IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCU	JIT FILED
	U.S. COURT OF APPEALS
	ELEVENTH CIRCUIT
No. 10-10148	APR 7, 2011
NO. 10-10146	JOHN LEY
	– CLERK
D.C. Docket No. 1:07-cv-00631-	TWT
ANNA C. MOORE, a minor child, by and through her mother and natural guardian Pamela Moore,	
	Plaintiff - Appellee,
versus	
CLYDE L. REESE, III, in his official capacity as Commissioner of the Department of Community Hea	lth,
	Defendant - Appellant.
	_
Appeal from the United States Distr	ict Court
* *	
for the Northern District of Geo	rgia
(April 7, 2011)	_

Before HULL and MARCUS, Circuit Judges, and WHITTEMORE,* District Judge.
HULL, Circuit Judge:

Plaintiff Anna "Callie" Moore ("Moore") sued Defendant Clyde Reese, Commissioner of Georgia's Department of Community Health ("DCH"),¹ for allegedly violating the Medicaid Act ("the Act") by reducing Moore's Medicaid-funded private duty nursing care from 94 to 84 hours per week. The district court granted Moore's motion for partial summary judgment and denied DCH's crossmotion for summary judgment. This appeal concerns the extent to which a state Medicaid agency may review Moore's treating physician's determination of medical necessity under 42 U.S.C. § 1396d(r) of the Medicaid Act. After review and oral argument, we reverse and remand for further proceedings.

I. FACTUAL BACKGROUND

A. Moore's Medical Conditions

Plaintiff Callie Moore is a 16-year-old Medicaid recipient who is severely disabled. Due to a stroke suffered in utero, Moore developed numerous chronic conditions, including spastic quadriplegic cerebral palsy, refractory seizure

^{*}Honorable James D. Whittemore, United States District Judge for the Middle District of Florida, sitting by designation.

¹Reese, sued in his official capacity, was substituted as the party Defendant-Appellant, succeeding former DCH Commissioner Rhonda Medows. For clarity, we refer to the Defendant throughout as "DCH."

disorder, mental retardation, gastroesophageal reflux disease, central apnea, cortical blindness, dysphagia, and restrictive lung disease.² This complex and extensive combination of maladies requires that Moore receive continuous treatment, monitoring, and interventions by her caregivers and skilled nurses.

Even with her medical conditions, Moore is enrolled part-time in school, where she receives special education services. At school, she practices using a communication device to interact with others, including school staff and "lunch buddies" from the student body. A nurse paid for by the school accompanies Moore on the school bus and at school. Outside of school, Moore is able to participate in a limited range of activities. For instance, with the accompaniment of her mother, Moore regularly attends church and sometimes visits the mall with a friend.

B. Moore's Nursing Requirements

²Moore's first amended complaint summarized her conditions:

Callie has severe physical disabilities including spinal deformities in two directions, she is blind and non-verbal, she has seizures that are difficult to control with multiple medications, she has difficulty swallowing even her own saliva, she has difficulties with breathing consistently, she is cognitively impaired, and she has a host of other physical manifestations and medical complications as a result of the damage in her brain.

Am. Compl. ¶ 8.

Beginning in 1998 when she was three years old, Moore has received Medicaid-funded private duty nursing services at home.³ To be eligible for these nursing services, Moore must "require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing staff of [a] hospital or skilled nursing facility." 42 C.F.R. § 440.80. Since 2002, DCH has employed the Georgia Pediatric Program ("GAPP") as its service-delivery model for providing nursing care in the home to medically fragile children with multiple systems diagnoses, such as Moore.⁴ As discussed later, Moore is a GAPP member, and DCH publishes a manual that sets forth the policies and procedures for GAPP, including the process for requesting and receiving private duty nursing hours. See Part II Policies and Procedures for the Georgia Pediatric Program ("GAPP Manual").

Dr. Charles L. Braucher, Jr.⁵ has treated Moore since she was an infant. He examines Moore approximately six to eight times a year. In a 2007 deposition, Dr.

³This appeal involves only the nursing services at Moore's home and not any nursing services provided by the school.

⁴Initially, Moore received private duty nursing care through a state program called the Exceptional Children Service ("ECS"). In August 2002, Georgia implemented GAPP. In April 2003, ECS was merged into GAPP. Moore did not suffer any lapse of nursing services during this transition period and has been receiving private duty nursing care through GAPP ever since.

⁵Dr. Braucher is board-certified in pediatrics and in internal medicine.

Braucher detailed the myriad duties Moore's nurse or caregiver must perform, including, among other tasks: (1) monitoring her seizures to determine what medication is needed, (2) checking her oxygen levels, (3) assisting with gastric tube feedings, (4) administering a complex regimen of medications, and (5) repositioning her body approximately every two hours to prevent pressure sores.

Dr. Braucher estimated that there was not a four-hour period in which Moore did not require the services of a skilled nurse or someone with comparable training and experience, such as Moore's mother Pam.⁶ Although Moore suffers occasional health setbacks, her care and treatment needs have largely stabilized during the previous eight years.⁷

⁶Dr. Braucher described Moore's medical need for trained caregivers:

Because of the multiple medicines she has to get and because of her seizures, which are unpredictable and frequent, often; and then all the other problems I've mentioned, you know, there's probably not four hours. There's not four hours where she goes where she doesn't need somebody who knows what they're doing; and that would be a licensed medical, you know; skilled nurse or a—

Her mother does not have formal nursing training; but is going to be good at recognizing Callie, and so she's skilled as far as we call. You know, if it was just somebody off the street, they would not know how to do medicines or observe her, anything like that.

⁷Dr. Braucher described Moore's condition:

Well, her care needs are about the same as they've been, well, for the last eight years. She'll go through episodes, like when she was real sick with diarrhea and had to be intravenously fed. She'll go through episodes where she needs lots of—needs a lot of care, and then it will back off a little bit.

But, you know, where she's been in the last six months has been how she's been probably 70 percent of the time over the last ten years; so I consider it stable; but she never gets below what she's getting now. There's always lots of medicine,

C. Dr. Braucher's Weekly Nursing Hours Requests

Over the years, Dr. Braucher, as the treating physician, has provided assessments of Moore's weekly nursing requirements to DCH, along with its predecessors and contractors. Dr. Braucher files documentation, including a "Letter of Medical Necessity" detailing Moore's diagnosis and care needs, with the Georgia Medical Care Foundation ("GMCF").

DCH retains GMCF as a third-party vendor of medical experts, including doctors and nurses. GMCF's medical experts ("GMCF Medical Review Team") examine whether GAPP members have met eligibility requirements, assess whether requested services are medically necessary, and determine the amount of services (here, the number of private duty nursing hours) that should be provided to qualifying GAPP members, also based on medical necessity. The GMCF Medical Review Team maintains and reviews the medical records of GAPP members. In Moore's case, the medical records span a period of years. GMCF has no financial incentive to reduce the nursing hours it authorizes, nor does DCH influence or provide recommendations to GMCF.

respiratory stuff, feeds, positioning.

⁸GMCF is a subcontractor of Affiliated Computer Services, which serves as a fiscal intermediary.

At various stages in Moore's treatment, Dr. Braucher modified his nursing hours recommendations due to changes in Moore's condition or other external circumstances. For instance, in 2002 Dr. Braucher requested additional nursing hours when Moore experienced severe diarrhea. In 2003, Dr. Braucher requested a reduction from 96 to 84 skilled nursing hours, with an additional 12 hours of care provided by a trainable certified nursing assistant in lieu of skilled nursing. Dr. Braucher's change was prompted by his understanding that Georgia policy allowed Moore to be institutionalized if the care provided in the institution was less expensive than the same amount of home care. Between 2005 and 2006, however, the GMCF Medical Review Team regularly authorized 94 hours of private duty nursing care for Moore, based upon Dr. Braucher's recommendations.

Lawyer:

Did [a DCH doctor] make a representation to you that if Callie required greater than 96 hours per week of skilled nursing, that she would no longer qualify for the program and would require institutionalization in order to stay in a state-funded program?

Braucher:

Well, I remember the conversation fairly well, even though it was four and a half years ago; and what she related to me was that at some point—I don't remember the exact hours; in my letter I've written 96 hours—the State would have the option—The State was required to provide care for Callie; and at some point, if care in the home became more expensive than the same amount of care that could be provided in an institution, then the State could exercise an option to put her in an institution.

And I guess, but I don't remember this from my mind, but from what I've written, it may have been right around 96 hours. She didn't say they would, but she said they could put her into an institution.

⁹Dr. Braucher explained the reason behind his hours reduction in 2003:

Dr. Braucher explained the criteria used for his nursing hours recommendations. He estimates the total hours of care Moore requires and subtracts the hours of care her family can provide.¹⁰ In estimating the family hours, Dr. Braucher described how he factors in a caregiver's work schedule, along with sleeping, shopping, and homemaking obligations.¹¹

In October 2006, Dr. Braucher requested that Moore continue receiving 94 hours of nursing care per week. Dr. Braucher cited five problems requiring 94 nursing hours. Dr. Braucher noticed the first problem in 2001, when Moore began experiencing acute respiratory distress, erratic breathing patterns, and increased

Lawyer: Now you recently—You said you've recently submitted the request

for 104 hours. And can you tell me again the basis for the additional

ten hours now?

Braucher: I—What did I do with all that? Basically I just decided that she

needed 16 hours on Monday through Friday—

Lawyer: Yes.

Braucher: —per day, and that's 16 times five is equal to 80, and that would

allow the mother to work and to get seven hours of sleep and one

hour to do shopping or something.

Lawyer: Okay.

Braucher: And then the mother would provide the other eight hours of—during

that time, and then I asked for 12 hours on Saturday and Sunday, and that would allow the mother time to sleep. And then she would have four hours to do whatever she needed to do to keep her—their household going. So 12 times two days is 24, and 80 plus 24 is 104

hours a week, and that's how I determined that.

¹⁰On occasion, Dr. Braucher requested an increase in nursing hours at the prompting of Moore's mother, following GMCF decisions to reduce Moore's authorized nursing hours.

¹¹Dr. Braucher provided an example of how he calculates his recommended hours:

risk of airway obstructions and seizures. Since this respiratory problem has neurological roots, Moore's pulmonologist recommended behavioral management to treat the problem, as opposed to more drastic measures. This requires nursing interventions when episodes occur.

Second, Dr. Braucher cited Moore's inability to move herself during sleep, which requires Moore to be repositioned during the night to prevent damage to skin integrity or obstruction of airways. The third problem surfaced in 2002, when Moore developed rotovirus gastroenteritis, necessitating multiple hospitalizations and nurses to monitor her hydration and quickly intervene.

Fourth, Dr. Braucher noted that Moore's seizures were increasingly difficult to manage and required constant monitoring. Fifth, Dr. Braucher explained that Moore suffered recurrent acute urinary retention, which necessitated frequent monitoring of her bladder size and occasional catheterization.

D. GMCF Reduces Moore's Nursing Hours in 2006

In November 2006, GMCF notified the Moores that, effective December 2006, Callie's nursing care would be reduced from 94 to 84 hours per week. The GMCF Medical Review Team determined that now 84 hours, not 94 hours, were medically necessary to correct or ameliorate Moore's medical condition.

In its "Letter of Notification of Approved Skilled Nursing Hours," GMCF cited four policies in the GAPP Manual to support its revised 84 hours allotment:

Chapter 701: The cost analysis should be made to determine that the cost of caring for the member in the home & community is below cost of providing the same care in an institution.

Chapter 702.2 part b. The Primary caregiver must assist with the member's care in the home.

Chapter 702.2 C. The availability and ability of caregiver(s) or significant other to actively participate in the care of the member.

Chapter 702.2 E. The expectation that the primary caregiver(s) will become competent to assume some responsibility to care for the child.

GAPP Medical Director Dr. Joseph M. Rosenfeld¹² served on the GMCF Medical Review Team that assesses GAPP members' medical necessities. Dr. Rosenfeld made the final decision to reduce Moore's nursing care from 94 to 84 hours per week.

In a 2007 deposition, Dr. Rosenfeld testified about his definition of medical necessity, explaining that it is "based upon the general accepted medical practices in the community" and can vary by regional expectations. Dr. Rosenfeld derived this standard from the GAPP Manual and from the factors typically considered by the GMCF Medical Review Team. Dr. Rosenfeld's concept of medical necessity hinges on the medical well-being of the GAPP member, not the convenience of the

¹²Dr. Rosenfeld specializes in pediatrics, and, in addition to his work as GAPP Medical Director, he holds a clinical faculty appointment to the Emory School of Medicine's Department of Pediatrics.

GAPP member or health care provider. Lastly, Dr. Rosenfeld's understanding of medical necessity is informed by his belief that "it should be the most effective or conservative way and cost less than hospitalizing the child." This is consistent with the GAPP policies referenced in GMCF's letter above: (1) "[t]he Primary caregiver must assist with the member's care in the home" and (2) a "cost analysis should be made to determine that the cost of caring for the member in the home & community is below cost of providing the same care in an institution."

Dr. Rosenfeld discussed the factors he considers when determining what nursing hours are medically necessary. Dr. Rosenfeld does not apply a strict formula but considers various elements, including (1) the severity of a child's condition, (2) how unstable they are, (3) what needs can be provided by family members, and (4) hospitalizations.¹³ Dr. Rosenfeld's understanding is that GAPP

Rosenfeld: It's based upon the child's diagnosis, what their needs are, and to

determine the number of—well, this is for a new patient. To determine the number of hours the child is going to start out with. So you're looking at medical condition, how unstable. Sometimes we look at the family situation a little bit, whether a child is in foster care versus in their own private family, and then, of course, the medical condition that's gotten the child into the program. So we look at all

those things to try to make a formulation.

Attorney: Is there a formula? Rosenfeld: There is no formula.

Attorney: Okay. So there's no one factor that's weighed more or less?

Rosenfeld: Well, the severity of the diagnosis or the condition determines, helps

determine the formula.

¹³Dr. Rosenfeld discussed these relevant factors in determining the number of nursing hours a GAPP member requires:

was designed as a "weaning program based on the parents' ability to care for the child." Under GAPP's model, primary and secondary caregivers are trained to care for the GAPP member and, over time, nursing hours are reduced "based upon the competency, [and] knowledge of the parents."

Dr. Rosenfeld justified his ten-hour reduction—94 to 84 hours—in weekly nursing hours based on several considerations. First, Moore had not been hospitalized in the recent past, a factor he frequently takes into account when reducing nursing hours.¹⁴

. .

It's much easier on a child that's already in the program who's been in the program many years or many months versus a child coming into the program.

. . .

[T]hey've had a certain number of hours for many, many months or many years. And then there are other factors then you can look at, such as stability, not getting worse, hospitalizations, new additional medical programs that would either make you swing—how well the mother is learning to be taught—how well she has learned the care of the child in the home.

They have that in the packet where they show what the mother needs more help with, with instruction, or if she's competent or she needs more help. So we look at those things in deciding the stability.

We never reduce hours in children who are chronically being—or frequently being rehospitalized for either new conditions or old conditions. . . . Because that would indicate the child's disease process is getting worse. There was nothing that we saw in her review that made us think she was getting worse.

