



IN THE SUPREME COURT OF THE STATE OF DELAWARE

Edward and Pamela Prunckun,)	
as parents and legal guardians of)	
Robert Prunckun)	
)	
Plaintiffs below,)	No. 93, 2018
Appellants,)	
)	
v.)	Court Below: Superior Court of
)	Delaware,
Delaware Department of Health and)	C.A. No. N16A-05-010 FWW
Social Services,)	N16A-05-009 FWW
)	CONSOLIDATED
Defendant Below,)	
Appellee.)	

APPELLEE'S AMENDED ANSWERING BRIEF

**STATE OF DELAWARE
DEPARTMENT OF JUSTICE**

/s/ Lauren E. Maguire
Lauren E. Maguire (#4261)
Adria B. Martinelli (#4056)
Deputy Attorneys General
Carvel State Office Building
820 N. French Street, 6th Floor
Wilmington, DE 19801
(302) 577-8400

Dated: July 10, 2018

Attorneys for Defendant Below, Appellee

TABLE OF CONTENTS

TABLE OF AUTHORITIES iii

NATURE OF PROCEEDINGS 1

SUMMARY OF ARGUMENT 7

STATEMENT OF FACTS 8

 Overview of Medicaid HCBS Waiver Program..... 8

 The Recipients’ Placement and Treatment at JRC 10

 Regulations Governing Use of Aversives Subject to Increased and Changing
 State and Federal Scrutiny 12

 CMS Advisory Materials 16

ARGUMENT 20

 I. The Administrative Process Was Proper and Did Not Violate
 Appellants’ Due Process Rights 20

 A. Question Presented 20

 B. Scope of Review 20

 C. Merits of the Argument 21

 1. The Due Process Clause Does Not Provide Appellants a Basis
 to Challenge the Determination to Prohibit the Use of all
 Coercion 22

 2. The Hearing Officer Afforded Appellants a Meaningful Fair
 Hearing to Contest Any Factual Disputes as to Whether the Ban
 on Coercion and Averse Conditioning Applies to GED 28

 3. Appellants were Given Adequate Notice Regarding the
 Prohibition on GED 30

II.	The Hearing Officer Correctly Found that GED is Not a Covered Service	32
	A. Question Presented.....	32
	B. Scope of Review	32
	C. Merits of the Argument.....	32
	1. GED is Banned Under Federal Law	33
	2. GED is Banned Under Delaware’s HCBS Waiver.....	36
	3. Medical Necessity Does Not Determine Medicaid Coverage ..	38
III.	The Final Decision is Not Discriminatory in Violation of Title II of the Americans with Disabilities Act	40
	A. Question Presented.....	40
	B. Scope of Review	40
	C. Merits of the Argument.....	40
	CONCLUSION.....	44

TABLE OF AUTHORITIES

CASES

<i>Am. Airlines, Inc. v. C. A. B.</i> , 359 F.2d 624 (D.C. Cir. 1966).....	25, 27
<i>Avallone v. DHSS</i> , 14 A.3d 566 (Del. 2011).....	40
<i>Beal v. Doe</i> , 432 U.S. 438 (1977).....	39
<i>Benton v. Rhodes</i> , 586 F.2d 1 (6th Cir. 1978)	24, 28, 36
<i>Bertrand v. Maram</i> , 2006 WL 2735494 (N.D. Ill. Sept. 25, 2006).....	37
<i>Bi-Metallic Inv. Co. v. State Bd. of Equalization</i> , 239 U.S. 441 (1915).....	22, 23
<i>Brewster v. Heckler</i> , 786 F.2d 581 (3d Cir. 1986)	20
<i>Capitol Airways, Inc. v. C.A.B.</i> , 292 F.2d 755 (D.C. Cir. 1961).....	27
<i>Cnty. Health Ctr. v. Wilson-Coker</i> , 311 F.3d 132 (2nd Cir. 2002)	23, 26, 34, 35
<i>Elgin Nursing & Rehab. Ctr. v. U.S. Dep't of Health & Human Servs.</i> , 718 F.3d 488 (5th Cir. 2013)	34
<i>Judge Rotenberg Educ. Ctr. v. Office of Admin. Hearings</i> , 2009 WL 162066 (Cal. App. 3d. Dist. Jan. 26, 2009).....	14
<i>Lankford v. Sherman</i> , 451 F.3d 496 (8th Cir. 2006)	40

<i>Logan v. Zimmerman Brush Co.</i> , 455 U.S. 422 (1982).....	24
<i>The Maryland Dep't of Health & Mental Hygiene v. Centers For Medicare & Medicaid Servs.</i> , 542 F.3d 424 (4th Cir. 2008)	37
<i>Massachusetts v. Sebelius</i> , 638 F.3d 24 (1st Cir. 2011).....	36
<i>Minnesota State Bd. for Cmty. Colleges v. Knight</i> , 465 U.S. 271 (1984).....	23
<i>Nat'l Fuel Gas Distribution Corp. v. TGX Corp.</i> , 749 F. Supp. 466 (W.D.N.Y. 1990).....	30
<i>Onyx Properties LLC v. Bd. of Cty. Commissioners of Elbert Cty.</i> , 838 F.3d 1039 (10th Cir. 2016)	23, 27
<i>Ramunno on Behalf of McClain v. Delaware Dep't of Health & Soc. Servs., Div. of Soc. Servs.</i> , 2014 WL 1312681 (Del. Super. Ct. Feb. 28, 2014)	20
<i>Rosen v. Goetz</i> , 410 F.3d 919 (6th Cir. 2005)	24, 28, 37
<i>S.D. ex rel. Dickson v. Hood</i> , 391 F.3d 581 (5th Cir. 2004)	26
<i>Skandalis v. Rowe</i> , 14 F.3d 173 (2d Cir. 1994)	34
<i>Stogsdill v. S. Carolina Dep't of Health & Human Servs.</i> , 410 S.C. 273 (S.C. App. 2014).....	37
<i>Stoltz Management Co., Inc. v. Consumer Affairs Bd.</i> , 616 A.2d 1205 (Del. 1992).....	20, 32
<i>Tatten Partners, L.P. v. New Castle County Bd. Of Assessment Review</i> , 642 A.2d 1251 (Del. Super. 1993)	42

<i>Urban v. Meconi</i> , 930 A.2d 860 (Del. 2007)	20, 32
<i>Washington v. DeBeaugrine</i> , 658 F. Supp. 2d 1332 (N.D. Fla 2009)	29

STATUTES AND OTHER AUTHORITIES

42 U.S.C. § 1396n(c)	9
42 C.F.R. § 441.530	<i>passim</i>
42 C.F.R § 441.301(c)(6).....	15
42 C.F.R § 431.220	24
42 C.F.R § 440.225	38
42 U.S.C §§ 12101-12213	40, 41, 42, 43
115 CMR 5.14(3)(d)(1).....	16
76 Fed. Reg. 21311	12
77 Fed. Reg. 26361	12
79 Fed. Reg. 3032	12
19 Fed. Reg. 2948-01	33
19 Fed. Reg. 2949	33
31 Del. C. § 520	5, 20, 32
29 Del. C. § 10141	38
17 DE Reg. 950 (04/01/14).....	15

17 DE Reg. 1179 (06/01/14).....	15
DSSM 5302(K)	31
Supr. Ct. R. 8.....	42
Super. Ct. Civ. R. 72	42

NATURE OF PROCEEDINGS

On November 27, 2013, Ashlee Oldham and Robert Prunckun (collectively, the “Recipients”), through their legal guardians (the “Guardians”) (together, the Recipients and Guardians may be individually or jointly referred to as “Appellants”), filed requests for a Medicaid fair hearing to contest the alleged reduction of Medicaid services. A0018-44. The requests were based on letters dated October 8 and 11, 2013, directing the Judge Rotenberg Educational Center, Inc. (“JRC”) to cease using a Graduated Electronic Decelerator (“GED”), which produces an electric shock, on Medicaid recipients. A0014-17. Appellants assert that the Recipients are entitled to receive electric shock therapy as a covered Medicaid service paid for by the Delaware Medicaid program operated by Delaware’s Division of Developmental Disabilities (“DDDS”), a division within Delaware’s Department of Health and Social Services (“DHSS”).

