IN THE COURT OF APPEALS OF THE
STATE OF OREGON

SAREPTA THERAPEUTICS, INC.,
Petitioner,

v.

OREGON HEALTH AUTHORITY,
Respondent.

Oregon Health Authority
A171320

Argued and submitted March 12, 2021.

Paul W. Conable argued the cause for petitioner. Also on the briefs were Stephanie Grant and Tonkon Torp LLP; and Jeffrey Handwerker, Paige Sharpe, Allison Gardner, and Arnold & Porter Kaye Scholer LLP, Washington, D.C.

Patricia G. Rincon, Assistant Attorney General, argued the cause for respondent. Also on the brief were Ellen F. Rosenblum, Attorney General, and Benjamin Gutman, Solicitor General.

Before Ortega, Presiding Judge, and Shorr, Judge, and Powers, Judge.

ORTEGA, P. J.

Motion to dismiss as moot denied. OAR 410-121-0040(3) (Jan 1, 2018) held valid.

ORTEGA, P. J.

Petitioner challenges, under ORS 183.400, the Oregon Health Authority's (OHA's) adoption of OAR 410-121-0040(3) (Jan 1, 2018), as it applies to the prescription drug Exondys 51 (Exondys).[1] Petitioner is the manufacturer of Exondys, which is used in the treatment of Duchenne muscular dystrophy for patients with specific gene mutations. Under OAR 410-121-0040(3), OHA incorporates by reference its Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria (PA Criteria). The PA Criteria includes prior authorization criteria that a patient must meet for Exondys to be covered under the Oregon Health Plan. Petitioner asserts that OHA exceeded its authority in adopting the PA Criteria, as it applies to Exondys, because it violates drug-coverage requirements under Title XIX of the federal Social Security Act (the Medicaid Act). OHA asserts that this rule challenge is moot because OAR 410-121-0040(3) has been amended, that petitioner's argument is not reviewable as a rule challenge under ORS 183.400, and that, on the merits, OHA was authorized to adopt the PA Criteria. We deny OHA's motion to dismiss and hold OAR 410-121-0040(3) valid.

OHA'S MOTION TO DISMISS FOR MOOTNESS

Before discussing the merits of petitioner's rule challenge, we first address OHA's renewed motion to dismiss the petition as moot. The Appellate Commissioner denied by order OHA's motion to dismiss, concluding that it was appropriate for us to exercise our discretion to review the case under ORS 14.175, because "[t]he challenged policy or practice, or similar acts, are likely to evade judicial review in the future." OHA renews its motion to dismiss in its answering brief. As explained below, we deny the renewed motion.

[1] The rule challenged by petitioner has since been amended by permanent and temporary rule many times. For purposes of this opinion, unless otherwise noted, when we cite OAR 410-121-0040(3), we are referring only to the version of the rule that incorporated the Oregon Medicaid Pharmaceutical Services Prior Authorization Criteria (PA Criteria) published on January 1, 2018; likewise, unless otherwise noted, when we refer to the PA Criteria, we are referring to the January 1, 2018, version.

We recognize that the version of the rule challenged by petitioner has expired and been amended. Petitioner stated in its petition that it was challenging "the Prior Authorization Criteria as first published on September 1, 2017, and as republished or amended." Petitioner attached to its petition, as the copy of the rule being challenged, the PA Criteria for Exondys dated August 21, 2017, and the PA Criteria for Exondys dated January 1, 2018. The history of OAR 410-121-0040 provides that the temporary amendment that went into effect on January 1, 2018, which incorporated the January 1, 2018, PA Criteria, was replaced by a temporary rule that went into effect on February 8, 2018, which was in turn replaced by a temporary rule that went into effect on May 2, 2018, which was in turn replaced by a permanent rule amendment that went into effect June 29, 2018, and so on. In fact, OAR 410-121-0040 has been amended by temporary and permanent rule amendments 39 times between January 1, 2018 and April 1, 2023. The rule is permanently amended every six months to update the reference to the latest version of the PA Criteria, and each permanent amendment is promptly amended by one or more temporary amendments for additional PA Criteria updates before the next permanent amendment is made.

Here, petitioner specifically challenges the PA Criteria as it applies to Exondys because, petitioner alleges, it requires that a patient must meet two criteria that are in addition to the FDA approved use for Exondys. In the January 1, 2018, PA Criteria, those two criteria provided that the patient must have been (1) "on a stable dose of corticosteroid for at least 6 months," and (2) evaluated for baseline function "using a validated tool such as the 6-minute walk test or North Star Ambulatory Assessment." PA Criteria, 75-76 (Jan 1, 2018). Those criteria remained unchanged until July 1, 2020, when OHA added to the first criterion "or have documented contraindication to steroids." PA Criteria, 116 (July 1, 2020). With that amendment, the criteria for Exondys have remained unchanged up to the current version, which is dated April 1, 2023. PA Criteria, 128-29 (Apr 1, 2023).

