIL | |
| HALDOL | PROLIXIN | GEODON | |
| LOXITANE | SERENTIL | RISPERDAL | |
| MELLARIL | STELAZINE | SEROQUEL | |
| MOBAN | THORAZINE | ZYPREXA | |
| NAVANE | TRILAFON | | |
| ORAP | | | |

6. Two or More Sedatives

| SEDATIVES/HYPNOTICS | | | |
|---------------------|------------------------|--|--|
| Benzodiazepines | Non-Benzodiazepines | | |
| ATIVAN | AMBIEN | | |
| DALMANE | AQUACHLORAL SUPPRETTES | | |
| DIASTAT | ATARAX | | |
| HALCION | BUSPAR | | |
| LIBRIUM | EQUANIL | | |
| PROSOM | SOMNOTE | | |
| RESTORIL | SONATA | | |
| SERAX | VISTARIL | | |
| TRANXENE T-TAB | | | |
| VALIUM | | | |

| VERSED | |
|--------|--|
| XANAX | |

7. Two or More SSRI

| | SSRI |
|---------|------|
| CELEXA | |
| LEXAPRO | |
| LUVOX | |
| PAXIL | |
| PROZAC | |
| SARAFEM | |
| ZOLOFT | |

Appendix B: ABC Residential Setting Code List

| 02 | Family home (parent, relative, guardian) | Family Home |
|----|--|------------------------------|
| 21 | Foster home devel.services (1-3) | Foster Home |
| 22 | Foster home Family Safety & Preservation (1-3) | Foster Home |
| 23 | Foster home adult services (1-3) | Foster Home |
| 01 | Independent living | Independent/Supported Living |
| 11 | Supported living (IFSSB) | Independent/Supported Living |
| 31 | Small group home devel. services (4-6) | Small Group Home |
| 32 | Small group home Family Safety & Preservation (4-6) | Small Group Home |
| 33 | Small group home adult services (4-6) | Small Group Home |
| 41 | Large group home devel. services (7-16) | Large Group Home |
| 42 | Large group home Family Safety & Preservation (7-16) | Large Group Home |
| 43 | Large group home adult services (7-16) | Large Group Home |
| 12 | Transitional Living | All Other |
| 35 | Home for special services (6 or less) | All Other |
| 44 | Mental health group home | All Other |
| 45 | Home for Special services (7-16) | All Other |
| 51 | Residential HAB center devel. Services (17+) | All Other |
| 52 | Residential HAB center non-DS (17+) | All Other |
| 53 | Residential school (non-correctional) | All Other |
| 55 | Home for special services (17+) | All Other |
| 61 | 6-Bed or less ICF/DD | All Other |
| 62 | Cluster | All Other |
| 63 | Community ICF/DD (7+) | All Other |
| 64 | Community ICF/DD CSLA program | All Other |
| 71 | Adult retarded defendant program | All Other |
| 72 | Juvenile retarded offender program | All Other |
| 81 | DSI non-ICF/DD | All Other |
| 82 | DSI ICF/DD | All Other |
| 83 | DSI ICF/DD CSLA program | All Other |
| 84 | DSI non-ICF/DD CSLA program general rev | All Other |
| 91 | Family Safety & Preservation commitment facility | All Other |
| 92 | Children & families mental hospital | All Other |
| 93 | Non-children and families psychiatric facility | All Other |
| 94 | Nursing home | All Other |
| 95 | Jail | All Other |
| 96 | Interstate compact client | All Other |
| 97 | Hospital | All Other |
| 98 | Nursing home | All Other |
| | | |