In response to Appellant’s fair hearing request, DDDS filed the required fair hearing summary on December 16, 2013¹, and thereafter, on March 6, 2014, DDDS filed a Motion to Dismiss the Appellants’ fair hearing request. A0096-284. DDDS noted that the disputed service, electric shock, was prohibited under its Home and Community Based Services Medicaid Waiver (“HCBS Waiver”). *Id.* DDDS offered

¹ A0046-95. The summary contained the required elements, including the action taken (none), and the authority and copy of the authority under which DDDS acted when it instructed JRC to cease the use of practices in violation of state law.

as support a December 14, 2012 letter from the Centers for Medicaid and Medicare Services (“CMS”) to the Massachusetts Medicaid agency prohibiting the continued use of electric shock therapy on Massachusetts HCBS waiver recipients, or otherwise risk placing Massachusetts’ entire waiver program in peril. A0812-814. On April 24, 2014, DDDS submitted a supplement to its Motion to Dismiss. A0325-349. DDDS provided as additional support the newly effective (March 17, 2014) federal Home and Community Based Setting Rule (“HCB Setting Rule”), which explicitly prohibited the use of coercion or restraint.

While DDDS’s Motion to Dismiss was pending, the parties sought a clarification conference with the Hearing Officer (“HO”). The HO issued a decision on April 25, 2014 that framed the scope of and procedure for the upcoming fair hearing. A0350-353.² After submitting a motion for reconsideration of the April 25, 2014 order, which was denied, Appellants appealed the HO’s decision to the Superior Court. A0358-381; A0383; A0385; A0387-394. DDDS sought to dismiss the appeal as an improper interlocutory appeal. Following oral argument on February 10, 2015, the Superior Court granted DDDS’s motion to dismiss from the bench. A0561-571.

² “[R]easonableness and necessity of using aversive behavioral interventions, also called ‘Level III interventions’, including an electrical device (graduated electronic decelerator), ... is not an issue in this fair hearing proceeding. Therefore, the parties shall not present evidence or argument regarding the issue of reasonableness and necessity.” A0350-353.

DDDS then renewed its request for a determination on its pending motion to dismiss the administrative fair hearing, submitting as additional support a March 10, 2015 letter from CMS to the Delaware Medicaid agency. A0573-576. That letter confirmed electric shock violates the federal HCB Setting Rule and thus is not a Medicaid-covered practice. A0576.³ Following a teleconference with the HO, the parties submitted supplemental briefing on DDDS's motion to dismiss Appellants' request for a fair hearing. A0600-646; A0647-783; A0785-821.

After consideration of briefing on DDDS's motion to dismiss, the HO denied the motion. A0850-853. In holding that the fair hearing would proceed, the HO also held that the hearing would be bifurcated. The HO ordered that she would first determine whether GED is a Medicaid-covered service. She ruled the issue of medical necessity would only be addressed if Medicaid coverage for GED was sustained.⁴

³ The letter states: "Electric shock therapies ... [is] not characteristic of HCBS settings; [CMS] therefore request[s] that the State provide immediate assurance that the use of these aversive interventions has been eliminated for any and all settings in which individuals enrolled in Medicaid live or receive services. Additionally, per the State's letter, procedures that include physical interventions that cause pain are considered aversive interventions prohibited by the State. Therefore, this condition must be met immediately and these practices must cease and desist. The State should cease all billing for FFP for individuals receiving Medicaid services through providers practicing *any* of the above referenced procedures."

⁴ "[B]efore considering whether the GED treatment services are medically necessary, the first issue that must be decided is whether these services are indeed covered services under Medicaid and/or whether the state erred when instructing

The Fair Hearing was held on January 13, 2016. A0905-948. On April 21, 2016, the HO issued her final decision, finding that GED was not a covered Medicaid service and affirming DDDS's regulatory action to cease coverage of GED for Delaware Medicaid recipients. A0965-967. The decision found that "the evidence supports that the DDDS instruction in October 2013 to JRC to cease using GED treatment services was correct and well within its authority under the Delaware HCBS Waiver." A966.

Recognizing that Medicaid coverage and medical necessity are conceptually independent from each other, the HO noted that, "consideration of whether the GED treatment services at issue are medically reasonable and necessary is a moot issue if Delaware's Medicaid program prohibits these treatment services." A0955. The decision held:

Despite Appellants repeatedly arguing that they should be permitted to introduce evidence of medical necessity to prove Medicaid coverage, and DHSS's recurrent directions to this Fair Hearing Officer on the limits of the administrative process, the sole issue in this portion of the Fair Hearing was whether DDDS correctly determined that GED treatment services were no longer covered services by Medicaid under the Delaware HCBS Waiver.

A0965.

JRC to permanently cease using the GED treatment services. Therefore, the Fair Hearing shall proceed as a bifurcated process considering the issue of Medicaid coverage first, followed by the medical necessity of GED treatment services, if Medicaid coverage is sustained." A0853.

Because the hearing largely addressed legal issues, the HO was not required to make extensive factual findings. However, the HO admitted 209 exhibits into evidence without objection from either party, and considered supporting policies in determining that GED is not a Medicaid-covered service. A0964-965; A0968-981. The decision noted that, while Appellants were not permitted to introduce evidence of medical necessity in the first phase of the fair hearing, there were no limitations on the parties' ability to offer evidence on the issue of Medicaid coverage. A0966-967.

Appellants filed an administrative appeal of the HO's decision in Superior Court, pursuant to 31 *Del. C.* § 520. A0983-995. After submission of the parties' briefs on appeal, the Court held oral argument on October 30, 2017. A0997-A1072. The Court issued an opinion affirming the HO's decision on January 30, 2018 (the "Op."), finding that the HO's conclusions were supported by substantial evidence and free from legal error. The Opinion noted that Appellants were given due process though "a full evidentiary Fair Hearing on the pertinent issues in what the Hearing Officer reasonably determined to be the most efficient and orderly manner." Op. at 14-15. The Court affirmed the HO's conclusion that GED is not a Medicaid-covered service.

As part of their Superior Court appeal, Appellants raised for the first time an argument that discontinuing all aversive treatment would place the Recipients at risk

of unjustified isolation and/or institutionalization in violation of Title II of the ADA. However, this argument was never raised in the fair hearing. Therefore, the Superior Court ruled it could not consider the argument.

Appellants filed their notices of appeal of the Superior Court ruling on February 21, 2018. On June 7, 2018, Appellants filed opening briefs (the “OB”)⁵ in support of their appeal. This is DHSS’s Answering Brief in response thereto.

⁵ Appellants filed separate notices of appeal, and the actions are pending individually as cases 93, 2018 and 94, 2018. The legal arguments contained in each Appellants’ opening brief are identical. Unless otherwise indicated, reference to OB will refer to the opening brief filed in No. 93, 2018.

SUMMARY OF ARGUMENT

I. Denied. Medicaid recipients lack a right to contest federal or state law or policy determinations that affect his or her Medicaid coverage. The HO properly bifurcated the fair hearing to first address whether GED was a covered service, without needing to take into account Appellants' arguments regarding the medical necessity of GED. CMS's and DHSS's prohibition against coercion and the use of aversives apply to all Medicaid-qualified providers of home and community based services and were not targeted to treatment received by Recipients.

II. Denied. Both federal and state law prohibit the use of GED in Medicaid funded home and community based settings. Moreover, Medicaid coverage and medical necessity are legally and conceptually different. Appellants' assertion that GED is medically necessary does not transform GED into a covered service.

III. Denied. Appellants' claim based on Title II of the ADA must be rejected because it was not raised at the fair hearing and was raised for the first time on appeal to the Superior Court. This issue has not been properly preserved, and the interests of justice do not require that it be addressed for the first time by this Court.