Based on the foregoing, we agree with OHA that petitioner's challenge is moot. The specific rule that

petitioner challenges has been replaced and the specific criteria challenged by petitioner in the PA Criteria have been amended. *See Joint Council of Teamsters #37 v. BOLI*, 168 Or App 398, 412, 11 P3d 247, *rev den*, 331 Or 429 (2000) (holding that "the validity of an expired or superseded rule is not 'kept alive' for mootness purposes by the fact that the superseded rule may have some continuing effect on the application or validity of a current rule"). Petitioner argues, however, that we should exercise our discretion and address its rule challenge under the exception to mootness provided in ORS 14.175. *See Couey v. Atkins*, 357 Or 460, 522, 355 P3d 866 (2015) (ORS 14.175 "leaves it to the court to determine whether it is appropriate to adjudicate an otherwise moot case under the circumstances of each case."). We conclude that it is appropriate to exercise our discretion in this case and review petitioner's challenge based on that exception.

ORS 14.175 provides:

> "In any action in which a party alleges that an act, policy or practice of a public body, as defined in ORS 174.109, or of any officer, employee or agent of a public body, as defined in ORS 174.109, is unconstitutional or is otherwise contrary to law, the party may continue to prosecute the action and the court may issue a judgment on the validity of the challenged act, policy or practice even though the specific act, policy or practice giving rise to the action no longer has a practical effect on the party if the court determines that:
>
> "(1) The party had standing to commence the action;
>
> "(2) The act challenged by the party is capable of repetition, or the policy or practice challenged by the party continues in effect; and
>
> "(3) The challenged policy or practice, or similar acts, are likely to evade judicial review in the future."

First, it is undisputed that Sarepta has standing to bring this challenge. Second, we agree with Sarepta and the Appellate Commissioner that the challenged policy "continues in effect." Here, Sarepta challenges OHA's authority to include the two prior authorization criteria at all. It is immaterial to the merits of Sarepta's challenge that OHA added "or have documented contraindication to steroids" to the first criteria. Although the rule has been amended 39

times since January 1, 2018, the policy requiring a patient to meet the two prior authorization criteria for Exondys remains intact. Third, we conclude that a challenge to OHA's authority to include those criteria in the PA Criteria for Exondys is likely to evade review due to the length of the judicial process. The rule is permanently amended every six months, and regularly amended on a temporary basis even more often. *See Couey*, 357 Or at 482 ("ORS 14.175 applies to types or categories of cases in which it is 'likely' that such challenges will avoid judicial review.").

We are not persuaded by OHA's assertion that the challenge will not likely evade review because a petitioner can simply file an amended petition for review with each additional rule amendment. Because of the frequency of permanent amendments, as well as the uncertainty of when a superseding temporary amendment may issue, requiring a petitioner to proceed in such a manner would be unduly burdensome. We also are not persuaded by OHA's argument that the challenge is not likely to evade review because an individual patient who is denied coverage for Exondys could challenge the OHA's authority for the rule in a contested case proceeding. A patient challenging a denial has a significantly different interest than petitioner, as the manufacturer of the drug, has in this case. Requiring petitioner to forgo its facial challenge in the hope that a patient might raise similar issues on a denial of coverage for Exondys is not required for the "likely to evade review" criteria. *See Eastern Oregon Mining Association v. DEQ*, 360 Or 10, 17, 376 P3d 288 (2016) ("[T]he focus of ORS 14.175(3) is whether the general type or category of challenge at issue is likely to evade being fully litigated—including by appellate courts—in the future, not whether a specific case might avoid becoming moot through expedited consideration or some other mechanism[.]"); *State v. Preston-Mittasch*, 319 Or App 507, 509-10, 510 P3d 931, *rev den*, 370 Or 212 (2022) ("Although not every single instance involving this challenged act would necessarily evade review, our standard is that a challenged act be 'likely' to evade review[.]").

Finally, we conclude that we should exercise our discretion to consider petitioner's rule challenge. In

determining whether to exercise our discretion, we consider, among other things, "the adversarial nature of the parties' interests, the effect of the decision on both the parties and others not before the court, judicial economy, and the extent of the public importance of the issues presented." *Eastern Oregon Mining Assoc. v. DEQ*, 285 Or App 821, 830, 398 P3d 449 (2017), *aff'd*, 365 Or 313, 445 P3d 251 (2019), *cert den*, ___ US ___, 141 S Ct 111, 207 L Ed 2d 1052 (2020). Here, the parties' interests remain adverse, the issue raised in this case—the authority of OHA to include any criterion in the PA Criteria beyond just the FDA indicated use—has broader relevance than just this case or even just this covered prescription drug and has great importance to many people to whom the PA Criteria apply. In sum, we deny OHA's renewed motion to dismiss.

