STATE OF FLORIDA DIVISION OF ADMINISTRATIVE HEARINGS

WILLARD BELL and JUSTIN POWELL, by and through his next friend and)	
parent, BARBARA POWELL,)	
Petitioners,)	
vs.) Case	No. 99-2060RX
AGENCY FOR HEALTH CARE ADMINISTRATION,)	
Respondent.)))	

FINAL ORDER

On June 7, 1999, a formal administrative hearing was held in this case in Tallahassee, Florida, before J. Lawrence Johnston, Administrative Law Judge (ALJ), Division of Administrative Hearings (DOAH).

APPEARANCES

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STATEMENT OF THE ISSUE

The issue in this case is whether Florida Administrative Code Rule 59G-4.070--including pages 2-2 and 3-3 and Appendices B and C of the Florida Medicaid Provider Handbook, Durable Medical Equipment/Medical Supply Services, which is incorporated in the rule by reference--is an invalid exercise of delegated legislative authority.

PRELIMINARY STATEMENT

On May 5, 1999, Willard Bell and Justin Powell, by and through his next friend and parent, Barbara Powell, filed a Petition to Determine Invalidity of Rule 59G-4.070 and Portions of the Florida Medicaid Provider Handbook, Durable Medical Equipment (DME)/Medical Supplies. After assignment of the ALJ, final hearing was scheduled for June 7, 1999. An Order of Pre-Hearing Instructions also was entered requiring the parties to file a prehearing stipulation.

Several subsequent prehearing motions were considered and rulings made on the record of a hearing held on June 1, 1999. Initially, the Agency for Health Care Administration (AHCA) stipulated to the filing of the Petitioners' Amended Petition to Determine Invalidity of Rule 59G-4.070 and Portions of the Florida Medicaid Provider Handbook, Durable Medical Equipment

(DME)/Medical Supplies; the Petitioners agreed that AHCA's Motion to Dismiss or for Summary Final Order should be deemed to address the amended petition. After oral argument (in addition to the written arguments), AHCA's Motion to Dismiss or for Summary Final Order and the Petitioners' Motion for Summary Final Order Declaring Rule Invalid were denied. AHCA's Motion to Exclude Evidence at Final Hearing also was denied. AHCA stipulated to the Petitioner's [sic] Motion to Take [Allen] Deposition by Telephone, which was granted. The Petitioners' Motion for Leave to Take Telephone Testimony or Alternatively for a Change in Venue for the Final Hearing was granted to the extent that the Petitioners' testimony would be taken by videoconference, by video deposition, or by telephone. (Ultimately, arrangements were made for their testimony, as well as the testimony of Rhonda Allen, DS Waiver Support Coordinator, to be taken by videoconference.) The Petitioners also made several requests to compel discovery, which were denied. Finally, the Petitioners requested that AHCA be ordered to negotiate settlement and the required prehearing stipulation in good faith; during the hearing, the Petitioners withdrew the request regarding settlement, and the parties were ordered to try again to reach the required prehearing stipulation. Nevertheless, the parties were unable to reach a prehearing stipulation; instead, they each filed a unilateral proposed prehearing statement.

On June 3, 1999, the Petitioners filed a Motion for Administrative Notice. No ruling on the motion was made prehearing; ultimately, the subjects of the motion came into evidence as exhibits during the course of final hearing, and the motion became moot.

At final hearing, the parties made the rule in issue Joint Exhibit 1. The Petitioners called four witnesses and had Bell Exhibits 1 through 5 and Petitioners' Exhibits 1 through 5 admitted in evidence. (AHCA initially objected to Petitioners' Exhibits 2 and 5 but withdrew the objections posthearing.) AHCA also objected to Petitioners' Exhibit 6. Ruling was reserved, but the objection is now overruled, and Petitioners' Exhibit 6 is admitted in evidence. AHCA called five witnesses and had AHCA Exhibits 1 through 4 admitted in evidence.

At the close of evidence, AHCA ordered a transcript of the final hearing, and the parties requested and were given 20 days from the filing of the transcript in which to file proposed final orders. The transcript was filed on June 21, 1999, making proposed final orders due on July 11, 1999. The proposed final orders filed by the parties have been considered.

