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COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
CIVIL ACTION
No. 2081CV01893

DAYANNE N. & others[1]

vs.

CHARLES BAKER, GOVERNOR & others[2]

DECISION AND ORDER ON PLAINTIFFS' MOTION FOR INJUNCTIVE RELIEF

Dayanne N., Natalya M., Aslyn P., Charmaine C., and Ana R. ("child plaintiffs"), along with the Medicaid Orthodontists of Massachusetts Association, Inc. ("MOMA") (collectively with child plaintiffs, "plaintiffs"), filed this action against Charles Baker, Governor of Massachusetts; Marylou Sudders, Secretary of the Executive Office of Health and Human Services; and Daniel Tsai, Assistant Secretary for MassHealth (collectively, "EOHHS") concerning changes to MassHealth's authorization process, which allegedly restricts coverage for child and youth orthodontic treatment. The matter is presently before the court on the plaintiffs' motion for a preliminary injunction, pursuant to Mass. R. Civ. P. 65, seeking to enjoin the EOHHS from: (1) denying coverage to eligible children and youth based on the purported unlawful changes to the authorization process; and (2) eliminating the Peer-to-Peer Review process, which previously allowed providers to challenge incorrectly denied authorizations for orthodontic coverage. After hearing and review of all materials submitted, including those which have been impounded, the plaintiffs' motion is **ALLOWED** in part and **DENIED** in part for the following reasons.

[1] Natalya M., Aslyn P., Charmaine C., and Ana R., on behalf of themselves and all others similarly situated; and Medicaid Orthodontists of Massachusetts Association, Inc.
[2] Marylou Sudders, Secretary of the Executive Office of Health and Human Services; and Daniel Tsai, Assistant Secretary for MassHealth.

FACTUAL BACKGROUND

The record before the court, consisting of the verified complaint, exhibits thereto, and affidavits, provides the following factual background.[3] Additional facts are reserved for discussion below.

A. MassHealth Medicaid Program

The Medicaid program, authorized by Title XIX of the Social Security Act, is a voluntary, cooperative federal and state program, which provides medical services for low-income persons. See 42 U.S.C. §§ 1396 et seq. If a state chooses to participate in the program, it must comply with requirements imposed by the Medicaid statutes and by the Secretary of Health and Human Services. One of the requirements is that participating states must cover Early and Periodic Screening, Diagnostic and Treatment ("EPSDT") for Medicaid-eligible children under age twenty-one. 42 U.S.C. §§ 1396a(a)(10)(A), 1396a(a)(43), 1396d(a)(4)(B), 1396d(r). EPSDT includes dental services for "relief of pain and infections, restoration of teeth, and maintenance of dental health." 42 U.S.C. § 1396d(r)(3)(B).

Massachusetts participates in the Medicaid program via the establishment of MassHealth, statutorily known as the Division of Medical Assistance. G. L. c. 118E, § 9. It is an agency of the EOHHS, and DentaQuest is the third-party subcontractor that runs the MassHealth dental program pursuant to a contract with the EOHHS.

MassHealth must provide EPSDT "in accordance with reasonable standards of medical and dental practice determined by the agency after consultation with recognized medical and dental organizations involved in child health care." 42 C.F.R. § 441.56(b)(2). All medically

[3] The Massachusetts Law Reform Institute submitted a brief as amicus curiae in support of the plaintiffs' motion for a preliminary injunction.

necessary services must meet professionally recognized standards of health care. 130 Code Mass. Regs. § 450.204(B).