PETITIONER'S RULE CHALLENGE

Turning to the merits of petitioner's challenge, which challenges only the January 1, 2018, version of the rule, we first describe our scope of review under ORS 183.400. We may declare a rule invalid only if we determine that the rule "[v]iolates constitutional provisions," "[e]xceeds the statutory authority of the agency," or "[w]as adopted without compliance with applicable rulemaking procedures." ORS 183.400(4). Petitioner contends only that OHA exceeded its statutory authority, and, specifically, petitioner contends that OHA exceeded its authority because the rule conflicts with federal law, and not because OHA's action fell outside of the scope of authority delegated to it by the Oregon Legislative Assembly. In that circumstance, the question we must answer is "whether the substance of the action, though within the scope of the agency's or official's general authority, departed from a legal standard expressed or implied in the particular statute being administered, or contravened some other applicable statute." *Nay v. Dept. of Human Services*, 360 Or 668, 680-81, 385 P3d 1001 (2016) (quoting *Planned Parenthood Assn. v. Dept. of Human Res.*, 297 Or 562, 565, 687 P2d 785 (1984)). In conducting that review, we are limited to considering solely "the face of the rule and the laws pertinent to it." *AFSCME Local 2623 v. Dept. of Corrections*, 315 Or 74, 79, 843 P2d 409 (1992).

With that limited scope of review in mind, we set out the federal and state statutory background for OHA's rule, which involves Oregon Medicaid coverage for prescription drugs. "Medicaid 'is a cooperative endeavor in which the Federal Government provides financial assistance to participating States to aid them in furnishing health care to needy persons.'" *Nay*, 360 Or at 670 (quoting *Harris v. McRae*, 448 US 297, 308, 100 S Ct 2671, 65 L Ed 2d 784 (1980)). "The [federal Medicaid] Act gives the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in 'the best interests of the recipients.'" *Alexander v. Choate*, 469 US 287, 303, 105 S Ct 712, 83 L Ed 2d 661 (1985) (quoting 42 USC § 1396a(a)(19)). Congress requires participating states to provide assistance in a number of general categories of medical services for most people who receive services under the state's plan, 42 USC § 1396a(a)(10)(A), and states may also elect to provide listed optional services, one of which is prescription drug coverage, 42 USC § 1396d(a)(12).

Once a state elects to provide Medicaid services, the state must act in compliance with the Medicaid Act and applicable federal regulations. *See, e.g.*, *Alexander*, 469 US at 289 n 1. The state plan must "include reasonable standards *** for determining eligibility for and the extent of medical assistance under the plan which *** are consistent with the objectives of [the Medicaid Act]." 42 USC § 1396a(a)(17). A state plan must also "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan *** as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care[.]" 42 USC § 1396a(a)(30). Under 42 CFR section 440.230, a state plan "must specify the amount, duration, and scope of each service that it provides" and "[e]ach service must be sufficient in amount, duration, and scope to reasonably achieve its purpose." 42 CFR § 440.230(a), (b). In addition, that regulation provides that "[t]he agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 CFR § 440.230(d).

Petitioner's challenge in this case specifically falls under the federal Medicaid Drug Rebate Program (MDRP) in the Medicaid Act. "In response to increasing Medicaid expenditures for prescription drugs, Congress enacted a cost-saving measure in 1990 that requires drug companies to pay rebates to States on their Medicaid purchases." *Pharm. Research & Mfrs. of America v. Walsh*, 538 US 644, 649, 1243 S Ct 1855, 155 L Ed 2d 889 (2003) (*Walsh*) (footnote omitted). The Supreme Court in *Walsh* explained that the MDRP, has two basic parts. "First, it imposed a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements either with the Secretary [of Health and Human Services] or, if authorized by the Secretary, with individual States, to provide rebates on their Medicaid sales of outpatient prescription drugs." *Id.* at 652. "Second, once a drug manufacturer enters into a rebate agreement, the law requires the State to provide coverage for that drug under its plan unless the State complies with one of the exclusion or restriction provisions in the Medicaid Act." *Id.* (citing 42 USC § 1396r-8(d)); *see also* 42 USC § 1396a(a)(54) ("A State plan for medical assistance must * * * in the case of a State plan that provides medical assistance for covered outpatient drugs (as defined in section 1396r-8(k) of this title), comply with the applicable requirements of section 1396r-8 of this title[.]").

The permissible restrictions for a state providing drug coverage are set out in 42 USC section 1396r-8(d)(1):

> "(d) Limitations on coverage of drugs
>
> "(1) Permissible restrictions
>
> "(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).
>
> "(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—
>
> "(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));
>
> "(ii) the drug is contained in the list referred to in paragraph (2);

> "(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or
>
> "(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4)."

