Gabriel Myers Workgroup
June 8, 2009
Tampa, Florida
Meeting Summary/Minutes

Members Present: Jim Sewell, Chairman
Bill Janes
Anne Wells
Robin Rosenberg
Rajiv Tandon
Mike Haney
Betty Busbee

CALL TO ORDER

Chairman Sewell called the meeting to order at 9:15 a.m. He asked that workgroup members review the minutes of the May 14, 2009 meeting and notify Jennifer Prather of any changes by Wednesday, June 10. Minutes will be finalized and posted on the website by the end of the week.

Chairman Sewell introduced Jan Gregory, Deputy Regional Director of the Department's Suncoast Region, who welcomed the workgroup members and meeting attendees on behalf of Regional Director Nick Cox.

DCF DATA VALIDATION PROJECT (John Cooper/Alan Abramowitz)

Chairman Sewell introduced John Cooper, Department of Children and Families' Acting Assistant Secretary for Operations, to provide an update on the Data Validation Project.

Mr. Cooper advised that he had provided a brief update on this project to the workgroup previously in Ft. Lauderdale and that he would continue that presentation today with the findings through Friday, June 5.

He advised that, after the tragic death of Gabriel Myers, the Department of Children and Families conducted a quality assurance review of the case. Among the deficiencies identified during this review was the lack of informed consent or court order for psychotropic medications. It was also determined that Gabriel's medication was not listed in Florida Safe Families Network (FSFN), the Department's database.

As this information regarding the deficiencies identified in the quality assurance review surfaced, Secretary Sheldon ordered a complete review of every child in out of home care. The review has been a three step process. The first step involved identifying all children in out of home care taking psychotropic medication. This was done through file review without relying on the information contained in FSFN. Each case manager was tasked to review their case load and identify all children on one or more psychotropic medications. Once these children were

identified, the second part of the validation project was to update FSFN with the most accurate information. Step three is to ensure informed parental consent or court order.

Mr. Cooper reminded the workgroup members that at the time of their previous meeting, 1,950 children were identified in FSFN on psychotropic medications. Data as of June 5 indicate that number is 3,093. There are 8,944 children in the 0 – 5 age range in out of home care; 122 of those children are taking one or more psychotropic medications, representing about 1.36 percent of children in out of home care. In the 6 – 12 age group, there are 5,798 children in out of home care; 1,270 are prescribed psychotropic medications, representing about 21.9 percent of the out of home care population. In the 13 – 17 age range, there are 5,444 children in out of home care; approximately 1,701, or 31.25 percent, are prescribed psychotropic medication.

Some of the other data reflect that 17 percent of the children that are prescribed psychotropic medications are in the custody of a relative or non-relative. Eighty-three percent of children are in some sort of licensed foster home or group home. Thirteen percent of the current number of children (3,093) lacks a valid court order or parental consent. Fifty-two percent of children taking psychotropic medications are male, and three out of ten are teenagers. Over 50 percent of the children are taking two or more psychotropic medications.

Mr. Cooper noted the expectation is that the 13 percent without court order or parental consent will increase as the quality assurance review continues.

Mr. Cooper advised that an internal action plan has been developed. This action plan is divided into five different focus areas. Those five areas are project management, data integrity, rule and policy, quality assurance, and legal.

The project management focus involves establishment of an executive steering committee. In addition to Mr. Cooper, other members of that committee include Workgroup Member Bill Janes and Dr. David Fairbanks, Department of Children and Families Assistant Secretary of Programs. External stakeholders, community based care partners, guardians, the judiciary, advocacy groups, and others will be brought in to look at oversight. A point of contact has been identified in each circuit and region at the Department of Children and Families level and the community based care lead agency level for a series of weekly conference calls led by John Cooper, David Fairbanks, and Alan Abramowitz. Additionally, the Department is looking at strengthening the current requirements in contracts with community based care lead agencies and mental health providers.

The data integrity focus includes the current validation project, which will continue. Later this month, the Department of Children and Families leadership team plans to meet with the Florida Psychiatric Association. The Department also plans to develop some ad hoc capability in FSFN for community based care partners to run reports on psychotropic medications. Another part of the data integrity focus involves comparing the Agency for Health Care Administration (AHCA) data with the Department's FSFN data.

Allen Abramowitz advised that he will be team leader for the rule and policy focus of the action plan. He noted that the Department is reviewing all community based care psychotropic

medication policies to ensure compliance with the rule and statute. The Department is also creating business rules. One of the issues is not just whether the action appropriate in the field is being done but also if it is being entered appropriately into the system. There are many interpretations for how to enter the data. By getting consistency and business rules aligned with legal, quality assurance, community based care, advocates, and Children's Mental Health the data will actually represent what it should. The Department is also looking at an emergency rule change on the definition of psychotropic medication. It is not defined in Chapter 39 of the Florida Statutes. It is defined in a couple of other places in the statutes under competency to proceed and the education provision. Mr. Abramowitz noted that the Department will be looking to the workgroup for guidance on what is appropriate before moving forward. The rule and policy focus of the action plan also includes modification of bilateral agreements with foster parents. Mr. Abramowitz also noted that all training will be reviewed to ensure inclusion of the most up-to-date statutes, rules, policy, and FSFN data entry requirements on psychotropic medication.

Mr. Abramowitz added that the Department conducted a quality assurance review in partnership with community based care providers, Children's Legal Services, and quality assurance staff in the field. Some of the findings in children age five and under were that there are generally not treatment plans and the required medical consult from the University of Florida is not occurring in most cases. The Department has a contract with the University of Florida, and the community based care providers have access to call and use that medical consult. The Department is reviewing that contract.