B. Coverage for Orthodontic Care and the HLD Index

MassHealth covers certain dental services, including orthodontic treatment, subject to prior authorization, once per member per lifetime before age twenty-one if the care is medically necessary. 130 Code Mass. Regs. § 420.431(C)(3). A provider submitting a prior authorization request for orthodontic services must include appropriate and sufficient documentation to justify the medical necessity for the service. 130 Code Mass. Regs. § 420.410(C)(1). Orthodontic treatment is medically necessary when a child's teeth are so badly misaligned (maloccluded) that it constitutes a handicap (handicapping malocclusion). 130 Code Mass. Regs. § 420.431(C)(3). MassHealth determines whether a malocclusion is handicapping based on clinical standards for medical necessity as provided in Appendix D of the MassHealth Dental Manual. Id. Appendix D is a form called the Handicapping Labio-Lingual Deviations Index ("HLD form" or "HLD Index"), which serves as the screening tool, i.e., the prior authorization, to determine whether MassHealth will cover treatment.

The HLD form contains detailed instructions on how to take measurements and score a child's condition. To complete the HLD form, the orthodontist examines the child and takes diagnostic measurements, photographs, and x-rays. The HLD Index then assigns scores for various dental conditions, and if the sum of the scores is high enough, MassHealth provides coverage for treatment.[4] If the sum of the scores is not high enough, MassHealth denies coverage. Where a patient does not meet the threshold score on the HLD Index, a provider can submit a medical necessity narrative with supporting documentation to demonstrate why

[4] There are certain conditions that automatically qualify as a handicapping malocclusion.

treatment is medically necessary. If the prior authorization is denied, the provider can submit an online request for reconsideration of the decision. Generally, a dental reviewer who is different than the original reviewer conducts the reconsideration.[5]

Until recently, the diagnostic instructions were consistent with national standards. However, on March 25, 2020, MassHealth changed the scoring instructions on the HLD Index via Transmittal Letter DEN-104, and again, on June 26, 2020, via Transmittal Letter DEN-106 (collectively, "Transmittal Letters"). These changes were promulgated without notice or a public hearing.[6]

Although MassHealth referred to the changes as a "clarification," the plaintiffs claim that these new standards are more restrictive than the prior instructions, and as a result, it has caused hundreds of children, including the child plaintiffs, who previously were eligible to become ineligible for orthodontic treatment.[7] The plaintiffs also claim that most of the changes are a departure from professionally recognized standards of care, and as such, most providers feel they are unable to certify the current HLD form under the pains and penalties of perjury, as is required. Consequently, the plaintiffs claim, these changes have virtually foreclosed MassHealth members' access to orthodontic care across the state.

The plaintiffs also allege that MassHealth was aware that these changes were not "technical edits" or a clarification of standards, because on May 21, 2018, Tracy Gilman Chase ("Chase"), the Regional Director of DentaQuest, sent her supervisor, James E. Thommes ("Thommes"), DentaQuest's Vice President of Clinical Management, an email inquiring about

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[5] MassHealth members also may request a fair hearing to appeal the denial of a prior authorization. 130 Code Mass. Regs. §§ 610.012(A), 610.031(A), 610.032(A)(1).

[6] For the sake of brevity, the court will not list the changes to the instructions; however, they are set forth in the Complaint.

[7] MOMA's board of directors estimate that sixty percent of children, who were eligible previously, no longer meet the HLD Index threshold for coverage.

the effect of these changes. Thommes stated, "Approvals . . . would drop," and "[e]xpect significant noise."

C. Peer-to-Peer Review Process

Several years ago, MassHealth promulgated rules that allowed providers to challenge incorrectly denied authorizations for orthodontic coverage. The rules regarding the Peer-to-Peer Review process are set forth in MassHealth's Office Reference Manual. Through the establishment of this process, providers can appeal denials on their patients' behalf by conferring over the phone with MassHealth orthodontic consultants and pointing out conditions that were missed or overlooked. The plaintiffs allege that between 2014 and 2019, one doctor in particular, Dr. Mouhab Z. Rizkallah ("Dr. Rizkallah"), had 62% of initially denied cases overturned via the Peer-to-Peer Review. Because such a high number of denials are overturned, the plaintiffs argue that the Peer-to-Peer Review process is critical to protecting patients' rights.

On April 27, 2020, MassHealth notified providers via email that as of May 1, 2020, MassHealth would no longer offer Peer-to-Peer Review. Rather, requests for reconsideration must be submitted through the online portal or via a patient's request for a fair hearing.