¹⁴Conversely, Dr. Rosenfeld explained that hours reductions are never authorized when a child experiences frequent hospitalizations:

We are aware that she is . . . not being hospitalized but being cared for in the home [which] is a consideration in reducing the hours.

Second, Dr. Rosenfeld concluded that many of the conditions that Dr. Braucher highlighted in his "Letter of Medical Necessity" would not be affected by a reduction in nursing hours. Specifically, Dr. Rosenfeld concluded that neither Moore's gastroenteritis complications nor her acute urinary retention would be adversely impacted by the nursing reduction. Moore's malabsorption difficulties posed a "potential problem," but "not an actual problem." Furthermore, Moore's need to be repositioned while she slept was a "home healthcare issue" and did not require skilled nursing.¹⁵

Lastly, Dr. Rosenfeld's decision to reduce Moore's nursing hours was due to "her being relatively stable and the fact that her parents . . . could be able to

¹⁵Dr. Rosenfeld's analysis of Dr. Braucher's letter is provided below:

It was based upon . . . [Dr. Braucher's] letter, who [sic] I feel knows her better than any of the subspecialists, that problem by problem did not justify the 94 hours. Specifically, a problem that began in 2002, four years ago, with respect to her gastroenteritis issue; number five, acute urinary retention where she has to be cathed four times a day. We didn't think either one of those would be affected by a reduction in hours. The issues of—also, the issue of not being able to move herself was not a skilled nursing issue. It was a home healthcare issue and not a skilled nursing issue.

So the first problem, in my mind, was the most serious, followed by the seizures, the urinary retention, the issue of potential problems with prolonged diarrhea. Malabsorption is a potential problem, [but] is not an actual problem. And then the issue of her inability to move herself doesn't require highly skilled nursing care.

So based upon those problems, that's why we came up with the conclusion of less hours.

assume one hour and a couple of minutes of extra care per day since she had been on this many hours for a very long time." Given the competency of Moore's parents in her care, Dr. Rosenfeld determined the hours reduction would not endanger Moore's welfare and "she would continue to basically receive the same type of care that she has received prior to that."

Dr. Rosenfeld characterized Moore's conditions as "chronically stable," a term he used to describe "children who are going to never get better who are . . . very ill, but who are stable in the sense that . . . the disease process is not getting worse, not getting better, and they're not requiring hospitalizations, and they're going to stay at this steady state for a long time."

When asked if he considered Moore's mother's needs when calculating medically necessary nursing hours, Dr. Rosenfeld commented that his GMCF Medical Review Team generally did not factor in a caregiver's convenience: "We're looking at strictly what is medically necessary for the care of the child. The only time we really take into consideration the caregivers is when it's in a foster situation and the foster parent is really helping the state out." When calculating medically necessary nursing hours, Dr. Rosenfeld takes into account a caregiver's work schedule and sleeping needs, but not such activities as going to the grocery store or attending social functions.

E. Moore Contests Nursing Hours Reduction

Through her mother, Moore appealed GMCF's reduction from 94 to 84 nursing hours. A hearing was scheduled before the Office of State Administrative Hearings.

In a January 2007 letter sent to Moore's mother prior to that hearing, DCH's Legal Services Officer Cynthia Price explained that GAPP's nursing services could be reduced "when the medical condition of the [GAPP] member stabilizes to give more of the responsibility of the care to the parent(s) and or caregiver(s)." Price cited the "Letter of Understanding" signed by Moore's mother, which stated, "The GAPP program is designed to teach me on the care of my child's medical condition. I understand that services may be reduced over time based on the medical needs of my child." Price attached the "Caregiver Teaching Checklist," which indicated that Moore's mother was competent in all areas of Moore's care. Price's letter concluded, "Based upon your child's stable condition and your competency in her care, it appears that the reduction in hours is appropriate."

The day before the administrative hearing, Moore's mother withdrew her hearing request and filed this lawsuit.

II. PROCEDURAL HISTORY

A. Moore's Complaint

In March 2007, Moore's mother, on behalf of her minor child, filed her original complaint under 42 U.S.C. § 1983, alleging violations of the Early and Periodic Screening, Diagnostic, and Treatment ("EPSDT") provision of the Medicaid Act. Plaintiff Moore moved for a temporary restraining order ("TRO"), which the district court granted. The TRO enjoined DCH from providing Moore with fewer than 94 hours of nursing care a week.

When the TRO was slated to expire, Moore filed a motion for a preliminary injunction or, alternatively, to extend the TRO. In September 2007, the district court denied Moore's motion because DCH represented that it would continue to provide 94 nursing hours during the pendency of Moore's suit unless an emergency event required an increase in hours.¹⁶

B. District Court's 2008 Summary Judgment Order

In February 2008, DCH filed its motion for summary judgment as to the 84 hours allotment. Moore filed her cross-motion for partial summary judgment requesting 94 hours.¹⁷

¹⁶In February 2008, the district court granted Moore's motion to file an amended complaint raising additional due process claims. Because leave to amend was granted immediately prior to the due date for summary judgment motions, Moore's present motion is considered a partial summary judgment motion.

¹⁷While these motions were pending, Moore's mother underwent surgery and Dr. Braucher requested a temporary increase to 168 nursing hours per week during the expected four weeks of the mother's recovery. In response, GAPP Medical Director Gary Miller advised that

In a June 2008 order, the district court denied DCH's motion for summary judgment and granted Moore's cross-motion in part. The district court commented that a 1989 Amendment to the Medicaid Act reflected Congress's intent to expand health care coverage for Medicaid-eligible children by modifying the Act's EPSDT provision. The EPSDT is Medicaid's preventive child health program for individuals under the age of 21. See 44 Fed. Reg. 29420 (May 18, 1979). The district court determined that the 1989 Amendment "took away a state's discretion not to provide necessary treatment for individuals under the age of twenty-one."

Moore v. Medows, 563 F. Supp. 2d 1354, 1357 (N.D. Ga. 2008).

The district court concluded that "[t]he state must provide for the amount of skilled nursing care which the Plaintiff's treating physician deems necessary to correct or ameliorate her condition. The Defendant may not deny or reduce the hours of skilled nursing care that is medically necessary based upon cost or the

Moore's 94-hours allotment would remain unchanged, observing that her condition "has remained stable with no exacerbations in disease process or hospitalizations since last precertification period." Moore's mother then filed an emergency motion for a temporary restraining order, which the district court granted. The district court entered a preliminary injunction, finding that the 168 hours of weekly nursing care was medically necessary during the four-week period of the mother's recovery.

DCH filed a motion for reconsideration and submitted the affidavit of GAPP specialist Miriam Henderson. Henderson averred that (1) Moore attended school three days a week for approximately four hours a day, during which time the school paid for Moore's nursing care and (2) Moore's request of 168 nursing hours did not take into account the time Moore attends school. The district court denied DCH's motion for reconsideration.

lack of a secondary caregiver." <u>Id.</u> The district court effectively deemed the treating physician's opinion of medical necessity dispositive and concluded that DCH had no discretion due to the 1989 Amendment. Accordingly, the district court ruled that Moore was entitled to declaratory and injunctive relief as to DCH's reduction to 84 nursing hours. DCH appealed.

C. DCH's First Appeal in 2009

In April 2009, this Court reversed and remanded. Moore v. Medows, 324 F. App'x 773 (11th Cir. 2009) (per curiam) (unpublished) ("Moore I"). A prior panel of this Court agreed that DCH was required to provide Moore with any medically necessary treatment or services but disagreed with the district court's ruling that the treating physician was the sole arbiter of medical necessity. The panel's two-paragraph opinion concluded that (1) the state is not "wholly excluded from the process of determining what treatment is necessary"; (2) "both the state and Moore's physician have roles in determining what medical measures are necessary to 'correct or ameliorate' Moore's medical conditions"; and (3) "[a] private physician's word on medical necessity is not dispositive." Id. at 774.

¹⁸Because the parties interpret Moore I differently, we quote the entire opinion:

The District Court held that "[t]he state must provide for the amount of skilled nursing care which the Plaintiff's treating physician deems necessary to correct or ameliorate her condition." Moore v. Medows, 563 F. Supp. 2d 1354, 1357 (N.D. Ga. 2008). While it is true that, after the 1989 amendments to the Medicaid Act, the state must fund any medically necessary treatment that Anna C. Moore

Beyond declaring that the state was not excluded, the treating physician's opinion was not dispositive, and both actors play roles in determining medical necessity, the Moore I decision did not address what happens when there are conflicting opinions about medical necessity by the treating physician and the state's medical expert. Moore I did not at all elucidate the respective roles of a treating physician and the state, or how to reconcile a treating physician's role visà-vis the state's oversight function. However, Moore I did cite our precedent in Rush v. Parham, 625 F.2d 1150 (5th Cir. 1980), 19 which we discuss later.

D. District Court's 2009 Order on Remand

requires, Pittman v. Department of Health and Rehabilitative Services, 998 F.2d 887, 891-92 (11th Cir. 1993), it does not follow that the state is wholly excluded from the process of determining what treatment is necessary. Instead, both the state and Moore's physician have roles in determining what medical measures are necessary to "correct or ameliorate" Moore's medical conditions. Rush v. Parham, 625 F.2d 1150, 1155 (5th Cir. 1980); 42 C.F.R. § 440.230 ("(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures."); see 42 U.S.C. § 1396d(r)(5). A private physician's word on medical necessity is not dispositive.

Therefore, after oral argument and careful consideration, we REVERSE the District Court's grant of partial summary judgment for Moore and REMAND for proceedings not inconsistent with this opinion.

Moore I, 324 F. App'x at 774 (footnote omitted).

¹⁹In <u>Bonner v. City of Prichard</u>, 661 F.2d 1206, 1209 (11th Cir. 1981) (<u>en banc</u>), we adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to the close of business on September 30, 1981.

After supplemental briefing on remand,²⁰ the district court once again denied Defendant DCH's motion for summary judgment and granted Plaintiff Moore's cross-motion for partial summary judgment. Moore v. Medows, 674 F. Supp. 2d 1366 (N.D. Ga. 2009) ("Moore II"). On remand, DCH asserted that, in light of the Eleventh Circuit's ruling in Moore I, "one can conclude that the state is the final arbiter of medical necessity." DCH argued that the state "has the authority and discretion to determine medical necessity as well as to determine the amount, scope, and duration of services paid for and provided by Medicaid in accordance with EPSDT."

The district court rejected DCH's position and agreed with Moore that the state had only a limited role. The district court held that the state could review a treating physician's determination of medically necessary services only for (1) fraud or abuse of the Medicaid system, and (2) whether the services are within the reasonable standards of medical care. <u>Id.</u> at 1370. The district court quoted <u>Rush v. Parham</u>'s approving citation of the 1965 Senate Finance Committee Report on the Medicaid Act, which stated that "[t]he physician is to be the key figure in determining utilization of health services." <u>Id.</u> at 1369 (quoting <u>Rush</u>, 625 F.2d at

²⁰In June 2009, a status conference was held, and the parties agreed to supplemental briefing in light of this Court's <u>Moore I</u> decision.

1157). The district court also cited <u>Pittman ex rel. Pope v. Secretary, Florida</u>

<u>Department of Health & Rehabilitative Services</u>, 998 F.2d 887 (11th Cir. 1993)

(per curiam), to support the proposition that DCH's discretionary role was strictly cabined by § 1396d(r)(5).

The district court then found that DCH raised no issue of fraud or abuse of the Medicaid system by the Moores or the treating physician, Dr. Braucher.

Moore II, 674 F. Supp. 2d at 1371. The district court noted that there was no genuine issue of material fact regarding whether Dr. Braucher's 94-hours nursing recommendation was based in fact, since his assessment was derived from 12 years of evaluating the patient and was supported by the medical records. Id. The district court again entered injunctive and declaratory relief for Moore. Id. DCH appealed again.

III. STANDARD OF REVIEW

We review <u>de novo</u> the district court's denial of DCH's summary judgment motion and grant of Moore's partial summary judgment motion, viewing the facts and drawing all reasonable inferences in favor of the nonmoving party. <u>Rosario v. Am. Corrective Counseling Servs.</u>, Inc., 506 F.3d 1039, 1043 (11th Cir. 2007). Summary judgment is appropriate when "there is no genuine dispute as to any material fact" and the moving party is entitled to judgment as a matter of law.

Fed. R. Civ. P. 56(a). A genuine issue of material fact exists when "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248, 106 S. Ct. 2505, 2510 (1986).

IV. DISCUSSION

As necessary background, we first review the Medicaid Act, the 1989 Amendment, and relevant regulations and manuals.

A. Medicaid Act and Regulations

In 1965, Congress enacted the Medicaid Act, 42 U.S.C. § 1396 et seq., as Title XIX of the Social Security Act. Medicaid is a jointly financed federal-state cooperative program, designed to help states furnish medical treatment to their needy citizens. States devise and fund their own medical assistance programs, subject to the requirements of the Medicaid Act, and the federal government provides partial reimbursement.²¹ See 42 U.S.C. §§ 1396b(a), 1396d(b). A state's participation in the Medicaid program is voluntary, but once a state opts to participate it must comply with federal statutory and regulatory requirements. See

²¹As <u>amicus curiae</u> Atlanta Legal Aid Society explains, the federal government reimburses states for a significant proportion of their Medicaid costs, based upon the state's per capita income. Section 1396d(b) provides that "the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum." 42 U.S.C. § 1396d(b). The federal matching rate for Georgia in fiscal year 2010 (October 1, 2010 through September 30, 2011) is 65.33%. 74 Fed. Reg. 62315 (Nov. 27, 2009).

Alexander v. Choate, 469 U.S. 287, 289 n.1, 105 S. Ct. 712, 714 n.1 (1985). All states, including Georgia, have chosen to participate in Medicaid.

The Medicaid Act, as supplemented by regulations promulgated by the Department of Health and Human Services ("HHS"), "prescribes substantive requirements governing the scope of each state's program." <u>Curtis v. Taylor</u>, 625 F.2d 645, 649 (5th Cir. 1980).²² Section 1396a provides that a "State plan for medical assistance" must meet various guidelines, including the provision of certain categories of care and services. <u>See</u> 42 U.S.C. § 1396a. Some of these categories are discretionary, while others are mandatory for participating states. <u>Id.</u> § 1396a(a)(10) (listing mandatory categories).

Section 1396a(a)(17) provides that "[a] State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance under the plan which . . . are consistent with the objectives of this [Title]." <u>Id.</u> § 1396a(a)(17). The Medicaid Act also requires that state plans "provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care

²²While <u>Curtis</u> referred to regulations issued by the Department of Health, Education, and Welfare ("HEW"), that entity was renamed the Department of Health and Human Services in 1979. <u>Curtis</u> is binding authority under <u>Bonner v. City of Prichard</u>. <u>See supra p.</u> 19, n.19.

and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients." Id. § 1396a(a)(19).