FINDINGS OF FACT

I. AHCA'S RULE ON MEDICAID COVERAGE FOR DME/MEDICAL SUPPLIES AND ITS IMPLEMENTATION

1. Florida Administrative Code Rule 59G-4.070 "applies to all durable medical equipment and supply providers enrolled in the Medicaid program." It requires the providers to "comply with

the Florida Medicaid Durable Medical Equipment and Supply Services Coverage and Limitations Handbook, April 1998, incorporated by reference, and the Florida Medicaid Provider Reimbursement Handbook, HCFA 1500 and EPSDT 221, incorporated by reference in 59G-5.020." (Joint Exhibit 1)

- 2. The DME Handbook "explains covered services, their limits and who is eligible to receive them." The Billing Handbook "describes how to complete and file claims for reimbursement by Medicaid." (DME Handbook, p. i).
- 3. DME is "medically necessary equipment that can withstand repeated use, serves a medical purpose, and is appropriate for use in the recipient's home"; medical supplies are "medically necessary medical or surgical items that are consumable, expendable, disposable or non-durable and appropriate for use in the recipient's home." (DME Handbook, pp. 1-2).
- 4. The DME Handbook specifies that "[m]any DME services are available only to recipients under 21 years of age. To determine if a service is available to all recipients or just a specific range of recipients see the DME Fee Schedule in Chapter 3 of this handbook, Appendix B: For All Medicaid Recipients and Appendix C: For Recipients Under Age 21." (DME Handbook, p. 2-2).
- 5. The DME fee schedule is a table of columns listing procedure codes, a description of the service or procedure associated with the procedure code, maximum reimbursement amounts

and other information pertinent to each code. (DME Handbook, pp. 3-3 to 3-7).

- 6. The DME Handbook states that "[t]he DME/medical supplies fee schedule is divided into 2 sections, Appendix B and C.

 Appendix B is a listing of covered DME/medical supplies for all Medicaid recipients, regardless of age. Appendix C is a listing of covered DME/medical supplies for Medicaid recipients under 21 years of age." (DME Handbook, p. 3-3).
- 7. The DME fee schedule includes a column identified as "BR" (an abbreviation for "by report") and a column identified as "PA" (an abbreviation for "prior authorization"). (DME Handbook, p. 3-5).
- 8. The DME Handbook states that the "BR" designation "identifies a 'non-classified' procedure code that requires a medical review to approve and price a procedure correctly." (DME Handbook, p. 3-5). "Non-classified" procedure codes "allow the provider to request reimbursement from Medicaid when a reimbursable item does not have an established fee identified." (DME Handbook, p. 3-5).
- 9. The DME Handbook states that the "PA" designation

 "identifies the procedure codes that require prior authorization

 before the service is performed." (DME Handbook, p. 3-5). The

 DME Handbook specifies which DME/medical supply procedure codes

 listed in Appendices B and C of the DME Fee Schedule require

 prior authorization. (DME Handbook, p. 2-5, Appendices B and C).

- 10. The Billing Handbook includes a Prior Authorization Request Form which providers must submit to the Medicaid office in order to obtain prior authorization for DME and medical supplies. The prior authorization form requires submission of a procedure code. (Billing Handbook, pp. 7-8 to 7-13; DME Handbook, p. 3-5).
- 11. Neither the DME Handbook or the Billing Handbook includes any prior authorization procedure that providers can follow to obtain Medicaid coverage for DME or medical supplies that do not have a procedure code listed in Appendices B or C of the DME Handbook.
- 12. In Appendix C of the DME Handbook, for Medicaid recipients under age 21, there is a miscellaneous code, "E1399", for durable medical equipment which requires prior authorization. No comparable code exists in Appendix B of the DME Handbook for Medicaid recipients age 21 and older. (DME Handbook, pp. 2-5 and C-14).
- 13. A Medicaid recipient who needs durable medical equipment or medical supplies will present the request in the form of a prescription or certificate of medical necessity from a physician to a DME provider. The provider then uses the DME Handbook to determine if an item is covered by the Medicaid program. If an adult presents a doctor's prescription for an item of DME which is not listed in Appendix B of the DME Handbook, the provider will most likely decline to provide the

services unless other arrangements are made to pay for the services. There is nothing in the DME Handbook which informs providers of any means by which adult Medicaid recipients can request coverage of items not listed in Appendix B. DME providers have not received any memo or directive from AHCA advising how DME providers could request coverage of items for adults not listed in Appendix B.