In turn, 42 USC section 1396r-8(5), governing a state prior authorization program, provides:

> "A State plan under this subchapter may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval-
>
> "(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and
>
> "(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary)."

Turning to Oregon law, the "[Oregon Health Plan (OHP)] is Oregon's Medicaid program, which provides health care assistance to qualifying residents." *Hasner v. Western Oregon Advanced Health*, 289 Or App 207, 208, 410 P3d 373 (2017); *see also* OAR 410-120-000(171) (defining "Oregon Health Plan"). OHA is the state agency responsible for administering and developing policies for the provision of publicly funded medical care, including under OHP, ORS 413.032(1), and has authority to "adopt rules necessary for the administration of the laws that the Oregon Health Authority is charged with administering," ORS 413.042. OHA is also authorized to establish prior authorization for prescription drugs. ORS 414.325(5)(a)(B) ("Notwithstanding subsections (1) to (4) of this section and except as provided in paragraph (b) of this subsection, the authority is authorized to: *** Require prior authorization of payment for drugs the authority has determined should be limited to those

conditions generally recognized as appropriate by the medical profession."); *see also* ORS 414.361(3) (providing that the Pharmacy and Therapeutics Committee shall recommend to OHA "all utilization controls, prior authorization requirements or other conditions for the coverage of a drug").

OHA has promulgated rules according to that authority, including OAR 410-121-0040. Under OAR 410-121-0040(1), prescribing practitioners are required to obtain prior authorization (PA) for the drugs covered by the rule, using the process in OAR 410-121-0060.[2] The drugs covered by the rule are described in subsection (3):

> "The Authority may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines (see OAR 410-141-0480). The drugs and categories of drugs that the Authority requires PA for this purpose are found in the Oregon Medicaid Fee-for-Service Prior Authorization Approval Criteria (PA Criteria guide) dated January 1, 2018, adopted and incorporated by reference and found at: http://www.oregon.gov/OHA/healthplan/pages/pharmacy-policy.aspx."

OAR 410-121-0040(3).

The PA Criteria provides in its general information section that OHA "may require PA for individual drugs and categories of drugs to ensure that the drugs prescribed are indicated for conditions funded by OHP and consistent with the Prioritized List of Health Services and its corresponding treatment guidelines." PA Criteria, 8. The PA Criteria includes a section covering drugs used to treat Duchenne muscular dystrophy (DMD), including Exondys (which has

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[2] "Prior Authorization (PA)" is defined as "payment authorization for specified medical services or items given by Authority staff or its contracted agencies before providing the service. A physician referral is not a PA." OAR 410-120-0000(203). "Prior Authorization Program (PA)" is defined as

> "a system of determining, through a series of therapeutic and clinical protocols, which drugs require authorization before dispensing:
>
> "(A) OAR 410-121-0040 lists the drugs or categories of drugs requiring PA;
>
> "(B) The practitioner or practitioner's licensed medical personnel listed in OAR 410-121-0060 may request a PA."

OAR 410-121-0000(3)(hh).

the generic name "eteplirsen"). The identified goals of the PA for eteplirsen are to "[e]ncourage use of corticosteroids which have demonstrated long-term efficacy" and "[r]estrict use of eteplirsen *** to patients with Duchenne Muscular Dystrophy." *Id.* at 75.

To obtain approval for Exondys, the criteria set out a series of questions. The first question asks, "Does the patient have a diagnosis of Duchenne Muscular Dystrophy with one of the following genetic mutations amenable to exon 51 skipping: ***?" If "Yes," the genetic testing is to be documented and the next question is asked; if "No," the PA provides "Pass to RPh.[3] Deny; medical appropriateness." The second question asks, "Has the patient been on a stable dose of corticosteroid for at least 6 months?" If "Yes," the next question is asked; if "No," the PA provides "Pass to RPh. Deny; medical appropriateness." The final question asks, "Has baseline functional assessment been evaluated using a validated tool such as the 6-minute walk test or North Star Ambulatory Assessment?" If "Yes," the PA provides, "Document baseline functional assessment and approve for up to 6 months"; if "No," the PA provides, "Pass to RPh. Deny; medical appropriateness."[4] *Id.* at 75-76. If the request is for a renewal of Exondys, rather than a new prescription, the question asked is, "Has the patient's baseline functional status been maintained at or above baseline level or not declined more than expected given the natural disease progression?" If "Yes," the PA provides "Approve for up to 6 months. Document functional status."; if "No," the PA provides "Pass to RPh. Deny; medical appropriateness."