STATEMENT OF FACTS

Appellants devote a significant portion of their opening submission discussing the medical disabilities and disorders affecting both Recipients. While each Recipient does live with significant disorders and disabilities, an acknowledgement of the various medical challenges faced by both men is not necessary for consideration of this appeal. Also irrelevant to consideration of the issues on appeal is the Guardians' support of GED.

Instead, this case is solely about the use of GED, and changes to federal and state rules that have altered the appropriateness of GED as a treatment modality.

Overview of Medicaid HCBS Waiver Program

Under traditional Medicaid, States and CMS enter a contract called the State Medicaid Plan, which has the force of law. Under a State's Medicaid Plan, the State must provide all federally mandated Medicaid services, as well as any optional services it has elected to cover at its discretion. Both mandatory Medicaid services and those optional services agreed to by a State are incorporated into a State's Medicaid Plan. CMS will contribute a percentage of the cost of such services. Apart from mandatory and optional services are prohibited services, *e.g.* services for which CMS will not reimburse a state.

Pursuant to Medicaid waivers, CMS has the authority to waive certain provisions of otherwise-applicable Medicaid law to further the interests of the

Medicaid program. The HCBS Waiver is a Medicaid option available to states under Section 1915(c) of the Social Security Act, 42 U.S.C. § 1396n(c). HCBS waivers allow states to offer services and supports to individuals who are elderly or have disabilities and live in a community setting in lieu of institutionalization. Nearly all States, including Delaware, offer services to persons with intellectual and developmental disabilities through a 1915(c) HCBS Waiver. In Delaware, DDDS administers the state's HCBS Waiver.

The HCB Setting Rule establishes requirements for the qualities of settings eligible for reimbursement for home and community based services provided under sections 1915(c), 1915(i) and 1915(k) of the Medicaid statute. The HCB Setting Rule also amends the regulations for the HCBS Waiver program. The HCB Setting Rule defines person-centered planning requirements for persons in Medicaid-funded community settings under HCBS Waivers. The rule seeks to ensure individual rights of privacy, dignity, respect, and freedom from coercion and restraint.

The Recipients' care at JRC was historically funded under Delaware's HCBS Waiver. When CMS determined GED was a prohibited Medicaid service, GED could no longer be covered under the HCBS Waiver. Moreover, because CMS has determined GED is not a service that is characteristic of a community setting under the HCB Setting Rule, Delaware is unable to receive federal reimbursement for any

of the Recipients' care while at JRC. Thus, Recipients' services are currently funded solely with State funds.

The Recipients' Placement and Treatment at JRC

JRC owns and operates a program in Massachusetts that houses adults and children with developmental disabilities. One of the aversives central to JRC's program is GED. JRC is the only entity nationwide that uses GED to control the behavior of its residents; other providers employ positive behavior support techniques to manage unwanted behaviors. GED is categorized as an "electrical stimulation," a "skin-shock[ing]" device that produces a voltage of 66v to normal skin and results in reddening of the skin, blisters, and a state of anxiety to the recipient. A0188-189; A0241-242.

DDDS provides support and services to Delaware residents with developmental disorders and disabilities and their families. As part of this work, DDDS facilitates placement of Delaware residents into residential settings when they can no longer be safely supported in the family home. DDDS oversees care for individuals receiving its services and is also responsible for quality oversight of providers of Delaware HCB services.

Recipients are Delaware residents with severe behavioral, developmental and emotional disorders and disabilities. They have resided at JRC in Massachusetts since 2004 and 2005, when Delaware placed them there. As part of their JRC-

developed treatment plans, both Recipients have been and continue to be subjected to aversive treatment procedures, including electric shock, during their placement at JRC. A0161-A0256. Although DDDS issued letters directing JRC to cease using electric shock on Medicaid recipients in October 2013, JRC has refused to stop the practice. A0014-17.

When the Recipients first began receiving GED, DDDS allowed JRC to use the aversive treatments pursuant to the JRC/DDDS provider contracts and allowed JRC to submit claims for those services under the HCBS Waiver. Over time, however, accepted treatment modalities and enabling regulations change. The final HCB Setting Rule was established to set forth appropriate qualities of home and community based settings that are eligible for reimbursement under Medicaid. Under current federal law, GED is not reflective of the characteristics of community settings and thus, Medicaid funding cannot be used for individuals residing in facilities that administer GED.

Due to the posture of the underlying proceedings, the factual record regarding both Recipients' medical histories is understandably limited. As noted, however, Recipients' individual histories are not relevant to whether GED is a covered Medicaid service. Practice standards for the treatment of aggressive behavior and self-injurious behavior have evolved to reject devices that use pain and fear to coerce desirable behavior, in favor of treatment modalities that use positive support to mold

behavior. To this end, the relevant federal and state standards have evolved in response to clinical practice.

Regulations Governing Use of Aversives Subject to Increased and Changing State and Federal Scrutiny

According to both DDDS and CMS, the federal agency charged with the promulgation and enforcement of Medicaid regulations and the approval of all states' HCBS Waivers, electric shock used by JRC violates federal and state law. The background of this legal development involves both federal and state action with respect to regulations governing treatment of individuals with developmental disabilities and disorders.

CMS adopted the final HCB Setting Rule effective March 17, 2014, after many years of dialogue with stakeholders. Published as proposed regulations on April 15, 2011⁶, and again on May 3, 2012⁷, the HCB Setting Rule was published as a final regulation on January 16, 2014.⁸ A review of the Federal Register comments reveals no evidence that JRC or Appellants, or indeed any person or entity, opposed the provisions of 42 C.F.R. §441.530(a)(1)(iii) banning the use of coercion and restraint in community settings.

⁶ 76 Fed. Reg. 21311.

⁷ 77 Fed. Reg. 26361.

⁸ 79 Fed. Reg. 3032.

In the HCB Setting Rule, CMS unequivocally prohibited the use of coercive devices, which includes GED. The HCB Setting Rule reads:

Home and community based settings must have all of the following qualities, and such other qualities as the Secretary determines to be appropriate, based on the needs of the individual as indicated in their person-centered service plan:

* * *

Ensures an individual's rights of privacy, dignity and respect, and *freedom from coercion and restraint.*

42 C.F.R. § 441.530(a)(1)(iii) (emphasis added).

DHSS's prohibition on the use of aversives was expressly incorporated into Delaware's HCBS Waiver, which was renewed and approved by CMS in 2014.⁹

Delaware's waiver language reads, in pertinent part:

As articulated in the DDDS Policy on Behavior and/or Mental Health Support, positive supports are the essential foundation upon which all programs and individual plans are developed. Further, the policy discourages the use of restrictive procedures. A restrictive procedure is defined as a practice which limits an individual's movement, ability to acquire positive reinforcement, results in the loss of valued objects or activities, or requires an individual to engage in a behavior the individual would not engage in given freedom of choice. ***The use of aversive conditioning, defined as the contingent application of startling, painful or noxious stimuli is prohibited.*** (emphasis added)¹⁰

⁹ http://dhss.delaware.gov/dhss/ddds/files/de_0009_r07_00_070114.pdf.

¹⁰ On October 7, 2015, DDDS amended its policies to expressly incorporate the definition of aversive developed and adopted by the National Association of State Directors of Developmental Disabilities Services ("NASDDDS"). The definition reads:

A0503. *See also* DDDS Policies at B000001-27. The prohibition on aversives set forth in Delaware’s HCBS Waiver includes the GED received by Recipients.¹¹

Delaware’s HCBS Waiver also bans the use of corporal punishment. *See* A0499-500 (corporal punishment or the threat of corporal punishment is expressly prohibited). It is hard to imagine a better example of corporal punishment than the use of electric shock to coerce a person to remain in his seat or cease clapping.¹²

Aversive interventions are those intended to inflict pain, discomfort and/or social humiliation or any intervention as perceived by the person to inflict pain, discomfort or social humiliation in order to reduce behavior. Examples of aversive interventions include, but are not limited to, *electric skin shock*, liquid spray to ones face and strong, non-preferred tastes applied in the mouth. (emphasis added). B000004.

