

**The Epidemiology of Anti-Seizure and Psychotropic
Medication Use in Persons with Developmental Disabilities in
Florida on the Developmental Disabilities Home and
Community-Based Services Waiver**

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Introduction

The practice of treating mental illness and/or behavior problems in persons with developmental disabilities using anti-seizure and psychotropic¹ medications has been common for the past 40 years. Anti-psychotics such as Thorazine, as well as other psychotropic medications, were falsely perceived as a panacea for behavioral problems and mental illness in persons with profound mental retardation, especially among those with self-abusive behavior. Over the past 20 years, we have learned that these medications can have serious temporary and permanent side effects, and their effectiveness is limited for many types of mental health problems in this population. As a result of both increased understanding of these medications and the etiology of mental illnesses in the general population as well as those with development disabilities, the use of anti-psychotic medication has decreased. However, their use is still commonplace.

During the past 30 years there have been enormous advances both in understanding the etiology of and in the treatment of mental illness. New medications have been developed that are very effective for specific mental health disorders in persons with and without developmental disabilities. As a result, the indications for the use of anti-seizure and psychotropic medications in the general public have become more specific. Furthermore, there have also been advances in the understanding of and management of maladaptive behavior in persons with developmental disabilities. Development and use of behavior management techniques has lessened the need to manage maladaptive behavior with medication.

With the increased use and understanding of anti-seizure and psychotropic medication in persons with developmental disabilities, class action lawsuits have been initiated to decrease obvious abuses of these medicines. The use of these medications to sedate individuals with developmental disabilities, so-called “medical restraints,” was successfully attacked in class action suits and prohibited by the Supreme Court in 1977. As persons with developmental disabilities have moved out of the medical-institutional environments and into community settings and the majority of other individuals with developmental disabilities remain in home or community based settings, there has also been some decrease and changes in use of anti-seizure and psychotropic medication.

Anti-seizure and psychotropic medication usage is controversial among persons with developmental disabilities due to the difficulties associated with making an accurate psychiatric diagnosis on which to base therapy. There is good evidence, however, that these medications can greatly help persons with developmental disabilities who have anxiety or depressive disorders, who are psychotic or who have some difficult behaviors that are not controlled by behavior management approaches. Therefore, the use of anti-seizure and psychotropic medications is a double-edged sword. If used appropriately these medications can be a very positive support for consumers in their efforts to live in the least restricted environment and to fulfill their social, educational and occupational potential.

This study was undertaken to better understand the use of anti-seizure and psychotropic medications in Florida’s population of persons with developmental disabilities living in the community who receive services from the Developmental Services Home and Community Based Services (DS HCBS) Medicaid Waiver. This study is a component of a larger quality assurance/improvement initiative to address all services offered to the Floridians receiving services under the Developmental Services Home and Community-Based Services Waiver. Both were funded through a contract with the Florida Agency for

¹ “Anti-seizure and psychotropic medications” is the term we will use to describe all psychoactive medications. Anti-seizure medications are used for specific mental health disorders as well as for seizures, which are also common in this population. The anti-seizure class of medications is divided into the following sub-classes; a) Carbamazepine; b) Valproic acid; c) other. The term “psychotropic medications” includes the following classes of medications: a) anti-psychotic medications, also referred to as neuroleptics and major tranquilizers—2 classes: Typical (old) and Atypical (new); b) sedatives/hypnotics of diazepam class, also referred to as minor tranquilizers; c) sedative/hypnotics not of the diazepam class, which includes barbiturates; d) anti-mania medications (e.g., Lithium, Valproic acid, Carbamazepine); e) stimulants (e.g., Ritalin); f) anti-depressants grouped as (a) Tricyclics, (b) SSRI’s (c) other; and g) anti-anxiety medications; and h) anti-mania (Lithium, Valproic acid)

Health Care Administration, in cooperation with the Department of Children & Families, Developmental Disabilities Program Office.

Specific Questions and Aims

1. We describe the frequency of use of anti-seizure and psychotropic medications in persons enrolled in the DS HCBS Waiver. We describe the medications use by type of anti-seizure or psychotropic class of medications and then show the frequency of use for each class of medication by:
 - a. Age,
 - b. Gender,
 - c. Living situation (see definition below)
 - d. Developmental Disabilities Program Districts
 - e. Level of Need (1-5). The level of need is based on an assessment of the consumers' abilities and problems in the areas of physical health, mental health and activities of daily living upon entry into the program.
2. Using the Consensus Handbook (Reiss and Aman 1998), which was an international consensus process among experts in the management of persons with developmental disabilities and mental health/behavioral problems, as a guideline, we identified 3 specific multiple medication profiles that could possibly put individuals with developmental disabilities at increased risk for complications and/or decreased quality of life:
 - a. On 2 or more sedative/hypnotic medications concurrently (Appendix 1 - Guideline 2)
 - b. On 2 or more anti-psychotic medications concurrently (Appendix 1 - Guideline 2)
 - c. On Phenobarbital while taking another anti-seizure medication. (Appendix 1 - Guideline 2, high potential for side-effect, lack of effectiveness)
3. We also analyzed Medicaid claims to assess indicators of the quality of care for person on an anti-psychotic medication by measuring access to mental health providers as evidenced by visits to a mental health provider before or after starting an anti-psychotic medication. We analyzed claims data to determine those consumers who appeared to receive medical care and treatment and prescription drugs through Medicaid. This analysis was completed to eliminate individuals who may be receiving medical care through another primary funding source such as Medicare. We reviewed and defined a mental health visit through the selection of a broad range of billing claims codes (Appendix 2). We then determined the proportion of estimated "Medicaid funded only" consumers starting an anti-psychotic medication that had a mental health visit in the 6 months prior to or 6 months after they had started. (Guideline 6 & 9). While individuals with Medicaid prescriptions drug claims and no Medicaid physician or medical claims were excluded from the analysis, there is likely a percentage of individuals who did have a mental health visit through another funding source for which data was not available.

Background.

Evidence from the limited literature indicates that there still exists a wide a variety of problems in the prescribing of anti-seizure and psychotropic medications for persons with developmental disabilities. The literature describes a number of 'medication errors,' a term that has come into vogue with the patient safety initiative. (IOM, 2000) The patient safety initiative has broadened the concept of "medication errors" beyond the realm of the medication dispensing and administration errors most commonly cited. It is important to note that medication errors threaten the safety and function of persons with developmental disabilities. Persons with developmental disabilities on inappropriate or incorrect medications may be inhibited in their ability to be involved in a range of activities that allow them to live in the least restrictive environment and to maximize their quality of life. The following are examples of the types of medication errors found by researchers in the developmentally disabled population.