Here, petitioner challenges only the second and third questions for a new prescription of Exondys, arguing that OHA did not have authority to include those requirements in its PA Criteria. Petitioner's argument is that, under 42 USC section 1396r-8(d), OHA cannot deny coverage for Exondys when prescribed for its "medically accepted indication," *i.e.*,

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[3] We understand "RPh" to be an acronym for "registered pharmacist."

[4] As discussed above, the approval criteria for Exondys remains the same under the January 1, 2023, PA Criteria, except that the first criterion now includes an exception for "documented contraindication to steroids." PA Criteria, 130 (Jan 1, 2023).

its FDA-approved use.[5] Petitioner acknowledges that 42 USC section 1396r-8(d)(5) allows states to establish prior authorization programs, but asserts that prior authorization under that section allows only a time-limited administration process to ensure that the prescription is for its FDA-approved use and not otherwise excluded from coverage based on the permissible restrictions set out in 42 USC section 1396r-8(d)(1)(B). Petitioner concludes that, because the PA Criteria includes two prerequisites for coverage that are not part of the FDA-approved use for Exondys, OHA exceeded its statutory authority and the PA Criteria for Exondys is invalid.[6]

On the merits, OHA argues that the PA Criteria complies with 42 USC section 1396r-8(d)(5), because the plain text of that section places only two limitations on a state's prior authorization program—a response within 24 hours and allowing the dispensing of at least a 72-hour emergency supply of the drug—both of which requirements are met in OAR 410-121-0060. OHA further asserts that the general provisions of the Medicaid Act and its implementing regulations confer broad discretion on the states to use prior authorization criteria that are based on medical necessity and utilization control considerations, which are not circumscribed by 42 USC section 1396r-8(d). OHA argues that those general Medicaid provisions apply equally to covered prescription drugs because the MDRP operates in the context of the existing Medicaid framework. OHA also asserts that the prior authorization criteria for Exondys are, on the face of the rule, reasonable limitations based on medical necessity and utilization control.

Petitioner's argument requires us to construe federal law. In doing so, "we follow the methodology prescribed

[5] "Medically accepted indication" is defined in 42 USC section 1396r-8(k)(6) as "any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act [21 USC section 301 *et seq.*] or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i)." (Brackets in original.)

[6] We note that petitioner has also relied on certain other materials for its argument, such as a June 27, 2018 "notice" issued by the federal Department of Health & Human Services, Center for Medicare and Medicaid Services (CMS), and the FDA-approved label for Exondys. Our scope of review on a direct rule challenge under ORS 183.400 does not permit us to consider that evidence, as we are restricted to the face of the rule and other relevant law, and, thus, we do not consider it.

by the federal courts." *Corp. of Presiding Bishop v. City of West Linn*, 338 Or 453, 463, 111 P3d 1123 (2005). "Federal courts generally determine the meaning of a statute by examining its text and structure and, if necessary, its legislative history." *Id.* (citing *Dep't of Rev. of Oregon v. ACF Indus., Inc.*, 510 US 332, 339-46, 114 S Ct 843, 127 L Ed 2d 165 (1994)). Using that methodology, we begin "with the 'cardinal canon' of statutory construction: Congress 'says in a statute what it means and means in a statute what it says there.'" *Planned Parenthood v. Betlach*, 727 F3d 960, 968 (9th Cir 2013) (quoting *Conn. Nat'l Bank v. Germain*, 503 US 249, 253-54, 112 S Ct 1146, 117 L Ed 2d 391 (1992)). In examining the text, we "'giv[e] the words used their ordinary meaning, unless Congress has directed us to do otherwise.'" *Id.* at 968 (quoting *Moskal v. United States*, 498 US 103, 108, 111 S Ct 461, 112 L Ed 2d 449 (1990) (bracket in *Betlach*)).

Under 42 USC section 1396r-8(d)(1), the Medicaid Act sets out the "permissible restrictions" on coverage of drugs under MDRP:

> "(d) Limitations on coverage of drugs
>
> "(1) Permissible restrictions
>
> "(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).
>
> "(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—
>
> "(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));
>
> "(ii) the drug is contained in the list referred to in paragraph (2);
>
> "(iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or
>
> "(iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4)."

The permissible restriction of subjecting "*any* covered outpatient drug" (emphasis added) to a prior authorization program means just that: it may be applied to any or all covered outpatient drugs. *See, e.g.*, *Betlach*, 727 F3d at 969 (in a federal statute "any means all" unless Congress limited the breadth of the word in the statute). That broad permissible restriction is set out in its own subparagraph—42 USC section 1396r-8(d)(1)(A)—which is separate from the subparagraph that sets out the bases on which a state can "exclude or otherwise restrict coverage" of a drug—42 USC section 1396r-8(d)(1)(B). The text of the statute does not link those two types of permissible restrictions—that is, the statute does not suggest that a prior authorization denial may *only* be based on one of the permissible restrictions set out in 42 USC section 1396r-8(d)(1)(B). If Congress had meant to so narrowly limit the scope of a prior authorization program it could have easily done so in this statutory section, but it did not, and we will not add words to the statute to include that limitation.