D. Claims

The plaintiffs have asserted six claims. Count 1 alleges that the defendants violated the plaintiffs' civil rights pursuant to 42 U.S.C. § 1983 as well as the plaintiffs' rights under the Medicaid EPSDT statutes by denying coverage for orthodontic services. Count 2 alleges that the defendants violated the Administrative Procedures Act, G. L. c. 30A, § 2, by failing to comply with the notice and hearing requirements before promulgating the Transmittal Letters and eliminating the Peer-to-Peer Review process. Count 3 asserts a claim of unlawful discrimination under G. L. c. 151B, § 4(10). Count 4 seeks to enjoin the EOHHS from enforcing the

Transmittal Letters. Count 5 asserts a due process violation under 42 U.S.C. § 1396a(a)(3). Finally, Count 6 asserts a claim for declaratory relief, in which the plaintiffs seek a declaration of their rights under the relevant Medicaid statutes.

DISCUSSION

The plaintiffs seek a preliminary injunction pursuant to Mass. R. Civ. P. 65, alleging that the defendants failed to comply with the notice and hearing requirements set forth in G. L. c. 30A, § 2 and G. L. c. 118E, § 12 before issuing the Transmittal Letters and eliminating the Peer-to-Peer Review program. As such, the plaintiffs seek to enjoin the EOHHS from: (1) withholding prior authorization for comprehensive orthodontic treatment to eligible children and youth based on the new criteria and instructions set forth in the Transmittal Letters; and (2) eliminating the Peer-to-Peer Review appeal process. Because the plaintiffs' preliminary injunction request implicates Count 2 (violation of G. L. c. 30A, § 2 and G. L. c. 118E, § 12), the court will limit its discussion to that claim.[8]

A. Standard of Review

Under the well-known standard for granting a preliminary injunction, the plaintiffs must show that they are likely to succeed on the merits and that in the absence of an injunction they will suffer irreparable harm sufficient to outweigh the harm that an erroneous injunction would impose on the defendants. GTE Prods. Corp. v. Stewart, 414 Mass. 721, 722-723 (1993); Packaging Indus. Grp., Inc. v. Cheney, 380 Mass. 609, 617 (1980). Where, as here, the plaintiffs seek to enjoin governmental action, the court must also determine if the relief requested promotes the public interest or, alternatively, will not adversely affect the public.

[8] The motion also implicates the plaintiffs' civil rights claim (Count 1), but because the plaintiffs are entitled to the relief requested with respect to their Administrative Procedures Act claim (Count 2), the court need not discuss Count 1.

Commonwealth v. Mass. CRINC, 392 Mass. 79, 89 (1984). A preliminary injunction is a significant remedy that should not be granted unless the plaintiffs have made a clear showing of entitlement thereto. Student No. 9 v. Board of Educ., 440 Mass. 752, 762 (2004). In balancing these factors, the court considers not so much "the raw amount of irreparable harm the party might conceivably suffer, but rather the risk of such harm in light of the party's chance of success on the merits. Only where the balance between these risks cuts in favor of the moving party may a preliminary injunction properly issue." Packaging Indus. Grp., Inc., 380 Mass. at 617.

B. Analysis

Pursuant to G. L. c. 118E, § 12, MassHealth may adopt, promulgate, amend, and rescind rules and regulations that are suitable or necessary to carry out the provisions relating to the utilization of and payment for care and services available under the state's Medicaid plan. "Rules and regulations which restrict eligibility or covered services require a public hearing under section 2 of chapter 30A ["Section 2"]." Id. Section 2 also requires certain notices to be sent prior to the hearing. The crucial question presently before the court is whether the Transmittal Letters and the elimination of the Peer-to-Peer Review program constitute regulations that restrict eligibility or covered services, such that they are subject to the notice and hearing requirements in Section 2 and G. L. c. 118E, § 12.