- Inappropriately high dosing of anti-psychotic and anti-epilepsy medications (Buck and Sprague, 1989; Aman et al., 1986—in Reiss and Aman, 1998)

- Use of complex combinations of multiple medications which lead to behavioral and psychiatric complications from drug interactions and/or side effects (Buck and Sprague, 1989; Gadow and Poling, 1988—in Reiss and Aman, 1997);
- Use of sedative medications as chemical restraints, despite regulatory prohibition of the practice since the 1970's (Reiss and Aman, 1998)
- Increased mortality and hospitalizations due to drug overdosing or medication complications.
- Under diagnosis or misdiagnosis of psychiatric illness in persons with developmental disabilities leading to lack of treatment or inappropriate treatment. (Santos and Baird, 1999)
- Under or misdiagnosis of the side effects of anti-epilepsy medications, which include dysarthria, ataxia, drowsiness and confusion, symptoms are also common in persons with developmental disabilities. (Logan and Freeman 1969; Vallarta et al. 1974—in Reiss and Aman, 1998)

Many of these “medication errors” were identified in the 1970s and 1980s. During that period there was an increased awareness of the problem described in medical literature. In the ensuing years little was done to take the next step and guide the appropriate prescribing of anti-seizure and psychotropic medications for persons with developmental disabilities.

Beginning in the late 1970's, persons with developmental disabilities have steadily moved from large, self-contained institutional programs to community-based programs. Persons with developmental disabilities who live at home or in the community now tend to remain in the community settings. As a result, medical and psychiatric care and treatment are now provided in the community. Unfortunately, there are not an adequate number of general or specialty physicians with extensive training or experience in treating persons with developmental disabilities.

Because of these considerations, an international group of expert clinicians and researchers were brought together to develop evidenced based and expert consensus guidelines for anti-seizure and psychotropic medication usage in persons with developmental disabilities. (International Consensus Handbook, 1998). From this meeting of experts, a consensus statement was developed, with in-depth discussions of each class of anti-seizure and psychotropic medication. A summary of the major recommendations is listed in Appendix 1. In addition, the American Academy of Child and Adolescent Psychiatry recently published guidelines for the care of persons with developmental disabilities and mental illness or behavior problems. (AACAP, 1999) Their recommendations overlap significantly with those of the Consensus Handbook. Therefore, we incorporated the major recommendations from the AACAP guidelines with those from the Handbook to form the synthesized guidelines referenced in **Appendix 1**.

Study Design.

Dataset Development. This study is based on Medicaid claims data from the Florida Medical Management Information System (FMMIS) and consumer demographic and billing data from the Department of Children and Families, Allocation, Budget and Contract (ABC) database. The FMMIS database contains the claims for all persons on Medicaid in the State of Florida, including claims for State Plan services including medical visits, prescription medications, hospitalizations and emergency room visits, durable medical equipment and medical supplies as well as claims for Medicaid Waiver services. The medical visit claims include the type of visit (primary care, mental health, etc.), the primary medical diagnosis for the encounter medication and the prescribing physician's name. For this study, only claims data for individuals who are eligible for services through the Developmental Services Home and Community Based Services (DS HCBS) Waiver were available for analysis. Claims data or other medical expenditure or health care utilization data from any funding source other than Medicaid is not available to the Delmarva Florida Statewide Quality Assurance Program or this study. As a result, we do not know how much consumers use other sources of payment for health care services and are unable to estimate the size of the bias introduced by looking at only Medicaid as the source of payment for health care services.

The FMMIS database also includes demographic information from the eligibility files. Other demographic data about individuals served through the DS HCBS Waiver was available through the ABC database which included the person's primary qualifying diagnosis, the overall Level of Need score from the Florida Status Tracking Survey (FSTS) and all billing data for DS HCBS Waiver services

We compiled FMMIS and ABC data on all persons served on the DS HCBS Waiver over a continuous 27-month period from January 2000 to December 2001, incurred with a 6-month lag time, which allows time for the claims to be received, processed and entered.

Medication classification. Using NDC codes and pharmacy classification criteria the principal investigator organized all medications of interest listed in the Medicaid claims database into the following medication classes.

- i) Psychotropic/anti-psychotic
- ii) Sedative/Barbiturates/Hypnotic
- iii) Anti-anxiety medications
- iv) Anti-seizure medications
- v) Anti-depressive
- vi) Lithium & anti-mania
- vii) Anti-cholinergic
- viii) Serotonin related medications

A Registered Nurse and Pharmacist experienced in the use of anti-seizure and psychotropic medications validated these classifications.

Population Characteristics. Based on demographic information available in FMMIS and the ABC databases, five demographic characteristics were selected for analysis: age; gender; primary condition; level of need; and living situation.

Age was displayed by child and adult with sub age groups for each. Primary condition referred to the disability category under which the person qualifies for the Developmental Disabilities Program. Those with Cerebral Palsy (CP) often have Mental Retardation, however they are left in the CP category. Similarly, if any children with Spina Bifida, Autism or Prader Willi also had a diagnosis of Mental Retardation, they would be categorized by their other diagnosis. Living situation was grouped into six categories and include:

- a) Independent living or supported living
- b) Family Home
- c) Foster home (0-3 persons)
- d) Small Group Home (4-6 persons)
- e) Large Group Home (7 or more persons)
- f) Other

Six Level of Need categories were derived from the Florida Status Tracking Survey and included Zero; Limited; Minimal; Moderate; Intensive; and Extensive.

Analysis Methods

For each of the medication classes listed the proportion that use any medications from that class over the past 2 years were profiled by the following demographic characteristics:

- a. Geographic distribution based on the Florida Department of Children and Families districts (13 Districts and 1 Region)
- b. Living situation)
- c. Age
- d. Level of need
- e. Primary disability

Identification of individuals for medication profiles. Next in our analyses of the FMMIS data, using the Consensus Guidelines and the AACAP Guidelines, we identified three specific multiple medication-use profiles. These medication profiles or use patterns carry an increased risk for complications, such as impaired affect and/or intellectual functioning. We identified the frequency of these profiles by primary diagnosis, Level of Need, Department of Children and Families District, age, living situation, etc.

- a. On two or more sedative/hypnotic medications concurrently (Appendix 1 - Guideline 2)
- b. On 2 or more major tranquilizers (antipsychotic) medications concurrently (Appendix 1 - Guideline 2)
- c. On Phenobarbital and another anti-seizure medication concurrently. (Appendix 1 - Guideline 2, high potential for side effect, lack of effectiveness).

Access to mental health providers We further analyzed the population of individuals identified above to determine access to mental health providers. We excluded those individuals who appeared to have a funding source for medical care other than Medicaid (as evidenced by a minimal number of Medicaid claims for physician visits). We estimated the number and percentage of individuals who had not had a visit with a psychiatrist within the 6 months prior to or 6 months after being prescribed an antipsychotic medication. (Guideline 6 & 9).

Adjusted Comparisons. Comparing the medication usage rates between districts or between age groups can be confounded by differences within each of the comparison groups on other characteristics related to medication usage, such as level of need or primary disability category. In order to make fair comparisons between the groups, we adjusted for the differences in the distribution of persons within the other categories. We found that age and district were not potential confounders for any of the comparisons and they were not used. We did adjusted comparisons of the following with the adjustments noted:

- a) Rate for Urban vs. rural/suburban adjusted for level of need and primary disability category
- b) Living situation adjusted for level of need and primary disability category
- c) Age-child vs adult adjusted for level of need and primary disability category

Urban versus Rural/Suburban were not significantly different after adjusting for level of need and primary disability category. Living situation groups' comparison was significant and is presented under the results section.