However, applying the words chosen by Congress, we also conclude that a state can only exclude or restrict coverage of a covered drug, on a drug-wide basis—that is, regardless of the circumstances of the individual patient—based on the restrictions in 42 USC section 1396r-8(d)(1)(B). That reading is informed by the wording and structure of the statute, which provides that "[a] State may exclude or otherwise restrict coverage of a covered outpatient drug if" and then lists permissible restrictions that address drug coverage on a drug-wide basis: excluding or restricting coverage for a particular use because it is not a "medically accepted indication," excluding or restricting coverage because it appears on the statutory list, restricting coverage based on manufacturer agreement, or excluding coverage through a formulary. Further, the statutory list provides that "[t]he following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted," and then primarily describes drugs when used for particular purposes, suggesting that "otherwise restricted" means restrictions related to particular uses.[7] That is, the statute

[7] The subsection setting out the statutory list provides:

"(2) List of drugs subject to restriction

describes exclusions from coverage entirely or restriction of uses for an otherwise covered drug that applies to all patients; in general, there is no allowance for the drug to be used by anyone if it is excluded from coverage or if the particular use is restricted.[8] But, as stated above, we do not read that list to be the exclusive types of controls that a state could use with respect to covered outpatient drugs. That the prior authorization program may include controls other than exclusions from coverage and restrictions of use under 42 USC section 1396r-8(d)(1)(B) is further informed by 42 USC section 1396r-8(d)(1)(A), by only requiring that such a program "shall comply with the requirements of paragraph (5)."

The text of 42 USC section 1396r-8(d)(5) provides that a state can "require, *as a condition of coverage* or

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"The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

"(A) Agents when used for anorexia, weight loss, or weight gain.

"(B) Agents when used to promote fertility.

"(C) Agents when used for cosmetic purposes or hair growth.

"(D) Agents when used for the symptomatic relief of cough and colds.

"(E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

"(F) Nonprescription drugs, except, in the case of pregnant women when recommended in accordance with the Guideline referred to in section 1396d(bb)(2)(A) of this title, agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.

"(G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

"(H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration."

[8] *See also Merriam-Webster Unabridged Dictionary*, http://unabridged.merriam-webster.com/unabridged/exclude (accessed Apr 20, 2023) ("exclude" as a transitive verb means "to shut out : restrain or hinder the entrance of"; "to bar from participation, enjoyment, consideration, or inclusion *** <that request must be *excluded* from further consideration>"; "to prevent or refuse to tolerate the occurrence, use, or existence of"); *id.*, http://unabridged.merriam-webster.com/unabridged/restrict (accessed Apr 20, 2023) ("restrict" as a transitive verb means "to set bounds or limits to : hold within bounds : such as *** to check, bound, or decrease the range, scope, or incidence of : set what is to be included or embraced by : bar or carefully govern addition or increment to").

payment for a covered outpatient drug *** the approval of the drug before its dispensing for any medically accepted indication." (Emphasis added.) That text does not indicate that a state may never deny coverage for an individual patient if the drug is being dispensed for any medically accepted indication. Rather, it provides that the state can require its approval of the drug "as a condition of coverage" for a medically accepted indication. *See Merriam-Webster Unabridged Dictionary*, http://unabridged.merriam-webster.com/unabridged/condition (accessed Apr 20, 2023) ("[C]ondition" is "something established or agreed upon as a requisite to doing or taking effect of something else."). To provide that an approval is required for something necessarily implies that a denial is a potential outcome. The only statutory limitations placed on a state's prior authorization program are that the state must provide a 24-hour response and allow coverage for at least a 72-hour supply of a drug for emergency situations. *See Pharm. Research & Mfrs. of America v. Concannon*, 249 F3d 66, 75 (1st Cir 2001), *aff'd on other grounds sub nom*, *Pharm. Research & Mfrs. of America v. Walsh*, 538 US 644, 123 S Ct 1855, 155 L Ed 2d 889 (2003) (observing that "[t]he statute sets forth only two limitations on a state's use of prior authorization"); *see also Pharm. Research & Mfrs. of America v. Meadows*, 304 F3d 1197, 1207 (11th Cir 2002), *cert den*, 538 US 1056 (2003) ("[T]he text of the Medicaid statute contains only two specific limitations on prior authorization: a response within 24 hours and the availability of an emergency 72 hour supply of the drug."). Those specific limitations do not circumscribe what controls a state might use in its prior authorization program under the authority granted to states in 42 USC section 1396r-8(d)(1)(A). *See, e.g.*, *Betlach*, 727 F3d at 969 ("We must give effect, if possible, to every word of a statute." (Internal quotation marks and ellipsis omitted.)).

