Respectfully submitted,

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August 24, 2020

CERTIFICATE OF SERVICE

I certify that on this date I served by email a copy of the forgoing Memorandum in Opposition to Plaintiffs Motion for Preliminary Injunction and in Support of Defendants' Motion to Dismiss on counsel for the plaintiffs—Joel Rosen and Matthew Perry.

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August 24, 2020

COMMONWEALTH OF MASSACHUSETTS

MIDDLESEX, ss.

SUPERIOR COURT
C.A. NO. 2081CV01893

DAYANNE N. et al.,

Plaintiffs,

v.

CHARLES BAKER, Governor, et al.,

Defendants.

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION AND IN SUPPORT OF DEFENDANTS' EMERGENCY MOTION TO DISMISS

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INTRODUCTION

This case is about the instructions for MassHealth's "prior authorization" process for comprehensive orthodontic treatment. In accordance with federal law, MassHealth requires providers to seek prior authorization from MassHealth before providing comprehensive orthodontic treatment to MassHealth members. A provider submitting a request must include "sufficient documentation to justify the medical necessity for the service," which, for comprehensive orthodontic treatment, means establishing that the member has a "handicapping malocclusion." (This is to be contrasted with a malocclusion that is purely cosmetic, for which orthodontic treatment is not a medical necessity and for which Medicaid does not pay.)

MassHealth uses the HLD Index Form to administer the prior authorization process for orthodontic treatment. (HLD stands for "handicapping labio-lingual deviations.") This sub-regulatory form, explicitly envisioned and described in 130 C.M.R. § 420.431(C)(3), gives providers three alternative methods to establish that a member has a medical need for orthodontic treatment. First, the provider may show that the member has one of seven conditions that automatically qualifies the member for treatment, each of which alone constitutes a "handicapping malocclusion." Second, the provider may score the member based on several measurements, with a score of 22 or more automatically qualifying the member for treatment. Finally, the provider may submit a medical necessity narrative, with accompanying detail and documentation, explaining why treatment is medically necessary to treat the member's handicapping malocclusion even though the patient might not have qualified under the first two methods. If MassHealth's third-party administrator ultimately determines that the provider's showing on all three prongs is inadequate, MassHealth denies the prior authorization and the member has a right to an administrative hearing, followed by judicial review under G.L. c. 30A.

According to the complaint's allegations, unidentified orthodontists sought prior authorization from MassHealth to provide comprehensive orthodontic treatment to five named

child plaintiffs. MassHealth's third-party provider denied the prior authorization requests as to each child. Although neither the prior authorization requests nor the notices of denial are attached as exhibits to the complaint, the child plaintiffs, accompanied by an associational plaintiff, attribute the denials to technical modifications MassHealth made to the instructions that accompany the HLD Index Form in March and June of this year. They claim that these technical changes amount to an impermissible restriction on comprehensive orthodontic treatment, that such restrictions can only be accomplished via regulation, and therefore that MassHealth's current HLD Index Form (with the instructions) should be enjoined.

This Court should deny plaintiffs' preliminary injunction motion, and instead dismiss the complaint, because they lack standing. The children lack standing because there are no allegations in the complaint that they have handicapping malocclusions that make comprehensive orthodontic treatment medically necessary under MassHealth regulations, that their alleged injuries are the direct result a specific change to the instructions, that they separately completed all three aspects of the HLD Index Form (including the medical necessity narrative), or that they exhausted available administrative remedies after the prior authorization denials. The association lacks standing because it has failed to establish that its members have individual standing to bring these claims on their own behalf. And even if plaintiffs establish standing, their claims should be dismissed for failure to state a claim for the reasons set forth below.

BACKGROUND

Relevant Requirements of a State Plan for Medical Assistance

A state plan for medical assistance must define eligible persons and the specific services covered by the plan. 42 U.S.C. § 1396a(a)(10), (17). It must provide EPSDT services for Medicaid-eligible individuals under the age of 21. It must also provide for (1) informing all such persons of the availability of EPSDT services, as described in 42 U.S.C. § 1396d(r); (2) provide or arrange for such screening services in all cases where requested; (3) arrange for necessary

corrective treatment identified by such child health screening services; and (4) annually report to the federal government certain EPSDT utilization data. 42 U.S.C. § 1396a(a)(43).

EPSDT services must include dental services "(i) at intervals which meet reasonable standards of dental practice, as determined by the State after consultation with recognized dental organizations involved in child health care, and (ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition." 42 U.S.C. § 1396d(r)(3). These services must "include relief of pain and infections, restoration of teeth, and maintenance of dental health." *Id.* The federal agency responsible for overseeing the Medicaid program, the Centers for Medicare and Medicaid Services ("CMS"), interprets this requirement to include coverage for "[o]rthodontic treatment when medically necessary to correct handicapping malocclusion." *See* CMS, The State Medicaid Manual, § 5124.B.2.b.

A state plan need not, however, provide unlimited coverage; to the contrary it must set "reasonable standards … for determining eligibility for and the extent of medical assistance under the plan," as well as provide for procedures and methods of utilization control sufficient to "safeguard against unnecessary utilization of … care and services." 42 U.S.C. §§ 1396a(a)(17) & 1396a(a)(30)(A). In other words, states must develop reasonable standards to ensure they pay for medically necessary services and, at the same time, safeguard against the utilization of services that are not medically necessary. A state plan also must provide "an opportunity for a fair hearing before the State agency" to individuals whose claims are denied. *Id.* § 1396a(a)(3).