Results

Demographic Characteristics Table 1 presents the DS HCBS Waiver population (2001) by age grouping, gender, primary qualifying diagnosis, level of need and living situation. This is an informational data display only. No analysis has been made with regard to medication usage from this information. Within each characteristic, the total number and proportion within that category are listed. It is interesting to note that 8,200 or 31% of the person served on the DS HCBS Waiver are 21 years of age or under, with most being in the 12-21 age range (61%, or 5023) and very few being in the under 5 category (only 411 total). There are more males than females in the DS HCBS Waiver population. The vast majority of people served on the DS HCBS Waiver qualify by having Mental Retardation as their primary condition; 85% had MR versus only 9% with Cerebral Palsy, 4% with Spina Bifida and 3% with Autism. In the living situation categories, most individuals lived in the Family Home (62%). Small group home and Independent living/Supported living were next with 15% and 11.6% respectively. Few were in Foster Homes but almost 7% were in large group homes, which number from 7-16 residents per home.

Table 1
Florida Developmental Services Home and Community-Based
Services Waiver
Population Demographic Characteristics
(2001)

Population Characteristics	Number of Persons	Proportion of Total Waiver Population
Age Groups		
Age: 3-5 years of age	411	1.6%
Age: 6-11 years of age	2,671	10.2%
Age: 12-14 years of age	1,432	5.5%
Age: 15-21 years of age	3,691	14.1%
Total Children	8,205	31.4%
Adults 22-64 years of age	17,514	66.9%
Adults 65 years and older	444	1.7%
Total Adults	17,958	68.7%
Gender		
Female	11,301	43.2%
Male	14,862	56.8%
Primary Qualifying Condition		
Mental Retardation	22,061	84.3%
Cerebral Palsy	2,253	8.6%
Autism	1,121	4.3%
Spina Bifida	702	2.7%
Prader Willi	24	0.1%
Level of Need		
Limited	6,801	26.6%
Minimal	3,176	12.4%
Moderate	4,983	19.5%
Extensive	6,949	27.2%
Intensive	3,671	14.4%
Living Situation		
Independent living/ Supported living	3,047	11.6%
Family home	16,211	62.0%
Foster home	514	2.0%
Small group home	3,967	15.2%
Large group home	1,747	6.7%
All Other	667	2.5%
Total Waiver Population	26,163	100%

Medication Usage Frequency and Expenditures by Classification. Table 2 displays the number of consumers on each class of medication and the average cost per consumer on that class of medications per year. Almost half of the individuals on the DS HCBS Waiver were on some type of anti-seizure and/or psychotropic medication. For the consumer on at least one medication, they averaged 13 prescriptions per year and the average annual expenditure for medication was \$2,173. Over 28% of the population was on anti-seizure medications, the medication category with the largest number of persons in it. Almost that many were on anti-psychotic medications but these were divided into the typical (older and

inexpensive) anti-psychotics and the atypical (newer and expensive) antipsychotics. While many of the anti-seizure medications are new and expensive, many are appropriately on older, generic, less costly medications. Therefore, the expenditure/consumer while high at over \$1300 was not as high as the expenditure/consumer for those on atypical antipsychotics medications. Seventeen percent of consumers were on atypical antipsychotics; however, this class of medication represented almost half of the total expenditures for anti-seizure and psychotropic medications.

The following represent some important observations from our findings: (1) While only 533 persons, or 2% were on stimulant medication, 511 of those were children which represents 6.2% of the children in the DS HCBS Waiver program. (2) Over 12% of persons on the waiver were on at least a single sedatives/hypnotic of the benzodiazepine class and almost 7% were on at least a single sedative hypnotic of the non-benzodiazepine type. These medications are easily abused and can be addictive, and therefore, these numbers are concerning. (3) A relatively high number of consumers (over 4600) were on anti-depressants, which may indicate that there is concern about this problem in persons with developmental disabilities and the diagnosis of depression is being made more consistently with the general population. Under-reporting of the diagnosis of depression has been a major problem; so this could also indicate that we are making progress in medicine in appropriate screening and reporting for this disease.

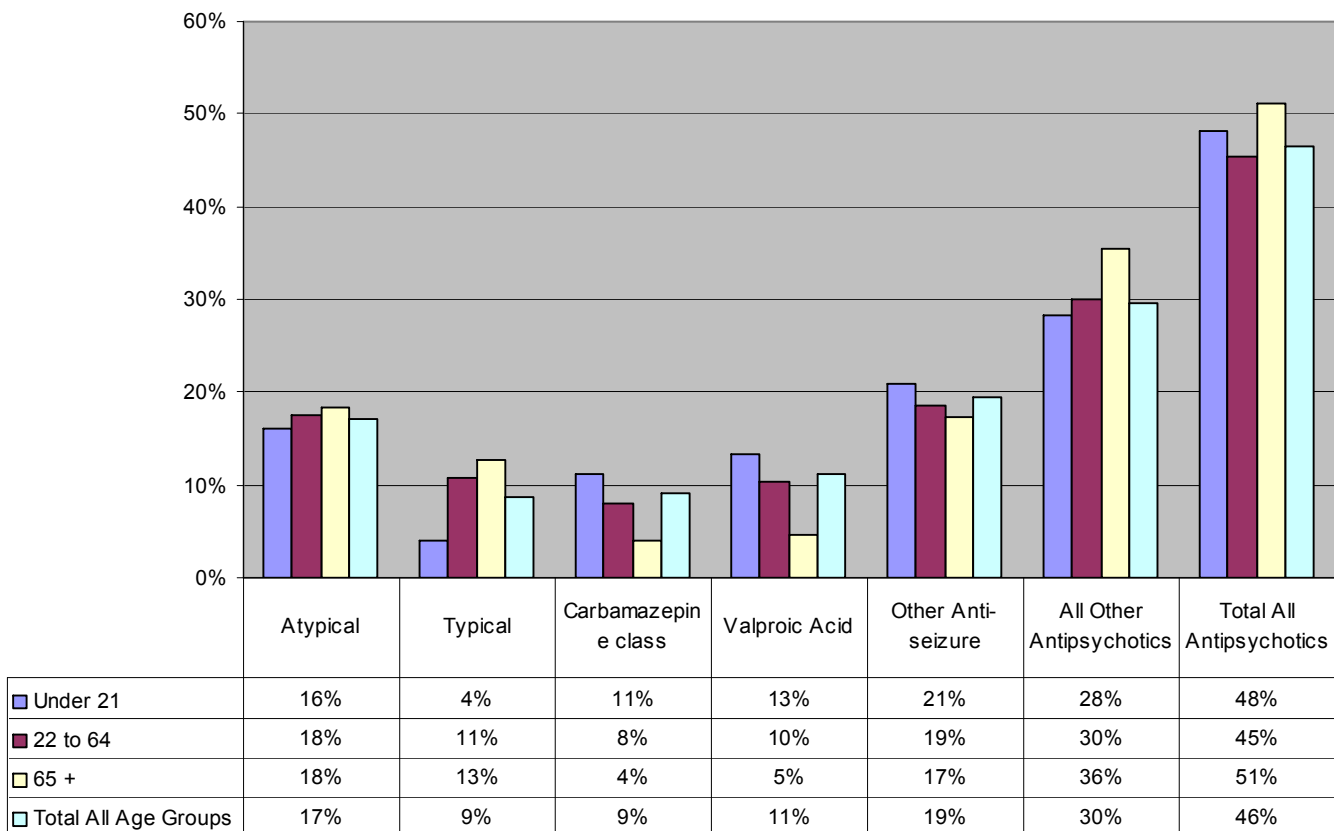
Table 2 represents individuals with actual Medicaid pharmacy claims only and does not reflect individuals who may have received medication paid for by other sources including Medicare, private insurance and out-of-pocket expenditures.