Although the standard of "medical necessity" is not explicitly denoted in the Medicaid Act, it has become a judicially accepted component of the federal legislative scheme. See, e.g., Beal v. Doe, 432 U.S. 438, 444, 97 S. Ct. 2366, 2371 (1977) (indicating that "serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage"); Murray v. Auslander, 244 F.3d 807, 809 n.2 (11th Cir. 2001) ("Federal law allows Medicaid plans to apply a 'medical necessity' test to all applicants."); Prado-Steinman ex rel. Prado v. Bush, 221 F.3d 1266, 1268 (11th Cir. 2000) (indicating that the Medicaid Act allows states "to apply a 'medical necessity' test to all applicants to ensure that applicants receive medical services in order of need"); Curtis, 625 F.2d at 652 (concluding that participating states may limit required Medicaid services "in a manner based upon a judgment of degree of medical necessity so long as it does not discriminate on the basis of the kind of medical condition that occasions the need"); Pinneke v. Preisser, 623 F.2d 546, 548 n.2 (8th Cir. 1980) (observing that the "standard of medical necessity is not explicit in the [Medicaid] statute, but has become judicially accepted as implicit to the legislative scheme and is apparently endorsed by the Supreme Court" (citing Beal,

432 U.S. at 444-45 & n.9, 97 S. Ct. at 2370-71 & n.9)); see also 42 C.F.R. § 440.230(d) (providing that state Medicaid agencies "may place appropriate limits on a service based on such criteria as medical necessity"). Accordingly, even if a category of medical services or treatments is mandatory under the Medicaid Act, participating states must provide those medical services or treatments for Medicaid recipients only if they are "medically necessary."

B. 1989 Amendment and EPSDT Program

In 1989, Congress amended the Medicaid Act to broaden the categories of services that participating states must provide to Medicaid-eligible children. The 1989 Amendment mandates that participating states provide EPSDT services to all Medicaid-eligible persons under the age of 21.²³ Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6403, 103 Stat. 2106, 2262-64; 42 U.S.C. § 1396d(a)(4)(B), (r). The goal of the EPSDT program is to provide low-income children with comprehensive health care. The EPSDT program, codified at 42 U.S.C. § 1396d(r), mandates four specific categories of services: screening, vision, dental, and hearing services. 42 U.S.C. § 1396d(r)(1)-(4).

²³Section 1396d(a)(4)(B) provides that EPSDT services are available to "individuals who are eligible under the plan and are under the age of 21." 42 U.S.C. § 1396d(a)(4)(B).

Additionally, the catch-all EPSDT provision in § 1396d(r)(5), which is the focus of this appeal, mandates that participating states provide to Medicaid-eligible children "[s]uch other <u>necessary</u> health care, diagnostic services, treatment, <u>and other measures described in subsection (a) of this section</u> to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, <u>whether or not such services are covered under the State plan</u>." <u>Id.</u> § 1396d(r)(5) (emphasis added).

In other words, in addition to the four categories of services listed above, a state's mandatory EPSDT obligations to Medicaid-eligible children under § 1396d(r)(5) include "health care, diagnostic services, treatment, and other measures" that are (1) outlined in § 1396d(a) and (2) "necessary . . . to correct or ameliorate . . . conditions discovered by the screening services," (3) regardless of whether a state plan provides such services to adults. Id. As to Medicaid-eligible children, § 1396d(r)(5) requires that participating states must "cover every type of health care or service necessary for EPSDT corrective or ameliorative purposes that is allowable under § 1396d(a)." S.D. ex rel. Dickson v. Hood, 391 F.3d 581, 590 (5th Cir. 2004); see also Katie A. ex rel. Ludin v. Los Angeles Cnty., 481 F.3d 1150, 1154 (9th Cir. 2007) (quoting same); Collins v. Hamilton, 349 F.3d 371 (7th Cir. 2003); Pediatric Speciality Care, Inc. v. Ark. Dep't of Human Servs., 293 F.3d

472 (8th Cir. 2002); <u>Pereira ex rel. Pereira v. Kozlowski</u>, 996 F.2d 723 (4th Cir. 1993).

In turn, § 1396d(a)(1)-(29) enumerates 29 categories of care and services defined as "medical assistance," including "private duty nursing services" in § 1396d(a)(8). 42 U.S.C. § 1396d(a)(8). Section 1396a(a)(10) lists only eight of the categories listed in § 1396d(a) as mandatory for participating states to provide Medicaid-eligible adults. See 42 U.S.C. § 1396a(a)(10)(A) (providing that states must supply "at least the care and services listed in paragraphs (1) through (5), (17), (21), and (28) of section 1396d(a)"). The 1989 Amendment, however, made it incumbent upon states to provide all 29 categories of care, including "private duty nursing services," to Medicaid-eligible children who qualify under the EPSDT provision. Although eliminating a state's discretion over the categories of medical services and treatment that must be provided to children, the 1989 Amendment did not change the "medical necessity" limitation on such Medicaidrequired services and treatment.

To clarify the contours of the "private duty nursing services" mentioned in § 1396d(a)(8), a federal regulation provides that "[p]rivate duty nursing services means nursing services for recipients who require more individual and continuous care than is available from a visiting nurse or routinely provided by the nursing

staff of the hospital or skilled nursing facility." 42 C.F.R. § 440.80. That federal regulation specifies that the state has the option to provide the required private duty nursing services in a home, hospital, or skilled nursing facility:

These services are provided—

- (a) By a registered nurse or a licensed practical nurse;
- (b) Under the direction of the recipient's physician; and
- (c) To a recipient in one or more of the following locations at the option of the State—
 - (1) His or her own home;
 - (2) A hospital; or
 - (3) A skilled nursing facility.

<u>Id.</u> In addition, another federal regulation provides that each service in the state plan "must be sufficient in amount, duration, and scope to reasonably achieve its purpose" and that the state Medicaid agency "may place appropriate limits on a service based on . . . medical necessity":

- (a) The plan must specify the amount, duration, and scope of each service that it provides for—
 - (1) The categorically needy; and
 - (2) Each covered group of medically needy.
- (b) <u>Each service must be sufficient in amount, duration, and scope to</u> reasonably achieve its purpose.
- (c) The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition.

(d) The agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures.²⁴

<u>Id.</u> § 440.230 (emphasis added).²⁵

Given the above statutes, regulations, and precedents, read in conjunction with the record, we readily conclude that (1) under § 1396d(r)(5), DCH is required to provide all medical services and treatment "necessary . . . to correct or ameliorate" Moore's conditions; (2) Moore meets the criteria for "private duty nursing services" under § 440.80, and such services are medically necessary for Moore; and (3) under § 440.230(b) and (d), DCH must provide private duty nursing care to Moore that is "sufficient in amount, duration, and scope to reasonably achieve its purpose," but "may place appropriate limits on a service based on such criteria as medical necessity." In addition, Moore I tells us that the treating physician and the state both have roles to play in determining medical necessity, and the treating physician's opinion is not dispositive. Moore I, 324 F. App'x at 774. The parties largely do not dispute these starting points.

²⁴At oral argument, DCH's counsel stated that "utilization control procedures" refers to the auditing of medical services to prevent fraud and abuse by Medicaid providers, a function administered by DCH's Office of Inspector General Program Integrity Unit.

²⁵Section 440.230 is contained in a Code section entitled "Requirements and Limits Applicable to All [Medicaid] Services." 42 C.F.R. § 440, Subpart B.

Rather, the hotly disputed issues here concern what amount of private duty nursing hours the state must provide to Moore under the Medicaid Act, the parameters of the roles played by the treating physician and the state Medicaid agency in making that determination, and what happens when Moore's treating physician and the state's medical expert disagree about what amount of nursing hours are medically necessary. Although mandating several categories of medical services for children, the Medicaid Act, and specifically the 1989 Amendment, do not address what happens when the medical experts agree that a type or category of medical service is medically necessary for an individual child but disagree as to the amount or duration of the service, such as the private duty nursing hours here. To resolve these issues, the parties primarily cite and discuss a federal Medicaid manual and a state health services manual, along with some of our court precedents. We review them below.

C. CMS Manual

The Centers for Medicare and Medicaid Services ("CMS"), a federal agency within HHS, is charged with administering the Medicaid Act. Among other things, CMS sets forth guidelines for participating states to follow in their Medicaid programs and monitors state agency compliance with Medicaid requirements. See Emerald Shores Health Care Assocs. v. U.S. Dep't Health &

<u>Human Servs.</u>, 545 F.3d 1292, 1293 (11th Cir. 2008). CMS is required to determine that each state plan is in conformity with the specific requirements of the EPSDT mandate in the Medicaid Act. <u>See Hood</u>, 391 F.3d at 596 (citing 42 U.S.C. § 1396a(b) and 42 C.F.R. §§ 430.10, 430.15).

Manual to direct participating states in their implementation of Medicaid requirements, including the EPSDT mandate in the Medicaid Act. See CMS, U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. NO. 45, STATE MEDICAID MANUAL ("CMS Manual"). In the chapter devoted to EPSDT services, the CMS Manual describes the EPSDT mandate of the Medicaid Act as "a comprehensive child health program of prevention and treatment" designed to "[a]ssure that health

²⁶Internal agency guidelines, while not "subject to the rigors of the Administrative Procedure Act, including public notice and comment," are nevertheless "entitled to some deference." Reno v. Koray, 515 U.S. 50, 61, 115 S. Ct. 2021, 2027 (1995) (reviewing Bureau of Prisons Program Statement interpreting 18 U.S.C. § 3585(b)) (internal quotation marks and alteration omitted). Interpretations in agency manuals warrant Skidmore deference, meaning that they are "entitled to respect" but "only to the extent that those interpretations have the 'power to persuade." Christensen v. Harris Cntv., 529 U.S. 576, 587, 120 S. Ct. 1655, 1663 (2000) (quoting Skidmore v. Swift & Co., 323 U.S. 134, 140, 65 S. Ct. 161, 164 (1944)); see also Schweiker v. Gray Panthers, 453 U.S. 34, 43, 101 S. Ct. 2633, 2640 (1981) (stating that "Congress conferred on the [HHS] Secretary exceptionally broad authority to prescribe standards for applying certain sections of the [Medicaid] Act"); Sai Kwan Wong v. Doar, 571 F.3d 247, 250 (2d Cir. 2009) (according Skidmore deference to CMS Manual); United States ex rel. Walker v. R & F Props. of Lake Cnty., Inc., 433 F.3d 1349, 1357 (11th Cir. 2005) (applying Skidmore deference to Medicare Carriers Manual); Hood, 391 F.3d at 590 n.6 (concluding that CMS Manual was "entitled to respectful consideration" due to CMS's "significant expertise, the technical complexity of the Medicaid program, and the exceptionally broad authority conferred upon the Secretary under the Act"); Katie A., 481 F.3d at 1155 n.11 (same).

problems found are diagnosed and treated early, before they become more complex and their treatment more costly." <u>Id.</u> § 5110(B).

In the subsection entitled "Limitation of Services," the CMS Manual advises participating states, in language tracking § 1396d(r)(5),²⁷ that they make the determination as to whether a Medicaid-required service is medically necessary:

[EPSDT] services must be "necessary . . . to correct or ameliorate defects and physical or mental illnesses or conditions . . . " and the defects, illnesses and conditions must have been discovered or shown to have increased in severity by the screening services. You make the determination as to whether the service is necessary. You are not required to provide any items or services which you determine are not safe and effective or which are considered experimental.

Id. § 5122(F) (emphasis added).

The CMS Manual also instructs the states that 42 C.F.R. § 440.230 allows the state Medicaid agency "to establish the amount, duration and scope of services provided under the EPSDT benefit" so long as (1) any limitations imposed are reasonable; (2) the EPSDT service is sufficient to achieve its purpose; and (3) the state's definition of the service comports with the statutory requirement that the

²⁷As noted above, § 1396d(r)(5) provides that EPSDT services include, in part, "other necessary health care . . . to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services." 42 U.S.C. § 1396d(r)(5).

state provide all services "that are medically necessary to ameliorate or correct . . . conditions discovered by the screening services":

42 CFR 440.230 allows you to establish the amount, duration and scope of services provided under the EPSDT benefit. Any limitations imposed must be reasonable and services must be sufficient to achieve their purpose (within the context of serving the needs of individuals under age 21). You may define the service as long as the definition comports with the requirements of the statute in that all services included in §1905(a) of the Act [42 U.S.C. § 1396d(a)] that are medically necessary to ameliorate or correct defects and physical or mental illnesses and conditions discovered by the screening services are provided.

Id. (emphasis and brackets added); see also Hood, 391 F.3d at 591 (indicating that "under the CMS interpretation, a state Medicaid agency may regulate the amount, duration and scope of medical assistance provided, but its regulation must comply with the statutory requirement that all health care and services described in § 1396d(a) that are necessary to the corrective and ameliorative purposes of the EPSDT program must be provided").

While emphasizing the need for state Medicaid agencies to fulfill their EPSDT obligations, the CMS Manual underscores the need for the state agency to avoid "unnecessary services":

Although "case management" does not appear in the statutory provisions pertaining to the EPSDT benefit, the concept has been recognized as a means of increasing program efficiency and effectiveness by assuring that needed services are provided timely and efficiently, and that duplicated and unnecessary services are avoided.

CMS Manual § 5010(B); see also 42 U.S.C. § 1396a(a)(30)(A) (requiring State Medicaid plans to "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care").

In addition to the CMS Manual, the federal HHS or its sub-agencies periodically advise participating states of their EPSDT obligations. In this regard, a 1993 letter from the Acting Director of the federal Medicaid Bureau to State Medicaid Directors apprised states of their EPSDT obligations in the wake of the 1989 Amendment. See Letter from Rozann Abato, Acting Director, Medicaid Bureau, Health Care Financing Administration, to State Medicaid Directors (May 26, 1993) (Exhibit A to Amicus Curiae Brief for Atlanta Legal Aid Society, Inc.).

In this 1993 letter, the Medicaid Bureau's Acting Director expressed concern that "some States may not be fully aware of the flexibility which States may exercise in administering the [EPSDT] benefit under Medicaid." Id. The letter reiterated that the 1989 Amendment "did not take away a State's authority to

²⁸CMS was previously known as the Health Care Financing Administration.

use medical necessity or utilization controls to manage the State's Medicaid program." Id. The letter clarified that "States may place tentative limits on EPSDT services," noting by way of illustration that "a State may limit physical therapy services to 10 sessions for each Medicaid recipient" so long as "additional sessions are available to EPSDT recipients, if they are determined by the State to be medically necessary." Id. (second emphasis added). The letter explained that "a State may exclude any item or service that it determines is not medically necessary, is unsafe or experimental, or is not generally recognized as an accepted method of medical practice or treatment." Id.

The 1993 Medicaid Bureau letter also stated that "[a] State may choose to provide medically necessary services in the most economic mode, as long as the treatment made available is similarly efficacious, the determination process does not delay the delivery of the needed service and the determination does not, in essence, limit the recipient's right to a free choice of providers." <u>Id.</u> (citing 42 U.S.C. § 1396a(a)(30)(A)) (emphasis omitted). The letter listed "a system of prior approval of selected types of costly health care" as one method by which a state could "assure that services are furnished in a cost-effective manner." <u>Id.</u> The letter identified the objective of this prior authorization system:

The goal of prior authorization is to assure that the care and services proposed to be provided are actually needed, that all equally effective, less expensive alternatives have been given consideration and that the proposed service and materials conform to commonly accepted standards. For example, a State would not be required to provide an airfluidized bed if it determines that a less costly egg-crate mattress will serve the same medical needs.

