FOR IMMEDIATE RELEASE

Egyptian Regional Human Rights Authority
Report of Findings
13-110-9035
Illinois Department of Healthcare and Family Services

The Egyptian Regional Human Rights Authority (HRA) of the Illinois Guardianship and Advocacy Commission has completed its investigation concerning the Illinois Department of Healthcare and Family Services (HFS). The specific allegations are as follows:

A person with a disability was denied medication that had proven to significantly reduce maladaptive behaviors causing undue stress and jeopardizing her community placement.

If substantiated, the allegations would be violations of the Mental Health and Developmental Disabilities Code (405 ILCS 5/2) and the Illinois Administrative Code (50 Ill. Adm. Code).

Investigation Information

To investigate the allegation, the HRA Investigation Team (Team), consisting of two members and the HRA Coordinator spoke with the recipient's guardian, psychologist and pharmacist and also conducted a site visit at the CILA home where the recipient resides. During the visit, the Team spoke with the house manager and reviewed the recipient's clinical chart, with written authorization from her guardian. Policies relevant to the complaints were also reviewed.

I. Interviews:

A. Guardian: The guardian stated that the recipient was benefiting from Abilify. However, due to a change in what Medicaid was willing to pay for, she was required to switch to another medication, Zyprexa. After a trial of Zyprexa, her psychiatrist had recommended returning to Abilify due to her receiving more therapeutic benefit from the Abilify. The director of her community integrated living arrangement (CILA) home spoke with a representative from HFS who indicated she would be required to try at least 4 or 5 other psychotropic medications before being allowed to return to Abilify. The director and psychiatrist appealed the initial refusal by Medicaid to cover the use of Abilify but lost the appeal. The guardian additionally stated that the recipient's interdisciplinary team (IDT) strongly supported the reintroduction of Abilify based on behavioral documentation completed by CILA home staff and the psychiatrist's notes of Abilify's efficacy versus Zyprexa. The guardian believed that denial of a beneficial medication is a violation of this recipient’s human rights.

B. CILA Home Director: The director runs an 8 bed CILA home and the current census at the time of our interview was 7. Their clients range from those who have mild to severe developmental disabilities. This recipient was admitted to the CILA home from a state operated facility in May, 2012 after 6 months of visits to the home. He said that they had her visit for so long because her behaviors were "manic and were not being treated." She had resided at the state operated facility for 6 years after being admitted from her previous community placement for physical aggression. At the time of our interview, she had lived at the CILA home for approximately 14 months.

Since the recipient was on Medicaid, HFS required her to try another, less expensive medication first before they would pay for Abilify, which was not a preferred medication due to a change in their policy. The director estimated the cost of Abilify to be between $1,100 and $1,400 per month since there is currently no generic form of the medication. Other, HFS preferred medications included Zyprexa, Geodon, Risperdal, Latuda and Seroquel. After the change in medication from Abilify to Zyprexa, the home had "more problems" with her and she was "difficult to handle." She became physically aggressive, anxious and her activities of daily living (ADLs) were hindered. Zyprexa also increased her appetite and she had a weight gain of 26 pounds in 6 months, so there was also concern for health related issues. The director said she was worse on Zyprexa than she was with no medication at all. **Her psychiatrist did not agree to the change and was hesitant to even try the Zyprexa** because she had done so well on Abilify; however, he finally agreed to try the Zyprexa per HFS requirements. After the trial of Zyprexa which lasted approximately 2 months, the psychiatrist switched her back to Abilify. After the switch back, she received another denial letter from HFS stating that she would have to try 4 other medications that are "in the same category" as Abilify before HFS would pay for Abilify. The director felt like they were "**experimenting with her** and that decisions were being made for the state's benefit and not the patient's." He said while she was on Abilify, she "was more comfortable and content than ever." The director sent an appeal letter in September, 2012 but received no response. He appealed again in May, 2013 and received a court date for July. After our interview, the director informed the HRA that the state pharmacist, the qualified intellectual disabilities professional (QIDP) for the CILA home, the guardian and the house supervisor all attended the court hearing and when the pharmacist learned of all the medications that the recipient had been given at the state operated facility and then how just one medication, Abilify, was working so well, she approved the Abilify for one year.

C. Psychiatrist: The HRA interviewed the recipient's treating psychiatrist who is also the Medical Director for a community counseling service. He has approximately 200 patients with developmental disabilities and mental illnesses and has over 22 years of experience and 7 years at the community counseling service. He explained that Abilify is different than the other medications listed in the approved medications list, in that most antipsychotics suppress all dopamine but if you don't have enough, it impairs drive and motivation. Abilify **suppresses and increases** dopamine; no other antipsychotic medication does that. He expressed his concern over "the state" unilaterally making medication decisions based solely on the cost of the medication. He explained that it takes time to find a medication or combination of medications that works with this population and different individuals can have different reactions to the same medication. He said that when you find something that works you don't want to change it because it is "an art and science" to find a drug regimen that is successful for each person.

Another concern is that if symptoms go untreated or partially treated long enough, the brain structure could possibly change and medications may not work. Sometimes, individuals can be more resistive to treatment since the chemical balance in the brain has shifted again. He informed the HRA that he has been treating this recipient since June of 2012 when she moved from the state operated facility to the CILA home. He informed the HRA that she was actually worse on Zyprexa than when she was on no medication at all. She also gained weight and was hungrier which increased her irritability. The psychiatrist stated that he wrote a letter to "fair hearings at HFS" about this recipient but did not hear from HFS or the pharmacy. He said obtaining prior authorization for medications as required by "the state" takes a lot of time and effort and it is very discouraging when no response is received. Then, the whole process has to be repeated which is very time consuming and tedious for his staff who could be focusing their attention on other patient centered tasks.