**Table 2. Medication Costs Per Consumer
For Calendar Years 2000 & 2001**

Medication	Number of Consumers On Medication	Proportion of Total DD HCBS Waiver Population	Average Annual Expenditure/ Consumer
ANTI-PSYCHOTIC-TYPICAL	2,283	8.7%	\$339
ANTI-PSYCHOTIC-ATYPICAL	4,476	17.1%	\$2,410
SEDATIVE/HYPNOTICS - BENZODIAZAPINE	3,254	12.4%	\$153
SEDATIVE/HYPNOTICS - NON-BENZODIAZAPINE	1,782	6.8%	\$479
ANTI-DEPRESSANTS	4,609	17.6%	\$695
ADHD Medication (Stimulants)	533	2.0%	\$300
ANTI-MANIA/LITHIUM	285	1.1%	\$223
ANTI-SEIZURE MEDICATIONS	7,430	28.4%	\$1,325
ANTICHOLINERGICS	259	1.0%	\$438
ANY ANTI-SEIZURE AND/OR PSYCHOTROPIC MEDICATION	12,139	46.4%	\$2,167

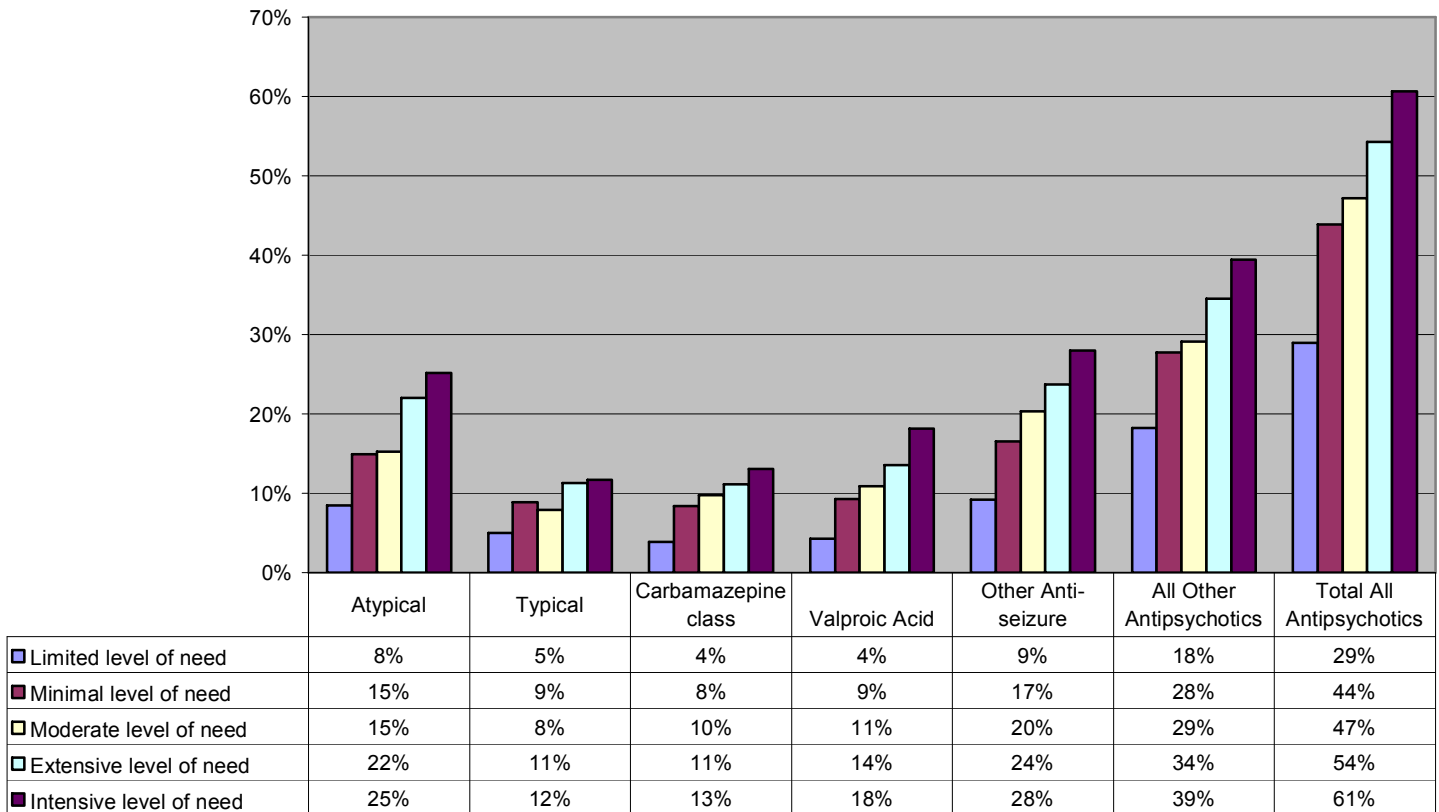
Percentage of Medication Usage by Demographic Characteristics. The first graph shows the proportion of persons within each of four age groups (<21, 22-64, >64 and total population) on each type of medication by class. Children and adults were equally as likely to be on atypical antipsychotics (16% versus 17%), but children were much less likely to be on typical antipsychotics (4% vs 11%). Children were more likely than adults to be on the common anti-seizure medications of Carbamazepine or Valproic acid (11-13% versus 8-10%). Children were a bit more likely compared to adults 22-64 years of age to be on any anti-seizure and psychotropic medication (48% versus 45%), however adults over 65 had the highest rate of anti-seizure and psychotropic medication use at 51%

Graph 1: Percent of Persons on Anti-seizure & Psychotropic Medication by Type and Age Group