<u>Id.</u> Lastly, the state Medicaid agency "is not required to furnish the service through every setting or provider type," so long as it can "demonstrate sufficient access" to an EPSDT-required service. <u>Id.</u>

Having reviewed CMS's interpretation of a state's EPSDT obligations, we next examine Georgia's efforts to satisfy the EPSDT mandate.

D. Georgia's EPSDT Mandate and Its GAPP Manual

In Georgia, Defendant DCH is the single state agency tasked with administering the Medicaid program. See 42 U.S.C. § 1396a(a)(5); O.C.G.A. § 49-4-142. Each participating state must create its own administrative rules and regulations for operating the Medicaid program in that state. Alacare, Inc.-North v. Baggiano, 785 F.2d 963, 964 (11th Cir. 1986). While states must meet the substantive requirements of the federal Medicaid Act, they nonetheless retain discretion to design and administer their Medicaid programs. See Fla. Ass'n of Rehab. Facilities, Inc. v. Fla. Dep't of Health & Rehabilitative Servs., 225 F.3d 1208, 1211 (11th Cir. 2000) (commenting that participating states are "granted").

broad latitude in defining the scope of covered services as well as many other key characteristics of their [Medicaid] programs"). That same flexibility extends to the EPSDT mandate. See Katie A., 481 F.3d at 1159 ("While the states must live up to their obligations to provide all EPSDT services, the statute and regulations afford them discretion as to how to do so."); see also Frew ex rel. Frew v. Hawkins, 540 U.S. 431, 439, 124 S. Ct. 899, 904-05 (2004) (noting that consent decree at issue represented one choice among "various ways that a State could implement the Medicaid Act" to comply with the "general EPSDT statute"). While the EPSDT mandate requires Georgia's DCH to provide children, who meet the eligibility requirements, with medically necessary "private duty nursing services" to "correct or ameliorate" their conditions, 42 U.S.C. § 1396d(a)(4)(B), (a)(8) & (r)(5), 42 C.F.R. § 440.80, the Medicaid Act does not set forth a uniform manner in which states must implement that EPSDT mandate.

We thus examine the particular service-delivery model, and standards therein, that DCH has adopted and implemented to satisfy its EPSDT mandate. As an alternative to institutionalizing Moore and providing private duty nursing services in a hospital or skilled nursing facility, pursuant to 42 C.F.R. § 440.80(c),

DCH employs the Georgia Pediatric Program²⁹ (referred to earlier as "GAPP") as a service-delivery model to provide private duty nursing care in a member's own home setting.³⁰ Specifically, the GAPP model provides private duty nursing services "to medically fragile children in their homes and communities and in a 'medical' daycare setting as an alternative to placing children in a nursing care facility." GAPP Manual § 601. Many children who enroll in GAPP are directly discharged from a hospital setting to begin receiving private duty nursing care in

²⁹There appears to be some dispute regarding the extent of CMS's approval of GAPP. In its motion for summary judgment, Defendant DCH stated, "GAPP was approved by CMS which means GAPP is in conformance with federal standards." In its reply brief in the district court, however, DCH conceded that it "did not represent that CMS approved the actual policy and procedure manual but rather that CMS approved the way in which the Department administers the program." The district court interpreted this statement to mean that CMS approved the manner in which DCH administers the entire Medicaid program, not GAPP specifically. See Moore II, 674 F. Supp. 2d at 1369. On appeal, Defendant DCH contends:

Contrary to what is noted in the district court's order, Defendant has maintained, and continues to maintain, that CMS has approved DCH's administration of the GAPP program Although CMS has approved DCH's administration of the entire Medicaid program, Defendant noted in [its summary judgment reply] brief that CMS also has specifically approved DCH's provision of private duty nursing services, which it provides through GAPP.

Appellant's Br. at 13 & n.4. In this opinion, we do not rely on DCH's contention that CMS has already approved its administration of GAPP but make our own assessment of whether, as to Moore's medical condition, DCH is complying with the requirements of the EPSDT mandate in the Medicaid Act.

³⁰The GAPP Manual states: "Skilled nursing care is provided in the home. Nurses caring for GAPP members must have a current background in pediatric critical care nursing within the past two years." GAPP Manual § 601.3(A). This case concerns only GAPP's provision of "private duty in-home nursing services," not "medical day care services," "transportation services," or "personal care attendants"—the other services offered through GAPP. See id. § 601.3(A)-(D).

the home. Miriam Henderson, a registered nurse and program specialist for GAPP, testified in a deposition that a majority of new GAPP members are direct admissions from hospitals.³¹

In addition, DCH, through its "Division of Medical Assistance," publishes a manual entitled "Part II Policies and Procedures for the Georgia Pediatric Program" (referred to earlier as the "GAPP Manual"). The GAPP Manual lists the following five goals for its member services, including the private duty nursing program:

1. To provide continuous skilled nursing care to medically fragile children under the age of twenty years 11 months. The children's medical condition must require skilled nursing care equivalent to the care received in an institutional setting, i.e., hospital or skilled

³¹The GAPP Manual specifies that nursing services provided by GAPP "cannot be rendered in a hospital, skilled nursing facility, intermediate care facility, school training center, public, charter, or private school, intermediate care facility for the mentally retarded, or any other similar facility." GAPP Manual § 602.4.

³²The billing manual for Georgia's Medicaid program is entitled "Part I Policies and Procedures for Medicaid/Peachcare for Kids." This manual, designed primarily as a reference for medical providers, contains terms and conditions for Medicaid reimbursement. DCH also publishes various manuals—many of which are entitled "Part II Policies and Procedures"—describing the policies of Georgia's Medicaid sub-programs.

³³The GAPP Manual in the record was published on July 1, 2006. DCH contends this is the relevant manual because this lawsuit concerns the 2006 reduction in private skilled nursing hours. Moore, however, contends that the October 1, 2006 GAPP Manual is the applicable manual, because it represents GAPP's governing policies at the time of the hours reduction, which occurred on or around November 16, 2006.

We need not resolve this issue because the July 2006 GAPP Manual is the only manual in the record, and because Moore has not alleged any material differences between this version and the October 2006 edition. All references herein are to the July 2006 GAPP Manual.

- nursing facility. The caregivers must be knowledgeable and competent in the care of the child. When deemed appropriate by the GMCF Medical Review Team, skilled nursing hours may be reduced.
- 2. To provide quality services, consistent with the needs of the individual child. All services requested must be accompanied by a physician's order.
- 3. <u>To provide cost effective services to eligible members in the home environment.</u>
- 4. <u>To involve the</u> physician and <u>child's caregiver(s)</u> or representative(s) <u>in the provision of the child's care</u>.
- 5. To demonstrate compassion for the members by treating the children and caregivers with dignity and respect while providing quality services in the home or daycare setting.

<u>Id.</u> § 601.1(1)-(5) (emphasis added).

Consistent with these goals, the GAPP Manual sets forth certain requirements that a GAPP member must meet to qualify for private duty nursing services in a home setting, including: (1) "[m]embers must be medically fragile with multiple systems diagnoses and require continuous skilled nursing care," id. § 601; (2) members must "meet the same level of care for admission to a hospital or nursing facility and must be Medicaid eligible," id.; (3) there must be a primary and secondary caregiver available, id. §§ 702.2(C), 801.2; (4) "[t]he caregivers must be knowledgeable and competent in the care of the child," id. § 601.1(1), and "[t]he primary caregiver must assist with the member's care in the home and must frequently communicate with the staff in the medical day care facility," id.

§ 702.2(B) (emphasis omitted); (5) a "cost analysis should be made to determine that the cost of caring for the member in the home and community is below the cost of providing the same care in an institution," <u>id.</u> § 701; and (6) the GAPP member must not require 16 or more hours of daily nursing care for a period greater than one week, <u>id.</u> § 905(d).³⁴ Thus, DCH conditions a GAPP member's receipt of private duty nursing services in the home (as an alternative to an institutional setting) on the presence of a caregiver in the home and the expectation that the primary caregiver will assist with the member's care in the home. <u>Id.</u> § 702.2(E).

The GAPP Manual contemplates roles for both the treating physician and the state in making private duty nursing hours authorizations, stating: "The primary care physician develops the child's initial plan of care. The GHP (GMCF Medical Review Team) determines the level of care, reviews prior approvals, determines the appropriateness of services, and makes approval or denial determinations." <u>Id.</u> § 601.2(C). The GMCF Medical Review Team determines the number of nursing hours by assessing the medical needs of GAPP recipients,

³⁴In a deposition, GAPP Medical Director Dr. Rosenfeld testified that, to his understanding, this requirement reflected a judgment that medically fragile children requiring more than 16 hours of daily nursing care are medically unstable and would be better served in an institutional setting.

the training needs of their caregivers, and the treating physicians' orders. <u>Id.</u> § 702.2(D).³⁵ When GMCF authorizes private duty nursing hours, "[a]pprovals are granted on a time-limited period not to exceed three (3) months." <u>Id.</u> § 801.1. In other words, GAPP members must reapply at least every three months in order to retain nursing care. Meanwhile, "[r]eauthorization requests are due thirty (30) days prior to the expiration of the existing approval period to ensure that there will be no interruption in services." <u>Id.</u> § 801.3.

A prospective GAPP member must file various documents when applying for nursing hours, many of which are periodically updated and resubmitted so that the GMCF Medical Review Team can assess a GAPP member's changing medical needs. These documents include a "DMA-6 A" form (the "Physician's Recommendation for Pediatric Care") and a "DMA-80" form (the "Prior Authorization Request Form"), which are filed early in the process. <u>Id.</u> § 801.2; see also id. apps. E, F.

³⁵Section 702.2(D) of the GAPP Manual provides:

The number of hours for which approval will be granted is based on specific medical treatment needs of the member confirmed by available medical information and the documented training needs of the primary caregiver confirmed by an established teaching plan. Hours may be reduced based on an evaluation of the current medical plan of treatment (physician orders); updated physician summaries; provider agency documented current assessments and nursing care.

GAPP Manual § 702.2(D).

Meanwhile, the treating physician submits a "Letter of Medical Necessity" with each nursing hours reauthorization request and must include:

[A] detailed Medical history—including related medical conditions, hospitalizations and medical course, explanation of medical necessity for nursing, oxygen/ventilator settings and hours of use per day, recommended nursing hours and weaning schedule, estimated duration of services, present and/or future readiness for medically fragile daycare and medical plan of treatment—including all medications, therapies and treatments, etc.

<u>Id.</u> § 801.2; <u>see also id.</u> app. J.

A GAPP member or the member's representative must sign a "Freedom of Choice" form, which indicates their informed consent to enroll in GAPP and choose among various service options. <u>Id.</u> § 801.2; <u>see also id.</u> app. H. The Freedom of Choice form states that "[o]nce a member is determined to be likely to require the level of care provided in a nursing facility or hospital, the member and his/her authorized representative will be . . . given the choice of either . . . institutional or home and community-based services." Id. app. H.

DCH also requires that members submit the "GAPP Assessment Form," signed by each planning team member (including the primary and secondary caregivers, treating physician and physician specialist, and nursing provider). <u>Id.</u> § 801.2; <u>see also id.</u> app. K. This document includes information on medical history, diagnosis, medication regimen, respiratory care information, caregiver

competency and work schedules, school requirements, and nursing needs. <u>Id.</u> app. K.

Additionally, DCH requires a prospective GAPP member's primary caregiver to sign a "Letter of Understanding" indicating acknowledgment and acceptance of GAPP policies. <u>Id.</u> § 801.2; <u>see also id.</u> app. L. By signing this form, the primary caregiver warrants, among other attestations, that (1) "[t]his GAPP program is designed to teach me on the care of my child's medical condition. I also understand that services may be reduced over time based on the medical needs of my child the (member)" and (2) "[t]he primary caregiver must be available and able to learn to participate in my child's (the member's) care." <u>Id.</u> app. L.

With respect to both the treating physician's initial recommendation of nursing hours and the GMCF Medical Review Team's final authorization of nursing hours, the GAPP Manual mandates that the nursing hours be medically necessary, stating: "The need for services is based on medical necessity, taking into consideration the overall medical condition of the member, the equipment and the level and frequency of care required for the member." <u>Id.</u> § 702.2(A); <u>see also id.</u> § 801.2 ("Services will <u>only</u> be approved based on medical necessity and

treatment needs of the member."); <u>id.</u> § 905(g) (excluding "[s]ervices for back up support or respite purposes for the primary or secondary caregiver").

The GAPP Manual describes GAPP as a "teaching program" in the home that is intended to shift some responsibility to the child's caregiver incrementally, as the caregiver acquires the necessary training and skills. <u>Id.</u> § 803(c). If the medical condition of a GAPP member stabilizes, the GAPP Manual states that skilled nursing hours in the home may be reduced over time:

Skilled nursing care services may be reduced when the medical condition of the member stabilizes to give more of the responsibility of the care of the member to the parent(s) and or caregiver(s). One of the goals of the Georgia Pediatric Program is to teach the parents and caregivers how to care for the member in the absence of a nurse. The Georgia Pediatric Program (GAPP) is not intended to be a permanent solution to skilled care. It is a teaching program.

Id. (emphasis added).

The GAPP Manual apprises members of their right to appeal a reduction in services and outlines the administrative review process. <u>Id.</u> §§ 805(b), 805.1. First, the GMCF Medical Review Team notifies the GAPP member of any reduction in nursing hours in its "Initial Letter of Notification." <u>Id.</u> § 805.1. Parents of GAPP members may request an administrative review of the hours reduction within ten days of this "Initial Letter of Notification." <u>Id.</u> If no such request is made, or if the parent fails to supply additional documentation to be

used in reviewing the appropriateness of the hours reduction, the denial will become final ten days after the date of the "Initial Letter of Notification." <u>Id.</u>

Within 30 days of the "Final Letter of Notification," parents may request a hearing before an administrative law judge. <u>Id.</u> Any party dissatisfied with the administrative law judge's decision retains appeal rights.³⁶ Id.

Having discussed Medicaid's EPSDT requirements and GAPP's private duty nursing program, we turn to the relevant court precedents.

E. Court Precedents

Several cases shed some light on the respective roles played by the treating physician and the state under the Medicaid Act and related regulations. While these cases do not answer the precise issue here, they, read together, provide guiding principles.

1. Beal v. Doe

In 1977, the Supreme Court in <u>Beal v. Doe</u> confronted whether the Medicaid Act required participating states to fund nontherapeutic abortions. 432 U.S. at 440, 97 S. Ct. at 2368. Pennsylvania's Medicaid plan provided state

³⁶Nothing in this opinion should be construed as addressing the standard of review, or the scope of review, when there has been an appeal through the administrative process, a fully developed record, and a decision by an administrative law judge.

funding only for abortions certified as medically necessary by physicians.³⁷ <u>Id.</u> at 441, 97 S. Ct. at 2369. The plaintiffs did not provide physician certifications, and Pennsylvania denied them Medicaid funding. <u>Id.</u> at 441-42, 97 S. Ct. at 2369. Plaintiffs' lawsuit alleged that Pennsylvania's requirement of a medical necessity certificate violated the Medicaid Act and the Equal Protection Clause. <u>Id.</u> at 441-42, 97 S. Ct. at 2369-70.