The MassHealth Dental Program

MassHealth has an EPSDT program for eligible members younger than 21 years old. 130 C.M.R. § 450.140(A)(1). MassHealth "pays for all medically necessary dental services for EPSDT-eligible members in accordance with 130 CMR 450.140 *et seq.*, without regard to service limitations described in 130 CMR 420.000, and with prior authorization." *Id.* § 420.408. Prior authorization—a form of utilization control—is required for certain dental services, including orthodontic services. *See id.* § 420.410(B)(1) (services with the abbreviation "P.A."

require prior authorization); MassHealth *Dental Manual*, Subchapter 6.

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 C.M.R. § 420.410(C)(1). For comprehensive orthodontic services, the provider must show that the member "has a handicapping malocclusion." *Id.* § 420.431(C)(3). A provider submits this information on the HLD Index Form, found in Appendix D of MassHealth's Dental Manual. *Id*. This sub-regulatory form gives providers three alternative ways to show the member's need for treatment. First, the provider may show that the member has one of seven conditions that automatically qualifies them for treatment. Second, the provider may score the member based on several measurements, with a score of 22 or more qualifying the member for treatment. Finally, the provider may submit a medical necessity narrative, with accompanying documentation, specifically explaining why comprehensive orthodontic treatment is medically necessary to treat the individual member's handicapping malocclusion. If MassHealth's third-party administrator ultimately determines that the provider's showing on all three prongs is inadequate, MassHealth denies the prior authorization and the member has a right to an administrative hearing on appeal.[1]

When notifying a member of an adverse prior authorization determination, MassHealth must inform the member in writing of the right to a fair hearing, how to request the hearing, and of the right to an "appeal representative."[2] 130 C.M.R. §§ 610.031(A), 610.032(A)(1). A fair hearing provides "an administrative determination of the appropriateness of [the prior authorization denial]." 130 C.M.R. § 610.012(A). The request must be received by MassHealth's Board of Hearings within 30 days after the member receives written notice of the denial. *Id.*

[1] MassHealth also gives providers a separate avenue to request reconsideration of the decision. *See* Cmp. Exh. I.

[2] An "appeal representative" is someone who, at the appellant's own expense, may "exercise on the appellant's behalf any of the appellant's rights under 130 CMR 610.000." *Id.* § 610.016(A).

§ 610.015(B). During the hearing, the member (or their appeal representative) may present witnesses, introduce documentary evidence and oral testimony, cross-examine adverse witnesses, and advance pertinent arguments. *Id.* § 610.061(A)-(F). The hearing officer's final decision is subject to judicial review under G.L. c. 30A. 130 C.M.R. § 610.092.

MassHealth's Technical Alterations to the HLD Index Form

In March and June 2020, MassHealth made several updates and clarifications to the two pages of instructions that accompany the HLD Index Form. *See* Cmp., Exh. E, pp. 7-8. MassHealth noted the technical edits and clarifications in transmittal letter 104. Cmp. Exh. D, p. 1. Transmittal letter 106, which attached the operative HLD Index, describes the cumulative updates in detail. Cmp. Exh E, p. 1. The plaintiffs complain about three of those changes in their five-count verified complaint. *See* Cmp. ¶¶ 78-95. They are:

- **Labio-Lingual spread**: MassHealth now instructs providers to score labio-lingual spread by measuring the arch with the greatest spacing. It made this technical change to maintain consistency with medical research and the practices of other state Medicaid agencies.[3]

- **Mandibular Protrusion**: MassHealth changed the instruction for measuring mandibular protrusion so that it is recorded with the patient in the centric occlusion and measured from the labial of the lower permanent incisor to the labial of the upper permanent incisor. The instruction further clarifies that the condition must involve two or more adjacent permanent incisors in reverse overjet, not just a single permanent tooth in crossbite. The instruction is consistent with medical research and at least 14 other states use the incisors instead of a back tooth as the reference point.

- **Open Bite**: MassHealth clarified the instruction for measuring open bite (*i.e.*, the absence of vertical overlap of a maxillary and mandibular permanent incisor) to have consistency between the HLD Index Form (which required measurement from the incisors) and the instruction, which lacked that specificity. The instruction now tells providers not to count permanent canines or end to end or edge to edge permanent incisors when measuring open bite. Rather, to be counted the entire maxillary incisal edge must not have any end to end contact with a mandibular incisor or any vertical overlap of the mandibular incisor. It is measured from the incisal edge of the permanent maxillary incisor to the incisal edge of the permanent mandibular incisor.

[3] The HLD Index was developed by and largely follows the instructions of Harry Draker. *See* Harry L. Draker, *Handicapping Labio-Lingual Deviations: A Proposed Index For Public Health Purposes,* American Journal of Orthodontics, Vol. 46, No. 4, pp. 295-305 (April 1960).