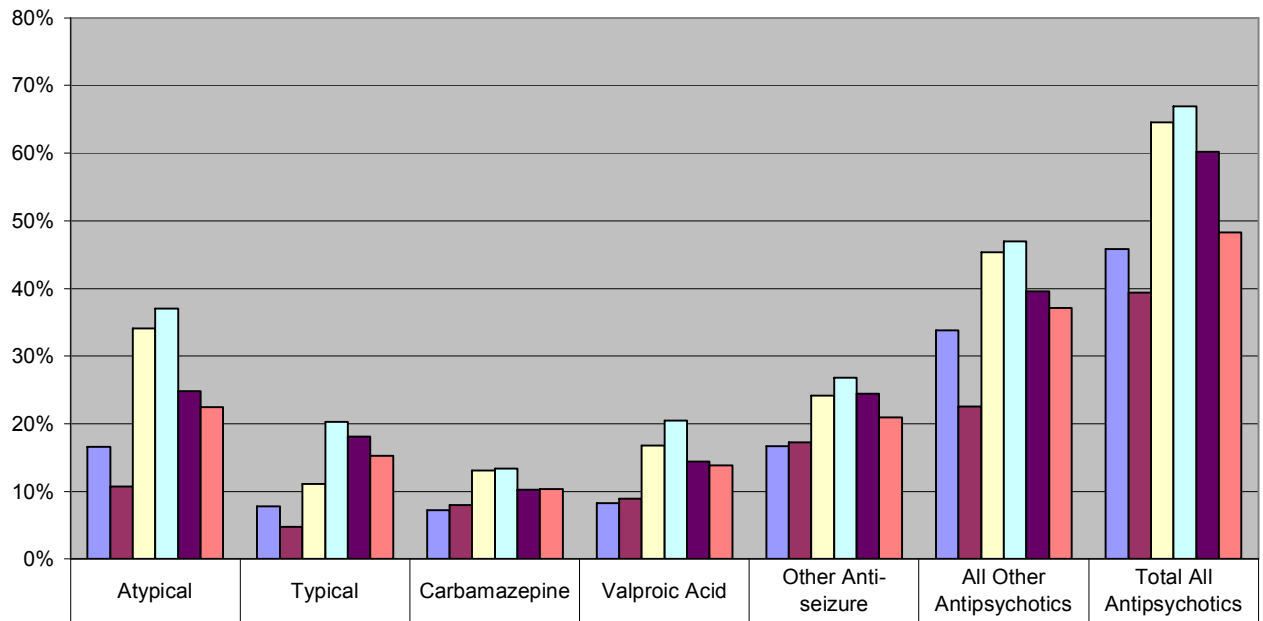
Graph 2 shows the proportion of persons on each type of medication by class by level of need. As might be expected, there is an increasing proportion of persons on each type of medication class as the level of need increases. This is consistent with observed increased rates and types of behavioral or mental health problems in persons with more intensive or extensive needs.

Graph 2: Percent of Persons on Anti-seizure and Psychotropic Medication by Type and by Level of Need



Graph 3 shows the percent of persons on anti-seizure and psychotropic medication by type of medication and by living situation. Those residing in family homes are much less likely to be on atypical and typical antipsychotics, than those in group homes. However, they were equally likely to be on anti-epilepsy drugs. This may be an indication of more severe behavior problems among persons in group homes compared to family homes, or it may be related to an increased use by group homes versus family members to use medication to control behavior. Overall, persons in small group homes are much more likely to be on any of the medications, except anti seizure medications.

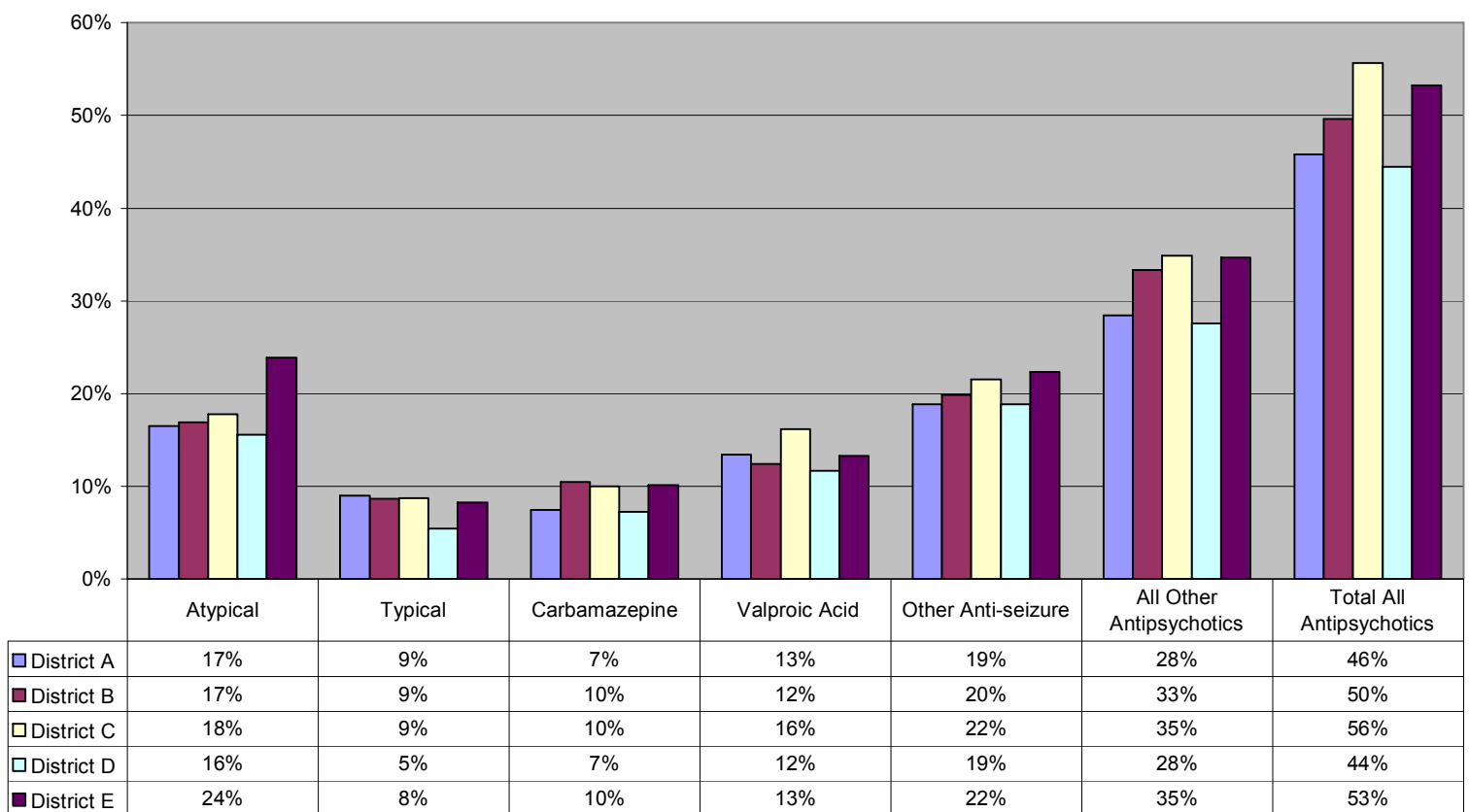
**Graph 3:
Percent of Persons on Anti-seizure and psychotropic Medication
By Type of Living Arrangement**



	Atypical	Typical	Carbamazepine	Valproic Acid	Other Anti-seizure	All Other Antipsychotics	Total All Antipsychotics
Independent/Supported living	17%	8%	7%	8%	17%	34%	46%
Family home	11%	5%	8%	9%	17%	23%	39%
Foster home	34%	11%	13%	17%	24%	45%	65%
Small group home	37%	20%	13%	20%	27%	47%	67%
Large group home	25%	18%	10%	14%	24%	40%	60%
All Other	22%	15%	10%	14%	21%	37%	48%

Graph 4 below shows the variation by random district selection in the proportion of individuals on the different anti-seizure and psychotropic medications. There is moderate variation in the use of antipsychotics and other types of anti-seizure and psychotropic medications. Overall, there is less variation than would be expected, given the great variation in physician prescribing practices of these medications.