Considering the broader context of the Medicaid Act, we also do not find support for petitioner's argument that no controls may be included in a prior authorization program other than the drug-wide exclusions or restrictions allowed by 42 USC section 1396r-8(d)(1)(B). *See, e.g.*, *Betlach*, 727 F3d at 971 (stating that "a section of a statute should not be read in isolation from the context of the

whole Act" (internal quotation marks omitted)). As set out above, with regard to a state's Medicaid plan, the state must "include reasonable standards *** for determining eligibility for and the extent of medical assistance under the plan which *** are consistent with the objectives of this [act]." 42 USC § 1396a(a)(17). A state plan must also "provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan *** as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care[.]" 42 USC § 1396a(a)(30). The U. S. Supreme Court has stated that the Medicaid Act "confers broad discretion on the States to adopt standards for determining the extent of medical assistance, requiring only that such standards be 'reasonable' and 'consistent with the objectives' of the Act." *Beal v. Doe*, 432 US 438, 444, 97 S Ct 2366, 53 L Ed 2d 464 (1977); *see also Walsh*, 538 US at 665 ("[T]he Medicaid Act gives the States substantial discretion to choose the proper mix of amount, scope, and duration limitations on coverage, as long as care and services are provided in the best interest of the recipients." (Internal quotation marks and citation omitted.)). The Court has also explained that prior authorization may be used to serve Medicaid-related purposes, which includes to reduce Medicaid costs. *Walsh*, 538 US at 664 (plurality); *see also id.* at 684 (O'Connor, J., dissenting) (stating that prior authorization may serve a Medicaid purpose such as "safeguarding against unnecessary utilization and assuring that payments are consistent with efficiency, economy and quality of care. A State accordingly may impose prior authorization to reduce Medicaid costs." (Internal quotation marks and citation omitted.)).

Further, 42 CFR section 440, subpart B, sets out regulations that apply to "all services." 42 CFR § 440.200(b) ("The requirements and limits of this subpart apply for all services defined in subpart A of this part."). Coverage of prescription drugs is such a "service." 42 CFR § 440.120(a) (in subpart A, defining "prescribed drugs"); *see also* 42 CFR § 440.1 (providing that subpart A implements, among others, section 1905(a) of the Medicare Act, which is 42 USC section 1396d(a), which sets out "[s]ervices included in the term

'medical assistance'); *see also* 42 USC § 1396d(a)(12) (providing that "[t]he term 'medical assistance' means payment of part or all of the cost of the following care and services or the care and services themselves, or both *** for individuals [meeting the eligibility requirement]— *** (12) prescribed drugs"). In those regulations, a state plan "must specify the amount, duration, and scope of each service that it provides" and "[e]ach service must be sufficient in amount, duration, and scope to reasonably achieve its purpose." 42 CFR § 440.230(a), (b). In addition, that rule provides that "[t]he agency may place appropriate limits on a service based on such criteria as medical necessity or on utilization control procedures." 42 CFR § 440.230(d). Under those sections, a state can adopt reasonable standards for a service sufficient to achieve the purpose of the Medicaid Act and can include appropriate limits on a service based on medical necessity or utilization control. Those regulations specifically apply to coverage of prescribed drugs, and no exceptions are set out for drugs in the rebate program, contrary to petitioner's assertion at oral argument.

Finally, we consider the legislative history the parties have provided. Petitioner cites to a House Report from the Committee on the Budget that accompanied House Resolution (HR) 5835, which included the amendment to the Medicaid Act enacting the MDRP. *See* Omnibus Budget Reconciliation Act of 1990, Pub Law 101-508, title IV, 104 Stat 1388 (1990). That report provides, in part, with respect to the MDRP:

> "States that elect to offer prescription drug coverage under their Medicaid programs would be required to cover all of the drugs of any manufacturer entering into and complying with such an agreement with the Secretary. This requirement would take effect April 1, 1991. *As under current law, States would have the option of imposing prior authorization requirements with respect to covered prescription drugs in order to safeguard against unnecessary utilization and assure that payments are consistent with efficiency, economy, and quality of care.* However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the

> Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e., assuring access by Medicaid beneficiaries to prescription drugs where medically necessary.
>
> "* * * * *
>
> "The Committee emphasizes that the bill is framed to achieve significant Medicaid savings with the minimum possible amount of disruption of current program arrangements. The bill would not require therapeutic substitution or in any other way alter in any way the current relationships between Medicaid beneficiaries and their physicians or their pharmacists. It would not alter the relationship between physicians and pharmacists. Nor would it alter the current payment arrangements between State Medicaid programs and pharmacists. *Finally, the bill would not affect any authority States have under current law to impose prior authorization controls on prescription drugs*."