D. HFS Representative: The HRA interviewed a representative via telephone on the medication review, approval and denial process. She explained that HFS has a preferred medication list and a panel of 12 clinical pharmacists who review medication requests as they are received and one of them would have made the decision of whether to approve or deny a specific request. This decision is based on the patient's diagnosis and prescription "fill history" with Medicaid and whether or not the individual has tried a medication in that class before. If not, and the medication requested is a non-preferred medication, then it is denied with a request to try a medication in the same class from the preferred list first. When a denial letter is received, it is up to the physician to contact HFS to discuss the reasons why a non-preferred drug was prescribed. In this case, the medication history that she accessed on their data base showed that the recipient had just begun filling prescriptions in May, 2012 [when she moved to this CILA home] and there was no history prior to that. So when they reviewed her "fill history" it showed that she had never tried any other medications in this same class of drugs even though her true medication history was that she had tried Risperdal at her previous placement and it was ineffective in treating her symptoms.

When questioned about the reason for the length of time it took from the appeal being sent and the hearing to occur, she stated that in 2012 when the first medication denials occurred for this recipient, it took approximately 8 months from the time the appeal was received until the time when the hearing would occur. They have since improved the process and in 2014 it would take an average of 4-6 weeks. The representative also explained that approximately 3-6 months ago (around January, 2014) their policy changed and now, after the third denial for a medication, HFS will contact the physician directly to clarify and discuss why the medication requests are still being sent to HFS after denials and also the reason for denial. This allows HFS to better understand the physician's reason for prescribing certain medications and also to discuss medication history that may not be in the "Medicaid fill history" system that HFS accesses. She explained that if this policy had been in place during the time of this recipient's denials, they would have "caught it" and would have contacted the doctor to discuss it and the Abilify would have most likely been approved without going through the appeals process. She did concede that the communication may not have been such that the doctor knew he could simply call HFS to discuss rather than filing the appeals or if he would have known what contact number to use since the denial letters come from a different department than hers, she was unfamiliar with what information was on that form. She said the denial form may just list the local office contact

information; if the local office told the doctor to file the appeal that could explain why he chose that route. She further explained that it is the preference of HFS that the doctor contact them directly first, to discuss the specific reasons for a particular medication being prescribed, prior to filing an appeal and request for hearing. This is accomplished by the doctor calling the same telephone number used to "put in the request for the prescription" she said this is the fastest way to get a response. She stated that the doctor can also look online on the "Medi system" to see which medications need prior approval, but it did not look like the doctor in this case uses that system because all of this recipient's medication prescriptions were phoned in by a pharmacy.

II. Clinical Chart Review:

A. Discharge Summary/Transition Plan: The discharge summary dated May 1, 2012 stated that the recipient was admitted to the state operated facility from an intermediate care facility for developmental disabilities (ICFDD) "on an emergency admission status" due to increasing physical aggression towards staff and individuals at the ICFDD. Her behavior was "escalating and becoming unpredictable." Shortly after admission, her status was changed to an administrative admission. The summary listed her diagnosis as "Axis I: Autistic Disorder 299.00; Generalized Anxiety Disorder 300.02; Psychotic Disorder NOS [not otherwise specified] 298.2; Post-Traumatic Stress Disorder 309.81; Axis II: Moderate Mental Retardation 318; Axis III: History of Seizures V12.49; Dysmenorrhea 625.3." The condition on discharge section stated that she "appeared happy to be transitioning to her new home. Throughout the transition process, she has completed numerous successful evening, overnight and weekend visits to [CILA home]." It also stated that her guardian "concurs with placement to this setting."

The Transition Plan dated April 18, 2012 listed her diagnosis as "(Axis I) Pervasive Developmental Disorder; Generalized Anxiety Disorder; (Axis II) Moderate Mental Retardation; (Axis III) Menstrual Cramps; History of Seizure disorder with abnormal EEG; Osteopenia." The summary of her visits to the CILA home indicated that visits began in November, 2011 and that she first had visits with staff from the state operated facility, then additional visits were scheduled in the evening with her riding the bus from her workshop to the home and finally overnight visits were scheduled in February and March and stated "all visits went well." Potential issues that might occur after transition are listed as "becomes anxious at times…" Her discharge medications were listed as Tapazole twice daily for hyperthyroidism, multivitamin 1 tablet daily, calcium with vitamin D three times daily and Depo Provera every 3 months for birth control/menstrual cramps. It stated that the recipient "does not receive psychoactive medication." Her medication plan for psychotropic medication listed her as being admitted to the state operated facility on "Abilify, Depakote and Paxil. Abilify was discontinued and Paxil tapered to discontinuation. On 9/10/08 Depakote was discontinued. She is currently not taking any psychotropic medication." Her target behavior is listed as verbal aggression. It stated that she "completes her daily routine independently, including self-care activities to spending small amounts of money. She displays appropriate behavior in the community and does not require psychoactive medication. She has successfully met her behavioral objectives; thus eliminating the following maladaptive behaviors: physical aggression, self-injurious behavior, property destruction and inappropriate sexual behavior."