Graph 4: Percent of Persons on Anti-seizure and psychotropic Medication by DCF District (Random selection of 5 of 14)



Adjusted Rates of Anti-seizure and Psychotropic Medication Use. We examined differences between age (adult and child), districts (urban districts and rural/suburban districts grouped together) and living situation. Adjusted for differences in distribution of persons within level of need and primary qualifying diagnosis categories, there were no differences in overall anti-seizure and psychotropic medication use by adults versus children or Districts grouped into rural/suburban versus urban. In Table 3, we present adjusted relative rates of use of any anti-seizure and psychotropic medication by living situation—relative to the overall average rate of use of anti-seizure and psychotropic medication across the entire Waiver population. As shown below, those in Independent living/supported living arrangements or in family homes were less likely (rate < 1) to be on any anti-seizure and psychotropic medications than the average Waiver consumer. Adjusted for differences in distribution of level of need and primary qualifying diagnosis, persons in any type of group home situation (small group homes, large group homes

and foster homes) were approximately 40% more likely than those in independent living/supported living or family homes to be on anti-seizure and psychotropic medications. There were no substantive differences between the group home categories.

Table 3
Any Anti-seizure and Psychotropic Medication Usage by
Type of Living Arrangement (Adjusted Relative Rates).

Living Arrangement	<u>Adjusted relative rate of anti-seizure and psychotropic Medication use</u>
Independent living/ Supported living	0.88
Family home	0.86
Foster home	1.28
Small group home	1.34
Large group home	1.23
All Other	0.97

Usage rate of Selected Multiple Medication Profiles. Table 4 (below) displays the proportion of individuals on the DS HCBS Waiver that have one of the three multiple medication profiles we selected to study. These populations are described by age group, gender, primary qualifying condition, living situation and district. The three specific medication profiles are labeled above each column and described under **Study Design**.

Use of two or more sedative/hypnotics varied by age (adult vs. child), by primary qualifying condition, by living situation and by district. The variation was greatest among the different living situations with 5% of those in group homes on two or more sedative hypnotics versus 1.4% of those in family homes. District rates varied from a low of 1.4% to a high of 4.0%.

Two or more concurrent antipsychotics, while sometimes appropriate, may indicate inappropriate or non-traditional use of medications. An interesting finding is that 8.5% of children overall were on 2 or more antipsychotics, and over 12% of children ages 15-21 were on two antipsychotic medications concurrently. Persons with autism were most likely among the qualifying conditions to be on two or more antipsychotics, followed closely by those with mental retardation (11%) but a distant third and fourth were CP and spina bifida (3.0% and 0.6% respectively). The variation in living situation is the greatest with 5.0% in family homes versus 26.9% in small group homes being on two or more antipsychotics. The variation by district is substantial, with an almost two-fold variation between District 2 (7.8%) and District 15 (14.1%).

The medication profile of being on phenobarbital and a second anti-seizure medication is not common, with about 1.4% on the total DS HCBS Waiver population having this medication profile. Moreover, the variation is not at all as great as for the other two specific medication scenarios. This, again, may be due to the fact that there is less variation overall with anti-seizure medications than with anti-psychotics or with other medications. The variation by qualifying condition and age is what would be expected. There was little variation across different living situations and district.

Table 4 Selected Medication Profiles

Population Characteristic	More than 2 Sedative/Hypnotics	Two or More Anti-psychotics	Phenobarbital And Second Anti-seizure Medication
Age Groups			
3-5 years old	0.24%	2.2%	1.5%
6-11 years old	0.79%	5.9%	2.8%
12-14 years old	1.33	9.6%	2.4%
15-21 years old	2.03	12.4%	1.3%
Total Children (3-21)	1.10%	8.5%	2.0%
Total Adults (22 & older)	2.76%	11.2%	1.2%
Gender			
Female	2.4	8.9%	1.6%
Male	2.3	11.4%	1.3%
Primary Qualifying Condition			
Mental Retardation	2.5%	11.2%	2.3%
Cerebral Palsy	1.3%	3.0%	1.5%
Autism	1.6%	13.7%	0.3%
Spina Bifida	1.0%	0.6%	0%
Living Situation			
Independent living/ Supported living	2.6%	9.8%	0.8%
Family home	1.4%	5.1%	1.4%
Foster home	3.5%	22.6%	2.9%
Small group home	5.0%	25.9%	1.7%
Large group home	3.1%	18.9%	2.0%
Urban Districts			
4 Jacksonville	2.2%	10.8%	1.4%
7 Orlando	1.4%	8.9%	1.8%
9 West Palm Beach	1.7%	11.7%	1.6%
10 Ft. Lauderdale	1.3%	13.0%	1.4%
11 Miami	4.0%	13.8%	2.2%
23 Tampa/St. Petersburg	2.8%	11.1%	1.2%
Rural/Suburban Districts			
1 Pensacola	3.7%	8.1%	1.0%
2 Tallahassee	1.7%	7.8%	1.3%
3 Gainesville	1.9%	8.4%	2.1%
8 Ft. Myers	1.3%	10.5%	1.2%
12 Daytona Beach	3.5%	9.7%	1.6%
13 Ocala	2.7%	10.6%	1.2%
14 Lakeland	2.1%	9.0%	1.3%
15 Stuart/Ft. Pierce	2.2%	14.1%	1.2%
Total Waiver Population	2.3%	10.3%	1.4%

Mental or Behavioral Health Treatment or Visits. We also examined Medicaid claims to determine access to mental or behavioral health care for persons taking antipsychotic medication (either typical or atypical). We looked at the proportion of persons who received health services through Medicaid who saw a psychiatrist or other mental health professional within 6 months before being placed on an antipsychotic medication and within 6 months after being on the antipsychotic medication. To identify a visit to a psychiatrist or mental health professional, we reviewed the claims data for all mental health visit codes. From 55 visit codes that related to mental health visits, we included almost all as qualifying for a psychiatry visit. We created an inclusive measure of psychiatric visit so that we would produce a conservative estimate, one more likely to overestimate rather than under estimate the proportion with a visit. **Appendix 2** lists the mental health visit codes that we included and excluded as qualifying for 'psychiatrist visit.' Of the 5,489 consumers receiving an antipsychotic between January 2000 and through December 2001, 3130 or 57% received a mental health visit before the prescription was filled. Of the 5082 unique consumers who were dispensed an antipsychotic medication between January 2000 and June 2001, 2710 or 53% had a mental health visit within 6 months after receiving the prescription.