ARGUMENT

I. The Plaintiffs Lack Standing.

The children and the organizational plaintiff, Medicaid Orthodontists of Massachusetts, Association, Inc., ("MOMA") lack standing. This Court should therefore dismiss the complaint for lack of subject matter jurisdiction. *HSBC Bank U.S.A., N.A. v. Matt*, 464 Mass. 193, 199 (2013) ("Courts … have both the power and obligation to resolve questions of subject matter jurisdiction whenever they become apparent"); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) ("Without jurisdiction the court cannot proceed at all in any cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.").

The Child Plaintiffs. The five named child plaintiffs lack standing for three reasons. Each one is independent grounds to dismiss them from the case.

First, the children's allegations about their injury, the cause of their injury, and the linkage between the two are deficient. *See Ginther v. Comm'r of Ins.*, 427 Mass. 319, 323 (1998), quoting *Northbridge v. Natick*, 394 Mass. 70, 75 (1985) ("Alleging '[i]njury alone is not enough; a plaintiff must allege a breach of duty owed to it by the public defendant.' "). Whatever orthodontic complications the children may have, the complaint does not allege that they have handicapping malocclusions that make comprehensive orthodontic treatment medically necessary under MassHealth regulations.[4] It also offers no factual allegations or supporting exhibits (*i.e.*, the prior authorization forms, with supporting documentation, submitted on the children's behalf) to support the conclusory statements in paragraphs 96-128 that the prior authorization requests would have been approved but for MassHealth's changes to the HLD Index Form's instructions. *Slama v. Attorney Gen.*, 384 Mass. 620, 624 (1981) ("To have

[4] Paragraph 120 does allege that Ana has a handicapping malocclusion, but it does not allege that comprehensive orthodontic treatment is medically necessary.

standing in any capacity, a litigant must show that the challenged action has caused the litigant injury"). Finally, it fails to connect the prior authorization request denials to the three instructional changes the plaintiffs challenge.[5] *Id*. Without these critical facts, this Court should give no weight, for purposes of standing, to the plaintiffs' conclusory allegations that they have been injured by MassHealth's clarifications to the HLD's instructions. *See Pishev v. City of Somerville*, 95 Mass. App. Ct. 678, 682 (2019) ("A factual challenge to subject matter jurisdiction gives no presumptive weight to the averments in the plaintiffs' complaint, and requires the court to address the merits of the jurisdictional claim by resolving the factual disputes between the plaintiffs and the defendants.") (internal quotations omitted).

Second, even if the plaintiffs had alleged that the children have a handicapping malocclusion for which comprehensive orthodontic treatment is medically necessary *and* attributed their individual harm to a specific change in the HLD Index Form, the complaint fails to allege that the children's orthodontists completed all three aspects of the form. This missing allegation is crucial here, because establishing an automatically qualifying condition, or a score of 22 or greater, are not the only ways for a provider to demonstrate medical necessity for orthodontic treatment. Indeed, the form offers providers a third method to establish a patient's medical need due to a handicapping malocclusion, called the medical necessity narrative, to be used in cases where qualification is not established under the form's first two prongs. Moreover, the instructions for the narrative expressly state that it should be used in cases like the plaintiffs, where the member has an inability to eat or chew that the provider believes amounts to a

[5] In paragraphs 78-94, plaintiffs focus on changes to three aspects of the HLD—the instructions for determining labio-lingual spread, *see* Cmp., ¶ 78, the instructions for determining mandibular protrusion, *see id.*, ¶¶ 80, 82-27, and the definition of anterior open bite, *see id.* ¶¶ 90-95. But nowhere in the complaint do they link these conditions to the children. And although plaintiffs offer further details on the children's alleged conditions on page 8 of their memorandum, they offer no citation for the conditions, a critical omission where these details are not mentioned in the verified complaint or Dr. Rizkallah's supporting affidavit.

handicapping malocclusion. *See* Cmp. Exh. E, p. 5. *See also id*. ¶¶ 97, 104, 109, 114, 120 (detailing each child's difficulty chewing). Thus, any alleged shortcoming in the form's instructions cannot cause a patient injury unless the complaint also alleges that a handicapping malocclusion has been established using the narrative but was erroneously denied nonetheless by MassHealth. Since the complaint does not include such allegations and plaintiffs failed to attach their prior authorization requests to the complaint,[6] plaintiffs cannot establish any harm.[7]

Finally, even if the child plaintiffs satisfied those standing prerequisites, they have an additional problem—they failed to exhaust administrative remedies after their prior authorization request denials. *See Wilczweski v. Comm'r of Dep't of Envt'l Quality Eng'g*, 404 Mass. 787, 782 (1989) ("administrative remedies should be exhausted before resort to the courts."); *see also Villages Dev. Co. v. Sec'y of Exec. Office of Envtl. Affairs*, 410 Mass. 100, 106 (1991) ("To secure declaratory relief in a case involving administrative action, a plaintiff must show that (1) there is an actual controversy; (2) he has standing; (3) necessary parties have been joined; and (4) available administrative remedies have been exhausted."). Under MassHealth regulations, a member (or their appeal representative) may request a fair hearing to challenge "the appropriateness of [the prior authorization denial]." 130 C.M.R. § 610.012(A)(1). During that hearing, the member (or their appeal representative) may present witnesses, introduce

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[6] Because this Court may consider "affidavits and other matters outside the face of the complaint relevant to the issue of subject matter jurisdiction," *see Ginther*, 427 Mass. at 323 n.6, to supplement this argument, the defendants intend to seek permission during tomorrow's motion hearing to file under seal an authenticating affidavit with the child plaintiffs' redacted prior authorization requests and the redacted prior authorization denials.