B. Individual Service Plan (ISP) from the CILA home: The ISP/Annual Review dated May 7, 2013 listed the recipient's diagnosis as "Axis I Psychosis NOS; Autistic Disorder; Generalized Anxiety Disorder; Axis II Moderate Mental Retardation; Axis III Hyperthyroidism; Osteopenia; [and] Hx [history] of seizures." Her medications are listed as Oyster Shell TID [three times daily] [for calcium]; Methimazole [for hyperthyroidism]; Thera-M [multivitamin]; Depo Provera [birth control/menstrual cramps]; Docusate Sodium [stool softener] and Zyprexa [antipsychotic]. A team discussion report **listed a change in mental status that occurred "as her medications have been changed**, most recently she has become more agitated and aggressive when her Zyprexa had been increased." Under *change in medications* it stated "**She was placed on Abilify last September with positive results and remained on that drug until we found that the state would not pay for the medication and suggested we change it to Zyprexa 2.5 mg**. We argued against the Zyprexa trial but in the end in March we changed her medication to their recommendation and we increased it to 5 mg in April. She became more agitated and aggressive after the increase to 5 mg. After seeing the Psychiatrist on 5/10 he recommended she be placed back on Abilify as she did so well on that medicine-we were hopeful it would be approved as we met the state's recommendation. He prescribed Abilify 5 mg AM." Under *med reduction plan* it stated "no formal medication schedule can be implemented because of the many state mandated medication changes. We will continue to collect behavioral data." Her behavior summary for the year listed "physical aggression [PA] - 15 episodes, verbal aggression [VA] 34 episodes, perseverative [repetitive] verbal behavior [PVB]- 23 episodes." This report included the following behavioral data:

Before meds were prescribed 5/12/12-9/11/12:
PA-8, 2/mo; VA-15, 3.75/mo; PVB-11, 2.75/mo

Abilify prescribed 5 mg & 7 mg 9/11/12-3/01/13:
PA-4, .67/mo; VA-9, 1.5/mo; PVB-6, 1.0/mo

Zyprexa prescribed 2.5 mg & 5 mg 3/01/13-4/30/13:
PA-3, 1.5/mo; VA-10, 5/mo; PVB-6, 3/mo

C. Notice of Appeal dated 9/26/12 from the CILA home requested a fair hearing to appeal the Abilify being denied. The notice prepared for the recipient by the QIDP [Qualified Intellectual Disabilities Professional] and CILA home director stated that she needed the medication to manage her schizophrenia, without this medication her symptoms are worse and she is more agitated. It continued to say that this group of behaviors put her at risk of losing her community placement and put others at risk of physical harm.

Another Notice of Appeal dated 5/21/13 prepared by the CILA home director stated that she did a trial with a medication from the approved medications list (Zyprexa) and the recipient was worse. She had an increase in verbal and physical aggression. It continued to say that **the only professionally recommended and clinically supported medication** for the recipient is Aripiprazole [Abilify]. The appeal concluded by stating that “without this specific medication her mental health needs are not being met.”

D. Behavior Management/Human Rights Committee Reviews: This review by the CILA home dated 11/5/12 listed a rights restriction of "behavior medication Abilify 7 mg." Under the *medication changes* section it stated that the recipient was admitted in May, 2012 from the state operated facility on "no psychotropic medications despite having several major psychiatric classifications. Her behavior has been monitored and data collected and 3 months of this information was shared with [psychiatrist] and her guardian. [Psychiatrist] reviewed this information and recommended she be prescribed Abilify 5 mg. The team including the guardian agreed with this recommendation and the medication was started on 09/11. Then on a f/u [follow up] evaluation with [psychiatrist] on 11/05/12 he recommended her Abilify be increased to 7 mg. The team including the guardian approved of this recommendation." The current behavioral data was listed as "physical aggression 3 episodes/mo; perseverative verbal behavior - 3 episodes/mo; verbal aggression/abuse - 4 episodes/mo."

A review dated 4/15/13 listed a rights restriction as "behavior medication Zyprexa 5 mg." The *medication changes* section stated verbatim what the 11/5/12 section stated and added the following "On 3/01/13 her medication was changed to Zyprexa 2.5 mg as the state would not fund her previous medication (Abilify) and suggested we try the Zyprexa. We have followed their recommendation and on 4/15/13 [psychiatrist] **increased it to 5 mg as she had several behavioral outbursts**." Under the *medication plan* section it stated "at this time her response to medication is being evaluated. There is the possibility the medication may again be changed back to the Abilify if she does not stabilize on her current medication."

Another review dated 7/26/13 listed a rights restriction of "behavior medication at 8/12/13 review: Abilify 7.5 mg." The *medication changes* section stated verbatim what the 4/15/13 review said and added that the recipient was again seen by her psychiatrist on 5/10/13. The review stated that the psychiatrist "reviewed the behavioral data on [recipient] before any medications were prescribed, while she was on Abilify and the Zyprexa that was prescribed at the recommendation of the State of Illinois to take the place of Abilify which they would not fund. **After careful review of the data and observations made of [recipient] during the meeting he discontinued the Zyprexa and reordered the Abilify 5 mg.** The team including the guardian concurred with his recommendation. Today we attended a hearing as we were appealing the state's ruling on not funding her Abilify. We presented behavioral data we felt was appropriate along with a history of medications she has taken in [the] past to try and help stabilize her condition. The pharmacist who attended the meeting accepted our information as presented and approved her Abilify. As the medication was approved we withdrew our appeal. It was suggested we (psychiatrist name) write the prescription for 15 mg and give the medication in divided doses 7.5 mg/day in an effort to help the state save money by not giving 2 doses (5 mg & 2 mg)."