II. <u>ALTERNATIVES FOR RECIPIENTS NEEDING</u> DME/MEDICAL SUPPLIES NOT LISTED IN THE DME HANDBOOK

14. There are alternatives for Medicaid recipients to obtain DME/medical supplies which are not listed in the DME Handbook. They include the Medicaid Waiver Program, coverage through other Medicaid programs, an "exception authorization" process, and the fair hearing process.

A. The Medicaid Waiver Program

- 15. Section 1915(c) of the Social Security Act authorizes states to provide Medicaid home and community-based waiver programs. 42 U.S.C. Section 1396n(c). Under Medicaid waiver programs, states can provide services in addition to those authorized under their regular Medicaid program through the Medicaid state plan. Home and community-based waiver programs are targeted towards populations at risk of institutionalization. See 42 U.S.C. Section 1396n(c)(1).
- 16. The federal Health Care Financing Administration (HCFA) has authorized Florida to administer a home and community-based waiver program for persons with developmental disabilities ("DS

waiver program"). HCFA places a cap on the number of individuals who may participate in the waiver.

- 17. The DS waiver program offers specialized medical equipment and supplies. However, before any service can be funded under the DS waiver program, it must be approved by the Developmental Services district office. Whether the services are approved or not is based, in part, on available funding. Both state and federal funding are capped under the DS waiver program.
- 18. The DS Waiver program Services Directory states on pp. 3-4 that "the waiver endorses the supports already provided by family, friends and neighbors, and discourages the replacement of such natural and free supports with government-funded services[,]" and "[w]hen a service must be purchased, those available under the Medicaid State Plan must be accessed before purchasing services through the waiver."

B. Coverage Through Other Medicaid Programs

19. AHCA administers about 35 different programs within the regular Medicaid program. Some medical equipment is covered by programs other than the DME/Medical Supplies program. Hearing aides are covered by the hearing program; saline used with medical equipment is covered by the pharmacy program; and cochlear implants are covered under the physician services program. However, there was no evidence that any other Medicaid programs covered any of the medical equipment or supplies needed by Bell or Powell.

C. Exception Authorization/Prior Authorization Process

The "exception authorization" process is the same as the prior authorization process described in the DME Handbook and Billing Handbook. See Findings 7-12, supra. As found, AHCA's form for requesting prior authorization requires submission of a procedure code; there is no general DME miscellaneous code listed in the rule for Medicaid recipients over age 21; and there are no instructions included in the DME or Billing Handbook which authorize providers to bill for DME on behalf of adult recipients under code E1399. (DME Handbook, Appendix B). Nonetheless, it is technically possible for AHCA administrators to override the Agency's computer (by "forcing the age edit") to provide for payment of items for adults which are not listed in Appendix B of the DME Handbook. Although the Florida Legislature has declined AHCA's requests to appropriate funds for DME for adult Medicaid recipients for the past four legislative sessions, AHCA administrators have overridden the computer to get coverage of durable medical equipment and supplies that are not listed in the DME Handbook for three Medicaid recipients. However, this procedure is not described in Rule 59G-4.070.

D. Fair Hearing Process

21. Another alternative for Medicaid recipients who need coverage of DME/medical supplies not included in the DME Handbook is through the fair hearing process. Recipients are informed about their fair hearing rights when they are enrolled in the

Medicaid program and also when a prior authorization request is denied.

- 22. There are no form AHCA notices included in the DME Handbook or Billing Handbook advising recipients about their fair hearing rights when prior authorization for DME is denied. placed in evidence a form used by AHCA to advise recipients of their fair hearing rights when prior authorization for DME/medical supplies is denied. The form notice is out-of-date. It states that it is from the Department of Health and Rehabilitative Services (HRS) and refers to Consultec as the fiscal agent. It is the fiscal agent for AHCA, not HRS, which generates this notice; and Unisys, not Consultec, has been AHCA's fiscal agent for about the past five years. The form notice states that if individuals want a fair hearing they should write to the Office of Public Assistance, Appeal Hearing, in Jacksonville, Florida. At least one other Appeal Hearing office is located in Tallahassee.
- 23. If no prior authorization request is made because no procedure code is listed in the DME Handbook, there would be no notice of denial of a prior authorization request.