Under the Administrative Procedures Act ("APA"), see G. L. c. 30A, §§ 1-25, "a regulation 'includes the whole or any part of every rule, regulation, standard or other requirement of general application and future effect, including the amendment or repeal thereof, adopted by an agency to implement or interpret the law enforced or administered by it.'" Carey v. Commission of Corr., 479 Mass. 367, 371 (2018), quoting G. L. c. 30A, § 1(5). Given the

purpose of the APA, courts interpret the definition of regulation broadly.[9] Id. "Nevertheless, the definition excludes 'regulations concerning only the internal management of the agency . . . and not substantially affecting the rights of or the procedures available to the public or that portion of the public affected by the agency's activities" [alterations omitted].[10] Id. at 371-372; quoting G. L. c. 30A, § 1(5)(b).

Here, the evidence weighs in the plaintiffs' favor that the Transmittal Letters, which changed the instructions and criteria on the HLD Index, substantially affected the rights available to MassHealth members. According to Dr. Rizkallah's affidavit, the new scoring instructions and criteria severely restrict coverage. In fact, MOMA estimates that sixty percent of children who previously qualified as having a medical necessity for orthodontic treatment no longer qualify. Although the defendants argue that the instructional changes were merely technical edits and clarifications and were "intended to fill in the details or clear up an ambiguity of an established policy," the court is not persuaded. Massachusetts Gen. Hosp. v. Rate Setting Comm'n, 371 Mass. 705, 707 (1977).

By the defendants' own admission in an email on May 21, 2018 from Thommes to Chase, the defendants were aware that the instructional changes would cause approvals to drop. However, "eligibility requirements can only be accomplished through the promulgation of rules since . . . [they] substantially affect the rights of the regulated parties." Trust Ins. Co. v. Commissioner of the Div. of Ins., 1997 Mass. Super. LEXIS 344 at *11 (Mass. Super. 1997). As a result, changes to eligibility requirements must be implemented in accordance with pertinent

[9] Although courts accord substantial deference to an agency's interpretation of its own regulations, courts do not defer to an agency's interpretation of the APA. Carey, 479 Mass. at 371.

[10] Regulations concerning the internal management of an agency are "those that concern the organizational structure of [the] agency . . . or those that are directed toward agency employees, instructing them on how they should perform their duties." Carey, 479 Mass. at 372. The regulations at issue in this case do not concern the internal management of MassHealth.

rulemaking requirements, such as the notice and public hearing requirements set forth in Section 2 and G. L. c. 118E, § 12.

The defendants, nonetheless, argue that the child plaintiffs cannot meet their burden because their providers failed to complete the medical necessity narrative portion on their HLD forms and because the child plaintiffs failed to exhaust their administrative remedies by failing to request a fair hearing. According to Dr. Rizkallah, the medical necessity narrative portion on the HLD form is rarely used by providers and rarely approved – under 1% of the time. Therefore, although this is an alternative basis for approving treatment, the lack of utilization and significantly low approval rate suggests that it is not a viable process for obtaining prior authorization. Additionally, although the child plaintiffs did not request a fair hearing to appeal their denials, it seems that pursuit of a fair hearing would have been fruitless in light of the new eligibility criteria. Accordingly, the court concludes that the plaintiffs have demonstrated a likelihood of succeeding in establishing that the promulgation of the Transmittal Letters are not exempt from the APA notice and hearing requirements and that the defendants failed to comply with same.[11]

As for the elimination of the Peer-to-Peer Review program, based on the competing facts and applicable regulations, the court concludes that the plaintiffs cannot meet their burden of demonstrating a likelihood of success in establishing that the elimination of the telephone review program substantially affects the rights of or procedures available to MassHealth members. See Carey, 479 Mass. at 371. The Peer-to-Peer Review program is not codified in any statute or

[11] The defendants also argue that the plaintiffs lack standing, and thus, the complaint should be dismissed. However, as stated during the motion hearing, the court will entertain the defendants' motion to dismiss at a later date. Nevertheless, the court has reviewed and considered the defendants' arguments in connection with the plaintiffs' burden in demonstrating a likelihood of success on the merits and finds them to be unavailing at this juncture.