E. On 12/5/12 the recipient's pharmacy sent a notice to the CILA home and psychiatrist notifying them of "urgent – non-covered medication" stating that he had prescribed a drug for the recipient that her insurance company would not pay for and that this medication would not be sent without authorization from the insurance company or approval for a temporary supply to be sent and billed to the facility. It stated "you may wish to choose one of the covered formulary options listed below for the resident's insurance plan. If you wish to use the drug you originally prescribed, you will need to contact the resident's insurance provider to obtain a prior

authorization or medical exception." The medication being denied was listed as Abilify 5 mg and the formulary alternative was listed as Olanzapine [Zyprexa] 2.5 mg and also noted "PA [pre-approval] denied for Abilify, trial/failure Clozapine [Clozaril], Olanzapine, Ziprasidone [Geodon] needed." Another notice dated 6/5/13 was also reviewed which stated verbatim what the 12/5/12 notice had but suggested Risperidone as the formulary medication.

F. CILA home letter to the Department of Human Services' (DHS) Southern Network Facilitator dated 5/31/13: This letter sent by the QIDP was regarding "necessary medication for [recipient]." This letter outlined the same behavioral data listed above under section B and gave more specific information on her behaviors between 5/12/12 through 9/11/12 (before any medication). The behaviors included "eating too fast, vomiting purposefully-daily basis; pulling pants down in public, disrobing averages 2 times per week; incontinent of BM [bowel movement] during shower and in bed and rectal digging - almost daily; daily agitation (loud angry nonsensical verbalization); physical aggression (slapping/striking others) - as many as 8 per month and preservative verbal behavior (loud angry verbalizations…as many as 15 episodes per month. This preservative verbal behavior upsets the environment in general and everyone living in the home…" The letter continued to provide the history of sharing this information with her psychiatrist and him prescribing Abilify "as she had a previous positive response to this medication at another placement." The letter stated that "her behaviors became significantly less frequent, intense and severe and generally she became more redirectable, more relaxed and better able to engage in house and work activities." The letter continued by providing the following account of the medication change on 3/1/13 to Zyprexa "as the state would not fund her Abilify and suggested we try the Zyprexa. [Psychiatrist] disagreed with this action and argued against it with the state. The state refused to accommodate to the mental health needs of [recipient] and [psychiatrist] with no recourse available to him, prescribed Zyprexa per the state's recommendation. This medication and dosage (2.5 mg/day) was ineffective for [recipient]. On 4/15/13 [psychiatrist] increased it to 5 mg HS [at night] as she had several behavioral outbursts. [Recipient] was again seen by [psychiatrist] on 5/10/13 for a follow up on the Zyprexa 5 mg he prescribed on 4/15/13. During that period of time she became more agitated and aggressive. On 5/10/13 [psychiatrist] after having noted the failure of Zyprexa, recommended she be placed back on Abilify as we prescribed what was recommended to us by the state, in fact we had the medication increased as we found the lower dose not effective in managing her maladaptive behavior. The increase to 5 mg only made the situation worse (paradoxical reaction) as it strengthened and increased the number of her maladaptive behaviors. We felt we had met the recommendation given to us and were comfortable with the notion of again trying Abilify. Within days, [recipient's] behavior started to improve. Soon after, the state again refused to provide for [recipient's] well being (denying Abilify), and requested that another medication (Risperidone) be experimented with on [recipient]." The QIDP was requesting the assistance of DHS in addressing the issue since her response to Abilify "allows her to function in a manner that promotes her well being and allows her to enjoy life without having to endure medications with severe side effects (metabolic syndrome, diabetes, Neuroleptic malignant syndrome and tardive dyskinesia) just to control her maladaptive behavior." The letter concluded by stating that since her return to Abilify (5/1 to 5/31) she had only experienced 1 verbal aggression and 1 perseverative verbal behavior and her placement "is not in jeopardy." The director informed the HRA that the network facilitator's response was that there was not anything he could do to help

because they have tried before with others with no success and suggested that the appeals process through HFS was the only option.

G. CILA home letter to the Fair Hearing Officer dated 7/19/13: This letter from the QIDP regarding the "necessary medication for [recipient]" listed her admitting medications from the ICFDD [Intermediate Care Facility for the Developmentally Disabled] to the state operated facility as Depakote, Risperdal, Zoloft, Bromocriptine [prescribed for hormone imbalance] and Mircette [prescribed to prevent ovulation]. The letter continued to address each of the medications (Zyprexa, Seroquel, Risperdal, Geodon and Latuda) recommended by the state to try before Abilify would be paid for as follows: "Zyprexa was tried and her symptoms became worse, she became more aggressive and out of control…Zyprexa is a Dibenzapine derivative as is Seroquel. She has been prescribed Risperdal at her former placement and it did not help control her aggressive behavior and subsequently she was admitted to a SOF [state operated facility]. Risperdal is a Benzisoxazole derivative as is Geodon…Latuda, another recommended medication we try is a medication whose effectiveness is in question as longer-term use, that is, for more than 6 weeks, has not been established in controlled studies." The letter continued to state that the CILA home had consulted with a Clinical Pharmacist at a state operated facility and he indicated that Abilify "has new indications of using it for irritability associated with autistic disorder and also it has a partial agonist activity at D2 and serotonin 1A receptors and antagonist activity at serotonin 2A receptors. **If there is insufficient dopamine activity, Abilify increases activity and if there is too much activity, Abilify decreases the activity to provide stability unlike the other medications previously mentioned."** The QIDP concluded the letter by stating that their concern is for the recipient's well being and felt that if she had to spend the next several months enduring mandated medications, she will more than likely return to a state operated facility as **she cannot tolerate the trials**. The letter also noted that the guardian indicated that she is more stable now than he has ever seen her and also **that she can be maintained on 1 medication rather than several different medications as previously prescribed.**

H. The HRA reviewed "HFS [Healthcare and Family Services] Notice of Decision on Request for Pharmaceutical Service" letters. The first one dated 9/19/12 states "A request for prior approval for pharmaceutical service(s) or item(s) was received in the HFS drug unit from your medical provider on September 19, 2012. The request has been denied for the following item: Drug name: NDC from LBL Aripiprazole [Abilify] tablet 5 mg. The item was denied for the following reason: This request was denied."