[7] The specific orthodontic conditions scored require making certain measurements and placing them on the form. The complaint, however, offers no measurements, instead describing how each child plaintiff is impacted by their condition, e.g., Dayanne N. "has difficulty chewing . . . has to pull [her food] forward out of her mouth with her hands . . . [which] has damaged her lower front teeth." Cmp. ¶¶ 97, 98. The medical necessity narrative gives the provider the opportunity to specifically describe the patient's condition, including "a substantiated inability to eat or chew caused by the patient's malocclusion," but the complaint fails to allege that any information was given to MassHealth to help show medical necessity. Cmp., Exh. E.

documentary evidence and oral testimony, cross-examine adverse witnesses, and argue why treatment is medically necessary. *Id.* § 610.061(A)-(F). The hearing officer's final decision is subject to judicial review under G.L. c. 30A. 130 C.M.R. § 610.092. Because the complaint does not allege that the child plaintiffs (or their appeal representatives) sought administrative review of their prior authorization denials, they failed to exhaust administrative remedies, depriving MassHealth of "a full and fair opportunity to apply its expertise" to the circumstances of the child-plaintiffs' claims that they should have been approved for treatment. *See Mass. Resp. Hosp. v. Dep't of Pub. Welf.*, 414 Mass. 330, 336-337 (1993) (hospital precluded from seeking judicial review of Medicaid claims denial where hospitals failed to pursue administrative remedies); *Gill v. Bd. of Reg. of Psych.*, 399 Mass. 724, 727 (1987). *See also Athol Mem. Hosp. v. Comm'r of Div. of Med. Assist.*, 437 Mass. 417, 421-422 (2002) (hospitals required to pursue administrative appeals of and properly denied judicial review where they failed to do so).

MOMA. MOMA also lacks standing. *See Statewide Towing Ass'n v. City of Lowell*, 68 Mass App. Ct. 791, 794 (2007). When an association like MOMA "asserts associational standing on behalf of its members, it must establish that its members would independently have standing to pursue the claim." *Id.*, citing *Animal Legal Def. Fund, Inc., v. Fisheries & Wildlife Bd.*, 416 Mass. 635, 638 n.4 (1993). But here, the sole paragraph in the verified complaint about MOMA, *see* Cmp. ¶ 7, fails to meet that jurisdictional obligation. All it alleges is that "MOMA's members include [1] families and children who are Medicaid beneficiaries who need or may need orthodontic services and [2] orthodontists who participate as providers in the MassHealth Medicaid program who are personally aggrieved by the denial of necessary orthodontic services to their Medicaid patients." *Id.* It does not establish that any of MOMA's unidentified child members had a prior authorization request filed on their behalf, that the prior authorization request was denied, that the denial was a direct result of MassHealth's changes to the HLD, and that the member exhausted their available administrative remedy. *See Statewide*, 68 Mass. App. Ct. at 795 ("[s]peculative injuries insufficient to confer standing"). Similarly, while paragraph 7

does contain a conclusory allegation that some MOMA-member orthodontists are "aggrieved," that they "will not be paid for services that [they] ha[ve] not been authorized to perform does not make [them] aggrieved part[ies]."[8] *Rizkallah v. Dir. of the Mass. Office of Medicaid*, 85 Mass. App. Ct. 1104, *1 (2014) (Rule 1:28 decision). *See Ginther*, 427 Mass. at 322 ("[O]nly persons who have themselves suffered, or who are in danger of suffering, legal harm can compel the courts to assume the difficult … duty of passing upon the validity of acts of a coordinate branch of government") (internal citations omitted). Plaintiffs cite no law supporting the notion that a provider suffers an injury when a patient's claim is denied. Nor can they—only MassHealth members have claims for coverage of medical conditions.

II. Plaintiffs Do Not Have a Likelihood of Success on Their Claims.

Plaintiffs do not have a likelihood of success on the merits of their claims because each count of the complaint should be dismissed for failure to state a claim.

A. MassHealth's Administrative Changes to the HLD Index Form's Instructions Do Not Interfere with the Plaintiffs' EPSDT Rights.

In Count I, plaintiffs claim that the administrative changes to the HLD Index Form's instructions interfere with several EPSDT provisions. Their claim should be dismissed.

1. Where the Medical Necessity Narrative is Available For Use By Providers to Show the Member's Handicapping Malocclusion, Plaintiffs Cannot Establish that MassHealth's Administrative Changes to Other Portions of the HLD Index Form's Instructions Interfere with the Plaintiffs' EPSDT Rights.