¹¹ The Recipients’ treatment plans describe the “aversive procedures,” including GED, used when Ashlee or Robert display problematic behavior. A0186-189; A0238-242. The behaviors for which GED are authorized for Ashlee include, *inter alia*, getting out of his seat without permission. A0243-244. Robert’s treatment plan is similar, except that JRC employs GED-4, a device with a much stronger electrical current than that used on Ashlee. A0188. Robert wears three GED-4 devices and JRC uses the devices to shock Robert when he gets out of his seat without permission, spits at others, refuses to follow staff directions, swears, or claps more than twice in a one-minute period. A0190-192. The side effects of GED are described as reddening of the skin, blistering and anxiety. A0188-189; A0242.

¹² *See Judge Rotenberg Educ. Ctr. v. Office of Admin. Hearings*, 2009 WL 162066 (Cal. App. 3. Dist. Jan. 26, 2009) (upholding ruling by administrative hearing officer that GED used by JRC constitutes corporal punishment.)

Delaware's HCBS Waiver was scheduled for renewal in 2014, and DDDS submitted its Waiver application to CMS in March 2014. However, DDDS began efforts to gather input from providers and advocates many months before that submission. DDDS published notice of the Delaware HCBS Waiver renewal application on its website and in the Delaware Register of Regulations for notice and comment before adoption. DDDS also convened public hearings in each of Delaware's three counties, accepted and responded to all public comments, and informed Delaware's major advocacy groups about the HCBS Waiver renewal. A0402. Delaware's Medicaid division published notice of the Waiver in the April 2014 Delaware Registry as a proposed regulation. 17 DE Reg. 950 (04/01/14). Notice of the HCBS Waiver renewal was published in the June 2014 Delaware Registry as a final regulation, effective June 10, 2014. 17 DE Reg. 1179 (06/01/14). Neither Appellants nor JRC submitted any comments on the prohibition on use of aversive conditioning. CMS approved Delaware's HCBS Waiver effective July 1, 2014.¹³ Appellants ignore this procedural history and have failed to provide a proper basis to justify why the prohibition on aversives does not apply to Recipients.

¹³ States that offer Medicaid HCB services under the authorities of 1915(c), (i) and (k), were required to develop a Statewide Transition Plan, pursuant to notice and comment, outlining how they would come into compliance with the HCB Setting Rule. 42 CFR § 441.301(c)(6). Delaware completed its plan, <http://dhss.delaware.gov/dhss/dmma/files/statewidetransitionplan.pdf>, and reviewed each provider of services, including DDDS providers, to assure compliance with the HCB Setting Rule. Appellants cannot cite to any record

The prohibition on the use of GED by JRC is also contractual. By contract with DDDS, all Delaware-qualified Medicaid providers who serve individuals through DDDS programming agree to comply with all statutes, regulations, policies and procedures of DDDS. A0121. DDDS last renewed its provider contract with JRC on July 01, 2013.¹⁴ A0107-153. In that contract, JRC agreed to comply with “all State and Federal licensing standards and all other applicable standards as required to provide services under this Contract.” A0109.

CMS Advisory Materials

CMS has also issued significant advisory materials regarding the legality of the use of GED on HCBS Medicaid recipients. On December 14, 2012, Richard McGreal, a CMS Associate Regional I Administrator, issued a letter to the Secretary of Massachusetts’ Office of Health and Human Services (the “Region I letter”). CMS concluded JRC’s use of certain aversive behavioral interventions, including GED, on Massachusetts residents, known as “Level III interventions,”¹⁵ violated federal rules regarding the standard of care for waiver recipients. A0812-814.

evidence to support their conclusory assertion that the prohibition against use of aversive conditioning facially targeted and discriminated against Appellants.

¹⁴ The contract expired September 30, 2014, when JRC refused to cease use of GED on Recipients.

¹⁵ Level III intervention is defined, in relevant part, as “[a]ny Intervention which involves the contingent application of physical contact aversive stimuli such as spanking, slapping, hitting or contingent skin shock.” 115 CMR 5.14(3)(d)(1).

Specifically, CMS determined that JRC's use of GED, a "painful aversive stimuli," had no place in the home or community, a view that, CMS noted, was held by reasonable people.

Consequently, CMS directed Massachusetts to immediately cease use of such procedures on individuals enrolled in the HCBS Waiver program. As part of a remedial effort, CMS also required Massachusetts to provide a written corrective plan, demonstrating how the state would ensure that all recipients under the HCBS Waiver program would be free from Level III aversive interventions. CMS found that, because of JRC's use of GED on Medicaid recipients, "the State has not demonstrated that it substantially meets the waiver assurance for participant health and welfare," an assurance that must be demonstrated in order to maintain eligibility for federal funding under the HCBS Waiver program. A0812. Thus, the use of GED placed the entire Massachusetts HCBS Waiver in jeopardy.

In light of the CMS directive to Massachusetts and in preparation for renewal of its own HCBS Waiver, DDDS undertook several measures. It met with the Guardians to explain that JRC would no longer be permitted to use GED on the Recipients. DDDS explained that it would offer the Recipients a residential setting from a Delaware-qualified provider that did not use such aversives if JRC refused to discontinue application of GED. By letters dated October 8 and 11, 2013, DDDS listed prohibited procedures under the HCBS Waiver and directed JRC to cease

application of those prohibited practices on the Recipients. A0014-17. DDDS required JRC to discontinue use of all aversives within sixty days, or jeopardize its standing as a qualified provider.¹⁶

Delaware falls within CMS Region III. Given the 2012 letter issued from Region I, Delaware's Medicaid Director, Stephen Groff, sought further clarification from Region III on the use of GED. A0632-633. By letter dated December 23, 2014, Mr. Groff wrote:

Delaware seeks the guidance of CMS on one very narrow point of interpretation: Is the administration of electrical shock using a Graduated Electronic Decelerator ("GED") device and GED 4 device, and the denial of a nutritionally adequate diet for the failure to show certain specified behaviors consistent with the characteristics of a Home and Community-Based Setting as defined in the recently adopted regulation?

CMS responded on March 10, 2015 (the "Region III letter"). A0576. The Region III letter was issued by the Director of Long Term Services, Ralph Lollar, and Francis McCullough, Associate Regional Administrator for CMS Region III. CMS wrote:

¹⁶ Appellants' Opening Briefs contains various assertions that DDDS stopped making medical assistance payments to JRC for Recipients' services. OB at 3, 11, 27. Appellants' allegation that DHSS stopped payments to JRC in an attempt to violate Appellants' due process rights is without merit. In fact, DHSS negotiated transition agreements for both Recipients at arm's length, with the attorneys for Appellants as well as with the involvement of the attorneys' other client, JRC. DDDS has warranted that it will pay for Recipients' care using State funds only during the transition period. A0782-783.

The State has requested clarification from the Centers for Medicaid and Medicare Services (CMS) regarding the use of GED devices and denial of nutritionally adequate diets in home and community-based settings. Electric shock therapies and withholding of meals are not characteristic of HCBS settings; we therefore request that the State provide immediate assurance that the use of these aversive interventions has been eliminated for any and all settings in which individuals enrolled in Medicaid live or receive services.

CMS unequivocally instructed that the administration of GED violates federal law and thus is a prohibited waiver service. As with Massachusetts in Region I, the CMS Region III Office required Delaware to acknowledge it would immediately cease using Medicaid funding for providers practicing GED.