Mr. Abramowitz continued that the last focus of the action plan is Legal. This involves dealing with legal issues and posting responses so there are consistent opinions around the state. It also involves training on how to appropriately obtain informed consent.

Mr. Cooper concluded the presentation by mentioning system limitations that are being seen as the data are being examined. He noted that the Department is working on very comprehensive clarifying guidelines for existing data entry in FSFN.

DEMONSTRATION OF FLORIDA SAFE FAMILIES NETWORK (FSFN) (Beth Pasek)

Beth Pasek, Department of Children and Families, Suncoast Region, was introduced to provide an overview of FSFN, and more specifically those screens that are involved in entering psychotropic medications into the system.

Ms. Pasek advised that FSFN is Florida's Statewide Automated Child Welfare Information System or SACWIS. FSFN rolled out in July 2007, replacing HomesafeNet, and it is the official case record of the child.

FSFN is utilized initially by the Florida Abuse Hotline. Calls to the Abuse Hotline are put in the FSFN system. From there, investigations are generated. The system is also utilized by community based care case managers, Legal, Licensing, and Department of Children and Families administration.

Ms. Pasek continued that the functionality of FSFN includes historical abuse records, placement information, both historical and current, educational providers, and medical information. FSFN also contains missing child reporting forms, which, until recently, were entered on a separate database. Other areas of functionality include photographs, fingerprints, verification that birth certificate has been checked, management and performance reports, family assessment, and judicial reviews.

Additional functionality will be available with the roll out of Release 2b, which should occur later this summer. With Release 2b, Legal will have a much larger role in FSFN than in the past. Legal will be actually entering dependency information into the system to ensure that all the legal requirements are accurate. Another area of functionality will involve licensing and placement information. The actual licensing workers will be using FSFN to track all information, making it a more complete child record. Trust accounts, trust funds, will be managed through FSFN. Release 2b will also add unified home study capability and Business Intelligence Environment, a data warehouse.

Ms. Pasek continued with her presentation by demonstrating screens in the worker's caseload desktop in FSFN. Through this avenue, investigators and case managers are able to see cases assigned to them, supervisors are notified when an action has been taken that requires supervisory review, cases can be transferred from the investigator to the supervisor and on to case management so everyone has access and knows what is assigned.

The second part of her presentation involved documentation of psychotherapeutic medication in FSFN. She shared information on the search capability within FSFN, which provides the ability to determine such things as basic demographic information, relatives, merged persons, intakes, investigations and special conditions referrals. Once a case is selected in FSFN, drop down boxes for education, family assessment, interim child information, and medical/mental health can be seen.

There are some basic screens the worker will enter from the medical/mental health drop down box. The first is medical profile which includes the names, addresses, and phone numbers of the doctors, dentists, etc. So, the case manager is creating the work and actually entering all this information. Not everyone is able to access this information due to its confidentiality.

Ms. Pasek directed the workgroup's attention to the medication screen, which includes the name of the physician/practitioner, if the medication is psychotropic, the date prescribed, and the date stopped. This information is input by the individual case manager.

Ms. Pasek moved forward with the presentation to the FSFN mental health profile tab. Information contained in that particular section includes prior treatment-inpatient, outpatient, comprehensive behavioral health summary and completion date, children in out of home care, any kind of substance abuse history, and psychological/psychiatric referrals. There are also drop down boxes for Axis I and Axis II diagnoses based on the most recent psychological/psychiatric evaluation and the diagnosis. At the bottom of the screen is a field for caregiver information that includes alcohol abuse, physical abuse, etc.

Ms. Pasek moved on to the medical history screen. This includes dental and medical treatment history as well as the mental health piece and a description of the diagnosis, assessments, and/or treatment for the child. An actual medical and medication history can be built if the information is input correctly.

QUESTIONS/COMMENTS:

1. Members of the workgroup raised questions/concerns regarding the case manager entering the information and the source of the information used to determine if the medication being used is psychotropic.

Response: The information comes from the doctor. There is a form at the back of the rule (CFOP 175-98) that has a demographic section to be completed by the case manager and other sections to be completed by the prescribing psychiatrist. The Department is finding that it is not always the case manager at the visit with the doctor or the psychiatrist. It could be a transporter, someone from the group home or facility, or the foster parent. It is important that accurate information is getting back to the caseworker to input into the system.

2. On the medication screen there does not appear to be a check off box indicating parental consent.

Response: There is a drop down box, it just didn't appear on the slide, which ties in reason for medication, instructions, additional information, parental/guardian consent, date consent obtained, or court order required, and date court order obtained. There are a couple of screens that come up as edit fields. If you check parental consent, the system does not require you to input anything. If you check court order, it does not require the date. Or you could go back in and overwrite those dates or overwrite that medication or overwrite the new prescription date. There is no checkbox to indicate that the parent talked to the prescribing psychiatrist, and the Department has situations where the case manager is taking the form to the parent and having them sign it. That is not informed consent.

3. Do you have a process chart or a flow chart showing who does what and when? What are the qualifications for case manager? There is the risk that something is going to be misinterpreted or inappropriately transcribed.

Response: With 20 community based care lead agencies, you see things done differently. For example, in Volusia County, there is a clinical director. It is all centralized under one unit. Other places are decentralized to the case managers. All of the community based care lead agencies are discussing whether they are going to bring some of these issues in-house.

4. That may be something the workgroup should take a look at to see if there is a common way to approach this.

Response: In fact, that was one of the quality assurance questions on the 112 children 5 and under. That report will provide additional information.