The EPSDT claim under 42 U.S.C. §§ 1396a(a)(10)(A) and 1396d(a)(4)(B), which require MassHealth to provide EPSDT services to members, fails. This is because the success of the claim hinges on the erroneous assertion that the existence of a handicapping malocclusion

[8] Compounding the standing problem, paragraph 7 contains no factual support establishing that any MOMA orthodontist filed prior authorization requests on behalf of patients, that the requests were denied, that the denial was a direct result of MassHealth's HLD changes, and that the member exhausted available administrative remedies. *Statewide*, 68 Mass. App. Ct. at 794-95.

rises or falls solely by reference to the first two portions of the HLD Index Form (which they claim has been wrongly altered). This is not the case. Where medical necessity can be established using the medical necessity narrative and where there are no allegations that it has been used for plaintiffs, there simply cannot be a showing that the EPSDT standards have been violated. That the narrative's instructions specify that it should be used when there is a "substantiated inability to eat or chew caused by the patient's malocclusion," Cmp. Exh. E. p. 5, something the complaint alleges the child plaintiffs suffer from, compounds plaintiffs' problem.

Plaintiffs are also incorrect in suggesting that the changes to the language of certain definitions germane to the use of the HLD Index Form somehow violate the rules regarding the medically necessary nature of the services provided. For example, plaintiffs claim that the definitional changes violate 130 C.M.R. § 450.204 because the regulation requires that "medically necessary services must be of a quality that meets professionally recognized standards of healthcare," and they assert that the definitional changes are not standard in the industry. But the regulation they cite concerns medical services rendered by a provider. *See* 130 C.M.R. § 450.101 ("provider:" individual that "furnishes medical services and participates in MassHealth under a provider contract").[9] It says nothing about the methods MassHealth uses to assess whether there is a medical necessity for a provider to treat a patient. Moreover, the complaint does nothing more than assert, as a factual matter, that the definitions used in the HLD Index instructions, for example, depart from "well-established industry diagnostic definitions." Cmp. ¶ 80. This repeated assertion, without further explication, is inadequate to state a claim.[10]

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[9] So, for example, an orthodontist authorized to treat a member's handicapping malocclusion would violate this regulation if they used a sledgehammer to adjust the patient's teeth, and MassHealth would not be legally bound to pay, because such "treatment" does not "meet[] professionally recognized standards of healthcare," under 130 CMR § 450.204.

[10] It is also factually wrong: the HLD Indexes of California, Illinois, New Jersey, and New York use definitions and instructions similar to the Massachusetts HLD Index. Some of these states are stricter, not allowing for the scoring of spacing of the arches at all in calculating labio-lingual

(footnote continued)

2. Plaintiffs Have Not Established that MassHealth Failed to Arrange for Comprehensive Orthodontic Treatment.

Plaintiffs' EPSDT claim under 42 U.S.C. § 1396a(a)(43) also fails. That section requires MassHealth to (a) inform all eligible persons in the state under age 21 of the availability of EPSDT services, (b) provide or arrange for screening in all cases where they are requested, (c) arrange for corrective treatment if it is disclosed by the screening, and (d) report EPSDT utilization data to CMS. 42 U.S.C. §§ 1396a(a)(43)(A)-(D).

Although the complaint does not specify which subpart of Section 1396a(a)(43) the claim arises from, plaintiffs appear to confuse the requirements for EPSDT screening and treatment. They cite to the requirements of 42 C.F.R. § 441.56(b)(2) that EPSDT screening services must be "in accordance with reasonable standards of medical and dental practice determined by the agency ***after consultation with recognized medical and dental organizations****8* involved in child health care." PI Mem p. 6 (emphasis added by plaintiffs). But these requirements relate to screening services as set forth in a state agency's periodicity schedule, as opposed to the dispute over when treatment is required at issue in the current litigation.[11]

In fact, the only plausible claim arises under sub-section (C), which concerns the post-screening arrangement for corrective treatment.[12] But here, after plaintiffs were screened and

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spread. *See* https://www.denti-cal.ca.gov/DC_documents/providers/DC016.pdf; https://www.illinois.gov/hfs/SiteCollectionDocuments/2017DORM.pdf; https://www.njmmis.com/downloadDocuments/29-16.pdf; https://www.emedny.org/ProviderManuals/Dental/PDFS/HLD_Index_NY.pdf.

[11] *See* https://www.medicaid.gov/medicaid/benefits/early-and-periodic-screening-diagnostic-and-treatment/index.html ("At a minimum, dental services include relief of pain and infections, restoration of teeth, and maintenance of dental health. Dental services may not be limited to emergency services. Each state is required to develop a dental periodicity schedule in consultation with recognized dental organizations involved in child health.")

[12] Since the complaint alleges that all the named plaintiffs had prior authorization requests submitted on their behalf, they lack standing to challenge MassHealth's compliance with the obligations to inform members about, and then arrange for, screening services. 42 U.S.C.

(footnote continued)

their orthodontists submitted prior authorization requests, MassHealth's third-party administrator determined that the partially completed prior authorization requests did not establish that any plaintiff had a handicapping malocclusion or that treatment was medically necessary. No plaintiff pursued a fair hearing to challenge the prior authorization denials. And given the lack of administrative challenge to the determination that comprehensive orthodontic treatment was not medically necessary, MassHealth had nothing to "arrange" under Section 1396a(a)(43)(C).