III. HCFA LETTER

24. HCFA sent a letter to State Medicaid Directors on September 4, 1998, setting out federal Medicaid requirements regarding DME coverage.

25. The HCFA letter of interpretive guidance reminded state Medicaid directors that the mandatory home health services benefit under Medicaid includes medical supplies, equipment, and appliances suitable for use in the home and summarized the applicable federal law. It also stated:

An [i.e., DME] ME policy that provides no reasonable and meaningful procedure for requesting items that do not appear on a State's pre-approved list, is inconsistent with the federal law discussed above. In evaluating a request for an item of [D]ME, a State may not use a "Medicaid population as a whole" test, which requires a beneficiary to demonstrate that, absent coverage of the item requested, the needs of "most" Medicaid recipients will not be met. This test, in the [D]ME context, establishes a standard that virtually no individual item of [D]ME can meet. Requiring a beneficiary to meet this test as a criterion for determining whether an item is covered, therefore, fails to provide a meaningful opportunity for seeking modifications of or exceptions to a State's pre-approved list. Finally, the process for seeking modifications or exceptions must be made available to all beneficiaries and may not be limited to subclasses of the population (e.g., beneficiaries under the age of 21).

In light of this interpretation of the applicable statute and regulations, a State will be in compliance with federal Medicaid requirements only if, with respect to an individual applicant's request for an item of [D]ME, the following conditions are met:

The process is timely and employs reasonable and specific criteria by which an individual item of DME will be judged for coverage under the State's home health services benefit. These criteria must be sufficiently specific to permit a determination of whether an item of

[D]ME that does not appear on a State's pre-approved list has been arbitrarily excluded from coverage based solely on a diagnosis, type of illness, or condition.

The State's process and criteria, as well as the State's list of preapproved items are made available to beneficiaries and the public.

Beneficiaries are informed of their right, under 42 C.F.R. part 431 Subpart E, to a fair hearing to determine whether an adverse decision is contrary to the law cited above.

IV. PETITIONER WILLARD BELL

- 26. Willard Bell is a Medicaid recipient who is over age 21. Since 1992, he has been in a Medicaid health maintenance organization (HMO).
- 27. Bell is an insulin-dependent diabetic and has undergone numerous operations and hospitalizations as a result of his diabetes.
- 28. In 1996, Mr. Bell's doctor prescribed an insulin pump and supplies. AHCA district personnel did not know how to obtain coverage for Mr. Bell's insulin pump, since it is not covered by the regular Medicaid program for adults. They needed technical guidance on how to do so.
- 29. In February 1999, after over two years of requests and grievance proceedings, AHCA provided Bell an insulin pump under a settlement agreement with AHCA attorney Gordon Scott. In order to make payment for this insulin pump, AHCA used code E1399--the

miscellaneous durable medical equipment code that is designated only for recipients under 21--and "forced the age edit" on the computer.

- 30. Rule 59G-4.070 also does not provide Medicaid coverage for supplies necessary for the operation of an insulin pump (code E0781 applies to Medicaid recipients under 21 years of age).

 Bell's HMO now pays for the supplies for the insulin pump; but due to numerous problems with his HMO, Bell wants to switch from his HMO to the regular Medicaid program.
- 31. Bell did not want to switch until he was assured that he will be able to get his insulin pump supplies through Medicaid. Shortly after obtaining the insulin pump through the Gordon Scott settlement agreement, Bell and his attorney, Robert Bencivenga, requested Medicaid coverage for supplies necessary for the operation of his insulin pump. Bencivenga made several calls to Stephanie Perry, an AHCA employee at the AHCA Jacksonville office; he also faxed Perry a letter on March 15, 1999, requesting confirmation that the Agency would pay for Bell's pump supplies and indicating some urgency to this request. Bencivenga also left several messages with Gordon Scott.

 Bencivenga did not receive any response to his fax and never got to speak with Scott.
- 32. After receiving no response from AHCA, Bencivenga contacted Miriam Harmatz of Florida Legal Services to see what could be done next. Harmatz then wrote to Scott stating that

Bell wanted to switch from his HMO to the regular Medicaid program but that he first needed assurances from AHCA that the supplies necessary to continue utilization of the pump would be available from Medicaid. Moses Williams, another attorney for AHCA, wrote Harmatz a letter dated April 7, 1999, suggesting that Bell be patient with his HMO; the letter did not state whether or not AHCA would pay for the pump supplies should Bell leave his HMO.