5. If the case worker enters this information, who follows up to look for red flags?

Response: It should be the supervisor.

6. You do not have the medical oversight. You do not have the quality review or protocol. Optimally, the medical form is completed. If it's not legible then it should be someone's responsibility, ideally the case manager's, to make sure that he/she understands what is on that form. This information should also be provided to the court or whoever is providing informed consent because this is essential information that any authorizer of treatment should have in order to make an informed choice.

7. Is there a tickler system or anything that would tie the medication to the diagnosis?

Response: Not available at this time.

8. Can documents like the Psychotherapeutic Medication Treatment Plan be scanned or linked into the FSFN system?

Response: The Department is working on an electronic storage solution for FSFN so everything that is part of the case record will be electronically stored and linked to the case, including a medical module.

9. Many of the courts have their own forms/affidavits they want the doctors to use. Will this be a part of the legal focus of the action plan?

Response: Children's Legal Services is looking at the whole process statewide.

10. Dr. Sewell requested from Mr. Cooper a flow chart for the workgroup outlining all the stages of the decisions in the standard process.

TO MEDICATE OR NOT TO MEDICATE; THAT IS THE QUESTION (Dr. Rahul Mehra)

Dr. Mehra is a board certified child adolescent and adult psychiatrist. He attended college and medical school in Charleston, South Carolina and completed two years of residency at the Medical College of Georgia in Augusta. He then transferred to the University of South Florida in Tampa where he completed one year of general adult psychiatry and a two year child psychiatry fellowship. Since 1992, he has spent time working in community mental health centers. He was also on faculty at USF for a couple of years. He has his own health care company called MehraVista Health, which does employee assistance programs and manages behavioral health care benefits for companies. He is also the medical director for a community mental health center and two other group homes in Hillsborough County that treat and service children in the child welfare system. He initiated an entity called the Kamala Project, in memory of his mother, where he provides pro bono services to the child welfare system. He also works with the Guardian Ad Litem Program in Hillsborough County, providing training and education about child psychiatry.

Dr. Mehra began by explaining what he does on a day-to-day basis as a consultant in the group home setting, as well as in outpatient work in one of the community mental health centers. In the group home setting, a child is brought in as an emergency, either removed from the home for the first time or perhaps removed from an existing foster home. Within the first week or two, he is usually asked to do a psychiatric evaluation of this child. At that time, more often than not, he has very little information beyond the child's name and date of birth. Frequently, the current medications information is unavailable or inaccurate. Collateral information from the worker or the guardian becomes available. That information is critical as the treatment team formulates the treatment plan for this child. If, after observing the child for a period of time, it is determined that the child needs medication and the parent cannot consent, the affidavit is completed to be submitted to the court to obtain consent for the medication. The average length of time it can take to get that affidavit back can be extensive, sometimes as long as eight weeks.

Dr. Mehra noted that the informed consent process needs to be revised. He further noted that there needs to be a shift in thinking in terms of how medicating children is viewed. The term frequently used, especially by the media, is "drugging our children."

He shared that he had recently presented to the Public Interest Section of the Florida Bar and was asked how young is too young to medicate. His response was that he could not and would not give a definitive date as there could be those potential clinical scenarios where a child may need medication at age 3 or 4 even though it is rare. He noted that caution should be exercised in absolutes about trying to determine benchmark dates for certain clinical scenarios.

QUESTIONS/COMMENTS:

1. How do you determine with the information you have whether or not the child needs any treatment and whether medications should or should not be part of the treatment?

Response: There is a whole other side, the clinical side of how things manifest themselves. The information is gathered from a multitude of different sources. It may come from the school, from the cottage staff, and from observation of the child during evaluations, which is very important. It is also crucial to consider what the child has gone through, which can contribute metabolically and physiologically to the child's presentation of symptoms.

2. What is your threshold for determining need for treatment, and what is the threshold for deciding whether to use a stimulant medication or not?

Response: The threshold should be, whether it is a child or an adult patient, the degree of disturbance in terms of the activities of daily living. Are the symptoms and their duration causing enough impairment that is persisting even with the intervention of other forms of treatment and consistency in the child's environment? Then, perhaps in that situation a stimulant medication may be considered.

3. You are saying that not all attention impairment needs a specific treatment plan or medication.

Response: Correct. Even if a child were to have a bona fide ADHD, there is a subset of children that are able, in the right academic setting, to perform and not require medication.

4. One of the things the workgroup has to reconcile is how to align the differing opinions regarding medication between the practitioners. How can this be done? If overmedicating is occurring, with what frequency do you see it, and how does the workgroup make recommendations to the Secretary?

Response: Sometimes when it is just routine psychotropic medications that are being appropriately used, the reference is made to these being drugs and that we are drugging our children even with stimulant medication. The majority of psychotropic medications in this country are written by non-psychiatrists.

5. From a Medicaid perspective, data suggest that a little more than half is prescribed by psychiatrists and a little less than half is written by non-psychiatrists. Ultimately, all individual treatment decisions are between the child's parent and the physician in the case of children. How does one separate appropriate from inappropriate?

Response: This is a very difficult and challenging question. There again it requires the education of so many people.

6. In the nature of the foster care system with time constraints, Medicaid issues, lack of psychiatrists, is it a problem that psychiatrists are doing field expedient diagnoses rather than measured ones taking into account all those bits of information that should be evaluated? Sometimes psychiatrists have multiple appointments and spend maybe 15 minutes with a child before prescribing a psychotropic medication. Is that acceptable?

Response: It is acceptable in the right context, and in certain contexts it is not acceptable.