3. Plaintiffs Have Failed to Establish that MassHealth Violated 42 U.S.C. § 1396d(r)(3).

Plaintiffs also cite 42 U.S.C. § 1396d(r)(3)(B), which requires that dental services "shall at a minimum include relief of pain and infections, restoration of teeth, and maintenance of dental health." If this is an independent aspect of the EPSDT claim, it is undeveloped in both the complaint and the preliminary injunction memorandum, and for that reason alone, this Court should dismiss it. Further, the claim fails because the Medicaid Act requires MassHealth to use "reasonable standards … for determining eligibility" as well as implement methods of utilization control sufficient to "safeguard against unnecessary utilization of … care and services," *see* 42 U.S.C. §§ 1396a(a)(17) & 1396a(a)(30)(A), which is exactly what MassHealth did here. If the child plaintiffs were aggrieved by MassHealth's denial of their prior authorization requests, they should have submitted medical necessity narratives or requested fair hearings to explain how their pain and dental health problems amounted to handicapping malocclusions that make comprehensive orthodontic treatment medically necessary under MassHealth regulations.

B. MassHealth Was Not Required to Make Technical Alterations to the Directions for Using a Sub-Regulatory Form by Way of Regulation.

The HLD Index Form is a sub-regulatory document maintained by MassHealth to aid orthodontists submitting prior authorization requests. In Count II, plaintiffs claim that technical

§ 1396a(a)(43)(A)-(B). Likewise, they lack both standing and a cause of action to challenge the adequacy of MassHealth's reports to CMS. *Id.* § 1396a(a)(43)(D).

alterations MassHealth made to the form's instructions in March and June should have been done via regulation. *See* Cmp. ¶¶ 138-146; PI Mem. pp. 9-12. Their argument fails for two reasons.

First, the standard for comprehensive orthodontic treatment is unchanged. Just like before the complained-of alternations, the provider must demonstrate the patient has a handicapping malocclusion for which comprehensive treatment is medically necessary. Providers continue to have three ways to demonstrate this on the HLD Index Form. First, they can demonstrate that a patient has an automatically qualifying condition. Second, they may show that the patient scored 22 or higher on the HLD's scoring index. Third, the provider can present a medical necessity narrative detailing why the patient has a handicapping malocclusion. Here, MassHealth made minor adjustments to the form's first two aspects that function as shortcuts for showing medical necessity. That MassHealth clarified measuring instructions for those shortcuts because they were causing provider confusion and the lack of precise definitions was resulting in overutilization does not amount to a change that must follow the c. 30A. This is because the changes do not, as a matter of law, result in a material change in the policy that excludes medically necessary cases, as the third method (the catch-all) remains unchanged, with the provider retaining the ability to describe in a narrative why treatment is medically necessary.[13]

Second, the instructional clarifications and updates themselves, which, again, were intended to fill in details and clarify ambiguities that were resulting in provider confusion and overutilization, are themselves not the type of alterations that trigger the c. 30A process. *See Genworth Life Ins. Co. v. Comm'r of Ins.*, 95 Mass. App. Ct. 392, 396 (2019), quoting *Mass. Gen. Hosp. v. Rate Setting Comm'n*, 371 Mass. 705, 707 (1977) ("administrative agency may use

[13] That the narrative is not used as frequently as the other two methods does not mean that it is not a viable means of establishing medical necessity. Consistent with its regulations and federal law, MassHealth could require that every provider show medical necessity in narrative form. The two shortcuts to the narrative (autoqualifying conditions and scoring) ease administration of the prior authorization process, and MassHealth can of course determine that closer cases require a more precise evidentiary showing, whether in the form of measurements, narrative, or both.

sub-regulatory guidance to 'fill in the details or clear up an ambiguity of an established policy' without resort to formal rulemaking as long as it does not contradict its enabling statute or preexisting regulations"). They were instead designed to improve the accuracy and consistency of the medical necessity determinations.[14]

The instructions at issue here do not conflict with the applicable regulations, but rather align with the requirements in 130 C.M.R. § 420.431(C)(3) that the MassHealth agency describe the standards for medical necessity in sub-regulatory guidance. The case for the use of sub-regulatory guidance is especially compelling when it is called for by the regulation itself. The instructions provide a method to administer the prior authorization process in a manner that identifies medically necessary cases while still following the federal government's instruction that MassHealth not pay for treatment that is not medically necessary. *See Genworth Life Ins. Co.*, 95 Mass App. Ct. at 396. *See also Arthurs v. Bd. of Reg. in Med.*, 383 Mass. 299, 313 n.26 (1981) (agency filling in details or clarifying ambiguity may issue interpretation or informational pronouncements without going through the procedures required for promulgating regulations). In furtherance of that, the challenged instructions merely (1) clarify ambiguities in how providers should perform measurements required by the form for "open bite" and (2) offer greater detail on when labio-lingual spread and mandibular protrusion automatically amounts to a handicapping malocclusion for which comprehensive treatment is medically necessary, providing details and clarifying ambiguity on when a member has a handicapping malocclusion requiring treatment. These changes do not restrict eligibility or access to services. Rather, the test for coverage remains whether the patient has a handicapping malocclusion for which orthodontic treatment is medically necessary based on clinical standards described in Appendix D.[15]

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[14] *See, e.g.*, Cmp. Exh. F, p.2 (cited emails where the third-party administrator's vice president of clinical management notes the updates will make reviews "more accurate and consistent").