The next notices dated 10/10/12 and 10/24/12 both stated that a request for prior approval for Aripiprazole tablet 5 mg was denied for the following reason "The request was denied because other equally effective therapies are available without prior authorization."

On 1/2/13 and 6/17/13 a request for Aripiprazole tablet 2 mg were both denied for the following reason "because other equally effective therapies are available without prior authorization."

The HRA also reviewed a 6/17/13 notice which also denied Aripiprazole 5 mg tablet because "other equally effective therapies are available without prior authorization."

On 7/26/13 after the second appeal and hearing was held, HFS sent a notice of decision that approved Aripiprazole tablet 15 mg for the time period of 7/26/13 through 7/26/14.

I. Current behavior status: The Team reviewed this behavior summary completed by the CILA home and dated July, 2013 in her chart. The summary stated that her behaviors are a reflection of her internal state, her sense of well-being and are not meant to manipulate her environment or others. It noted that the behaviors are mostly manageable on Abilify and "moderately more difficult to manage on no medication, significantly more difficult on Zyprexa, and was admitted to SOF [state operated facility] on Risperdal. The current behaviors on Abilify are listed as Anxious/agitation (gritting teeth, strained look on her face, hands tightly bound, gripping tightly her lunch box or other security items, needs more reassurance and redirection). Inappropriate verbalizations (sexually explicit and offensive, verbal threats to staff and peers, perseverative in nature, needing regular staff redirection or escalation occurs). BM Issues (she thinks she is sick after every BM, takes 10-90 minutes to recover with staff assistance, redirection and reassurance that she is ok). BM issues also result in skipping meals and sleep disruption which results in routine disruptions resulting in constant inappropriate verbalizations." The summary also explained how her behaviors affect others in the home by causing environmental disruption. When this occurs, peers feel threatened and leave the common areas (hide). Her behavior puts herself and others at risk. On Abilify, she also does not require Ativan for medical visits, prior to Abilify it was required and the effective dose was such that she required a wheelchair and slept the rest of the day. On Abilify she does better on community outings. When she was on Zyprexa or no medication, she had inappropriate behaviors and verbalizations on every outing. The summary concluded that even on Abilify the "margin of error/safety for her is slim, thus our concern about testing medications. Her levels of behaviors are now consistently right below threshold of moderate or seriousness."

J. The psychiatrist's letter to HFS dated 7/19/13 was reviewed. This letter summarized the recipient's diagnoses and said that she was on Abilify 7 mg which "was significantly controlling her anxiety. However, due to the expense, the State of Illinois deemed it necessary to refuse to pay for this and demanded that she try other medications in the same family including Geodon, Risperdal, Zyprexa and Seroquel." He explained that when Abilify was discontinued and Zyprexa was started "her behavior dramatically worsened. She also voiced several complaints of hunger while on Zyprexa which is a common side effect of this medication." The psychiatrist explained that since her anxiety dramatically increased, they stopped the Zyprexa and "were forced to give her samples of Abilify, again because of refusal of the State of Illinois to pay for this. As a result, her behavior improved almost immediately." It was also noted in this letter that "a fair amount of time was spent completing a prior authorization for which was either ignored or simply denied without consideration as payment for the medication was still refused." The psychiatrist continued to state that they were advised to try multiple other medications that are less expensive but in his opinion "for a state that prides itself in advancing progressive social policies, **denying this patient a medication** which has been prove to work until several other medications have been tried **is at best inefficient and at worst cruel and inhumane**. It had already been documented that [the] patient responded well to Abilify and I feel it is pointless for the patient to continue to endure more suffering simply for the convenience of the State of Illinois." The psychiatrist concluded his letter by informing the HFS that "there is a new FDA approved indication for Abilify which essentially concerns irritability associated with Autistic

Disorder. This medication is known as a 'partial agonist' and therefore, **has unique properties not found in any other medication**. I urge you to reconsider your decision regarding denial of payment for Abilify…"