Now, through this proceeding, Appellants seek to challenge the federal and state regulatory model, arguing that GED is a Medicaid-covered service despite being prohibited by both federal and state law. Appellants contend that their due process rights were somehow violated because they were not allowed to introduce expert testimony to dispute the policy determinations of CMS and DHSS. They further contend GED is not prohibited by federal and state law and that the HO's decision finding GED is not a Medicaid service must be reversed. Along with those claims, Appellants seek reversal of the decision on the additional ground that protecting Medicaid recipients by not allowing them to be electrically shocked amounts to discrimination and violates the ADA.

ARGUMENT

I. The Administrative Process Was Proper and Did Not Violate Appellants' Due Process Rights

A. Question Presented

Whether the fair hearing proceedings violated Appellants' due process rights and whether Appellants are permitted to challenge determinations of Medicaid-covered services.

B. Scope of Review

On a statutory appeal of DHSS's fair hearing decision, pursuant to 31 *Del. C.* § 520, the reviewing court determines whether the decision is supported by substantial evidence and free from legal error. *Urban v. Meconi*, 930 A.2d 860, 864 (Del. 2007). "Substantial evidence" is defined as "such relevant evidence as a reasoning mind might accept as adequate to support a conclusion." *Id.* (quoting *Brewster v. Heckler*, 786 F.2d 581, 584 (3d Cir. 1986)). The appeal is on the record and "any factual findings . . . that are supported by substantial evidence on the record will be sustained." *Ramunno on Behalf of McClain v. Delaware Dep't of Health & Soc. Servs., Div. of Soc. Servs.*, 2014 WL 1312681, at *2 (Del. Super. Ct. Feb. 28, 2014). Absent an abuse of discretion, the agency decision must be affirmed. *Stoltz Management Co., Inc. v. Consumer Affairs Bd.*, 616 A.2d 1205, 1208 (Del. 1992).

C. Merits of the Argument

While Appellants allege they were “never afforded an opportunity to challenge DHSS’s action through ... an evidentiary fair hearing,”¹⁷ that assertion is simply false. Appellants are clearly disappointed by the HO’s determination that GED is not a covered service. However, their dissatisfaction with the ruling does not mean the HO did not fully and completely entertain a fair hearing.

Through the guise of this administrative appeal, Appellants seek to have this Court second-guess policy decisions of administrative agencies—federal and state entities charged with ensuring the safety and well-being of its Medicaid recipients, including vulnerable recipients with significant developmental disabilities. Appellants seek to challenge the policy decision to preclude from Medicaid funding a “treatment modality” that is no longer tolerated.

This prohibition against the use of electric shock and generally all other means of coercion and restraints in Medicaid-qualified home and community based settings was clarified by CMS through formal rulemaking. That regulation, the HCB Setting Rule, required unqualified assurances from states that home and community based settings in which Medicaid recipients receive services adhere to certain characteristics and qualities, including “ensur[ing] an individual’s rights of privacy, dignity, and respect, and freedom from coercion and restraint.” 42 C.F.R. §

¹⁷ OB at 2.

441.530(a)(1)(iii) . As explained by CMS, this necessarily prohibited the use of aversives on Medicaid recipients. As part of reviewing its own HCBS Waiver, Delaware, too, made unequivocal through the rulemaking process (and through review and approval by CMS), this explicit prohibition in its renewed HCBS Waiver application. The renewal application for the HCBS Waiver states that “[t]he use of aversive conditioning, defined as the contingent application of startling, painful or noxious stimuli is prohibited.” A0503.

To be clear, both the federal and State’s ban on coercion in home and community based settings was based in no part on any individual findings regarding Recipients, their medical history, or background. Rather, CMS directed, and DHSS agreed, that using coercive methods as a means for behavioral compliance was unacceptable for all Medicaid recipients receiving home and community based services and not characteristic of a community setting. Appellants now claim that due process somehow provides them with the ability to challenge that regulatory determination. The United States Supreme Court has long made clear, however, that no such right exists.

1. The Due Process Clause Does Not Provide Appellants a Basis to Challenge the Determination to Prohibit the Use of All Coercion.

Since as early as 1915, the Supreme Court has recognized that individuals do not have a constitutional right to be heard in every governmental decision that impacts, or has the potential to impact, them. *See generally Bi-Metallic Inv. Co. v.*

State Bd. of Equalization, 239 U.S. 441 (1915); *Onyx Properties LLC v. Bd. of Cty. Commissioners of Elbert Cty.*, 838 F.3d 1039, 1044–45 (10th Cir. 2016) (“The Supreme Court long ago established that the federal Constitution does not require a hearing on the adoption of legislation.”). As the Court observed, “the Constitution does not grant to members of the public generally a right to be heard by public bodies making decisions of policy.” *Minnesota State Bd. for Cmty. Colleges v. Knight*, 465 U.S. 271, 283 (1984). Acknowledging the practical concerns that would arise if individuals were allowed to challenge legislative determinations through separate, individual hearings, the Court held:

Where a rule of conduct applies to more than a few people, it is impracticable that everyone should have a direct voice in its adoption. The Constitution does not require all public acts to be done in town meetings or an assembly of the whole. General statutes within the state power are passed that affect the person or property of individuals, sometimes to the point of ruin, without giving them a chance to be heard. Their rights are protected in the only way that they can be in a complex society, by their power, immediate or remote, over those who make the rule. . . ***There must be a limit to individual argument in such matters if government is to go on.***

Bi-Metallic Inv. Co., 239 U.S. at 445 (emphasis added). As the Court explained more recently, “[p]olicymaking organs in our system of government have never operated under a constitutional constraint requiring them to afford every interested member of the public an opportunity to present testimony before any policy is adopted.” *Minnesota State Bd.*, 465 U.S. at 284.

This distinction between regulatory acts and adjudications (which may give rise to evidentiary hearings) is engrafted into the Medicaid statute itself. The statute provides a Medicaid recipient an opportunity to contest certain Medicaid decisions, *e.g.* factual disputes specific to that recipient. The next section of the statute, however, immediately limits that right, excepting from it issues of federal or state law “requiring an automatic change adversely affecting *some* or all beneficiaries.” 42 C.F.R § 431.220 (emphasis added). In other words, a Medicaid recipient lacks a right to contest federal or state law or policy determinations¹⁸ that affect his or her Medicaid coverage. *See generally Logan v. Zimmerman Brush Co.*, 455 U.S. 422 (1982) (observing that a state’s decision to terminate certain welfare benefits afforded recipients all the process that is due); *see also Rosen v. Goetz*, 410 F.3d 919, 926 (6th Cir. 2005) (rejecting recipient’s position that a hearing was required whenever recipient requests it or impermissibly seeks to challenge the State’s legal or policy judgment).

Here, CMS’s and DHSS’s determination to no longer fund what they deem an intolerable practice is a regulatory determination, which Appellants have no legal right to challenge. *See Benton*, 586 F.2d at 3 (“[M]atters of law and policy [as opposed to matters of fact or application of law] are not subject to any hearing

¹⁸ *Benton v. Rhodes*, 586 F.2d 1, 3 (6th Cir. 1978) (noting that there was no practicable difference between agency policy and state law).

requirements under the applicable regulations, whether the hearing be pre- or post-reduction.”); *Am. Airlines, Inc. v. C. A. B.*, 359 F.2d 624, 630 (D.C. Cir. 1966) (“Rule making has a unique value and importance as an administrative technique for evolution of general policy.”).