[15] In estimating that the clarification will result in 60% of previously approved cases being denied, Dr. Rizkallah offers no indication about how that would change if he utilized the medical

(footnote continued)

C. MassHealth is Not Discriminating Against Members in the Provision of Services.

Count III—a claim under G.L. c. 151B, § 4(10)—fails to state a viable claim, for four independent reasons. First, to state a claim under section 4(10), plaintiffs must establish that the state defendants are the "person[s] furnishing … services[.]" The defendants, however, do not "furnish" any services. Rather, MassHealth members seek out MassHealth providers to furnish the services and then the provider submits a bill to MassHealth for payment.

Second, plaintiffs are wrong that MassHealth's changes to the instructions for the HLD Index Form equate to a change to the service (comprehensive orthodontic treatment) itself. There are no allegations in the complaint that the service that providers perform on children who receive prior authorization for comprehensive orthodontic treatment is any different now than it was before March 2020. Nor could there be, as the allegations in the complaint only concern providers having to take different measurements than they would allegedly prefer to obtain prior authorization for the service they hope to provide. Further, the regulatory definition of "comprehensive orthodontic treatment" in 130 C.M.R. § 420.431(B)(3) is unchanged and MassHealth continues to pay for comprehensive orthodontic treatment to those children for whom it is medically necessary and have obtained prior authorization.

Third, even if plaintiffs could ultimately prove their allegations, they still need to establish that the defendants are discriminating against MassHealth members because they are MassHealth members. But a state agency adjusting its methodology for the administration of the prior authorization approval process for a service available to members is not, as a matter of law, discrimination against MassHealth members based on their status as MassHealth members.[16]

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necessity narrative, which he stated he uses in only 1% of the cases. Rizkallah Aff. ¶¶ 1, 24. There is thus not factual basis for plaintiffs' claim that the change substantially affects them.

[16] Rather, the complaint describes behavior by MassHealth orthodontic providers that amounts to discrimination by the providers, in violation of G.L. 151B, § 4(10), against MassHealth members *because* they are recipients of Medicaid benefits. That is, the providers are described as refusing

(footnote continued)

Finally, the allegations in paragraph 151, that MassHealth is "attempting to coerce providers to deny a proper diagnosis and deny an accurate medical record to MassHealth members, when they provide these services to all patients who are not MassHealth members," is wrong as a matter of fact and law. It is wrong as a matter of fact because an orthodontist can diagnose patients as they always have, explaining in what ways a patient's condition reveals a handicapping malocclusion. All the instructions for the HLD Index does is require providers to measure certain distances between certain teeth, measurements that MassHealth requires to verify that the patient's eligibility for treatment is medically necessary under the first two parts of the HLD Index Form. All a provider must do is certify the accuracy of the measurements and the accuracy of the facts presented to justify a claim of medical necessity. It is also wrong as a matter of law because providers are under no obligation to participate in MassHealth and are free to withdraw from program participation at any time. *See, e.g., Boston Med. Ctr. Corp. v. Sec'y of Exec. Office of Health & Human Servs.*, 463 Mass. 447, 459 (2012); cf 130 C.M.R. § 450.249(D) (describing process when MassHealth receives notification of the provider's intention to close or to withdraw from MassHealth). Moreover, it is certainly the case that MassHealth patients and private pay patients are not similarly situated for these purposes. MassHealth patients are only entitled to have MassHealth pay an orthodontist for treatment that is medically necessary, that is, to alleviate a handicapping malocclusion. Other, non-MassHealth, patients are free to have an orthodontist provide services for medically necessary, or solely cosmetic, purposes.

D. There is Not a Medicaid Due Process Right to Peer-to-Peer Review.

Count IV is a due process claim under 42 U.S.C. § 1983, alleging that the defendants have failed to provide adequate due process under the Act, 42 U.S.C. § 1396a(a)(3). Section 1396a(a)(3) requires MassHealth to "provide for granting an opportunity for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or

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to assess and treat MassHealth members for handicapping malocclusions *because* the providers disagree with the measurements MassHealth requires them to record on the HLD Index Form.

is not acted upon with reasonable promptness[.]" Because MassHealth provides the opportunity for a fair hearing to any member whose prior authorization request for comprehensive orthodontic treatment is denied, *see* 130 C.M.R. §§ 610.001(a) & 610.012, the plaintiffs' claim fails as a matter of law and should be dismissed for failure to state a claim.

Plaintiffs do not even acknowledge the fair hearing process in their complaint. Instead, they attempt to portray the informal peer-to-peer telephonic review process that MassHealth's third-party administrator offers orthodontists as a critical avenue for error-correction. But while the peer-to-peer process certainly helps orthodontists augment inadequacies in their prior authorization requests, it is not required by either federal or state law and neither providers nor members have a due process right to it. *Bd. of Regents of State Colleges v. Roth*, 408 U.S. 564, 577 (1972) (to have a protected property interest in a benefit, a person "must have more than an abstract need or desire for it. … He must, instead, have a legitimate claim of entitlement to it."). Indeed peer-to-peer review is mentioned nowhere in Massachusetts statute or regulation. Moreover, even the changes of which plaintiffs complain preserve the opportunity on the part of providers to respond to and augment the information they provide to request a prior authorization. Instead of the peer-to-peer process, providers have the opportunity to submit a reconsideration through the MassHealth provider web portal. *See* Cmp. Exh. I. And, contrary to plaintiffs' claims, limiting the mode of such requests for reconsideration does not limit benefits.