In <u>Beal</u>, the Supreme Court rejected the plaintiffs' contention that "participating States are required to fund every medical procedure that falls within the [Medicaid Act's] delineated categories of medical care." <u>Id.</u> at 444, 97 S. Ct. at 2370. The <u>Beal</u> majority noted that § 1396a(a)(17) of the Medicaid Act provides that "[a] State plan for medical assistance must . . . include reasonable standards . . . for determining eligibility for and the extent of medical assistance under the plan which . . . are consistent with the objectives of this [Title]." <u>Id.</u> at

³⁷The Pennsylvania Medicaid program defined an abortion as medically necessary if:

⁽¹⁾ There is documented medical evidence that continuance of the pregnancy may threaten the health of the mother;

⁽²⁾ There is documented medical evidence that an infant may be born with incapacitating physical deformity or mental deficiency; or

⁽³⁾ There is documented medical evidence that continuance of a pregnancy resulting from legally established statutory or forcible rape or incest, may constitute a threat to the mental or physical health of a patient; and

⁽⁴⁾ Two other physicians chosen because of their recognized professional competency have examined the patient and have concurred in writing; and

⁽⁵⁾ The procedure is performed in a hospital accredited by the Joint Commission on Accreditation of Hospitals.

Beal, 432 U.S. at 441 n.3, 97 S. Ct. at 2369 n.3 (internal quotation marks omitted).

444, 97 S. Ct. at 2370-71 (quoting 42 U.S.C. § 1396a(a)(17)) (alterations in original). The majority explained that "[t]his language confers broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives' of the [Medicaid] Act." <u>Id.</u> at 444, 97 S. Ct. at 2371.

The Beal majority concluded that Pennsylvania's Medicaid program was consonant with the Medicaid Act's objective of providing medically necessary services to low-income individuals. The majority instructed, "Although serious statutory questions might be presented if a state Medicaid plan excluded necessary medical treatment from its coverage, it is hardly inconsistent with the objectives of the Act for a State to refuse to fund unnecessary—though perhaps desirable—medical services." Id. at 444-45, 97 S. Ct. at 2371. Thus, state Medicaid funding of nontherapeutic abortions was permissible, but not mandatory. The Beal Court noted that HEW—HHS's precursor—supported this position and stated, "[W]e must be mindful that the construction of a statute by those charged

³⁸The <u>Beal</u> plaintiffs argued that Pennsylvania's refusal to make Medicaid reimbursements for nontherapeutic abortions was unreasonable, on both cost and health grounds, because (1) abortion is typically less costly than childbirth and (2) health risks posed by abortion are fewer than those posed by childbirth. 432 U.S. at 445, 97 S. Ct. at 2371. The <u>Beal Court rejected these arguments</u>, noting the "important and legitimate interest [of the State] . . . in protecting the potentiality of human life." <u>Id.</u> at 445-46, 97 S. Ct. at 2371 (quoting <u>Roe v. Wade</u>, 410 U.S. 113, 162, 93 S. Ct. 705, 731 (1973)) (alterations in original).

with its execution should be followed unless there are compelling indications that it is wrong." <u>Id.</u> at 447, 97 S. Ct. at 2372 (quoting <u>N.Y. Dep't of Soc. Servs. v. Dublino</u>, 413 U.S. 405, 421, 93 S. Ct. 2507, 2516-17 (1973)) (internal quotation marks omitted).

The <u>Beal</u> majority rejected the plaintiffs' argument that Pennsylvania's Medicaid plan trenches on a physician's medical judgment because the plan paid for abortions only if the physician certified the abortion was medically necessary.

<u>Id.</u> at 445 n.9, 97 S. Ct. at 2371 n.9. Thus, the Supreme Court upheld Pennsylvania's requirement of a medical necessity certification before covering an abortion. The <u>Beal</u> Court opted not to pass upon the portion of Pennsylvania's plan that posed a potential interference with the treating physician's medical judgment, however.³⁹

From <u>Beal</u>, we learn that (1) a participating state is not required to fund desirable but medically unnecessary services requested by a Medicaid recipient's physician and (2) the Medicaid Act endows participating states with broad

³⁹The <u>Beal</u> majority commented that one facet of Pennsylvania's plan could potentially violate the Medicaid Act; namely, the requirement that two physicians (in addition to the attending physician) must examine the patient and concur that the abortion is medically necessary before Medicaid reimbursement is permitted. 432 U.S. at 448, 97 S. Ct. at 2373. The majority stated that, based upon the record before it, "we are unable to ascertain whether this requirement interferes with the attending physician's medical judgment in a manner not contemplated by the Congress." <u>Id.</u> Accordingly, the <u>Beal</u> Court reversed the Third Circuit and remanded the case for consideration of this issue. <u>Id.</u>

discretion to fashion standards for determining the extent of medical assistance, so long as such standards are reasonable and congruous with the purposes of the Act.

2. Curtis v. Taylor

In 1980, three years after <u>Beal</u>, our predecessor Court decided <u>Curtis v.</u>

<u>Taylor.</u> ⁴⁰ In <u>Curtis</u>, plaintiffs filed a class action on behalf of all Florida Medicaid recipients against the Secretary of the Florida Department of Health and Rehabilitative Services for alleged constitutional and statutory violations arising from Florida's Medicaid plan. 625 F.2d at 647, 649. The <u>Curtis</u> plaintiffs challenged a modification of Florida's Medicaid program that limited Medicaid recipients to three doctor visits per month, excluding emergencies—a change precipitated by Florida's projected Medicaid deficit. <u>Id.</u> at 647. Like EPSDT services, physicians' services are a mandatory category of medical assistance that the Medicaid Act requires all state plans to fund. 42 U.S.C. §§ 1396a(a)(10)(A), ⁴¹ 1396d(a)(5). The district court enjoined Florida from implementing this Medicaid limitation. Curtis, 625 F.2d at 647.

On appeal, our predecessor Court in <u>Curtis</u> construed and applied 42 C.F.R. § 440.230(b), the federal Medicaid regulation requiring that "[e]ach service must

⁴⁰Curtis is binding precedent, as discussed earlier. See p. 23, n.22.

⁴¹When <u>Curtis</u> was decided, the Medicaid Act's delineation of mandatory categories of medical assistance was codified at § 1396a(a)(13)(B). 42 U.S.C. § 1396a(a)(13)(B) (1980).

be sufficient in amount, duration, and scope to reasonably achieve its purpose."

42 C.F.R. § 440.230(b). In analyzing whether Florida had discharged its Medicaid Act duties under § 440.230(b), the <u>Curtis</u> Court explained that the question hinged "on whether the state may place limits on the amount of physicians' services available to a recipient, even though those limits may result in a denial of some medically necessary treatment, if most recipients do not need treatment beyond that provided." 625 F.2d at 651. The <u>Curtis</u> Court answered this question in the affirmative and reversed the district court, stating, "[w]e hold that the state's payment for physicians' services was sufficient to 'reasonably achieve' the purpose of such care even though limited to three visits per month." Id. at 647.

In reaching this conclusion, the <u>Curtis</u> Court pointed to factors buttressing Florida's argument. First, the trial court record reflected that the vast majority of Medicaid recipients did not require more than three physician visits in any month.⁴³ <u>Id.</u> at 651. In a footnote, the <u>Curtis</u> Court noted that "[t]he state may place appropriate limits on a service based on medical necessity. The state does

⁴²The <u>Curtis</u> decision also discussed alleged jurisdictional and notice infirmities. 625 F.2d at 647-50. Because these issues are not relevant to this case, we do not address them here.

⁴³In <u>Curtis</u>, data in the record indicated that (1) Medicaid-eligible persons required on average 5.6 doctor visits per year in 1976; (2) in Florida, 3.9% of Medicaid recipients required more than three doctor visits in any month during the second quarter of 1977; and (3) only 0.5% of Florida Medicaid recipients required more than three visits in multiple months. 625 F.2d at 651 n.10.

not, however, contend that the three-visit limit is based on the lack of medical necessity of treatment for any individual. Indeed it could not. The plaintiffs include several persons with a documented need for more than three visits per month." <u>Id.</u> at 651 n.11. In other words, the <u>Curtis Court rejected the plaintiffs' contention that Florida's plan violated the Medicaid Act, despite acknowledging that it was medically necessary for the plaintiffs as individuals to receive more than three doctor visits per month.</u>

The <u>Curtis</u> Court thus dismissed the plaintiffs' arguments that (1) "the sufficiency of the service provided must be determined with regard to each individual who receives medical services" and (2) "if only a handful out of thousands needs to see a doctor more than three times a month, the limitation defeats the regulatory requirement." <u>Id.</u> at 651. The <u>Curtis</u> Court explained that if the plaintiffs' contention were accepted, it "would preclude any limitation on any medically necessary service," and Florida's Medicaid agency would be obligated to pay for "thirty visits per month if any Medicaid recipient needed such services or hospital stays of indefinite duration." <u>Id.</u>

Second, the <u>Curtis</u> Court noted that at least 17 states presently limited the frequency of physician visits, with the apparent approval of the federal HEW. <u>Id.</u>

The <u>Curtis</u> Court further relied upon HEW publications⁴⁴ suggesting that HEW interpreted § 440.230(b) as authorizing such Medicaid limitations and declared that "[w]hen the meaning of an agency's regulation is not clear, deference should be given to the interpretation adopted by the agency that promulgated the regulation and administers the statute." <u>Id.</u> at 652-53 (citing <u>Dublino</u>, 413 U.S. at 421, 93 S. Ct. at 2516).

Third, the <u>Curtis</u> Court distinguished its doctor visitation case from other cases in which state Medicaid plans had limited payments for certain <u>types</u> of diagnoses and medical conditions. <u>Id.</u> at 651-52 (citing <u>White v. Beal</u>, 555 F.2d 1146 (3d Cir. 1977) (invalidating Pennsylvania plan providing eyeglasses to Medicaid recipients suffering eye disease but not those suffering non-pathological eye conditions); <u>Preterm, Inc. v. Dukakis</u>, 591 F.2d 121 (1st Cir. 1979) (ruling Massachusetts plan violated the purposes of the Medicaid Act when it limited state-funded abortions to those necessary to save mother's life or where mother was victim of rape or incest)). The <u>Curtis</u> Court concluded that the state Medicaid plans in those cases did not draw distinctions based upon medical necessity, but discriminated against Medicaid recipients "solely on the basis of the 'diagnosis,

⁴⁴The <u>Curtis</u> Court cited, but did not quote, HEW's "Data on the Medicaid Program: Eligibility/Services/Expenditures Fiscal Years 1966-1978." 625 F.2d at 652-53.

type of illness, or condition," in contravention of \S 440.230(c)(1).⁴⁵ <u>Id.</u> at 652 (quoting 42 C.F.R. \S 440.230(c)(1)).

By contrast, Florida's Medicaid plan did not discriminate on the basis of "diagnosis, type of illness, or condition" between Medicaid recipients who needed more than three doctor visits a month and those requiring fewer, since the limitation applied to all Medicaid recipients regardless of medical infirmity suffered. Id. In this regard, the Curtis Court emphasized: "Here, no particular medical condition is singled out for unique treatment or given care only in restricted situations. All medical conditions are treated equally." Id. Additionally, Florida's exception for emergency visits did not discriminate against Medicaid recipients whose conditions were less severe. Id. Rather, Florida's emergency exception "simply reflects a judgment by the state that those persons who need emergency care have a higher degree of medical necessity than those who do not. That conclusion is compassionate as well as rational. The provision of emergency services beyond the three-visit-per-month limit is patently based on a medical necessity standard, the existence of an exigent need." Id.

⁴⁵Section 440.230 has since been amended. Former § 440.230(c)(1) tracks the language now found in § 440.230(c), which we quoted at p. 28.

In the <u>Curtis</u> Court's judgment, § 440.230 permits a state to place certain limitations on required Medicaid services based upon an assessment of medical necessity, so long as the services meet a standard of "reasonable adequacy" and the limitation does not discriminate on the basis of diagnosis or type of condition:

The rationale adopted by the courts that have considered the meaning of the applicable regulations [42 C.F.R. § 440.230] permits the state to place at least one type of limitation on its provision of required services: it may limit those services in a manner based upon a judgment of degree of medical necessity so long as it does not discriminate on the basis of the kind of medical condition that occasions the need. The proposed limitation in this case is not the type that courts of appeals have rejected in the past. It is based on a generally applicable standard of what is deemed reasonable adequacy.

<u>Id.</u> The <u>Curtis</u> Court concluded that "[t]he regulatory criterion is not whether the treatment suffices for a cure in all cases, but whether the plan is sufficient for reasonable accomplishment of its purpose. Florida's regulation is not inconsistent with [the Medicaid Act's] broad purpose of servicing the indigent. Nor is it inconsistent with the purpose of the provision of physicians' services to the Medicaid population as a whole." <u>Id.</u> at 653. Having dismissed the plaintiffs' contention that Florida's program violated the Medicaid Act, the <u>Curtis</u> Court remanded the case for consideration of the plaintiffs' equal protection claim. <u>Id.</u>

From <u>Curtis</u>, we learn that although a participating state may not refuse to fund a Medicaid-required type of medical service in toto, the state Medicaid

agency has the ability to place quantity and durational limits on required services so long as the services meet a standard of "reasonable adequacy" that does not run afoul of § 440.230(b). <u>Id.</u> at 652-53. The <u>Curtis Court stressed</u>, however, that any imposed limitations could not discriminate on the type of medical condition suffered by the Medicaid recipient. Lastly, the <u>Curtis Court appeared to take a particularly solicitous stance towards Florida's limitation in light of its exception for emergency situations. <u>Id.</u> at 652. It reasoned that such exceptions demonstrated an appropriate exercise of Florida's authority to make judgments of degrees of medical necessity. Id.</u>

3. Rush v. Parham

Four days after <u>Curtis</u> was filed, our predecessor Court decided <u>Rush v.</u>

<u>Parham</u>, which involved an anatomical male who was diagnosed as a transsexual and sought Medicaid funding for a sexual reassignment surgery. <u>Rush</u>, 625 F.2d at 1152-53. Because both parties here claim <u>Rush</u> militates in their favor, we analyze <u>Rush</u> in depth.

The <u>Rush</u> plaintiff claimed that the Medicaid Act required Georgia to pay for the proposed surgery. <u>Id.</u> at 1152. The plaintiff's two medical specialists certified that Rush "was a 'true transsexual,' <u>i.e.</u>, an anatomical male with a female gender identity, and that the only effective means of treatment was surgical change

of Rush's anatomical sex." <u>Id.</u> at 1153. The state responded that the surgery was "experimental" and also "inappropriate treatment for Rush" individually. <u>Id.</u>

The district court ruled that Georgia must pay for the surgery, concluding: (1) "Medicaid coverage is not optional or discretionary for necessary medical treatment of eligible recipients" and (2) "the state, and, for that matter, the courts, must not interfere with the physician's course of treatment deemed medically necessary." Rush v. Parham, 440 F. Supp. 383, 389-90 (N.D. Ga. 1977). The district court relied upon (1) the "preeminence of the attending physician" as revealed by the joint legislative history of the Medicaid Act and (2) the fact that a treating physician's decision was still "governed by the standards and ethics of his profession and by the dictates of federal and state law." Id.; see also id. at 390 n.12 (citing statutory criminal penalties for knowing or wilful misrepresentations in a Medicaid benefits application). 46

⁴⁶In a footnote, the district court stated, "This court is not presented in the Georgia State Plan or its attendant regulations with a requirement for physicians' confirmation of the attending physician's decision that certain procedures or services are medically necessary. The court, therefore, makes no judgment of the propriety of such a requirement in light of the Medicaid mandate, at this time." Rush, 440 F. Supp. at 390 n.11. In contrast, in this case, the GMCF Medical Review Team plays the role of reviewing the treating physician's recommendation of private duty nursing hours and approving or not approving them, as the case may be.