Appellants’ characterize the prohibition against the use of coercion including aversives as targeted discrimination, a manufactured litigation position, and an adjudication in the form of rulemaking. These characterizations are unsupported by anything in the record, unsupported by law, and nothing more than an attempt to seek to challenge regulatory determinations. There is nothing in the record to suggest that the Recipients are the only two individuals affected by CMS’s ban on coercion, like the use of aversives, or that this prohibition targeted Recipients in a discriminatory, after-the-fact fashion. The proposed HCB Setting Rule was published in the Federal Register in 2011, well before Appellants requested a fair hearing. CMS’s interpretation that the Rule’s ban on coercion includes aversives like GED also occurred before Appellants’ fair hearing request. Nor is Delaware’s HCBS Waiver a manufactured litigation position. Even before Appellants initiated this action, DDDS informed JRC (which in turn informed Appellants) that Delaware’s HCBS Waiver was in the process of being reviewed and renewed by CMS. More importantly, however, DHSS does not have the unilateral authority to amend its HCBS Waiver. The HCBS Waiver was renewed both through the formal

rulemaking notice and comment process as well as by approval of the provisions therein by CMS. *See S.D. ex rel. Dickson v. Hood*, 391 F.3d 581, 595-96 (5th Cir. 2004) (“As the agency entrusted with the administration of the Medicaid statute, CMS is required to determine that each state plan is in conformity with the specific requirements of the Medicaid act.”); *Cnty. Health Ctr. v. Wilson-Coker*, 311 F.3d 132, 134 (2nd Cir. 2002) (“[CMS] reviews each plan to assure that it complies with a long list of federal statutory and regulatory requirements.”).

Appellants have cited no authority for their proposition that because the ban on aversives affirmatively affects only two Delaware Medicaid recipients, it transforms the rule into an adjudication entitling Appellants to an opportunity to challenge it. In fact, this interpretation is flatly contradicted by Medicaid law itself, which states a hearing is not required for “if the sole issue is a federal or state law requiring an automatic change adversely affecting *some* or all beneficiaries.” 42 C.F.R § 431.220 (emphasis added). Nor is Appellants’ position supported by case law.

The only cases cited by Appellants recognize that adjudications are unlike rulemaking in that they normally require an evidentiary hearing.¹⁹ Those same

¹⁹ These cases also distinguish between rulemaking and adjudications. “The object of the rule making proceeding is the implementation or prescription of law or policy for the future, rather than the evaluation of a [recipient’s] past conduct. Typically, the issues relate not to the evidentiary facts, as to which the veracity and

cases, however, also make clear that CMS's and DHSS's ban on the use of aversives is a regulatory determination, not subject to individual, private challenges. In *Am. Airlines v. C. A. B.*, for instance, the District Court rejected plaintiff's claim that the rule at issue was in form and substance an adjudication because it affected only a few people. 359 F.2d at 631-32. In finding the regulation to have been properly promulgated through the rulemaking process, the court explained that the regulation was a "general regulation, applicable to all [recipients]" and that there was no basis to conclude the regulation was a sham rather than a genuine classification. *Id.* at 631.

Similarly, CMS's and DHSS's prohibition against coercion and the use of aversives is not an adjudication, but a duly promulgated regulation that applies to all Medicaid-qualified providers and recipients. There has been no "attempt to adjudicate the merits of individual [recipients]." *Id.* at 636. The regulations are not "based on grounds that are individually assessed." *Onyx Properties*, 838 F.3d at 1046. Nor are they, as one court described it, "'goats' being separated from favored sheep"—classification aimed to discriminate against or alternatively grant preferential treatment to a class of individuals. *Am. Airlines*, 359 F.2d at 631; *see also Capitol Airways, Inc. v. C.A.B.*, 292 F.2d 755, 758 (D.C. Cir. 1961) (finding a

demeanor of witnesses would often be important, but rather to the policy-making conclusions to be drawn from the facts." *Am. Airlines*, 359 F.2d at 630.

regulation that had redrawn the rules of the game to constitute rulemaking rather than adjudication as it applied to everyone in the industry). The prohibition against the use of coercion, such as aversive conditioning, is meant to ensure quality care in all Medicaid-qualified home and community based settings, a safeguard that is designed to protect all Medicaid recipients against unacceptable conditions. Neither federal or state law nor due process allow individual Medicaid recipients or their guardians to challenge these policy judgments, particularly on individualized grounds that played no part in that policy decision. *Benton*, 586 F.2d at 3 (explaining that a recipient is not entitled to a hearing to contest issues of federal law either after or in advance of the law’s implementation).

2. **The Hearing Officer Afforded Appellants a Meaningful Fair Hearing to Contest Any Factual Disputes as to Whether the Ban on Coercion and Aversive Conditioning Applies to GED.**

Appellants have failed to demonstrate a valid factual or legal dispute as to whether the HCB Setting Rule and Delaware’s HCBS Waiver ban the use of GED (*i.e.*, whether federal or state law automatically precluded GED from being a Medicaid-covered service). The HO nevertheless gave Appellants a fair hearing to contest any factual disputes as to whether the ban on coercion and aversive conditioning applied to GED. *See Rosen*, 410 F.3d at 926 (explaining the “dichotomy between impermissible challenges to a State’s legal or policy judgment on the one hand and permissible challenges to the relevant facts or application of

law to a given beneficiary”); *Washington v. DeBeaugrine*, 658 F. Supp. 2d 1332, 1335 (N.D. Fla 2009) (noting that the purpose of a fair hearing is to resolve factual disputes, like the alleged misapplication of the law to the facts). Appellants were provided a fair hearing as to the issue of Medicaid coverage and the HO further instructed that, should GED be found to be a covered service, Appellants would be afforded another fair hearing to demonstrate its medical necessity.

At the threshold fair hearing, and in the briefing preceding it, Appellants wholly sidestepped the issue of Medicaid coverage, instead using the opportunity to attack the federal and state laws’ prohibition on coercion and averse conditioning. Nowhere in their briefing or even at the fair hearing did Appellants attempt to explain how the use of GED is allowable under Medicaid law. This does not mean Appellants were not provided with an opportunity to contest any factual or legal issue as to Medicaid coverage. Rather, the HO noted there was no limit on Appellants’ “ability to present witness and/or testimony to prove Medicaid coverage.” A0966. Appellants’ deliberate choice not to present evidence but rather to use the hearing to challenge the underlying policy determination (something which they have no legal right to challenge) cannot later support their argument that they were denied due process.

3. Appellants were Given Adequate Notice Regarding the Prohibition on GED.

Likely because they are unable to plausibly argue that GED is not a prohibited form of coercion or averse conditioning, Appellants rely heavily on purported claims of procedural inadequacies in an attempt to overturn the decision that GED is not a Medicaid covered service. As a threshold matter, however, Appellants must show a right to a hearing before they are entitled to any notice under the Due Process Clause. As explained above, Appellants lack a right to challenge the policy decision banning the use of GED.²⁰ *Nat'l Fuel Gas Distribution Corp. v. TGX Corp.*, 749 F.Supp. 466, 469 (W.D.N.Y. 1990) (“The defendants’ due process claim has been rejected by this Court, it having been found that in the context of non-adjudicatory administrative proceedings formal notice is not required by the Constitution.”).

As to any notice required by state regulations, Appellants were given more than adequate notice regarding DHSS’s grounds for prohibiting GED. Appellants’ claims that they were given inadequate notice is remarkable considering the many letters and meetings that DHSS has issued and convened over the years with the

²⁰ Nor are Appellants entitled to formal notice regarding any amendments in Delaware’s HCBS Waiver. The only notice to which they are entitled, like everyone else, is a published version of the proposed waiver and an opportunity to submit comments. Neither Appellants nor JRC availed themselves of this opportunity.

Guardians, JRC, as well as their attorneys.²¹ Before directing JRC to cease the use of GED on Recipients, DDDS met with the families in October 2013 and explained GED would no longer be covered as part of Medicaid services. Additionally, DDDS sent letters to JRC, whose attorneys also represent Appellants, directing JRC to discontinue GED, noting GED would be prohibited under Delaware's proposed HCBS Waiver renewal and also citing to a portion of CMS's Region I letter. A0014-17.

The Fair Hearing Summary also provided sufficient notice to Appellants. The summary provided notice that GED was prohibited under Delaware's HCBS Waiver and policies, and the legal authority for this prohibition. Appellants were aware as a practical matter why GED was, and remains, prohibited under federal and state Medicaid law. Significantly, at no point during the fair hearing did counsel for Appellants suggest to the HO that they were unable to effectively address the issue of Medicaid coverage due to a lack of notice. The significant procedural history in this case documents that the Appellants have had appropriate regulatory notice regarding the Medicaid prohibition against use of GED.