V. PETITIONER JUSTIN POWELL AND HIS MOTHER BARBARA POWELL

- 33. Justin Powell is a 21 year-old Medicaid recipient.

 Justin has multiple severe disabilities, including mental retardation and cerebral palsy. He breathes through a tracheotomy and is tube-fed by means of a feeding pump. Justin's doctors have prescribed a number of items of specialized medical equipment and supplies for him, including: a tracheotomy mask or collar; inner cannula; enteral feeding supply kit, both pump fed and gravity fed; compressor; and nebulizer. Justin will need this equipment and supplies for the rest of his life.
- 34. Justin Powell has lived with his parents, Barbara and Phillip Powell, along with his brother, sister-in-law, and their children, for his entire life. Justin's mother is his primary caretaker. Justin is dependent on her for all of his activities of daily living, as well as for administering various health care treatments, including breathing treatments.

- 35. Until Justin turned 21, Medicaid provided him coverage for the following equipment and supplies he needs in order to breathe and eat: a tracheotomy mask or collar (code A4621); tracheostomy inner cannula (code A4623); enteral feeding supply kit, either pump fed or gravity fed (code B 4035, B 4036); nebulizer (code E 0575); and a compressor (code E 0570) that powers the nebulizer. (DME Handbook, Appendix B). In order to obtain necessary equipment and supplies, Mrs. Powell simply had to contact Lincare, a DME provider. If any of the equipment Justin needed broke down, Medicaid provided for immediate replacement.
- 36. When Justin turned 21, Lincare declined to provide further coverage for the DME and supplies because the Rule does not provide Medicaid coverage for Medicaid recipients 21 or older. In response to the information from Lincare, Barbara Powell made numerous calls to AHCA officials to request Medicaid coverage for the items. Eventually she was directed to the DS Waiver Program, which assigned Justin to DS Waiver Support Coordinator Rhonda Allen in July 1998.
- 37. When Mrs. Powell asked Allen about obtaining durable medical equipment and supplies through the DS Waiver Program, she was told that Allen has to submit requests to Developmental Services, which refers it to a budget committee. Allen then waits for a decision from the budget committee as to whether the item requested will be funded or not. Just because the support

coordinator requests an item does not necessarily mean it will get funded. The support coordinator does not make the decision as to whether or not a requested item is funded by the DS waiver. Therefore, Allen could not say whether or not additional items of durable medical equipment and supplies for Justin Powell would be approved for coverage under the DS Waiver program if she were to request them. The DS waiver provider has no role in determining what items get funded under the DS Waiver program.

- 38. Allen and Barbara Powell discussed Justin Powell's need for a G-tube, a trach, diapers, and the trach mask. Since the family was paying for a trach mask and a doctor was donating a G-tube, the DS waiver program would not cover these items. If there are resources in the community that will pay for items, the waiver program will not provide coverage.
- 39. The only supplies funded through the DS waiver to date have been Justin's feeding bags. The only piece of equipment funded through the waiver to date is Justin's suction machine.
- 40. Over the past year, Allen advised Barbara Powell that the DS waiver program could not cover all of the medical equipment and supplies Justin's needs because funds were low and the DS waiver program was waiting for additional funding.
- 41. If some of Justin's equipment ceases to operate,
 Barbara Powell will have to take Justin to the hospital while she
 waits for a decision from the DS Waiver program as to whether it
 will fund replacement equipment.

- 42. Justin's only income is \$500 per month SSI. Barbara Powell now spends family money to purchase DME and supplies for Justin which are no longer covered by Medicaid. The Powells are re-using some equipment and supplies that should be replaced if money were no object. Due at least in part to the cost of providing Justin's equipment and supplies since he turned 21, the Powell family is under financial stress. Currently, the family is behind in its electricity bill.
- 43. There was no evidence that AHCA gave the Powells specific written notice after Justin turned 21 that they could pursue a fair hearing to contest the termination of coverage of DME and medical supplies under the regular Medicaid program.

CONCLUSIONS OF LAW

44. Section 120.56(1)(a), Florida Statutes (1997), provides: "Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority." Section 120.52(8), Florida Statutes (Supp. 1998), provides in pertinent part:

"Invalid exercise of delegated legislative authority" means action which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:

(b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1...