On appeal, our predecessor Court reversed and expressly rejected the district court's rulings. As to medical necessity, the <u>Rush Court declared</u>, "<u>We . . . hold that state defendants should have been permitted to show at trial</u>":

- (1) "the Georgia Department of Medical Assistance⁴⁷ has a ban against making payment for experimental treatment because such treatment is not medically necessary, and that transsexual surgery is experimental"; or
- (2) "the Department of Medical Assistance provides for transsexual surgery in an appropriate case, but properly determined that it was medically inappropriate in plaintiff's case." 625 F.2d at 1152 (footnote omitted and emphases added).

The <u>Rush</u> Court expressly pointed out that the district court had held that Georgia "is required to pay for any services a physician determines to be medically necessary for the patient." <u>Id.</u> at 1154. The <u>Rush</u> Court stated, "We disagree with the district court, and <u>hold instead that a state may adopt a definition of medical necessity that places reasonable limits on a physician's discretion." <u>Id.</u> (emphasis added). The Rush Court further declared, "We also hold that a state</u>

⁴⁷The Georgia Department of Medical Assistance was the state agency then responsible for administering Georgia's Medicaid program. Rush, 625 F.2d at 1152 n.1.

⁴⁸We gave an example of a service the state is not required to pay for because it is not medically necessary: "One such limitation is the one Georgia contends it used in denying the surgery: a ban against reimbursement for experimental forms of treatment, <u>i.e.</u>, treatment not generally recognized as effective by the medical profession." <u>Rush</u>, 625 F.2d at 1154-55 (footnote omitted).

Medicaid agency can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis." Id. at 1155 (emphasis added).

In sum, <u>Rush</u> teaches that (1) a treating physician is not the sole arbiter of medical necessity; (2) the state may review the medical necessity of a treating physician's prescribed treatment; (3) the state may adopt a reasonable definition of medical necessity, even if it places some limits on a treating physician's discretion; and (4) the state at trial can present its own evidence of medical necessity in a dispute between the state and an individual Medicaid patient.

After announcing its holdings, the <u>Rush</u> Court proceeded to divide its analysis into three subparts, which we discuss sequentially.

a. Rush's Part A

In Part A, the <u>Rush</u> Court characterized the district court's decision—that "a state must pay for all treatment found by a doctor to be medically necessary"—as making the private physician "the sole arbiter of medical necessity" and as effectively holding that "a state has no role in determining whether a particular service is medically necessary." Id.

Contrary to the district court's view, the <u>Rush</u> Court instructed that "the Medicaid statutes and regulations permit a state to define medical necessity in a way tailored to the requirements of its own Medicaid program." <u>Id.</u> The <u>Rush</u>

Court found support for this statement in both statutory text and Supreme Court precedent. First, it noted that the Medicaid Act provides that "[a] State plan for medical assistance must . . . include <u>reasonable standards</u> . . . for determining eligibility for and the extent of medical assistance under the plan which . . . are <u>consistent with the objectives of this [Title]</u>." <u>Id.</u> (quoting 42 U.S.C. § 1396a(a)(17)) (emphasis added) (alterations in original). Second, the <u>Rush Court commented that "[t]he Supreme Court has interpreted this language as conferring broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be reasonable and consistent with the objectives of the Act." <u>Id.</u> (quoting <u>Beal</u>, 432 U.S. at 444, 97 S. Ct. at 2371) (internal quotation marks omitted).</u>

The <u>Rush</u> Court explained the meaning of this language—that states have "broad discretion" to adopt reasonable standards—from Beal:

The key to defining the states' role in determining the extent of coverage can be found in the Supreme Court's use of the word "standard" in the passage we quoted from <u>Beal v. Doe</u>. We think the Court was saying that a state may establish standards for individual physicians to use in determining what services are appropriate in a particular case. This state responsibility to establish standards extends at least to the shaping of a reasonable definition of medical necessity.

<u>Id.</u> at 1155-56. The <u>Rush</u> Court found further warrant for its conclusion that the state may shape a reasonable definition of medical necessity in the federal

regulation providing that "[t]he [state] agency may place appropriate limits on services based on such criteria as medical necessity." <u>Id.</u> at 1156 (quoting 42 C.F.R. § 440.230(c)(2)) (second alteration in original).⁴⁹ The <u>Rush Court clarified</u> that its decision "does not remove from the private physician the primary responsibility of determining what treatment should be made available to his patients. We hold only that the physician is required to operate within such reasonable limitations as the state may impose." <u>Id.</u>

Given its conclusion that the state agency can "establish standards" and "shape[] . . . a reasonable definition of medical necessity," the <u>Rush Court then</u> determined that "Georgia's definition of medically necessary services can reasonably exclude experimental treatment." <u>Id. The Rush Court found</u> "little merit to the contention that medically necessary services must be defined to include experimental treatment, with all its attendant risks to the recipient

 $^{^{49}}Section~440.230$ has since been amended. Former ~440.230(c)(2) tracks the language now found in ~440.230(d), which we quoted at p. 29.

⁵⁰In making this determination, the <u>Rush</u> Court found support by analogy to the Medicare administrators' interpretation of the Medicare Act. The <u>Rush</u> Court noted that a provision in the Medicare Act that excludes payment for medical services "which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member," 42 U.S.C. § 1395y(a)(1) (1976), had been read by Medicare administrators to foreclose reimbursement for experimental treatment and used to prohibit payment for certain types of services found to be experimental. <u>Rush</u>, 625 F.2d at 1156. In reaching this conclusion, the <u>Rush</u> Court consulted "Medicare Intermediary Letters" and the "Medicare Hospital Manual," both published in CCH's "Medicare & Medicaid Guide." <u>Id.</u>

population," and concluded that an interpretation of "medical necessity" that excludes experimental treatment "would be a valid exercise of Georgia's discretion to set standards under the Medicaid statute." Id.

The <u>Rush</u> Court remanded the case to the district court "to determine (1) whether Georgia, in fact, had a policy prohibiting payment for experimental services when it first rejected plaintiff's application; and, if it did, (2) whether its determination that transsexual surgery is experimental is reasonable." <u>Id.</u> at 1156-57 (footnote omitted).

b. Rush's Part B

In a separate Part B of the opinion, the <u>Rush</u> Court speculated about possible scenarios on remand. In Part B, the <u>Rush</u> Court stated: "If on remand, [1] the district court finds that the state defendants' decision to deny payment for Rush's surgery was not based on a prohibition against reimbursement for experimental treatment, or if [2] [the district court] finds that transsexual surgery was not experimental, it must consider defendants' second contention: that they reached a proper administrative determination that transsexual surgery was

⁵¹In a footnote, the <u>Rush</u> Court specified that the district court's reasonableness review of Georgia's determination that transsexual surgery is experimental, and therefore not medically necessary, "should be based on current medical opinion, regardless of the prevailing knowledge at the time of plaintiff's application." <u>Rush</u>, 625 F.2d at 1157 n.13.

inappropriate treatment for Rush." <u>Id.</u> at 1157. Consequently, <u>Rush</u>'s analysis in Part B applies only if the district court determines on remand that (1) Georgia's plan did not have a policy of excluding payment for all experimental services when it first rejected the plaintiff's request or (2) transsexual surgery is <u>not</u> experimental and thus may be medically necessary in some individual cases.

The Rush Court declared that, on review of the record before it, it was unclear whether Georgia's Medicaid agency made a determination that transsexual surgery was inappropriate treatment for Rush individually and, if so, what standard of review it employed in rejecting the opinion of the plaintiff's physician.

Id. Importantly for this case, the Rush Court cautioned that these were "material questions of fact that should not have been resolved by the district court on a motion for summary judgment." Id. This part of the discussion in Part B is clear and consistent with the earlier holdings of Rush, which concluded that the state can review the treating physician's recommendation on a case-by-case basis and can present its own evidence of medical necessity at trial. This in turn creates issues of material fact for the factfinder to decide at trial.

After speculating about possible scenarios on remand, the <u>Rush</u> Court then volunteered what could happen upon certain other hypothetical findings by the district court. These last two paragraphs of Rush's Part B, however, are far from

clear. While these last two paragraphs are now twice removed⁵² from the earlier holdings in <u>Rush</u>, we examine them thoroughly because this is the only portion of <u>Rush</u> cited by the district court in Moore's case. <u>See Moore II</u>, 674 F. Supp. 2d at 1369-70 (quoting Rush, 625 F.2d at 1157).

In the last two paragraphs of <u>Rush</u>'s Part B, our predecessor Court introduced the different, and collateral, concept of Medicaid coverage for experimental surgery in exceptional cases. The <u>Rush</u> Court postulated what should happen if "Georgia had a policy of limiting payment for experimental surgery to exceptional cases (and if it did, [that] transsexual surgery was experimental)," and "defendants were simply deciding whether Rush's case presented exceptional circumstances." <u>Rush</u>, 625 F.2d at 1157. Under this new hypothetical scenario, the <u>Rush</u> Court stated that the district court should defer to the state unless the plaintiff was able to "show compelling reasons why an exception should be made for her." <u>16.</u>

⁵²By twice removed, we mean that after announcing the holdings and ordering a remand, the <u>Rush</u> Court speculated about scenarios on remand and then hypothetical findings in even additional scenarios.

⁵³To prove such exceptional circumstances, the plaintiff needed to show that (1) "no other form of treatment would improve her [medical] condition" and (2) the proposed "transsexual surgery was unlikely to worsen it." Rush, 625 F.2d at 1157.

Under yet another hypothetical scenario, the last paragraph in Part B, the Rush Court offered further remarks about experimental surgery. In the last paragraph, the Court suggested that if the district court finds that "Georgia did not have a policy limiting payment for experimental surgery to exceptional cases (or that transsexual surgery was not experimental)," then the Medicaid agency's review of the physician's opinion "would have been such 'as may be necessary to safeguard against unnecessary utilization of . . . care and services." Id. (quoting 42 U.S.C. § 1396a(a)(30)) (emphasis added).⁵⁴ In this regard, the Rush Court cited legislative history from the 1965 Senate Finance Committee Report on the Medicaid Act, which stated that "[t]he physician is to be the key figure in determining utilization of health services." Id. (quoting S. REP. No. 89-404, at 46 (1965), as reprinted in 1965 U.S.C.C.A.N. 1943, 1986 ("Senate Report")

⁵⁴Section 1396a(a)(30) provides:

⁽a) Contents. A State plan for medical assistance must—

^{(30) (}A) provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b(i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area

⁴² U.S.C. § 1396a(a)(30). Section 1396a(a)(30) is not addressing medical necessity itself, but rather the "methods and procedures" regarding utilization of and payment for medical care that is already deemed necessary care under the state plan.

(emphasis added).⁵⁵ The <u>Rush</u> Court then remarked, "<u>Under these circumstances</u>, we <u>think</u> defendants would have been limited to determining whether the physician's diagnosis, or his opinion that the prescribed treatment was appropriate to the diagnosis, was without any basis in fact." <u>Id.</u> (emphases added).⁵⁶

This last paragraph seems inconsistent with <u>Rush</u>'s earlier holdings that:

(1) if the Georgia plan covers experimental surgery, the state is still entitled to present evidence at trial that it "properly determined that [transsexual surgery] was medically inappropriate in plaintiff's case," <u>id.</u> at 1152; (2) "a state may adopt a

Pinneke, 623 F.2d at 549 n.3 (quoting Senate Report).

⁵⁵The relevant portion of this legislative history was quoted at greater length in <u>Pinneke</u>: 3(a) Conditions and limitations on payment for services.

⁽¹⁾ Physicians' role

The committee's bill provides that the physician is to be the key figure in determining utilization of health services and provides that it is a physician who is to decide upon admission to a hospital, order tests, drugs and treatments, and determine the length of stay. For this reason the bill would require that payment could be made only if a physician certifies to the medical necessity of the services furnished.

⁵⁶We can reconcile <u>Rush</u> with <u>Curtis</u> because both indicate that the state not only has a role to play as to medical necessity but also is not required to accept the treating physician's opinion of medical necessity. Any differences in <u>Rush</u> and <u>Curtis</u> stem from the markedly disparate factual contexts in which the cases arose. Georgia's limitation in <u>Rush</u> was a blanket denial of a particular type of medical service, sex reassignment surgery. In contrast, Florida's limitation in <u>Curtis</u>—funding only three doctor visits a month, excluding emergencies—was quantitative in nature. See pp. 86-88, infra.

In any event, to the extent any portion of <u>Rush</u> arguably conflicts with the holding in <u>Curtis</u>, we are bound by <u>Curtis</u>, which preceded <u>Rush</u>. <u>See United States v. Smith</u>, 122 F.3d 1355, 1359 (11th Cir. 1997) (per curiam) ("Under the prior panel precedent rule, we are bound by earlier panel holdings . . . unless and until they are overruled en banc or by the Supreme Court.").

definition of medical necessity that places reasonable limits on a physician's discretion," <u>id.</u> at 1154; and (3) "a state Medicaid agency can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis," <u>id.</u> at 1155. At a minimum, this complicated postulation of multiple levels of scenarios on remand is dicta and does not undermine <u>Rush</u>'s earlier clear holdings. A decision can extend no further than the facts and circumstances of the case in which it arises. <u>See, e.g., Watts v. BellSouth Telecomms., Inc.</u>, 316 F.3d 1203, 1207 (11th Cir. 2003) ("Whatever their opinions say, judicial decisions cannot make law beyond the facts of the cases in which those decisions are announced."); <u>United States v. Aguillard</u>, 217 F.3d 1319, 1321 (11th Cir. 2000) (per curiam); <u>United States v. Eggersdorf</u>, 126 F.3d 1318, 1322 n.4 (11th Cir. 1997).

Alternatively, however we classify this last paragraph, the <u>Rush</u> Court's suggestions about "utilization review" appear to apply only in limited circumstances. To fully understand and place in context this "utilization review" paragraph of <u>Rush</u>, it is helpful first to examine what the district court did in <u>Rush</u> by comparison. The district court in <u>Rush</u> had opined that the state must pay for any medical services prescribed by the treating physician and that the state's review of a treating physician's recommendation was, in <u>all</u> circumstances, limited to a utilization review, id. at 1154 n.6—a conclusion which, on appeal, the Rush

Court explicitly rejected, <u>id.</u> at 1154-55. In the last paragraph of Part B, the <u>Rush</u> Court conjectured that the state is restricted to a utilization review only if (1) under Georgia's plan, experimental treatment was not limited to exceptional cases but provided more generally, or (2) if the district court made a threshold finding that Georgia was unreasonable in determining that sex reassignment surgery was experimental.