regulation. Moreover, even with the elimination of the program, there are two alternative ways in which MassHealth members can challenge denials of prior authorizations. Providers can submit an online request for reconsideration or MassHealth members can request a fair hearing to appeal a decision. 130 Code Mass. Regs. §§ 610.001(a), 610.012. Dr. Rizkallah avers that the success rate for the Peer-to-Peer Review program significantly outweighs the success rate for online requests for reconsideration. While this may be an important consideration for the fact finder at trial, for the purposes of the present motion, the court is not persuaded that this one factor satisfies the plaintiffs' initial burden. Accordingly, the plaintiffs are not entitled to preliminary injunctive relief with respect to the elimination of the Peer-to-Peer Review program.

Turning to the remaining considerations of the preliminary injunction standard, the court concludes that in the absence of an injunction the plaintiffs will suffer irreparable harm sufficient to outweigh the harm that an erroneous injunction would impose on the defendants. GTE Prods. Corp., 414 Mass. at 722-723. The irreparable harm that will result to the child plaintiffs in the absence of an injunction is evident. The children allegedly are suffering from developmental harm and no longer have access to proper treatment in light of the new eligibility requirements on the HLD Index. Their situation is further complicated by the fact that they are only eligible for orthodontic treatment until age twenty-one, and at least one of the child plaintiffs is at risk of aging out of the system. See Massachusetts Ass'n of Older Ams. v. Sharp, 700 F.2d 749, 753 (1st Cir. 1983) ("Termination of benefits that causes individuals to forego such necessary medical care is clearly irreparable injury."). Moreover, the balance of harms weighs in the plaintiffs' favor. The potential harm to the child plaintiffs outweighs the state's potential budgetary concerns, especially given that the defendants likely violated state law (i.e., the APA). See, e.g., Bontrager v. Indiana Family & Soc. Servs. Admin., 697 F.3d 604, 611 (7th Cir. 2012),

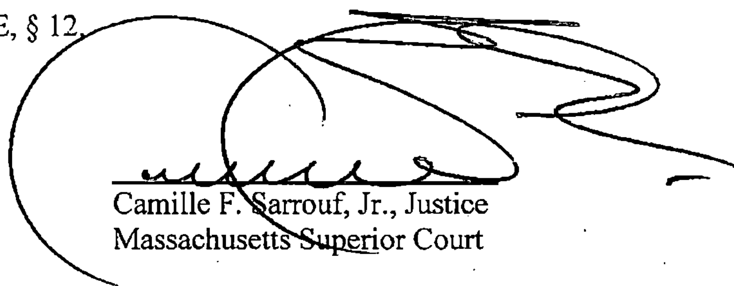
and cases cited. Finally, the public interest mirrors factors already considered above. The public interest lies with safeguarding public health rather than any potential budgetary interest the state may have. See, e.g., Pashby v. Delia, 709 F.3d 307, 331 (4th Cir. 2013) ("[T]here is a robust public interest in safeguarding access to health care for those eligible for Medicaid" [citation omitted]).

Accordingly, the court concludes that the plaintiffs have met their burden in proving an entitlement to the preliminary injunctive relief requested with respect to the new instructions in the Transmittal Letters.

ORDER

For the foregoing reasons, it is hereby **ORDERED** that the plaintiffs' motion for preliminary injunction is **ALLOWED** with respect to the new criteria set forth in the Transmittal Letters, and is **DENIED** with respect to the Peer-to-Peer Review program.

It is further **ORDERED** that the defendants are preliminary enjoined from implementing the changes to the scoring instructions on the HLD Index set forth in Transmittal Letters DEN-104 and DEN-106 unless and until they comply with the notice and a public hearing requirements of G. L. c. 30A, § 2 and G. L. c. 118E, § 12.



Camille F. Sarrouf, Jr., Justice
Massachusetts Superior Court

December 14, 2020