Dr. Mehra suggested that there needs to be a relationship building with organized child psychiatry, where messages are gotten out to address at a global level how things can be improved, educating them and talking to them about their medical staff and coming up with some guidelines or, at the state level, some protocols on how to address these children's behaviors.

7. What does black box mean and who is it for? What is appropriate treatment and what is inappropriate treatment?

Response: The issue of the black box obviously is related to the FDA. For certain antidepressants, the black box warning means there is an increased risk for suicide. It is the physician that has to pay attention to the black box warning.

8. The black box warning always indicates the importance of monitoring. Who is responsible for monitoring the black box implications?

Response: For children in the foster care system, it is the physician and case worker for that child. The expertise and responsibility in terms of making that appointment when initial antidepressants are started lies with the physician. The reality of it is that the child needs to return for the follow up appointment and that is outside the physician's control.

9. There are elements of informed consent that are critical: (1) whoever is authorizing the use of the treatment needs to understand benefits, risks, alternatives, and monitoring requirements before making a choice to authorize treatment; (2) it is critical that the foster parent, or whoever is living with child, fully understands what they can expect from the medication and what the black box means. Would you agree?

Response: Dr. Mehra responded that he agreed, but would add that the consequences of no treatment at all need to be clearly understood by all those involved.

10. What do you think are a few of the problems in the child welfare system the workgroup should be aware of?

Response: Sometimes it is education of people, primarily of case workers and other professionals involved. Education is a big component for the case worker. Additionally, the thing that is lacking is a sense of urgency.

11. The system needs to be non-adversarial, but once you start getting varying opinions, what should the department do?

Response: It depends on the source from which the disagreement is emanating.

FLORIDA BAKER ACT AS IT PERTAINS TO CHILDREN (Martha Lenderman)

Dr. Sewell indicated that there were a couple of unsuccessful attempts to have Gabriel Myers Baker Acted. He introduced Martha Lenderman to provide an overview of the Baker Act, particularly as it relates to children.

Ms. Lenderman retired in 1996 after 30 years with the Department of Children and Families. Since then, she has done work for the Department through a contract with the Florida Mental Health Institute. She does all survey instruments for the Agency for Health Care Administration. She also does work for private clients like law enforcement, professional associations, and hospitals, and serves on many occasions as an expert witness in malpractice litigation. She is also a gubernatorial appointee to the Juvenile Welfare Board of Pinellas County.

Ms. Lenderman provided a slide presentation and overview covering issues related to who is the guardian, legally, of children, voluntary/involuntary Baker Act, and informed consent.

Ms. Lenderman stated that there are numerous state laws, Florida Administrative Code, appellate cases, even rules of judicial procedure, governing children, and they are all different and sometimes mutually conflicting. The Baker Act itself has very few specific references to minors or children and you sometimes have to defer to other statutes or case law as it applies.

Sometimes you have general laws and specific laws that conflict, and in those cases the specific law trumps the general law. The important thing is that whoever is trying to make these decisions has to look to the whole context of the child.

She commented about who is a minor. Even in the Baker Act, sometimes the term minor is used, sometimes the term age 17 or under is used. They are not the same thing in some cases, because of certain other laws, emancipation, or court orders that may actually create a difference. She stated that generally, she takes the position that it is at age 17 or under that they cannot give consent under the Baker Act. Anyone who is under 18 is a minor unless they have been married or emancipated by a court. When they are adjudicated as adults in the Department of Corrections, there are different issues the courts can emancipate under certain circumstances.

With regard to parent or guardian, it is important, even in the dependency system, who is the parent or guardian of that child and the Guardianship Statute of Florida (744.301, F.S.) establishes the natural guardian.

In 2008, a new law was introduced (Chapter 61, F.S.) regarding dissolution of marriage, support and time sharing. New court orders relating to dissolution of marriage have a parenting plan and a time sharing schedule. Parents have either shared parental responsibility or sole parental responsibility. Both parents continue to have access to information/records unless the court specifically revokes that right. It could be the mother, the father, or both who have the authority to provide consent for medical care/treatment, even for these children in the dependency situation.

Ms. Lenderman noted that there is an important law, Chapter 743, F.S., that says if the parent has the authority as a natural guardian and is not available, certain other people can give informed consent for the child's medical care and treatment. The definition of medical care and treatment excludes certain things, including psychotropic medications, which require court order. Emergency medical care identifies what is to be done in situations of imminent danger when the conditions are such that the child cannot identify the parent or guardian or the parent or guardian cannot be contacted.

Ms. Lenderman continued that parent authority regarding Baker Act is important. For a minor, in the context of voluntary admission, the criteria of the law are that: (1) They have a mental illness. There is one legal definition of mental illness for people of all ages and it is in the Florida Mental Health Act. There are approximately three states in the country with a different definition for children and adolescents than adults. Florida is not one of those. Ms. Lenderman recommended that the workgroup at least consider a separate definition. (2) They have to be suitable for treatment at that particular facility. (3) The parent or guardian has to apply for their admission. (4) There must be a judicial hearing to confirm the voluntariness of admission. A legislative committee, in 1997, determined that the Florida Administrative Code promulgated by the Department was not legally sufficient because the voluntariness hearings were conducted in the context of the facility rather than as judicial hearings. However, 66 out of 67 counties in the state of Florida ignore this. Only Broward County actually has a proceeding. The rest either ignore the law or admit every child as involuntary and then transfer as opposed to admitting them

as voluntary and/or they still conduct voluntariness hearings with a staff member talking to the child alone.