In other words, the district court in <u>Rush</u> erred in concluding that the state's reviewing authority is limited to a "utilization review" in all circumstances.

Rather, the <u>Rush</u> Court's musings in the last paragraph of Part B suggest that the state is limited to a utilization review in circumstances where the state has placed no limitation at all on experimental treatment or where the state's attempt to place a medical necessity limitation on a service was deemed contrary to "current medical opinion," <u>id.</u> at 1157 n.13, and thus unreasonable.

c. Rush's Part C

In Part C, the <u>Rush</u> Court squarely returned to the issue of medical necessity and again made clear that the state is not required to pay for any treatment the treating physician finds medically necessary. In Part C, the <u>Rush</u> Court noted that some other courts had ordered state Medicaid agencies to pay for sex reassignment surgery, but found that these cases did not conflict with its opinion. Id. at 1157-

58. The Rush Court did not interpret those decisions as having (1) decided the question of whether a state may, in defining medical necessity, exclude experimental services or (2) prohibited a state Medicaid agency from reviewing "whether a doctor's diagnosis and recommendation of treatment for a particular patient are in error." Id. at 1158. Significantly, the Rush Court opined: "To the extent these cases do hold that a state must pay for any treatment a doctor finds to be medically necessary, thus eliminating the issues that we have found unripe for summary disposition, we disagree for the reasons given in the body of this opinion." Id. We read Parts A and C of Rush as consistently holding that a state is not required to pay automatically for any treatment a doctor finds medically necessary, and when the state's and a patient's experts disagree, material questions of fact arise as to whether a treatment is medically necessary.

Before leaving <u>Rush</u>, we note that our <u>Moore I</u> opinion cited <u>Rush</u> once, in support of the proposition that "both the state and Moore's physician have roles in determining what medical measures are necessary to 'correct or ameliorate' Moore's medical conditions." <u>Moore I</u>, 324 F. App'x at 774 (citing <u>Rush</u>, 625 F.2d at 1155). This citation does not reference <u>Rush</u>'s Part B, much less the district court's citation to the last paragraph in Part B.

As in our Moore I opinion, we find Rush's holdings on pages 1152 to 1155 and Part A to be the most helpful in resolving issues pertinent to Moore's claim, especially the holdings that "a state may adopt a definition of medical necessity that places reasonable limits on a physician's discretion," 625 F.2d at 1154, and "a state Medicaid agency can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis," id. at 1155. We also find instructive (1) Rush's express approval of a state Medicaid agency presenting its own evidence of medical necessity in Medicaid disputes with individual patients and (2) the notion that a treating physician maintains primary responsibility over a patient's treatment needs but must "operate within such reasonable limitations as the state may impose." Id. at 1156.

4. <u>Pittman ex rel. Pope v. Secretary, Florida Department of Health & Rehabilitative Services</u>

Next came <u>Pittman ex rel. Pope v. Secretary</u>, <u>Florida Department of Health</u> <u>& Rehabilitative Services</u>, which construed the 1989 Amendment and its effect on a state Medicaid agency's EPSDT obligations. The plaintiff in <u>Pittman</u>, a Medicaid-eligible child, sought a preliminary injunction requiring the state of Florida to pay for a liver-bowel transplant. 998 F.2d at 887. The plaintiff's doctors believed this transplant could save his life; otherwise, he was likely to die

of liver failure within a year. <u>Id.</u> at 888.⁵⁷ The Florida Department of Health and Rehabilitative Services denied the plaintiff's request for a transplant at the administrative level, contending that the liver-bowel transplant was experimental and, accordingly, Florida was not obligated to provide Medicaid funding. <u>Id.</u>

Once in the district court, Florida did not defend its denial of Medicaid funding on the ground that the transplant was experimental. <u>Id.</u> Florida instead staked its position on a provision of the Medicaid Act, 42 U.S.C. § 1396b(i)(1),⁵⁸ which it claimed vested states with discretion to deny coverage for organ transplants in the state's Medicaid plan. <u>Id.</u> The plaintiff, meanwhile, argued that

⁵⁷One of the plaintiff's doctors also observed that because of the plaintiff's immediate susceptibility to a variety of infections, his condition could worsen such that transplant surgery might not be recommended or feasible. Pittman, 998 F.2d at 888.

⁵⁸Section 1396b(i) addresses organ transplants and provides:

Payment under the preceding provisions of this section shall not be made—

⁽¹⁾ for organ transplant procedures unless the State plan provides for written standards respecting the coverage of such procedures and unless such standards provide that—

⁽A) similarly situated individuals are treated alike; and

⁽B) any restriction, on the facilities or practitioners which may provide such procedures, is consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan; . . .

^{. . . .}

Nothing in paragraph (1) shall be construed as permitting a State to provide services under its plan under this subchapter that are not reasonable in amount, duration, and scope to achieve their purpose.

⁴² U.S.C. § 1396b(i)(1).

§ 1396d(r)(5) of the Medicaid Act entitled him to coverage for all medically necessary care, regardless of whether a state plan allowed for it. <u>Id.</u> at 889.

This Court agreed with the plaintiff, concluding that Florida lacked discretion to withhold funding for medically necessary organ transplants with respect to Medicaid recipients under the age of 21. <u>Id.</u> at 891-92. In so doing, we acknowledged a circuit split regarding whether § 1396b(i)(1) provides an affirmative grant of discretion to states to deny coverage for organ transplants, or whether § 1396b(i)(1) merely delineates conditions for federal funding of organ transplants. <u>Id.</u> at 890-91.

The <u>Pittman</u> Court agreed with the reasoning of the Fourth Circuit, which previously addressed the issue in <u>Pereira ex rel. Pereira v. Kozlowski</u>, 996 F.2d 723 (4th Cir. 1993). <u>Pittman</u>, 998 F.2d at 891. The <u>Pittman</u> Court found persuasive the Fourth Circuit's conclusions in <u>Pereira</u> that (1) § 1396b(i)(1) merely imposed conditions on federal funding of organ transplants, rather than endowing participating states with discretion to exclude organ transplants from their plans and (2) the legislative history did not suggest otherwise. <u>Id.</u>

The <u>Pittman</u> Court ultimately determined it was unnecessary to decide whether § 1396b(i)(1) grants any such discretion, given the clear language of § 1396d(r)(5). <u>Id.</u> The <u>Pittman</u> Court concluded that, <u>even if</u> § 1396b(i)(1) vested

the states with authority to withhold organ transplant funding, § 1396d(r)(5) subsequently took this discretion away with respect to Medicaid-eligible individuals under the age of 21. <u>Id.</u> at 892. We therefore reversed the district court's denial of a preliminary injunction in plaintiff's favor against Florida. <u>Id.</u>

Ultimately, Pittman does not help answer the question presented here. DCH does not dispute that private duty nursing services are medically necessary for Moore and required under the Medicaid Act—DCH only disputes the amount of services that are medically necessary. Unlike the hours of nursing care involved here, the organ transplant in Pittman was an all-or-nothing transaction. More importantly, Florida did not argue that the plaintiff's liver-bowel transplant was not medically necessary. Rather, Florida placed all its eggs in the § 1396b(i)(1) basket, arguing it had discretion to exclude transplants under its state plan. Once the Pittman Court rejected this argument, therefore, it did not need to address whether the liver-bowel transplant was medically necessary—let alone the respective roles of state Medicaid agencies and treating physicians in making such determinations—thus demonstrating Pittman's limited applicability to this case. See id. at 888 n.3.59

⁵⁹The <u>Pittman</u> Court's footnote is worth quoting in full: In opposing Lexen's assertion that 42 U.S.C. § 1396d(r)(5) requires funding for this transplant, the Secretary argues that § 1396b(i)(1) gives the states discretion to elect

F. Summary of Guiding Principles

Our review of these Medicaid statutes, regulations, manuals, and precedents yields these guiding principles for Moore's appeal:

- (1) Georgia is required to provide private duty nursing services to Moore, who meets the EPSDT eligibility requirements, when such services are medically necessary to correct or ameliorate her illness and condition. See 42 U.S.C. § 1396d(r)(5); Beal, 432 U.S. at 444, 97 S. Ct. at 2371; Murray, 244 F.3d at 809 n.2; Pittman, 998 F.2d at 891-92; Curtis, 625 F.2d at 651 n.11; 42 C.F.R. § 440.230(d).
- (2) A state Medicaid plan must include "reasonable standards . . . for determining eligibility for and the extent of medical assistance"—here, the extent

not to cover organ transplants for children under age twenty-one. We address and reject that argument in the text. Thus, we need not, and we expressly do not, address other possible issues, including, but not limited to: (1) whether the decision to exclude liver-bowel transplants from coverage under the state plan was made pursuant to reasonable standards consistent with the Medicaid Act appropriately imposed by the state pursuant to 42 U.S.C. § 1396a(a)(17), see Beal v. Doe, 432 U.S. 438, 444-45, 97 S. Ct. 2366, 2370-71, 53 L. Ed. 2d 464 (1977); (2) whether this transplant is medically necessary; (3) whether "necessary health care" in § 1396d(r)(5) means reasonable health care so that the total circumstances, including (but not limited to) probability of a successful outcome would be considered even in cases in which a particular treatment offers the only possibility for the patient's survival; (4) what are the circumstances that may be considered if "necessary" in § 1396d(r)(5) means the same thing as reasonable; and (5) whether "discovered by the screening services" as used in § 1396d(r)(5) is a phrase of limitation and, if so, what does it mean in application.

of private duty nursing services for Moore—and such standards must be "consistent with the objectives of" the Medicaid Act, specifically its EPSDT program. See § 1396a(a)(17); see also Beal, 432 U.S. at 444, 97 S. Ct. at 2371; Rush, 625 F.2d at 1155.

- (3) A state may adopt a definition of medical necessity that places limits on a physician's discretion. Rush, 625 F.2d at 1154. A state may also limit required Medicaid services based upon its judgment of degree of medical necessity so long as such limitations do not discriminate on the basis of the kind of medical condition. Curtis, 625 F.2d at 652; 42 C.F.R. § 440.230(c). Furthermore, "a state may establish standards for individual physicians to use in determining what services are appropriate in a particular case" and a treating physician is "required to operate within such reasonable limitations as the state may impose." Rush, 625 F.2d at 1156.
- (4) The treating physician assumes "the primary responsibility of determining what treatment should be made available to his patients." <u>Id.</u> Both the treating physician and the state have roles to play, however, and "[a] private physician's word on medical necessity is not dispositive." <u>Moore I</u>, 324 F. App'x at 774.

- (5) A state may establish the amount, duration, and scope of private duty nursing services provided under the required EPSDT benefit. CMS Manual § 5122(F) (construing 42 C.F.R. § 440.230). The state is not required to provide medically unnecessary, albeit desirable, EPSDT services. See Beal, 432 U.S. at 444-45, 97 S. Ct. at 2371; CMS Manual § 5010(B). However, a state's provision of a required EPSDT benefit, such as private duty nursing services, "must be sufficient in amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b); see also CMS Manual § 5122(F).
- (6) A state "may place appropriate limits on a service based on such criteria as medical necessity." 42 C.F.R. § 440.230(d). In so doing, a state "can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis," and may present its own evidence of medical necessity in disputes between the state and Medicaid patients. Rush, 625 F.2d at 1152, 1155.

We now apply these principles to Moore's case.

G. Analysis of Moore's Appeal

Initially, we do not read Moore's brief on appeal to challenge the GAPP plan as beyond a state's discretionary authority in administering and implementing its obligations under the Medicaid Act, or as an unreasonable policy <u>per se</u> or on

its face.⁶⁰ For example, Moore does not argue that DCH's GAPP plan for in-home private duty nursing services discriminates on the basis of her type of medical diagnosis or condition in violation of 42 C.F.R. § 440.230(c).⁶¹ Indeed, each GAPP policy applies to all GAPP members no matter their specific medical diagnosis or condition.

Moore also does not contend that GAPP's explicit durational limitation—precluding in-home private duty nursing services when a GAPP member requires more than 16 hours of daily nursing care for periods in excess of

GAPP, on its face, violates the Medicaid Act. See, e.g., Am. Compl. ¶ 1 (citing DCH's "application of policies that conflict with federal Medicaid law"); id. ¶ 36 (alleging that DCH "impose[s] additional eligibility criteria for receipt of [private duty nursing], in excess of federal eligibility for EPSDT services"); id. ¶ 43 ("By expressly limiting the purpose and length of time for which private duty nursing services will be provided to the teaching of the beneficiary's parent or caregiver to provide care in the absence of a nurse, Georgia Medicaid fails to provide private duty nursing services to EPSDT beneficiaries in accordance with the Medicaid Act."); id. ¶ 45 ("Georgia Medicaid restricts eligibility for the EPSDT private duty nursing benefit on the basis of the cost of that care in violation of the Medicaid Act."); id. ¶ 52 ("GAPP's requirement of a secondary caregiver in order for an EPSDT beneficiary to be eligible to receive any EPSDT private duty nursing benefit limits the availability of this benefit in violation of Medicaid law.").

However, Moore's brief on appeal confines her arguments to challenging DCH's application of GAPP policies to Moore individually in its reduction of her private duty nursing hours. Given our clarification of the guiding principles and the need for remand, see infra p. 79-83, we leave it to the district court to shape the proceedings going forward.

⁶¹For the purpose of clarity, we note that § 440.230(c) states in full, "The Medicaid agency may not arbitrarily deny or reduce the amount, duration, or scope of a required service under §§ 440.210 and 440.220 to an otherwise eligible recipient solely because of the diagnosis, type of illness, or condition." 42 C.F.R. § 440.230(c) (emphasis added). Our reading of §§ 440.210 and 440.220 indicates that "private duty nursing services," as defined by 42 C.F.R. § 440.80, is not one of the required services listed in those sections. In any case, as Moore has made no showing of discrimination, this issue is immaterial.

one week, GAPP Manual § 905(d)—is unreasonable. Dr. Rosenfeld testified that this GAPP policy reflects a medical understanding that a medically fragile child requiring such levels of nursing care would be considered unstable and better suited in an institutional setting. Notably, the federal regulation defining the Medicaid Act's term "private duty nursing services" gives a participating state the option to provide nursing care in the recipient's home or in a "hospital" or "skilled nursing facility." 42 C.F.R. § 440.80(c). In fact, to be eligible for in-home nursing services through GAPP, a child must "meet the same level of care for admission to a hospital or nursing facility." GAPP Manual § 601. The GAPP policy that the "cost analysis should be made to determine that the cost of caring for the member in the home and community is below the cost of providing the same care in an institution," id. § 701, similarly reflects Georgia's discretionary authority to choose the setting in which the required nursing care will be provided.

Moore also does not contend that Georgia impermissibly requires the presence of caregivers to assist and be trained if a medically fragile child desires private duty nursing services in a home setting.

Rather, we read Moore's claim on appeal to be that DCH's <u>application</u> of the GAPP plan to her specific medical condition—specifically, its reduction of her nursing hours from 94 to 84 hours—violates the Medicaid Act because 94 nursing

hours at home are in fact medically necessary, given Moore's condition and illnesses. The dispute is purely over what amount of private duty nursing hours are now medically necessary for Moore and who makes that determination.