²¹ Appellants seem to take issue with the fact that neither CMS nor DDDS provided Appellants with evidentiary justifications for their policy decision—namely evidence that coercion including averse conditioning undermines the well-being of its recipients. However, adequate notice, to the extent Appellants were entitled to any, does not include requiring the State to provide detailed reasoning and evidentiary proof to support its policy judgments. *See* DSSM 5302(K).

II. The Hearing Officer Correctly Found that GED is Not a Covered Service

A. Question Presented

Whether aversives are “covered” services under Delaware’s HCBS Waiver.

B. Scope of Review

On a statutory appeal of DHSS’s fair hearing decision, pursuant to 31 *Del. C.* § 520, the reviewing court determines whether the decision is supported by substantial evidence and free from legal error. *Urban*, 930 A.2d at 864. Absent an abuse of discretion, the agency decision must be affirmed. *Stoltz Management Co.*, 616 A.2d at 1208.

C. Merits of Argument

As the HO found, both federal and state law prohibit the use of GED in Medicaid-funded home and community based settings. The proscription against the use of coercion without question prohibits the application of electric shock to modify and control behavior. Similarly, the prohibition in Delaware’s HCBS Waiver (reviewed and approved by CMS, and consistent with federal guidance from CMS) on the use of aversive conditioning, which defined the term as “contingent application of startling, painful or noxious stimuli,” unquestionably applies to GED.

To date, Appellants have offered no explanation as to why GED is outside the scope of this prohibition. Rather, Appellants attack the motive of DHSS and CMS and argue that CMS’s guidance letters interpreting GED as an impermissible form

of coercion are entitled to no deference. At no time during the proceedings have Appellants offered any other interpretation, let alone a reasonable one, in support of their position that GED is not prohibited. Notwithstanding Appellants' attempt to obfuscate the issue, there is no doubt that the use of electric shock to force individuals into compliance is a form of coercion and aversive conditioning banned under both federal and state law. As such, GED cannot, as a matter of law, be a Medicaid-covered service.

1. GED is Banned Under Federal Law.

The HCB Setting Rule, the proposed version first published in 2011 and finalized in 2014, sets forth acceptable qualities and characteristics of all HCB settings receiving federal Medicaid funds. *See generally* 42 C.F.R. § 441.530. The final rule makes clear that many of the qualities of a home and community based setting are not newly promulgated requirements, but serve to provide greater clarity as to what qualities settings must exhibit under a waiver program. 19 Fed. Reg. 2948-01, 2949. This regulation explicitly requires assurances from States that home and community based settings used to serve Medicaid recipients protect an individual's rights of privacy, dignity and respect, and freedom from coercion and restraint. 42 C.F.R. § 441.530(a)(1)(iii).

CMS, through its regional administrators, has interpreted this right as prohibiting the use of aversives such as GED on Medicaid recipients. Application

of GED, the Region I letter explained, violates acceptable characteristics of the home and community based settings, citing to the then-proposed HCB Setting Rule. This letter was issued well before Appellants initiated this proceeding. CMS more recently confirmed this interpretation in the Region III letter, noting GED was unacceptable under Delaware’s HCBS Waiver. The Region III letter was signed by the head of CMS’s Division of Long Term Care Services and Support, a division with nationwide jurisdiction.²²

These letters interpreting CMS’s own regulation are entitled to substantial, if not mandatory, deference. *Cnty. Health Ctr.*, 311 F.3d. at 138 (agency interpretation of its own regulation is entitled to mandatory judicial deference); *Skandalis v. Rowe*, 14 F.3d 173, 178 (2d Cir. 1994) (“When an agency construes its own regulations, such deference is particularly appropriate ... and even more appropriate where, as here, we consider a small corner of a labyrinthine [Medicaid] statute.”). This is because of the greater expertise and familiarity an agency has with its own enacted regulations than of federal statutes. *Elgin Nursing & Rehab. Ctr. v. U.S. Dep’t of Health & Human Servs.*, 718 F.3d 488, 493 (5th Cir. 2013) (“The most important reason for extending greater deference to an [agency’s opinion] that purports to interpret an agency’s own ambiguous regulation, than [that which]

²² The Division of Long Term Care Services and Supports is the arm of CMS that oversees the implementation of the HCB Setting Rule in all community settings paid for with Medicaid funds. Thus, this letter and its content are binding nationwide.

interprets the organic statute directly . . . is the greater expertise and familiarity of the agency with respect to the history and content of its own enacted rules.”).

Appellants complain that these letters are somehow too informal for them to be accorded any weight, because they were written by regional administrators. This argument has already been soundly rejected by the courts. As the United States Court of Appeal for the Second Circuit explained, “CMS regional staff reviews State plans and plan amendments, discusses any issues with the Medicaid agency, and consults with central office staff on questions regarding application of Federal policy.” *Cnty. Health Ctr.*, 311 F.3d at 138. Accordingly, the Court explained that courts “take care not lightly to disrupt the informed judgments of those who must labor daily in the minefield [like the regional administrators] of an often arcane policy, especially given the substantive complexities of the Medicaid statute.” *Id.*

Appellants next seek to undermine these interpretations by arguing that the letters amount to post hoc rationalizations for DHSS. This claim also fails for several reasons. One, CMS is not a party to the litigation. Two, it assumes, without any factual support, that a state agency like DHSS can dictate to the federal government how to issue decisions. Lastly, the Region I letter (citing to the proposed HCB Setting Rule) informing Massachusetts that GED is unacceptable in home and community based settings was issued months before Appellants sought to challenge termination of GED for the Recipients through a fair hearing.

Thus, CMS's position regarding the use of GED cannot constitute a post hoc litigation position. *See Massachusetts v. Sebelius*, 638 F.3d 24, 34 (1st Cir. 2011) (rejecting claim that the agency's letter was a litigation tactic and should be afforded no deference since the basis for the agency's position had been clear before the litigation began). Nothing in Appellants' claims demonstrates why CMS's interpretation of its regulation prohibiting the use of coercion is not reasonable or why the HO, or this Court, should not rely on these interpretations. As these CMS letters are the federal agency's interpretation of one of its own regulations, they must be binding unless shown to be clearly erroneous—a showing Appellants cannot satisfy.

2. GED is Banned Under Delaware's HCBS Waiver.

Delaware's HCBS Waiver carries the force and effect of law. *Benton*, 586 F.3d at 3 (“[W]hen agency regulations are validly promulgated pursuant to legislative authority they have the force and effect of law.”). The HCBS Waiver explicitly prohibits the use of GED. Before the HCBS Waiver renewal went into effect, it was published through the administrative process for notice and comment, and was concurrently reviewed and approved by CMS. Appellants seek to undermine its validity by claiming, with no factual support, that this was simply a

litigation tactic by DHSS and should thus be invalidated.²³ Critically, however, DHSS cannot unilaterally make changes to its HCBS Waiver. Not only must the HCBS Waiver go through the formal rulemaking process, but CMS, the federal entity tasked with ensuring compliance with Medicaid laws, had to approve the HCBS Waiver and contents. In other words, CMS determined that Delaware’s HCBS Waiver, including the ban on aversive conditioning, complied with Medicaid laws and regulations. This finding must be accorded substantial deference. *See Rosen*, 410 F.3d at 927 (“CMS, the agency that authored and promulgated the regulations, has approved the State’s policies as fully compliant with its regulations, a determination to which we owe substantial deference.”); *see also Bertrand v. Maram*, 2006 WL 2735494, at *6 (N.D. Ill. Sept. 25, 2006) (affording deference to CMS’s determination that the provision in a state waiver application was reasonable); *Stogsdill v. S. Carolina Dep’t of Health & Human Servs.*, 410 S.C. 273, 280 (S.C. App. 2014) (holding that the provisions in the waiver are given the force and effect of the law), *reh’g denied* (Oct. 23, 2014), *cert. granted* (Apr. 9, 2015); *The Maryland Dep’t of Health & Mental Hygiene v. Centers For Medicare & Medicaid*

²³ Appellants also claim that Delaware’s HCBS Waiver is in effect an adjudication on the merits, which Appellants are entitled to challenge. This is not true. The prohibition against aversive conditioning did not make any individual assessments regarding the Recipients, but as explained above, is a policy determination by CMS and DHSS to prohibit the use of coercion and ensure the safeguard and welfare of all Medicaid recipients.