K. The psychiatrist examination notes supported what he relayed to HFS and also what the CILA director had shared with the HRA that this recipient's condition worsened while on Zyprexa and improved on Abilify. Some specific notes of significance are as follows: on 3/1/13 "patient is stable. She is on Abilify 7 mg in the morning and **there are apparently no side effects to this**. The problem is that the state inappropriately refuses to pay for Abilify because it is expensive and they want us to try the cheaper Olanzapine first even if this means a risk of destabilizing patient's condition…No change in medication recommended at this time…however, we are forced to implement a medication change to see if the state can get away with paying for a cheaper medication. We will stop Abilify and start Olanzapine 2.5 mg at bedtime. **Side effects of dyslipidemia, hyperglycemia, diabetes, neuroleptic malignant syndrome and tardive dyskinesia** will be explained to guardian before this is instituted and patient will need a serum lipid profile also." A 4/15/13 note stated that "the patient was not seen today but the caretaker stated that she has been having some increased behavioral problems and would like to increase the Zyprexa; will increase to 5 mg at bedtime." On 5/10/13 the psychiatrist's examination note stated "since the state forced us to try a cheaper antipsychotic (Zyprexa) patient's behavior has increased dramatically since then. Of note is that she had been doing just fine on the Abilify at 7 mg a day…patient's condition has worsened since being on Zyprexa. Will discontinue Zyprexa and restart Abilify 5 mg in the morning and, if the state continues to inappropriately refuse to pay for Abilify, I will give her samples. Staff tell me that guardian has approved the change." A 6/10/13 psychiatric examination note stated "since we changed patient's medication back to Abilify 5 mg in the morning from Zyprexa, patient's behavior has been much improved. Staff states that although there is significant improvement they would like to increase to 7 mg in the morning as patient had previously been on this and experienced an optimum response. **She does not appear to display any side effects to the medication**…Will increase Abilify to 7 mg in the morning and will give her samples as the state continues to inappropriately refuse to pay for this."

III. HFS Policies:

The HRA reviewed the preferred drug list for Illinois Medicaid dated July 1, 2013 which does list Abilify as a non-preferred medication for Atypical Antipsychotics and Clozapine, Latuda, Olanzapine, Quetiapine, Risperidone and Ziprasidone are listed as preferred medications.

An informational notice dated 10/26/12 explained that the Medicaid reform law, called the *SMART Act* was signed into law in June, 2012 requiring the department to require prior approval for medications after a client has filled four prescriptions in the preceding 30 days. The notice also stated that "the purpose of the four prescription policy is to have providers review their patients' entire profile of maintenance medications and, where possible **and clinically appropriate**, reduce duplication, unnecessary medications and poly-pharmacy and avoid other problems. The four prescription policy **was developed as a result of budget negotiations**, but best-practices call for an annual review of the full regimen of prescriptions for any patient…Exceptions: the four prescription policy is not a 'hard' limit. **Medicaid patients can**

and should have access to medications that are medically necessary, even if they exceed four prescriptions per 30 days. The policy simply requires prior approval (PA) for prescriptions above four..."

Statutes

The Mental Health and Developmental Disabilities Code *Deprivation of rights, benefits, privileges or services* (405 ILCS 5/2-100) states that "No recipient of services shall be deprived of any rights, benefits, or privileges guaranteed by law, the Constitution of the State of Illinois, or the Constitution of the United States solely on account of the receipt of such services. (b) A person with a known or suspected mental illness or developmental disability shall not be denied mental health or developmental services because of age, sex, race, religious belief, ethnic origin, marital status, physical or mental disability or criminal record unrelated to present dangerousness."

The Code under *Care and services; psychotropic medication; religion* (405 ILCS 5/2-102) requires that a recipient of services "shall be provided with adequate and humane care and services in the least restrictive environment, pursuant to an individual services plan…" Adequate and Humane is defined as *"services reasonably calculated to result in a significant improvement of the condition of a recipient of services confined in an inpatient mental health facility so that he or she may be released or services reasonably calculated* ***to prevent further decline in the clinical condition of a recipient of services so that he or she does not present an imminent danger to self or others.****" (405 ILCS 5/1-101.2)*

The Code *Unusual, hazardous or experimental services or psychosurgery* (405 ILCS 5/2-110) states that "no recipient of services shall be subjected to any **unusual, hazardous or experimental** services or psychosurgery without his written and informed consent."

The Illinois Administrative Code regarding *Clients' Rights* (59 IL ADC 132.142) provides that "A client's rights shall be protected in accordance with Chapter 2 of the Mental Health and Developmental Disabilities Code…Staff shall inform the client prior to evaluation services and annually of the following…The right to have disabilities accommodated as required by the American With Disabilities Act, section 504 of the Rehabilitation Act and the Human Rights Act [775 ILCS 5]"

The Administrative Code *Treatment Services* (59 IL ADC 132.150) requires that services shall be provided with the following criteria "**The services shall be provided A) following a mental health assessment** or Admission Note, as applicable, and consistent with the client's ITP or Admission Note, as applicable; B) **Through face-to-face, video conference or telephone contact** as permitted under each specific service; C) To clients, and their families or collaterals at the client's request or agreement; with groups of clients; or with the client's family or collaterals as it relates to the primary benefit and well being of the client and when related to an assessed need and goal on the client's ITP…Crisis intervention services include interventions to stabilize a client in a psychiatric crisis to avoid more restrictive levels of treatment and that have the goal of immediate symptom reduction, stabilization and restoration to a previous level of role

functioning. A crisis is defined as a deterioration in the level of role functioning of the client within the past 7 days or an increase in acute symptomatology."

The Administrative Code *Medical Assistance Programs* (89 IL ADC 140.2) defines necessary medical care as "that which is generally recognized as standard medical care required because of disease, disability, infirmity or impairment." It further states that "The Department may impose prior approval requirements, as specified by rule, to determine whether the medical care is necessary and eligible for payment from the Department in individual situations. Such requirements shall be **based on recommendations of technical and professional staff and advisory committees**."

The Administrative Code under *Requirements for Prescriptions and Dispensing of Pharmacy Items* (89 IL ADC 140.414) states "A prescriber may prescribe any pharmacy item, not otherwise excluded, that, in the provider's professional judgment, is essential for the diagnosis or accepted treatment of a recipient's present symptoms. The Department may require prior approval of any drug except as outlined in Section 140.442(a)(9) of this section."