As to the issue of 94 or 84 hours, we agree with DCH that the district court, as a matter of law, erred in restricting Georgia's role to reviewing Moore's treating physician's determination of nursing hours only for "fraud . . . [or] abuse of the Medicaid system" and for "whether the service is within the reasonable standards of medical care."62 Moore II, 674 F. Supp. 2d at 1370-71 (internal quotation marks omitted). As illustrated above, both the treating physician and the state have roles to play in determining medical necessity. It is accurate that Moore's treating physician is a key figure and initially determines what amount of nursing services are medically necessary. Indeed, the GAPP plan pays heed to the salient principle that the treating physician should assume "the primary responsibility of determining what treatment should be made available to his patients." Rush, 625 F.2d at 1156. The GAPP Manual specifies that "[t]he primary care physician develops the child's initial plan of care." GAPP Manual § 601.2(C).

⁶²DCH points out that, on the front end, it must make a determination that services are medically necessary before providing payment, which is different from its ability to review previously paid services for fraud on the back end. The GMCF Medical Review Team performs the evaluation of medical necessity, while DCH's Office of Inspector General Program Integrity Unit reviews for fraud and abuse.

Nonetheless, a state may still review the medical necessity of the amount of nursing care prescribed by the treating physician and make its own determination of medical necessity. 42 C.F.R. § 440.230(d); CMS Manual § 5122(F); Rush, 625 F.2d at 1155. Georgia did precisely that here. The GMCF Medical Review Team (here, Dr. Rosenfeld and a team of nurses) evaluated Dr. Braucher's orders and the training needs of caregivers to arrive at its nursing hours decisions. GAPP Manual § 702.2(D). This is consistent with federal regulations, the federal CMS Manual, and our precedent. See 42 C.F.R. § 440.230(d) (providing that the state Medicaid agency "may place appropriate limits on a service based on such criteria as medical necessity"); CMS Manual § 5122(F) (instructing state Medicaid agencies that "[y]ou make the determination as to whether the service is necessary"); Rush, 625 F.2d at 1155 (holding that "a state Medicaid agency can review the medical necessity of treatment prescribed by a doctor on a case-by-case basis").

After that review, the state may limit required private duty nursing services based upon a medical expert's opinion of medical necessity so long as (1) the state's limitations do not discriminate on the basis of "diagnosis, type of illness, or condition" and (2) the services provided are sufficient in amount and duration to reasonably achieve the purpose of private duty nursing services. 42 C.F.R.

§ 440.230(b), (c). As noted earlier, there is no claim on appeal that Georgia is discriminating on the basis of "diagnosis, type of illness, or condition."

So, the pivotal issue is only whether 84 hours are sufficient in amount to reasonably achieve the purposes of private duty nursing services to correct or ameliorate Moore's condition. In this regard, the inquiry hinges on whether DCH—in exercising its ability to "place appropriate limits on a service based on such criteria as medical necessity," <u>id.</u> § 440.230(d)—fulfilled or breached its concomitant duty to ensure that Moore's private duty nursing care is "sufficient in amount, duration, and scope to reasonably achieve its purpose," <u>id.</u> § 440.230(b).

In such disputes between the state and Medicaid patients, our precedent teaches that the state may present its own evidence of medical necessity, which may create issues of material fact precluding summary judgment. That is also what happened here. Dr. Rosenfeld, DCH's medical expert, opined that, given the nature of Moore's current medical problems, her stable medical condition, and her lack of hospitalizations, only 84 hours of private duty nursing services at home are now medically necessary for Moore.⁶³ Consonant with Georgia's ability "to define medical necessity in a way tailored to the requirements of its own Medicaid

⁶³Notably, Moore has not rebutted Dr. Rosenfeld's characterization of Moore as "chronically stable."

program," Rush, 625 F.2d at 1155, DCH may permissibly conclude that persons whose conditions are worsening or who require frequent hospitalizations have a higher degree of medical necessity than those who are chronically stable. Cf. Curtis, 625 F.2d at 652 (concluding that Florida's "provision of emergency services beyond the three-visit-per-month limit is patently based on a medical necessity standard"). Dr. Rosenfeld also explained why his assessments of Moore's medical needs differed from those of Moore's treating physician, Dr. Braucher. See Section I.D, supra.

Accordingly, the district court erred in granting summary judgment for Moore and too narrowly limiting DCH's role. The record presents material issues of fact over what amount of private duty nursing hours are medically necessary for Moore, which must be resolved by a factfinder at trial. And at trial, as in civil cases generally, the plaintiff shall bear the burden of persuasion to establish by a preponderance of the evidence that 94 private duty nursing hours, not 84 hours, are medically necessary. In other words, the plaintiff will have to show that the limits the state imposed on her physician's discretion in reducing her nursing hours from 94 to 84 hours a week are not reasonable—that these limits are not sufficient in amount, duration, and scope to reasonably achieve the treatment's

purpose. Moore and the state may present their own experts, and the factfinder at trial will decide.

H. Final Observations

Lastly, we pause to address some overarching contentions raised by the parties, who argue for the primacy of their respective positions in adjudicating disputes over medical necessity.

During the course of these proceedings, DCH argued that the prior panel's statement in Moore I that "[a] private physician's word on medical necessity is not dispositive," 324 F. App'x at 774, could be used to infer that the state is the final arbiter of medical necessity. In particular, DCH's amicus argues that this "final arbiter" role of the state is necessary, given escalating Medicaid costs and the need to prudently manage the public fisc. See Brief for WellCare of Georgia, Inc. as Amicus Curiae in Support of Appellant & Reversal of the District Court Order at 21-24, Moore v. Reese, No. 10-10148 (11th Cir. Apr. 6, 2010).

While Congress could have conferred the "final arbiter" role to the state, it did not. However pressing budgetary burdens may be, we have previously commented that cost considerations alone do not grant participating states a license to shirk their statutory duties under the Medicaid Act. See Tallahassee Mem'l Reg'l Med. Ctr. v. Cook, 109 F.3d 693, 704 (11th Cir. 1997) (per curiam).

When a state Medicaid agency has exceeded the bounds of its authority by adopting an unreasonable definition of medical necessity or by failing to ensure that a required service is "sufficient in amount, duration, and scope to reasonably achieve its purpose," aggrieved Medicaid recipients have recourse in the courts.

See 42 C.F.R. § 440.230(c), (d).

For her part, Moore contends that the state, and the courts as well, should defer to her treating physician's judgment of how many hours are medically necessary for Moore, so long as the treating physician's nursing hours recommendation is within the reasonable standards of medical care and is not tainted with fraud or abuse of the Medicaid system. Congress could have said that too, but it did not. Instead, the Supreme Court has instructed that the Medicaid Act "confers broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives' of the Act." Beal, 432 U.S. at 444, 97 S. Ct. at 2371 (construing 42 U.S.C. § 1396a(a)(17)). While the 1989 Amendment took away participating states' discretion to provide certain EPSDT services, it did not strip those states of their regulatory authority to "place appropriate limits" on such required services "based on such criteria as medical necessity." 42 C.F.R. § 440.230(d). A state is obligated to provide EPSDT-eligible children with private duty nursing services, but only to the extent that they are medically necessary. It is unclear how a state Medicaid agency could effectively discharge its § 440.230(d) authority if the treating physician were the only actor effectively placing a "medical necessity" limitation on a required service.

Although the Medicaid statutes do not address how to resolve conflicting opinions by the state's medical expert and the treating physician, the relevant regulations, manuals, and precedents provide that guidance, which we follow here. By limiting a state Medicaid agency's role to merely auditing the treating physician for fraud, abuse, or unreasonable medical care, the district court's standard of review negates a state's ability to adopt reasonable standards, impermissibly circumscribes the state's role in a manner not authorized by the Medicaid Act, and is inconsistent with the <u>Curtis</u> and <u>Rush</u> holdings and the federal regulations implementing the Act.⁶⁴

⁶⁴Given the clarity of these federal regulations, the CMS Manual, and Curtis, Moore bases her argument mainly on the last paragraph of Rush's Part B. Whatever Part B of Rush might mean, and regardless of whether it purports to be a holding or merely dicta, it decidedly does not—and cannot—support the proposition that Moore cites it for. This is because the "fraud or abuse" and "without any basis in fact" articulation of a state's reviewing authority was essentially the standard adopted by the district court in Rush, which our predecessor Court considered but refused to adopt on appeal. See Rush, 625 F.2d at 1154 ("We disagree with the district court, and hold instead that a state may adopt a definition of medical necessity that places reasonable limits on a physician's discretion."). Thus, it is clear that the Rush Court unequivocally rejected the district court's—and now Moore's—contention that a treating physician's determination of medical necessity was unreviewable by the state, absent fraud, abuse, or unreasonable medical care.

In sum, the Medicaid Act does not give the treating physician unilateral discretion to define medical necessity so long as the physician does not violate the law or breach ethical duties any more than it gives such discretion to the state so long as the state does not refuse to provide a required service outright. It is a false dichotomy to say that one or the other, the state's medical expert or the treating physician, must have complete control, or must be deferred to, when assessing whether a service or treatment is medically necessary under the Medicaid Act.

Finally, both parties cite some cases from other circuits, but those decisions concerned all-or-nothing prohibitions of a type of Medicaid-required service, not a state agency placing a quantitative or durational limitation on a Medicaid-required service. See, e.g., Hood, 391 F.3d at 597 (Louisiana's denial of any funding for medically necessary incontinence supplies to EPSDT-eligible children violated Medicaid Act); Collins, 349 F.3d at 376 (Indiana's denial of any funding for placement in psychiatric residential treatment facilities to children when deemed medically necessary by EPSDT screening violated Medicaid Act); Pediatric Speciality Care, 293 F.3d at 480 (Arkansas's denial of any funding for early intervention day treatment to Medicaid-eligible individuals whose physician prescribes such services violated Medicaid Act); Pereira, 996 F.2d at 727 (Virginia's denial of any funding for medically necessary organ transplants to

EPSDT-eligible children violated Medicaid Act); Weaver v. Reagen, 886 F.2d 194, 200 (8th Cir. 1989) (Missouri's denial of any funding for off-label AZT treatment to Medicaid recipients infected with AIDS violated Medicaid Act); Pinneke, 623 F.2d at 549 (Iowa's denial of any funding for sex reassignment surgery deemed medically necessary by treating physician contravened Medicaid Act objectives and discriminated on the basis of "diagnosis, type of illness, or condition"); Preterm, 591 F.2d at 126 (Massachusetts's denial of any funding for abortions, unless necessary to save mother's life or where mother was victim of rape or incest, "crossed the line between permissible discrimination based on degree of need and entered into forbidden discrimination based on medical condition").

⁶⁵Interestingly, the Eighth Circuit reversed course 21 years later in Smith v. Rasmussen, 249 F.3d 755 (8th Cir. 2001), upholding a state ban on Medicaid funding for sex reassignment surgery. The Rasmussen court noted that, in Pinneke, Iowa's exclusionary policy of precluding funding for all sex reassignment surgery was arbitrary because it was adopted without consulting medical professionals and in disregard of the "current accumulated knowledge of the medical community." Id. at 760. However, upon revisiting the issue years later, Iowa had followed a rulemaking process that considered the knowledge of the medical community. Id. The Eighth Circuit concluded that "[i]n the light of the evidence before the Department questioning the efficacy of and the necessity for sex reassignment surgery, given other treatment options, we cannot conclude as a substantive matter that the Department's regulation is unreasonable, arbitrary, or inconsistent with the [Medicaid] Act." Id. at 761. Rasmussen underscores that whether a state has appropriately exercised its authority to "place appropriate limits on a service based on such criteria as medical necessity," 42 C.F.R. § 440.230(d), is a fact-intensive inquiry that may even change over time.

Here, by contrast, DCH has instituted no across-the-board prohibition on private duty nursing services, nor could it under the EPSDT requirement in § 1396d(r)(5). Rather, for years DCH has continuously provided private duty nursing services to Moore. Indeed, there is no dispute between Moore's treating physician and the state over whether private duty nursing services remain medically necessary for Moore; the only dispute is over what <u>quantity</u> of nursing hours is medically necessary. None of these cases addresses this type of question.⁶⁶

Second, under Florida state law, the state agency has the burden of proof in an administrative hearing when Medicaid services are reduced. See Fla. Admin. Code r. 65-2.060 ("The burden is upon the Department when the Department takes action which would reduce or terminate the benefits or payments being received by the recipient."). In this case, Moore chose to forgo her right to an administrative hearing and has cited no similar burden of proof requirement.

Lastly, the EPSDT-required service at issue in <u>C.F.</u>—"personal care services"—contained a statutory qualifier that does not similarly apply to "private duty nursing services." <u>Compare</u> 42 U.S.C. § 1396d(a)(24) (requiring states to furnish the "personal care services" that are "authorized for the individual by a physician in accordance with a plan of treatment"), <u>with id.</u>

⁶⁶ Moore's <u>amicus</u> does cite one case involving a durational or quantitative limitation, <u>C.F. v. Department of Children & Families</u>, 934 So. 2d 1 (Fla. Dist. Ct. App. 2005), where a state court held that the evidence was insufficient to support Florida's reduction of "personal care services" from six to four hours per day to a Medicaid-eligible child. <u>Id.</u> at 7. "Personal care services" are an EPSDT-required service. <u>See</u> 42 U.S.C. § 1396d(a)(24), (r)(5). However, this case is inapposite here.

First, the state's "expert" who recommended the hours reduction was not a licensed health care provider. <u>C.F.</u>, 934 So. 2d at 3. Nor was the state's expert even aware that the plaintiff's doctor had determined that six hours per day were medically necessary. <u>Id.</u> at 4. In fact, the state agency presented no testimony or written evidence from a physician to justify its hours reduction, and thus "[t]here was insufficient competent evidence to support the hearing officer's decision." <u>Id.</u> at 6. By contrast, the state in Moore's case introduced significant medical testimony by Dr. Rosenfeld, who had reviewed Dr. Braucher's recommendation, along with Moore's medical history and records.

Certainly, a participating state's refusal to provide any coverage for a Medicaid-required service is manifestly different from a state exercising its authority to "place appropriate limits on a service based on such criteria as medical necessity," 42 C.F.R. § 440.230(d), or to "include reasonable standards . . . for determining . . . the extent of medical assistance" so long as such standards are consistent with the objectives of the Medicaid Act, 42 U.S.C. § 1396a(a)(17). This does not mean that a state executes its Medicaid Act duties merely by providing a required service, of course. Among other obligations, a state still must ensure that each required service is "sufficient in amount, duration, and scope to reasonably achieve its purpose." 42 C.F.R. § 440.230(b).

In any event, we glean from our own precedents in <u>Curtis</u> and <u>Rush</u>, along with the federal regulations and federal CMS Manual, the answer here that we must adopt.

V. CONCLUSION

For the foregoing reasons, we reverse the district court's entry of summary judgment in favor of Moore and remand for further proceedings consistent with this opinion. Given our clarification of the dual roles of the state and treating

^{§ 1396}d(a)(8).

physician, the passage of time with two appeals, and Moore's ongoing medical conditions, the district court should afford the parties a reasonable opportunity, if requested, to develop the record further and then present additional evidence at trial.

REVERSED AND REMANDED.