Ms. Lenderman continued with the definition of mental illness (394.455(18) F.S.), which is a serious thought or mood disorder, mental or emotional. It is not a behavioral disorder. The only time it mentions the word "action" is in the context of being able to exercise conscious control of those actions, not the actions themselves. It also has a functional side, not just diagnostic, that it has to substantially interfere with a person's ability to meet the ordinary demands of living. It is this definition that excludes any kind of intoxication or substance impairment because that is governed by the Marchman Act. It excludes any kind of developmental disabilities, including autism, because that is governed by Chapter 393. It also excludes any antisocial behavior because that is governed by criminal justice and juvenile justice statutes.

Ms. Lenderman continued that the law says that anyone age 17 and under has to have an application made by his or her guardian, only after a hearing to verify the voluntariness of consent. Each person has to be asked to give express and informed consent for admission for the treatment. If the person is a minor, it has to be requested from the guardian, but such consent is required from the guardian.

Express and informed consent is consent voluntarily given by only a competent person without any element of force, fraud, deceit, duress, or other form of constraint or coercion. The other aspect is the definition of incompetent to consent. If a person cannot give well reasoned, willful and knowing decisions about their medical or mental health treatment, their admission cannot be voluntary under Florida law. No child is competent by virtue of the law due to age.

The criteria for involuntary admission is simply to have a reason to believe the person meets the criteria, has a mental illness and, because of the mental illness, has refused or is unable to determine if examination is needed. There also has to be either passive or active harm or a substantial likelihood that without treatment that person is going to cause serious bodily harm. They have to meet all criteria.

Ms. Lenderman advised that involuntary examinations can be initiated three ways: A court order, a law enforcement officer or certain specified mental health professional. On a court order, there generally is no hearing. It is ex parte which means one-sided communication with the court based upon a sworn testimony on how the person meets the criteria. A law enforcement officer, on the other hand, does not need to see it for him or herself. The law says they have to describe the circumstances under which the person meets those criteria. A mental health professional has to base his/her decision to initiate on an examination done no more than 48 hours prior to signing the form. They have to reach their conclusion based upon their own observations. The mental health professionals are defined in the Baker Act.

Ms. Lenderman discussed consent to treatment. You do not have informed consent unless you have full disclosure. The disclosure, by law, is different depending on the patient age or situation, but for minors, it has to be given by both the minor and his or her guardian. The only one that can give consent per se is that guardian.

Ms. Lenderman stated that as it relates to dependent youth consent for treatment, efforts are being made to overlay all that information with Chapter 39, which underwent significant changes in 2005. In dealing specifically with psychotropic medications with youth, clearly a parent or legal guardian is the only person authorized to give consent absent order of the court. It is not just a signature on a piece of paper. It is express and informed consent, whether it is the parent or the court. It is not valid unless even the judge has been given disclosure on it. When the Department takes a child into custody and they have psychotropic medication that is current and in its original container, the Department can continue to administer the medication until the shelter hearing takes place. However, at the shelter hearing, the Department has to get court authorization to continue the medication until the arraignment hearing or 28 days, whichever is sooner.

Ms. Lenderman advised that before filing a dependency petition, a physician has to evaluate the need for medication and report to the court. There is one exception. Psychotropic medications can be administered in advance of a court order only in hospitals, crisis units, and Statewide Intensive Inpatient Programs. Within three working days after the medication is begun, the Department has to seek court authority for continuing the medication.

Ms. Lenderman stated that the Baker Act is very clear. You cannot provide medications without the express and informed consent of someone legally authorized to provide it short of imminent danger, in which a very time limited treatment order can be done.

Ms. Lenderman closed with the following recommendations/issues for the workgroup to consider: (1) a definition of mental illness for children/minors; (2) assent/consent and consequences of not getting that; (3) a requirement that before a guardian advocate can give consent to patient's treatment, they have to speak with patient and physician in person if possible, or by telephone, and document that this occurred; (4) different ages for different decision issues; (5) alternatives to the voluntariness hearing issue; and, (6) perhaps the consistency in the various laws.

QUESTIONS/COMMENTS:

1. In terms of voluntariness, is it the voluntariness of the child or the parent?

Response: The child's consent must be sought, but it only requires the consent of the parent or guardian.

2. And there is no requirement for assent as exists in some?

Response: A state form for voluntary admission of children has been modified to indicate agreement to admission, which is assent, but it requires the consent.

3. Regarding consent to use of psychotherapeutic medications, is it only a parent who can consent, or in the absence of the parent, the court?

Response: Yes, the parent or legal guardian as appointed by the court for that purpose.

4. If the minor does not consent, clearly the parent's consent is required to admit them. But if the minor objects when the parent consents, what happens?

Response: Without assent, it has to revert to involuntary. Under involuntary, due process rights are protected and the person is appointed a public defender to represent their wishes as opposed to the state attorney that is going to be looking to the safety of the person and community.

3. In terms of the Baker Act, if one determines the need for emergency medical care, is it a one time decision? Is that allowed for ongoing treatment? Are there any specific court requirements that if you prescribe a treatment more than once or twice that there is a need to seek authorization from the court?

Response: For adults it is very clear. If more than one emergency treatment order occurs in a seven day period, there is a requirement to petition the court for involuntary and for the appointment of a guardian advocate. Children, by definition, are incompetent to consent; therefore, they appear to be incompetent to refuse consent that has been authorized by a legally authorized decision maker after full disclosure. It is not clear. Ms. Lenderman noted that this is one of the issues that she recommends be clarified as to consent and assent of the child to the admission and to treatment and should there be an age.