Servs., 542 F.3d 424, 428 (4th Cir. 2008) (holding that “[t]he administrative process through which state plan amendments are considered also counsels deference”). That deference requires a ruling that aversives, prohibited under the HCBS Waiver, are barred in all Delaware Medicaid-qualified home and community based settings.²⁴

3. Medical Necessity Does Not Determine Medicaid Coverage.

Seeking to challenge CMS’s and DHSS’s policy determination through the backdoor, Appellants incorrectly claim that if a treatment modality is “medically necessary,” as they argue they can prove GED is, then it must be covered by Medicaid. This is not, nor has it ever been, the law. The issues of Medicaid coverage and medical necessity are legally and conceptually distinct. As the Opinion correctly found, “medically necessary treatment does not automatically equate to medical coverage.” Op. at 4. Medicaid does not require states to fund all medically necessary services and treatment modalities for adults. For example, chiropractic and adult dental services are not covered services under Delaware’s State Plan or HCBS Waiver, irrespective of their medical necessity in a given situation. Thus, Delaware Medicaid recipients are not entitled to receive them using Medicaid funds. *See generally* 42 C.F.R. § 440.225.

²⁴ Appellants do not have a right to challenge the amendments to Delaware’s HCBS Waiver through this administrative appeal. Appellants could have challenged the amendments to the HCBS Waiver pursuant to 29 *Del. C.* § 10141. That right, though, expired 30 days after the changes went into effect.

Medicaid law imposes only a reasonableness standard in determining the scope and extent of services provided under the State Plan or through HCBS Waiver. *Beal v. Doe*, 432 U.S. 438, 444 (1977) (“This 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.” (internal quotation marks omitted)). Federal and state recognition that electrically shocking Medicaid recipients to control behavior is intolerable is reasonable and consistent with the objectives of Medicaid, one of which is to ensure the well-being of its recipients. Additionally, even if CMS did not prohibit the use of aversives for HCBS programming nationwide, Delaware would still have the authority to prohibit its use under this reasonableness standard.

Dismissing any harm to Recipients that could arise from electrically shocking them, Appellants claim that DHSS’s prohibition against coercion and electric shock treatment is unreasonable and arbitrary. Appellants go so far as to claim that Delaware’s HCBS Waiver permits individualized treatment plans to override the safeguards mandated by Delaware’s HCBS Waiver. This interpretation would provide case managers, clinicians or anyone determining the treatment plan for Medicaid recipients—including decisions by another state court—free rein to decide how best to “treat” Delaware Medicaid recipients, irrespective of the standard of

care imposed under Medicaid law. Appellants have cited to nothing for this remarkable position.²⁵ Nor can they, as this is not the law.

III. The Final Decision is Not Discriminatory in Violation of Title II of the Americans with Disabilities Act

A. Question Presented

Whether Appellants may challenge the HO decision as prohibited discrimination in violation of Title II of the ADA.

B. Scope of Review

This Court must review questions of law *de novo*. *Avallone v. DHSS*, 14 A.3d 566, 570 (Del. 2011).

C. Merits of Argument

Appellants argue that the Superior Court “erroneously concluded that Plaintiff failed, at the administrative proceeding, to preserve his claim that DHSS’ actions violated Title II of the ADA” OB at 42. The Superior Court ruled it could not consider the ADA argument because it was “not raise[d] . . . during the January 13, 2016 hearing and it is not part of the record.” Op. at 20. Appellants now assert that the “administrative record . . . clearly supports viable and substantive discrimination

²⁵ The only case cited by Appellants on the issue of optional coverage makes clear Medicaid coverage is assessed only by a reasonable standard. *Lankford v. Sherman*, 451 F.3d 496, 506 (8th Cir. 2006). That case does not suggest that CMS and the state entity tasked with administering Medicaid cannot impose reasonable, safeguard measures to ensure the wellbeing of its recipients.

claims against DHSS.” OB at 42. The fact the record provided in the Fair Hearing *may support* a viable ADA claim (a position which DHSS does not concede), does not mean that the ADA argument was raised or addressed in the Fair Hearing, or that it became part of the record below as to preserve it for appeal.

In support of their argument that the ADA claim was preserved at the administrative proceeding, Appellants provide a single record cite: their Request for a Fair Hearing, wherein they purport to “reserve” various rights and remedies in a few boilerplate sentences. A0028. Section F of that request (“Reservation of All Rights and Remedies”) states that “[a]ny and all other grounds upon which our Clients may seek damages . . . including pursuant to Title II of the [ADA] . . . are also expressly reserved.” A0028-29. The scope of the Fair Hearing was addressed in numerous subsequent pieces of correspondence, briefing, and conferences. In none of those communications or motions did Appellants again raise or discuss an ADA claim.

Appellants allege in their brief that “DHSS and the HO disregarded [Recipients’] ADA claim and dismissed [their] medical conditions and treatment needs as ‘just simply irrelevant.’” OB at 43. However, a review of the citations provided reveals that the ADA was not discussed in any of them. Instead, the citations provided reflect a discussion of whether consideration of “medical necessity” was necessary to determine if aversives were a covered service under

Delaware's HCBS Waiver. *See* A101 n. 9; A623; and A904 (as cited by Appellants).²⁶

Appellants appealed the Fair Hearing determination pursuant to Superior Court Rule 72, titled "Appeals from Certain Commissioners, Boards and Courts." Appellants' Notice of Appeal made clear they appealed the "specific ruling in the April 25, 2014 Dispositions that the 'reasonableness and necessity of using aversive behavioral interventions . . . is not an issue in this fair hearing proceeding.'" A0388. Subsection (g) of Rule 72 provides that the appeal shall be heard and determined "from the record of the proceedings below." *See also Tatten Partners, L.P. v. New Castle County Bd. Of Assessment Review*, 642 A.2d 1251, 1262 (Del. Super. 1993) (holding that "when [the Superior] Court acts in its appellate capacity on appeal from an administrative board, the Court will not consider issues not raised before the tribunal"). The Superior Court, therefore, properly ruled that it could not consider Appellants' ADA argument because it was not addressed at the Fair Hearing and was not a part of the record. *Op.* at 20.

This Court's jurisdiction is limited to "questions fairly presented to the trial court," except "when the interests of justice so requires." Supreme Ct. Rule 8. The

²⁶ A786-787 and 789 was also cited by Appellants for supporting the proposition that their ADA claim was dismissed as irrelevant. These pages, however, consist of a Table of Contents and Table of Authorities in DHSS's Reply Brief in the Fair Hearing proceedings.

claim of ADA violation was not presented or addressed below. With the exception of a passing mention in the boilerplate “reservation of rights” in the Request for Fair Hearing, the record below is silent with respect to an ADA claim. Justice does not require that this Court address the merits of this argument for the first time, now.

CONCLUSION

DHSS respectfully requests that this Court affirm the decision that GED is not a Medicaid covered service, dismiss Appellants' appeals with prejudice, and grant DHSS such further relief as this Court deems just and proper.

**STATE OF DELAWARE
DEPARTMENT OF JUSTICE**

/s/ Lauren E. Maguire _____

Lauren E. Maguire (#4261)
Adria B. Martinelli (#4056)
Deputy Attorneys General
Carvel State Office Building
820 N. French Street, 6th Floor
Wilmington, DE 19801
(302) 577-8400

Dated: July 10, 2018

Attorneys for Defendant Below, Appellee