Both Section 120.52(8) and Section 120.536(1), Florida Statutes (Supp. 1998), as amended by CS/HB 107, also provide:

A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the, or make specific the particular powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific the particular powers and duties conferred by the same statute.

(The additions and deletions of CS/HB 107--designated in the quoted language by underlining and striking-through, respectively--were the Legislature's response to the decision in St. Johns River Water Management Dist. v. Consolidated-Tomoka

Land Co., 717 So. 2d 72 (Fla. 1st DCA 1998).) Bell and Powell challenge the validity of Florida Administrative Code Rule 59G-4.070 under these statutes.

45. Rule 59G-4.070 was promulgated under the authority of Section 409.919, Florida Statutes (1997), which provides: "The department shall adopt any rules necessary to comply with or administer ss. 409.901-409.920 and all rules necessary to comply with federal requirements." Bell and Powell contend that Rule

- 59G-4.070 exceeds its rulemaking authority because it does not comply with federal Medicaid law, as explained in the HCFA interpretative letter. (See Finding 25, supra.)
- 46. The HCFA interpretive letter was sent to all state Medicaid directors after <u>Desario v. Thomas</u>, 139 F.3d 80 (2d Cir. 1998), held that states <u>can</u> use exclusive lists of covered items of DME. After the HCFA letter, the Supreme Court vacated the Second Circuit's judgment and remanded for further consideration in light of HCFA's letter of interpretive guidance. <u>See Slekis v. Thomas</u>, 119 S. Ct. 864, 142 L. Ed. 2d 767, 67 USLW 3457 (Jan. 14, 1999).
- 47. A Florida federal court recently reconsidered a previous order regarding coverage of DME in light of HCFA's letter of interpretative guidance, which the court viewed as "an intervening change in controlling law." See Esteban v. Cook, Case No. 97-2830-Civ-Graham (slip op., S.D. Fla., May 20, 1999, at page 2, and Final Summary Judgment entered June 14, 1999.) It is concluded that the HCFA letter is controlling as to the requirements of federal Medicaid law.
- 48. AHCA argues that the HCFA letter was aimed at precluding a state from using the "Medicaid as a whole test" and does not address age-based exclusions. To the contrary, the HCFA letter specifically states that "the process for seeking modifications or exceptions must be made available to all beneficiaries and may not be limited to sub-classes of the

population (e.g., beneficiaries under the age of 21)"; similarly, the letter's reference to arbitrary exclusions from coverage "based solely on a . . . condition" could well refer to age. In addition, Esteban v. Cook, supra, clearly addressed age-based exclusions. Besides, the issue raised in this case is not the exclusions from the pre-approved list but compliance with the federal requirements set out in the HCFA letter in the event such lists are used.

- 49. Rule 59G-4.070 itself does not comply with the HCFA letter in all respects. While it does make the list of preapproved items available to the beneficiaries and public, it does not itself make Florida's process for seeking modifications or exceptions available to all beneficiaries, employ and make available reasonable and specific criteria by which an individual item of DME will be judged for coverage, or inform beneficiaries of their right to a fair hearing. But the HCFA letter does not require that states comply with all federal requirements the letter sets out in the same official utterance (in this case, Rule 59G-4.070) creating the list of pre-approved items of coverage.
- 50. There are other Florida Administrative Code rules meeting most of the federal requirements set out in the letter. Rule 59G-1.010(85) defines "fair hearing," and Rule 65A-1.204(4) provides for fair hearings conducted in accordance with Florida Administrative Code Rules Chapter 65-2. Rules Chapter 65-2

describes a timely process for resolving coverage disputes, and there is no contention in this case that the provisions of Rules Chapter 65-2 do not meet the requirements of federal law, as interpreted by the HCFA letter. In addition, Section 408.7056, Florida Statutes (1997), created a grievance procedure for Medicaid recipients in an HMO (like Bell); under this cost-free grievance procedure, a subscriber assistance panel can recommend that either AHCA or the Department of Insurance require an HMO to provide medical equipment and supplies requested by a Medicaid recipient and refused by the HMO. The only federal requirement set out in the HCFA letter not addressed in Rules Chapter 65-2 is the requirement for specific criteria for judging items for coverage.