COMMENTS FROM THE SECRETARY

Secretary Sheldon expressed his appreciation to the workgroup. He advised that as of Friday, June 5, he commissioned Children's Legal Services to have court orders in front of judges. He noted the ongoing concern regarding informed parental consent and that the judges he has talked to have clearly indicated a lack of real knowledge of how to proceed with the judicial approval of the prescription of these kinds of medications.

INFORMED CONSENT (Professor William Allen)

Professor Allen is an Associate Professor at the University of Florida - College of Medicine.

Professor Allen began his presentation by explaining the difference between mere consent and informed consent. Mere consent is only authorization that avoids liability for battery. Battery in the law is unauthorized touching. Informed consent goes a big step beyond and is the most challenging. Informed consent requires sufficient disclosure of information for a reasonable decision maker to comprehend and appreciate the benefit/risk ratio.

Professor Allen continued that in terms of legal standards, there are two, customary practice of physicians or reasonable person standard. He noted that about half of the jurisdictions in the United States have the customary practice standard on disclosure. With regard to how much information is disclosed, it is never full disclosure. The traditional standard is customary practice or what is standard practice for physicians. Customary practice, to the extent that traditionally physicians were paternalistic and did not share enough information was physician centered, not patient centered. In 1972, the Canterbury v. Spence case set a patient centered

standard as the reasonable person. This still only prevails in about half of the states in the United States. Florida is still with the customary practice standard.

Professor Allen noted that the reasonable person standard is what a reasonable person would find material to a decision, or what they would need to know in order to accept or refuse the recommended treatment. That is patient centered and objective. The reasonable person standard is the minimal standard that should be sought in informed consent. The word objective is there because the courts in the law tried to postulate an imaginary reasonable person in order to say this is an objective standard. It's not subjective according to what does this person really want to know for their decision making, it's what would a reasonable ordinary kind of person want to know.

Professor Allen also discussed the subjective, which is patient centered, not in the objective sense of what would the average person want to know, but what does this individual want to know because there is no average person.

He advised that one other important point to note is that informed consent logically entails the possibility of informed refusal.

Professor Allen continued that with regard to the Baker Act with children and adults, one of the reasons we need to be careful, in addition to protecting liberty interests, particularly in psychiatry and psychology, and in medical care in general, is that trust is an essential part of the therapy. Anything done that forces people against their will or deceives them undermines trust and can be counterproductive to whatever medications or other kinds of therapeutic interventions are being used.

He further noted that there are several prerequisites for informed consent. Those are disclosure, comprehension, and voluntariness. Most of the emphasis on informed consent is disclosure. Disclosure is not enough. Comprehension is required to have informed consent. You cannot adequately assess comprehension by simply asking if the decision maker understands. The way to test comprehension is to ask open ended questions where understanding will be reflected in the answers and in a way that the person feels free to ask questions. Voluntariness must be absent coercion or manipulation.

Professor Allen added that informed consent in minors is grossly over simplified. There is presumption of parental consent or refusal. Much of our law in social orientation goes back to Aristotle and is still generally good. Children, ages 0-7, are generally unable to assent in much of a meaningful way. From ages 7-14, assent is generally required for research or other things. Assent means providing the child, in language and concepts they can understand, with what is going to be done and why, and soliciting their commitment or at least toleration or forbearance for it. After age 14, it is not that all adolescents can make all their own decisions, but we are in that zone where there are some exceptions in the law, that make this very difficult.

Professor Allen discussed parental consent and in loco parentis consent. Medical decision making is the best interest of the minor, but we have to be very careful to distinguish this from the convenience of the custodian.

Professor Allen continued with his presentation distinguishing between standard of care and research. Many people were abused, people in institutions, orphanages, old age homes or prisons, until we had regulations in this country in research. There are a lot of protections of vulnerable subjects in our research rules now. For a long time, advances in discovery of new therapies and new drugs for their care were not made because they were overprotected from research. The move now is to try and correct that. So, the FDA has said with things like antidepressants, that children have been protected to the point that there is no data. Now, the FDA has said we can do it; we are just going to have to be very careful. People who are making decisions need to understand the difference between standard of care where presumably there is the experience and expertise and probability of benefits in this and less unknowns about potential benefits and risks. It is one thing to give informed consent in that context. Most people who get involved in research have a therapeutic misconception.

Professor Allen continued that he does not think off label should be absolutely prohibited because there may be a small series of cases where somebody has accidently found that something seems to help and people who are knowledgeable and have good reasons with careful control and observation may legitimately use that. However, that should be a key to designing responsible research protocol and not to just continuing to use something off label without adequate studies. He noted that the FDA only tests to determine safety and efficacy, not superiority. Efficacy is a minimal standard. Drug companies are restricted in their marketing of off label uses but they nevertheless found ways to do so without adequate testing.

Professor Allen shared a summary of states that responded to one survey about who gives consent for psychotropic medications. Legal guardians or parents give consent in eight states, caseworkers in seven states, and court order in six states. Other states have come up with a system of specific individuals or offices within the child welfare agency to provide consent. In Illinois, it is the Department of Guardian and Advocacy. In Connecticut, program supervisors provide consent. In Tennessee, twelve regional health nurses provide consent.

Professor Allen noted that the *Medication for Children and Youth with Emotional, Behavioral, and Mental Health Needs: A Guidebook For Better Understanding* is available on the Department of Children and Families website and is an excellent reference guide.

He also provided a list of questions that should be asked about a child's medication.