The information contained in Table 5 reflects only those individuals for whom Medicaid was the primary payee as evidenced by the availability of claims data. The population was reduced by those who had no or few Medicaid claims for health care to eliminate individuals with Medicare, private insurance or those who pay for services out-of-pocket. Without knowing the utilization of other sources of payment, however, we are unable to definitely estimate the number of consumers who have other funding sources; thus the proportion in Table 5 might be slightly different than indicated.

Table 5

PSYCHIATRIC VISITS FOR CONSUMERS RECEIVING ANTIPSYCHOTIC MEDICATIONS

Number of unique consumers who were dispensed antipsychotic medications	5,489
Number of these consumers who had a psychiatric visit within six months <u>prior</u> to received antipsychotic medications	3,130 (57.0%)
Number of unique consumers who were dispensed antipsychotic medications between Jan 00 and Jun 01	5,082
Number of these consumers who had a psychiatric visit within six months <u>after</u> received antipsychotic medication	2,710 (53.3%)

Discussion

We studied the use of anti-seizure and psychotropic medication in persons on the home and community-based services waiver. The analysis is based on the Medicaid claims database which will not account for all health care services and/or medications obtained and taken by this population. We would like to highlight specific findings that may have direct policy implications for the Florida Developmental Services Home and Community Based Services Waiver Program and the Florida Medicaid Program.

First, almost half or 46% of the DS HCBS Waiver population was on some type of anti-seizure and/or psychotropic medication paid for by Medicaid. Many were on more than one anti-seizure or psychotropic medication. More than one-quarter were on anti-epilepsy medications, 17% were on atypical anti-psychotics and almost 9% were on typical anti-psychotics. These medications can have significant side effects, such as cognitive dulling or extrapyramidal side effects (EPS). Of those filling a prescription for an anti-psychotic who appeared to use Medicaid as the sole or primary funding source, we found that slightly over half had a mental health visit within 6 months of that date paid for by Medicaid. Furthermore, slightly less had a visit with a mental health professional within six months after receiving an

antipsychotic. Therefore only half of individuals started on the highest risk medications are getting to see a mental health professional. While these percentages may be slightly overestimated if another funding source was used to pay for mental health services despite Medicaid being the primary funding source for health care, the incidence rate is significant and one that should be noted. While general and other specialty health practitioners can and often do prescribe and provide medication management for persons taking anti-psychotic medications, these professionals may be less likely to have the necessary expertise and experience to manage these medications appropriately for individuals with developmental disabilities. Mental health providers are trained to manage people on these medications and to determine if they are needed or effective. Additional targeted reviews of these individuals is needed to determine the need for medications, if they are effective at ameliorating targeted mental or behavioral health problems and if they are causing any untoward side effects, many of which can be complicated and difficult to sort out from behavior disorders in some persons with developmental disabilities.

Second, the costs of these medications are significant. For the 4,476 consumers on atypical antipsychotics, the average annual cost was over \$2400. The late Edric Bates, PharmD and others have looked at the cost of professional monitoring of medications in this population and found that it not only improved the quality of life and function of the individuals on the medications, it saved 1.7 Medicaid medication dollars for every dollar spent on the monitoring program. Studies examining costs and economic benefits of a medication error prevention program indicate that the return on investment is very positive. (Schneider, 1995) One study estimated that medication errors cost 30 times the cost of an effective medication QI and error prevention program. (van den Bemt PM, et al, 2002) In addition to a substantial return on investment within the Medicaid program, a medication error prevention program in the DS HCBS Waiver has the potential of improving the quality of life and function of individuals served through the Waiver program.

The third finding we want to highlight is the high rate of anti-seizure and psychotropic use by children served on the DS HCBS Waiver. Children's rates of anti-seizure and psychotropic medication usage were comparable to those of adults even after adjusting for differences in level of need and primary qualifying diagnosis. When one considers that stimulants, the most commonly prescribed mental health associated medication for children, were not commonly used in this population, the issue of anti-seizure and psychotropic medication usage in children on the waiver is more significant. It is further underscored by the finding that 8.5% of children overall were on 2 or more antipsychotics, and over 12% of children ages 15-21 were on two or more antipsychotic medications concurrently. This finding deserves further investigation. The use of anti-seizure and psychotropic medication is often needed in children with severe behavior problems; however, two concurrent anti-psychotics requires psychiatric evaluation, frequent medication review by a trained mental health professional and an on going plan of professionally directed behavioral intervention.

Additionally, there was a significantly higher use of two or more anti-psychotics for persons who lived in settings that typically have paid supports (foster, small group and larger group homes) than for individual who live in their own homes or family homes (19% to 26% as opposed to 5-10%). Many individuals who reside in paid residential supports often do not have family members to monitor and advocate for appropriate health care. Targeted study of this group is definitely warranted.

Lastly, we found that the medication profile of two or more sedative/hypnotics used concurrently affected over 500 persons served on the DS HCBS Waiver. While this only represents 2.3% of the total DS HCBS Waiver population, the use of two sedative/hypnotics is rarely indicated. In fact, the ongoing use of one sedative/hypnotic is discouraged due to the significant waning of effectiveness over time and the very high potential these medications have for addiction. Individuals who currently are prescribed two or more concurrent sedative/hypnotic medications should be identified and further reviewed.

In summary, we found that almost half of the persons enrolled in the Developmental Services Home and Community Based Services Waiver had Medicaid claims for anti-seizure and psychotropic medications. While there were some database limitations in determining the exact number of individuals for whom Medicaid was the sole funding source for all health care services, adjusted data does indicate that increased mental or behavioral health care oversight of drug therapy is needed. Most health care

professionals agree that mental or behavioral health care oversight for persons with developmental disabilities is limited and a resource that needs continued development in terms of availability, access and specialized expertise.

On a positive note, the frequency of multiple medication usage for two of the selected medication profiles (more than 2 sedative/hypnotics and Phenobarbital and a second anti seizure medication were used very infrequently (2.3% and 1.4%) compared to the total population of individuals served through the DS HCBS Waiver.

The findings and specific recommendations reported in this report need further targeted study and analysis. Further, specific information and recommendations need to be provided to the Developmental Disabilities District Case Management Teams for individual case-by-case follow up and coordination with medical practitioners and appropriate mental or behavioral health care providers. District Medical Case Management Teams need to coordinate these activities with family members, waiver support coordinators and appropriate residential care staff to ensure that improved mental and behavioral health outcomes are being realized.

While increased access to mental and behavioral health care providers who are experienced in working with individuals with developmental disabilities is certainly a commonly identified need throughout the state, it is important to point out that there are services such as medication reviews, nursing assessments, behavioral assessment and therapy and specialized mental health therapy available through the DS HCBS Waiver that are unique and designed to address the types of medication profiles identified in this study. Efforts to support the increased and coordinated use of these services should continue to be required and supported with special emphasis given to the sub groups identified in this study who need additional monitoring and review.