51. It is not clear what kind of criteria the HCFA letter has in mind. It would appear from the HCFA letter that the criteria need only prohibit arbitrary exclusions from coverage based solely on a diagnosis, type of illness, or condition. To the extent that more is needed, the HCFA letter does not require states to use rulemaking to comply with the federal requirements set out in the letter. The HCFA letter does not prevent Florida from developing these criteria on a case-by-case basis and making them available to the beneficiaries and public in the form of final orders under Section 120.52(7), Florida Statutes (Supp. 1998), and Section 120.53(1), Florida Statutes (1997), until such

time that rulemaking is required under Section 120.54(1), Florida Statutes (Supp. 1998).

- 52. Even if additional rules are necessary to comply with federal requirements, it still would not follow that Rule 59G-4.070 exceeds its rulemaking authority. Section 409.919, Florida Statutes (1997), clearly authorizes "any rules necessary to comply with or administer ss. 409.901-409.920," and Rule 59G-4.070 clearly was promulgated for that purpose. If additional rules are necessary to comply with federal requirements, they also would be authorized by Section 409.919. If Willard Bell and Justin Powell want the criteria for judging items for coverage to be in rule form, the proper remedy would be to petition to initiate rulemaking under Section 120.54(7), Florida Statutes (Supp. 1998).
- 53. AHCA contends that neither Bell nor Powell had standing to bring this rule challenge. Section 120.56(1)(a), Florida Statutes (1997), authorizes challenges by "[a]ny person substantially affected by a rule . . . " To be "substantially affected," a person must show "a substantial injury in fact that is within the 'zone of interest to be protected or regulated' " Cole Vision Corp. and Visionworks, Inc. v. Dept. of Business and Prof. Reg., 688 So. 2d 404, 407 (Fla. 1st DCA 1997).
- 54. As adult Medicaid recipients, both Bell and Powell are subject to Rule 59G-4.070. The rule governs their benefits under Medicaid. Both were denied benefits under the rule because DME

and medical supplies are not available to recipients over age 21 under the rule. As such, Bell and Powell were "substantially affected" by the rule and had standing to challenge the rule's validity under Section 120.56(1)(a), Florida Statutes (1997).

- 55. AHCA contends that Justin Powell is not substantially affected by the rule because he is in the DS waiver program. But it was the effect of the rule on Powell that compelled him to enter the DS waiver program. The evidence was that there are significant differences in the ways in which DME and medical supplies are available to recipients under age 21 under the rule and under the DS waiver program. Those differences are having a significant impact on Powell at this time.
- 56. Powell moved to further amend his petition to permit Justin Powell and Barbara Powell to petition in his and her own right. But Justin Powell already has petitioned in his own right, albeit through his mother; and it is too late to add Barbara Powell as another party petitioner.
- 57. AHCA contended that Bell is not substantially affected by the rule because he has gotten an insulin pump under the Medicaid program and is getting the supplies for the pump through his HMO. But the impact of the rule on him necessitated a lengthy administrative and fair hearing process before he got the pump through Medicaid. It also forced him to remain in his HMO against his wishes to be sure he would continue to obtain pump supplies since the rule did not seem to include those benefits in

the Medicaid program. Meanwhile, the rule governs his attempt to ascertain whether Medicaid will cover the pump supplies. For these reasons, the rule is having a significant impact on Bell at this time.

DISPOSITION

Based on the foregoing Findings of Fact and Conclusions of
Law, the Petitioners' Amended Petition to Determine Invalidity of
Rule 59G-4.070 and Portions of the Florida Medicaid Provider
Handbook, Durable Medical Equipment (DME)/Medical Supplies is
denied.

DONE AND ORDERED this 3rd day of August, 1999, in Tallahassee, Leon County, Florida.

J. LAWRENCE JOHNSTON
Administrative Law Judge
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Filed with the Clerk of the Division of Administrative Hearings this 3rd day of August, 1999.

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Carroll Webb, Executive Director Administrative Procedures Committee 120 Holland Building Tallahassee, Florida 32399-1300

NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to Section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing one copy of a notice of appeal with the Clerk of the Division of Administrative Hearings and a second copy, accompanied by filing fees prescribed by law, with the District Court of Appeal, First District, or with the District Court of Appeal in the Appellate District where the party resides. The notice of appeal must be filed within 30 days of rendition of the order to be reviewed.