He added that with regard to informed consent it is hard not to focus on disclosure because we are thinking about what are the scientific and chemical risks of all these things and the physiological side effects. All of those are important, but that is just to take it out of the context of the functionality of the person in their lives. And that's why there needs to be an exchange of information. Informed consent isn't a monologue from the physician to the decision maker. The physician needs information and they need to get information from somebody that sees that child, including the child functioning in their lives, to really know how to apply all these other benefits or risks that are more the kind you see in medical literature.

QUESTIONS/COMMENTS:

1. How do you reconcile that behavior of a child that is annoying or distracting to the parent wanting the child calm?

Response: There are situations in homes with numerous children when the parental attention to one is going to compromise the others, where, within limits, that might be part of the solution. That is where medication may help calm one child down so parental attention to the others is not compromised. Ideally, some other way to meet that child's needs can be found.

2. Informed consent should be time limited?

Response: Informed consent is an ongoing process. It is not a mere point in time or signature on a form. It is an ongoing process because, as the circumstances change, as the treatment is altered, as the side effects change, as you have more input about what is working and what is not, it is an ongoing dialogue. So, it is not time limited in that sense.

MEDICAID DRUG THERAPY MANAGEMENT PROGRAM FOR BEHAVIORAL HEALTH AND ITS POSSIBLE APPLICATION TO THE CHILD WELFARE SYSTEM (Dr. Robert Constantine)

Dr. Bob Constantine is on the faculty of the Florida Mental Health Institute of University of South Florida. He has spent almost 30 years in some capacity working with the State's mental health and substance abuse system. He served as Assistant Secretary for the Department's Substance Abuse Mental Health Program and as the District Administrator for Southwest Florida for the old Department of Health and Rehabilitative Services.

Dr. Constantine presented a slide presentation regarding the Medicaid Drug Therapy Management Program for Behavioral Health. He noted that his presentation would describe the goals of the program as established by the Florida Legislature, the major activities of the program, and discuss ways the program can provide assistance to the Department in managing the use of psychotherapeutic medications by children in the child welfare system.

Dr. Constantine advised that the program is conducted by the Florida Mental Health Institute at the University of South Florida under a contract with the Agency for Health Care Administration. The program was actually created in statute in 2005 when the legislature passed the Medicaid reform statute. The goals of the program are to improve the quality of care and behavioral health drug prescribing practices based on best practices guidelines, to improve patient adherence to medication plans, to reduce clinical risks, and lower prescribed drug costs.

Dr. Constantine discussed the program activities, which include medication treatment guidelines and their development, complex care indicators, analysis of pharmacy claims (this involves identifying what prescriptions might be triggering complex indicators), interventions with physicians, ongoing surveillance and follow up, and re-measurement of what is going on.

Dr. Constantine talked about the reasons for using best practice medication treatment guidelines, including that they are based on all the research on the comprehensive benefits and risks of

different medication strategies. He noted that while data on children are limited, there is a significant amount available on adults. One of the purposes of evidenced based guidelines is to pull all that data together and determine what shows, if anything, about what makes the most sense.

Best practice guidelines provide guidance to clinicians. About half of the psychotherapeutic medications prescribed in the Medicaid program are prescribed by pediatricians. Providing some guidance and update on what the evidence is and what it might indicate is the most likely strategy to start with in terms of medicating for the treatment of serious emotional disturbances. So, the idea of guidelines is to try to keep people updated and present the latest evidence in a relatively digestible way.

Dr. Constantine covered the strategy the program uses in developing the best practice guidelines. The first thing the program does is try to find the best national experts on the treatment of specific emotional disorders in children. They invite a sampling of clinicians who are treating children in Florida, both in community mental health system and in the private practice system. This includes psychiatrists and pediatricians since they do much of the work. This expert panel meets for two to three days and reviews all the relevant literature and evidence and develops consensus recommendations about treatment of serious emotional disturbances of different kinds.

Dr. Constantine added that all of the guidelines for the treatment of every serious emotional disturbance recommend comprehensive evaluation before medication. They state that medications are, at best, one of several treatment strategies. Guidelines recommend more evidence based treatment strategies before less evidence based strategies. The guidelines are organized into levels. As the level of the recommendation increases, the amount of evidence supporting the practice decreases. Physicians may begin care at any level in the guidelines based on the patient's condition and history.

Dr. Constantine provided the workgroup with a listing of the child and adolescent guidelines, and highlighted, in particular, disruptive behavior disorder or severe aggression in children under age six. He noted that that target symptom often explains the use of a variety of medications in the treatment of children. He noted that it is critical that recommendations are provided on the treatment of compulsive aggression because it underlies a lot of what is being done with medications, particularly in the younger age group of children.

Dr. Constantine continued that the guidelines published in the fall have a great deal of detail about dosing recommendations and some information about medications and dosages that are FDA approved and those that are not.

One of the major activities of the program, having developed the guidelines, is to educate the community, physicians, and a variety of other constituencies. That is done through lectures, discussion groups, CMEs, medical staff meetings, and their website.

Dr. Constantine moved on to the next program activity, complex care indicators. He advised that purpose of the complex care indicators is to get the program from the guidelines to a

determination of what to intervene in and how. Complex care indicators are data filter derived from the guidelines and recommended by the expert panel. They are practices that are less well supported by evidence and/or may produce marginal benefit and/or increase risk. Generally, those practices that are triggered by these complex care indicators are things that should only be tried after better supported approaches have been tried and failed. Therefore, they should be relatively unusual and warrant greater review. He also noted that an important thing to say about these complex care indicators is they may be, in individual cases, the most beneficial and least risky strategy for a particular patient.