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Appendix 1 - Guidelines
Synthesized from the
“International Consensus Handbook”*
and the
“Practice Parameters American Academy of Child and Adolescent Psychiatry (AACAP)”**

Guideline 1: Definition of a psychotropic medication

- a) Any medication used to stabilize or improve mood, mental status or behavior.

Guideline 2: Psychotropic medication shall not be used excessively or inappropriately

- a) Is the person on the medication an inappropriately long time, dosed very high or is on more than one psychotropic drug within the same class used?

Guideline 3: Psychotropic medication must be used within the context of a coordinated multidisciplinary care plan designed to improve the individual’s quality of life.

Guideline 4. The use of psychotropic medication must be based on a psychiatric diagnosis or a specific behavioral-pharmacological hypothesis resulting from a full diagnostic and functional assessment.

- a) Is the documented diagnosis appropriate for the medication?
- b) What are the specific target behaviors being treated?
- c) Is there a documented monitoring plan for the medication?

Guideline 5. Written informed consent must be obtained from the individual, if competent or the individual’s guardian before the use of any psychotropic medication and must be periodically renewed.

Guideline 6: Specific index behaviors and quality of life outcomes must be objectively defined, quantified, and tracked using recognized empiric measurement methods in order to monitor psychotropic medication efficacy.

- b) If the consumer is stable on psychotropic medications, s/he should be seen by psychiatrist every 3 months (AACAP, practice parameter, 12;/99, p 26S.) and more often when medication dosages are changed or new medications started.

Guideline 7. Individual must be monitored for side effects on a regular and systematic basis using an accepted methodology that includes a standardized assessment instrument.

Guideline 8. When antipsychotic medication or other dopamine-blocking drugs are prescribed, the individual must be monitored for tardive dyskinesia (TD) on a regular and systematic basis using a standardized assessment⁶ instrument.

- a) Regular is at least once every 6 months using any of the existing TD screening instruments
- b) If TD occurs, there should be follow up of the individual for 6 months after terminating the medication.

Guideline 9: There must be regular and systematic reviews of all persons on psychotropic medications, which consist of regular clinical reviews by the professional prescribing the medication and regular behavioral reviews by other members of the multi-disciplinary team.

- a) Every 3 months to 6 months if the person is stable, pharmacist reviews at least every 12 months

Guideline 10: Practices to avoid (or medication practices to be monitored and reduced):

- a) Long-term use of PRN orders
- b) Long term use of benzodiazepines and/or anti-anxiety medications—addiction potential
- c) Anticholinergic drug use without documented signs of extra pyramidal side effects.
- d) High doses of any antipsychotic medication

* The International Consensus Handbook: Psychotropic Medications and Developmental Disabilities.

** Practice parameters of the assessment and treatment of children, adolescents and adults with mental retardation and comorbid mental disorders. *J Am Acad Child Adolesc Psychiatry.* 1999;38:5S-31S.

Appendix 2

Codes for Psychiatry Visit

Each code shows the frequency with which it appeared in the claims database for the consumers on psychoactive medications. Those in red were not included as codes for a psychiatry visit.

Code Number	Explanation of Code	Number Times Appears
90801	PSYCHIATRIC DIAGNOSTIC INTERVIEW EXAMINA	520
90802	INTERACTIVE PSYCHIATRIC DIAGNOSTIC INTER	5
90804	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	29
90805	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	657
90806	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	70
90807	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	346
90808	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	10
90809	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	15
90811	INDIVIDUAL PSYCHOTHERAPY, INTERACTIVE, U	11
90812	INDIVIDUAL PSYCHOTHERAPY, INTERACTIVE, U	1
90813	INDIVIDUAL PSYCHOTHERAPY, INTERACTIVE, U	3
90816	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	35
90817	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	114
90818	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	18
90819	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	90
90821	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	1
90822	INDIVIDUAL PSYCHOTHERAPY, INSIGHT ORIENT	12
90824	INDIVIDUAL PSYCHOTHERAPY, INTERACTIVE, U	11
90845	MEDICAL PSYCHOANALYSIS	1
90847	FAMILY MEDICAL PSYCHOTHERAPY (CONJOINT P	103
90853	GROUP MEDICAL PSYCHOTHERAPY (OTHER THAN	172
90862	PHARMACOLOGIC MANAGEMENT, INCLUDING PRES	1,202
90870	ELECTROCONVULSIVE THERAPY (INCLUDES NECE	3
90885	PSYCHIATRIC EVALUATION OF HOSPITAL RECOR	4
W 1023	COMMUNITY MENTAL HEALTH-PSYCHIATRIC DAY	242
W 1027	COMMUNITY MENTAL HEALTH-PSYCHOSOCIAL EVA	375
W 1030	PSYCHIATRIC EVALUATION	431
W 1031	PSYCHIATRIC EVALUATION OF HOSP RECORDS	23
W 1034	GROUP MEDICAL THERAPY	26
W 1036	INTERPRETATION OF PSYCH. EXAM.	102
W 1037	OFFICE & OUTPATIENT VISIT (NEW PATIENT)	50
W 1038	OFFICE & OUTPATIENT VISIT (EST. PATIENT)	81
W 1039	LIMITED FUNCTIONAL ASSESSMENT	254
W 1040	BEHAVIORIAL HEALTH OVERLAY-DJJ	4
W 1041	BEHAVIORIAL HEALTH OVERALY -DCF	2
W 1044	BASIC LIVING SKILLS TRAINING	229
W 1046	COMMUNITY MENTAL HEALTH-SOCIAL REHABILIT	265
W 1048	IN-DEPTH ASSESSMENT (NEW PT)	26
W 1049	IN DEPTH ASSESSMENT (EST. PT)	26
W 1050	MEDICAL/PSYCHIATRIC SERVICES	904
W 1058	SPEC. THERA. FOSTER CARE-LEVEL I	18
W 1059	COMPREHENSIVE ASSESSMENT	13
W 1060	SPEC. THERA. FOSTER CARE-LEVEL II	18
W 1061	CRISIS INTERVENTION SERVICES	2
W 1064	COMMUNITY MENTAL HEALTH-REHABILITATION D	184
W 1067	NEW PATIENT	292
W 1068	ESTABLISHED	137
W 1069	TREATMENT PLAN REVIEW	904
W 1070	MENTAL HLTH CLINIC/CENTER VISIT	446
W 1071	INTENSIVE THERAPEUTIC ON SITE SERVICES	190
W 1072	HOME & COMMUNITY BASED REHABILITATIVE	46
W 1073	PSYCH.TESTING W/WRITTEN RPT.NOT PHY.	23
W 1074	IND.THER.MTL HLTH PRAC.45-50MIN	297
W 1075	GRP THER.MTL HLTHPRAC	139
W 1078	PMHP CAPITATION PAYMENT	339