Since members do not participate in the peer-to-peer review process, they certainly have no entitlement to it. Some providers, by contrast, do participate in this process. But that they have no right or entitlement to peer-to-peer telephonic review is consistent with the procedural due process rules surrounding prior authorization denials. Nothing in federal or Massachusetts law confers on providers a protected property interest implicated by the denial of a member's prior authorization request. Additionally, a provider's desire to give an individual comprehensive orthodontic care in the future and be reimbursed is not a protected property interest. The only

property interest affected by such denials is the entitlement of MassHealth *members* to receive Medicaid benefits. This is why under federal law, only Medicaid beneficiaries or members—*not providers*—are entitled to a fair hearing challenging the denial of a prior authorization request. *See* 42 U.S.C. § 1396a(a)(3) (providing right to fair hearing to individual whose claim for medical assistance is denied); 42 C.F.R. §§ 431.200-250 (federal regulations governing fair hearings for applicants and beneficiaries). Similarly, under Massachusetts law, a provider has no independent right to request a fair hearing to challenge the denial of a prior authorization request. *See* G.L. c. 118E, § 47; 130 C.M.R. § 610.035(A)(7); *see also Rizkallah v. Dir. of the Mass. Office of Medicaid*, 85 Mass. App. Ct. 1104, *1 (2014) (Rule 1:28 decision), citing *Centennial Healthcare Inv. Corp. v. Comm'r of Div. of Med. Assist.*, 61 Mass. App. Ct. 320, 326-27 (2004) (dental provider has no independent basis to challenge denial of prior authorization request).

III. The Plaintiffs Have Not Demonstrated that They Will Suffer Irreparable Harm.

Because plaintiffs have failed to establish a likelihood of success on any of their claims, this Court need not proceed further. *See, e.g., Student No. 9 v. Board of Educ.*, 440 Mass. 752, 767 (2004). But even if this Court considers their allegations of harm, they fare no better, as they have not demonstrated a risk of irreparable harm in the absence of injunctive relief.

The child plaintiffs have failed to establish that they have been irreparably harmed by MassHealth. It was their orthodontists (not MassHealth) who decided not to complete the medical necessity narratives—narratives that could have explained why the child plaintiffs' chewing problems require comprehensive orthodontic treatment even though they did not qualify under the HLD's first two prongs. Likewise, it was the children and their families (not MassHealth) who decided not to exhaust their administrative remedies through the fair hearing process, a process designed to fix erroneous prior authorization denials and that might have resulted in the children obtaining approval for treatment. Where there is no allegation or evidence that any plaintiff has been, or will be, denied coverage on the ground of a lack of medical necessity, or that the

medical necessity narrative has been completed for such patient, the child plaintiffs cannot demonstrate that they have been irreparably harmed by MassHealth.

The "alleged" harms to MOMA's provider-members also do not compel a preliminary injunction, for three reasons. First, as the complaint's allegations make clear, they have known about these changes since March 2020 and have had ample time to file this lawsuit. Second, "[e]conomic harm alone … [does] not suffice as irreparable harm unless the loss threatens the very existence of the movant's business," *see Tri-Nel Mgmt., Inc. v. Bd. of Health of Barnstable*, 443 Mass. 217, 227-228 (2001) (internal citation & quotation omitted), and there are no allegations of that here. Finally, the mere (alleged) adjustment in the eligibility rate of potential patients cannot establish irreparable harm on the part of the providers, particularly where there has been no showing that providers have used the alternative medical necessity narrative.

IV. The Balance of the Harms and the Public Interest Strongly Favor Protecting the Integrity of MassHealth's Administration of Its Orthodontic Program.

Finally, the alleged harms to plaintiffs do not outweigh the harms to MassHealth or justify the interference with the internal administration of its orthodontic program. *See Loyal Order of Moose, Inc., Yarmouth Lodge #2270 v. Bd. of Health of Yarmouth*, 439 Mass. 439 Mass. 597, 601 (2003). MassHealth must provide only services that are medically necessary. Clarifying the HLD's instructions to reduce waste and enhance program integrity in accordance with 42 U.S.C. § 1396a(a)30(A), 64 and 68, ensures that MassHealth's funds are utilized as efficiently as possible. And there is no basis for granting preliminary relief to plaintiffs who neither completed the medical necessity narrative nor exhausted administrative remedies.

CONCLUSION

For the foregoing reasons, the state defendants respectfully request that this Court deny plaintiffs' motion for preliminary injunction and allow the state defendants' motion to dismiss.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on this date I served by email a copy of the forgoing Memorandum in Opposition to Plaintiffs Motion for Preliminary Injunction and in Support of Defendants' Motion to Dismiss on counsel for the plaintiffs—Joel Rosen and Matthew Perry.

/s/ Douglas S. Martland
Douglas S. Martland
Assistant Attorney General

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