Dr. Constantine shared the complex care indicators the program will be using in the upcoming fiscal year. Those indicators are: three or more antidepressants for 60 or more days; use of a high dose of antipsychotic medications; concurrent use of two or more antipsychotics for more than 60 days; concurrent use of three or more antipsychotics for more than 60 days; use of antipsychotics in children under six; use of antidepressants in children under six, use of stimulants in children under five, and concurrent use of antidepressants, stimulants and antipsychotics for more than 60 days. He added that this represents a relatively small selection of practices that might be monitored. The reason these were selected is they occur with some frequency, often enough that they are worth monitoring.

The program monitors by analyzing pharmacy claims from Medicaid. The pharmacy claims they receive represent only about half of the children in the Medicaid program that are not in HMOs. There are no pharmacy claims for the children that are in the HMOs. But in the context of child welfare, any child that is in Medicaid would be in the fee for service program, so all that data are available. Thus far, the program has done a quarterly retrospective analysis of pharmacy claims, identification of patients whose prescriptions trigger a complex care indicator and the associated prescriber, and identification of physicians whose prescriptions frequently trigger the complex care indicators.

Dr. Constantine explained the program has certain intervention strategies with regard to doctors whose prescriptions hit these complex care indicators with considerable frequency. The strategies are progressive and begin with a mailing advising that the program has analyzed pharmacy claims using the complex care indicators and asking the doctor to take another look at the medication in the context of the guidelines. They are also sent information that reflects the most recent evidence and research about the practice, the risk, and the benefits.

The next step is academic detailing contacts. Someone from the program talks to the doctor about their practices. Sometimes, there are peculiar things about their practice that at least partially explain why they are hitting the complex care indicators.

The next steps in the progressive intervention strategies are medical records reviews and, finally, expert consultation.

Dr. Constantine explained that the assumptions behind interventions are: the prescribing of any medication involves weighing of the potential benefits and risks associated with its use; prescribers will consider change in medication strategies based on information about greater potential benefit and/or less risk for their patients; and focusing on doctors whose medication

prescriptions trigger comparatively large numbers of the complex care indicators offers the greatest potential for increasing evidence based prescribing.

He added that the outcomes of interventions are better informed prescribers; review of prescriptions that trigger complex care indicators based on information provided through the intervention; change in medication strategy, only if the physician in collaboration with the patient and family, decides a change may increase benefit and/or reduce risk.

Dr. Constantine concluded his presentation by summing up how the program applies to the agenda of the workgroup. He believes the evidence based and best practice guidelines for the treatment of all the serious emotional disturbances are guidelines that will be helpful for many people dealing with children in the child welfare system. He added that, if the Department so desires and the workgroup recommends, he can spend time disseminating information about the program and the guidelines to Department staff, the judiciary, and child advocates. The program can also do an analysis of pharmacy plans for the subset of children in Medicaid that are in the child welfare system, which could identify (1) the number of children in different DCF child welfare program categories that receive different classes of medication, and (2) children in the child welfare system whose prescriptions trigger one or more complex care indicators.

He added that there are a large number of children on psychotropic medications in the child welfare system and that not all of them are at equal risk. In that regard, the complex care indicators do two things. (1) They provide an indication that the physician that is writing the prescription believes that the child's problem is quite complex, and it is likely that other more usual medication strategies have already been tried. If you are looking for the highest risk subgroup just for that reason it would seem that children that hit these complex care indicators are a reasonable target. (2) The other thing the program can do is monitor and track what is going on with these high risk children over time and provide the information to the Department.

QUESTIONS/COMMENTS:

1. What if you find that the doctor does not change their prescribing habits?

Response: The last strategy involves sending an experienced physician/psychiatrist to meet with them and explain where they stand in comparison to their peers and some of the potential risks and liabilities. The program has just started that last stage in the intervention and does not yet know the impact it will have. However, the data seem to indicate that, for the physicians that hit large numbers of these complex care indicators, almost all of them have changed. It is just a question of how much they have changed. There is some evidence that it is changing practices to some extent, even among physicians who initially don't change practices. Gradually, there is some evidence that they do, but even with those, the plan is to send an expert in to offer consultation to the physician about the specific practices they are using that are hitting these complex care indicators.

CLOSING COMMENTS

Dr. Sewell advised that the workgroup will meet again on June 18 in Ft. Lauderdale. Agenda items at this meeting include the performance improvement plan based on the analysis of the deficiencies in the Gabriel Myers case, an update on the quality assurance review that is in progress, an update on the status of court orders, a presentation from the Casey Foundation, and a presentation from Dr. David Moore. Dr. Punjwani will also be asked to join the meeting.

A meeting will also be held on July 6 in Tallahassee.

Dr. Sewell asked that, over the next several days, workgroup members review their notes and begin to identify any findings and any specific issues that still need to be dealt with and any speakers that might need to be heard. He added that the Secretary, in his charge, wanted the workgroup to deal with three things: (1) the death of Gabriel Myers and related issues; (2) the issue of psychotropic medications and their application in the foster care system; and, (3) child-on-child sexual abuse. He suggested that the members concentrate, between now and mid-July, on the first two and prepare a report for the next meeting of the Task Force on Fostering Success, which will occur in August.

PUBLIC COMMENT

Martha Lenderman commented that the Florida Mental Health Institute prepares an annual report for the Agency for Health Care Administration on the Baker Act. She added that they may be able to provide information by circuits on the frequency or rate of involuntary Baker Acting of children from the dependency or delinquency system.

Dr. Ann Blake-Tracie, head of the International Coalition for Drug Awareness, requested a means for getting information from that organization to the workgroup. She was directed to send the information to Dr. Sewell.

ADJOURNMENT

The meeting adjourned at 4:04 p.m.