Section 140.442 *Prior Approval of Prescriptions* a) states "The Department may require prior approval for the reimbursement of any drug, except as provided in this Section. Determinations of whether prior approval for any drug is required shall be made in the following manner:

1) The Department shall consult with individuals or organizations that possess appropriate expertise in the areas of pharmacology and medicine. In doing so, the Department shall consult with organizations composed of physicians, pharmacologists, or both, and shall, to the extent that it consults with organizations, limit its consultations to organizations which include within their membership physicians practicing in all of the representative geographic areas in which recipients reside and practicing in a majority of the areas of specialization for which the Department reimburses physicians for providing care to recipients…9) Effective July 1, 2012, the Department shall provide that the following types of drugs are available without prior approval: A) Contraceptive drugs and products; and B) Non-innovator products, listed in the State of Illinois Drug Product Selection Program's current Illinois Formulary, when the innovator product is available without prior approval. b) **Prior approval shall be given for drugs requiring authorization if**…Either: A) **The drug is necessary to prevent a higher level of care, such as institutionalization**; or B) **The prescriber has determined that the drug is medically necessary**. c) Decisions on all requests for prior approval by telephone or other telecommunications device and, upon the Department's receipt of the request, shall be made by the same time of the Department's next working day. In an emergency situation, the Department shall provide for the dispensing of at least a 72-hour supply of a covered prescription drug…d) 2) Brand name prescription drugs are exempt from the prior approval requirements of this subsection (d) if: A) there are no generic therapies for the condition treated within the same therapeutic drug class; or B) the Department determines that the brand name prescription drug is cost effective."

Conclusion

It was evident based on review of the chart documentation and the HRA's interview with the psychiatrist that he did not agree with the state's refusal to pay for Abilify and its decision to switch her medication to Zyprexa or another, less expensive medication. Reluctantly, her medication was changed and proved to be ineffective as the behavioral data showed an increase in maladaptive behavior to the point that her community placement was in jeopardy as well as the safety of other residents in the home. The psychiatrist and CILA home staff wrote letters and filed appeals on behalf of the recipient to advocate for her right to adequate and humane care and treatment. They received no response to the first appeal and filed a second appeal which resulted in a hearing approximately 10 months after Abilify was started and payment was denied by HFS. At the hearing, when the state pharmacist heard the facts of the case and how many medications had been tried and failed, the medication was approved for a one year time period. The HRA questions why the appeals process took so long and why there was no mental health assessment, face to face or telephone conference with the treating psychiatrist by HFS before denying payment for Abilify and requiring that several other medications be tried before the Abilify would be covered as required by the Administrative Code (59 IL ADC 132.150). This resulted in the recipient being forced to endure a trial of an ineffective medication resulting in a decline of her mental status and borders on unusual, hazardous or experimental treatment that is prohibited by the Mental Health Code (405 ILCS 5/2-110). Therefore, the allegation is **substantiated.** The HRA makes the following **recommendations**:

1. **Before requiring an individual to change a medication that is effectively treating symptoms, HFS should consult with the treating psychiatrist and/or physician along with the individual's guardian to assess the individual's mental status and obtain historical information on what other medications may have already been tried and proven ineffective before requiring the individual to undergo unnecessary trials of medications.**

2. **When requiring a medication change, HFS should take into consideration all aspects of the medication change and what the financial impact will actually be. (i.e. Can the individual be treated effectively with one, more expensive medication versus several less expensive medications; What are the side effects of the less expensive medication and what impact will it have on the overall health and related expenses.)**

3. **When, as the psychiatrist contended in this case, the medication is necessary to prevent institutionalization or is deemed medically necessary, HFS should grant prior approval as required by the Administrative Code (89 IL ADC 140.442).**

4. **If an appeal is received, HFS should respond promptly to the appeal, scheduling a hearing as soon as possible and allowing the current medication to be continued and paid for until the appeals process is completed.**

5. **HFS should review their medication denial forms to ensure that proper contact information for HFS is included on the form and should notify all regional offices that the <u>preferred</u> method for addressing medication denials is for the physician to**

contact HFS directly before filing an appeal and requesting a hearing. HFS should also review their policies and revise or create a policy stating said preference.

6. **Ensure that denial notices list sufficient reasons for denials instead of simply stating "the request was denied" in the reason section. See the 09-19012 denial notice.**

RESPONSE

Notice: The following page(s) contain the provider response. Due to technical requirements, some provider responses appear verbatim in retyped format.

REGIONAL HUMAN RIGHTS AUTHORITY

HRA CASE NO. 13-110-9035

SERVICE PROVIDER: Healthcare and Family Services

Pursuant to Section 23 of the Guardianship and Advocacy Act (20 ILCS 3955/1 *et seq.*), we have received the Human Rights Authority report of findings.

IMPORTANT NOTE

Human Rights Authority reports may be made a part of the public record. Reports voted public, along with any response you have provided and indicated you wish to be included in a public document may be posted on the Illinois Guardianship and Advocacy Commission Web Site. (Due to technical requirements, your response may be in a verbatim retyped format.) Reports are also provided to complainants and may be forwarded to regulatory agencies for their review.

We ask that the following action be taken:

__X__ We request that our response to any recommendation/s, plus any comments and/or objections be included as part of the public record. Please see attached three pages.

_____ We do not wish to include our response in the public record.

_____ No response is included.

Jennifer Barker
NAME

General Counsel
TITLE

7/3/2014
DATE

ILLINOIS DEPARTMENT OF
HFS Healthcare and Family Services

Pat Quinn, Governor
Julie Hamos, Director

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Chicago, Illinois 60607

Telephone: (312) 814-4805
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July 3, 2014

Clarence Russell
Chairperson
Egyptian Regional Human Rights Authority
#7 Cottage Drive
Anna, Illinois 62906
(SENT BY FAX to (618) 833-5219)

Re: HRA Case #13-110-9035

Dear Mr. Russell:

This letter responds to the Egyptian Regional Human Rights Authority's (HRA's) June 3, 2014, letter to the Department of Healthcare and Family Services (HFS). Although HFS is barred by federal privacy and state confidentiality laws, including the Health Insurance Portability and Accountability Act, from disclosing any information regarding the individual client's case that your letter purports to describe, it can respond to your general recommendations. For the reasons that follow, HFS cannot accept your recommendations, which are based on misstatements of HFS policy or which simply restate existing HFS policy, and has serious reason to question your findings of fact.

Response to Recommendations 1 through 3:
These recommendations are premised on a mischaracterization of HFS policy. HFS requires prior authorization for its coverage of certain drugs, including non-preferred drugs in cases in which less expensive drugs have been deemed to have similar therapeutic effect. Prior authorization is permissible under the Medicaid Act (42 USC § 1396r-8(d)) and has been endorsed by the courts (see *Pharmaceutical Research and Manufacturers of America v. Meadows*, 504 F.3d 1197, 1199-1201 (11th Cir. 2002)). The federal government has approved its usage in Illinois, and the detailed process by which HFS determines whether a drug requires prior approval is explained in 89 Ill. Admin. Code § 140.442.

Anyone seeking a non-preferred drug may submit a Drug Prior Authorization Request Form (Form Number HFS 3082) to HFS; the form invites requestors to describe any medications previously tried for the malady at issue, the results of using any prior medication, any side effects non-preferred drugs may help avoid, and any other explanation for their requesting the non-preferred drug. In reviewing a medication request, HFS will consider all of these factors, and assess the overall costs and benefits of the non-preferred drug and any alternatives. HFS will respond to the application typically in approximately two hours. HFS receives and processes approximately 750,000 of these requests each year.

Before approving a request for non-preferred drugs, HFS requires an explanation or some other justification such as the failure of preferred drugs, adverse side effects from preferred drugs or the success of non-preferred drugs. However, HFS has a longstanding policy — in effect throughout the time period described in your letter — of continuing coverage for any psychotropic drug (even non-preferred drugs) if a client has achieved stability using that drug. The fact that this policy would have applied under the facts you describe is one reason HFS questions the accuracy of your findings.

If a drug approval request is missing information or otherwise ambiguous, HFS will contact the prescribing practitioner for more information, and, if a drug is requested and rejected three times, HFS will contact the prescribing practitioner to discuss the matter. HFS does not recommend any specific drugs or dosages. Any client or practitioner who disagrees with an HFS determination, may, of course, contact HFS with any information or explanation that might be helpful. HFS always maintains a goal of covering medically necessary medication and avoiding unwanted institutionalization where possible.

In your letter, you avoid describing the client's request for HFS approval of her preferred medication, but you leave the impression that the client you describe failed to disclose her medical history to HFS when she allegedly requested approval for her non-preferred medication. If the requestor you describe had provided any indication of her justification for requesting a non-preferred drug, e.g. that the client had attained stability on the non-preferred drug – a justification the approval form invited her to make — HFS policy as described above would have dictated that her request be approved.

Response to Recommendation 4:
Your letter claims that a recipient properly requested a hearing in September 2012 yet did not receive a hearing until July 2013. However, excluding cases in which the recipient requested and received continuances, HFS is not aware of any fair hearing requests filed in September 2012 or later whose hearing was delayed by HFS for 10 months as you describe. Currently, as your letter seems to acknowledge, hearing requests are deemed ready for a hearing within 4 to 6 weeks after HFS receives them. For these reasons, your recommendation regarding the expeditious handling of appeals describes existing HFS policy, and thus does not suggest any change in HFS policy.

As for the recommendation that requested medication be covered pending an appeal, HFS ensures through emergency and other policies that clients receive adequate treatment and medication, and, as noted above, it does not discontinue psychotropic medications that have proven to be effective. It declines to cover all requested medications through the appeal process for good reason: that policy would, in effect, obviate the dictates of the Medicaid Act to administer a program that covers medically necessary treatment through a prior approval process for which HFS has received Federal approval.

Response to Recommendation 5:
Regarding your recommendation that HFS' notice forms contain information about appeals, HFS' medication denial forms clearly indicate that clients may contact their local offices — the

same local offices with which they have coordinated all other benefits and questions — to facilitate any appeal.

On the second point, HFS does not have an official "preferred method" that has doctors contact HFS to discuss denials before appeals are filed. HFS of course welcomes physicians to contact it to provide any missing or helpful information in lieu of the appeals process. This practice does not reflect a "preferred method" or even a "policy."

Response to Recommendation 6:

Your recommendation that denial notices supply the reason for any denial reflects current HFS policy. Your letter, which describes a 2013 notice that explains the reasons for a denial, indicates as much.

As this response explains, your letter is based on an erroneous conception of HFS' programs, and seems to be based on incomplete or misstated facts regarding the client situation you purport to describe. It is unfortunate that you sustained a human rights complaint, and even stated that HFS' policies "border[] on unusual, hazardous or experimental treatment," without a full understanding of the situation. HFS has no choice but to object to your letter.

Sincerely,

Jeanette Badrov
General Counsel
Department of Healthcare and Family Services