HR Rep No 101-881, 101st Cong, 2d Sess, *reprinted in* 1990 USCCAN 2017, 2110, 1990 WL 200617 (emphases added).

Contrary to petitioner's argument, that report confirms that the MDRP did not change the law on prior authorization; it stated that states may impose prior authorization requirements to "safeguard against unnecessary utilization" and assure that "payments are consistent with * * * quality of care," which is consistent with the broader Medicaid Act and implementing federal regulations discussed above. The U. S. Supreme Court has explained that, prior to the enactment of the MDRP, states "employed 'prior authorization programs' that required approval by a state agency to qualify a doctor's prescription for reimbursement. These programs were not specifically governed by any federal law or regulations, but rather were made part of the State Medicaid plans and approved by the Secretary because they aided in controlling Medicaid costs." *Walsh*, 538 US at 651-52 (citations omitted). The Court then noted that "Congress effectively ratified the Secretary's practice of approving state plans containing prior authorization requirements when it created [the MDRP]." *Id.*

As the report notes, prior authorization is not intended to allow controls that have "the effect of *preventing* competent physicians from prescribing in accordance with

their medical judgment" (emphasis added), because "[t]his would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e., assuring access by Medicaid beneficiaries to prescription drugs where medically necessary." That intent is embodied in 42 USC section 1396r-8(d)(1)(B), as discussed above, but does not indicate that no other controls can be used in a state's prior authorization program. *See Paleski v. State Dept. of Health Services*, 144 Cal App 4th 713, 735, 51 Cal Rptr 3d 28 (2006) (after reviewing the House Report, stating that "according to Medicaid's legislative history, state programs like Medi-Cal must strike a careful balance between the deference due a treating physician's decision to prescribe a particular drug and the implementation of utilization controls, including prior authorization criteria, which ensure that prescriptions are appropriate and medically necessary").

We also are not persuaded by the case law cited by petitioner to support its argument that the Medicaid Act prevents OHA from adopting any prior authorization controls other than the exclusions and restrictions listed in 42 USC section 1396r-8(d)(1)(B). Petitioner cites to three federal district court cases from Florida, Georgia, and Louisiana, that it asserts supports its construction. In those cases, however, the courts were called on to determine if the state could *exclude* coverage of a drug using a prior authorization program and determined that a state could not. Our reading of the Medicaid statute is not contrary to the ultimate holdings in those cases.[9]

[9] Having reviewed the federal district court opinions, we conclude that they either are not contrary to our analysis of the Medicaid Act and regulations or are unpersuasive, because the court did not engage in statutory construction. *See Edmonds v. Levine*, 417 F Supp 2d 1323 (SD Fla 2006) (addressing a state policy to exclude certain medically accepted indications for a drug through its prior authorization program, and concluding that it could not exclude coverage except as provided in 42 USC section 1396r-8(d)(1)(B)); *see also K-V Pharm. Co. v. Cook*, 2014 WL 11833266, at *3 (ND Ga Apr 7, 2014), *abrogated on other grounds by Armstrong v. Exceptional Child Center, Inc.*, 575 US 320, 135 S Ct 1378, 191 L Ed 2d 471 (2015) (in addressing the state's prior authorization program, which prefers a compounded drug, which is not a covered outpatient drug, over the drug Makena, a covered outpatient drug, the court concluded that "[c]onditioning reimbursement for a drug upon the unavailability or inability to use the non-FDA approved compound is not coverage" and, relying on *Edmonds*, stating that "the Medicaid Act does not authorize a state to use a prior authorization program

Turning back to OHA's prior authorization program, as discussed above, we agree with petitioner to the extent that, when what is at issue is the exclusion or restriction of coverage for a drug, on a drug-wide basis, 42 USC section 1396r-8(d)(1)(B) provides the only bases for that exclusion or restriction. We disagree with petitioner, however, that that is what OHA has done in the January 1, 2018, PA Criteria for Exondys.

OHA covers Exondys for use in treatment of DMD with genetic mutations amenable to exon 51 skipping. That criterion is a drug-wide restriction on the use of Exondys and would be subject to the limitations in 42 USC section 1396r-8(d)(1)(B). Petitioner does not argue that that coverage is more restrictive than the FDA-approved use and, thus, it would comply with that statutory section.

The remaining criteria, for a new prescription, are that a patient must have been on a stable dose of corticosteroids for six months and have taken a baseline functional assessment using a validated tool.[10] We conclude that neither criterion, on the face of the rule, is an exclusion or restriction of coverage within the meaning of 42 USC section 1396r-8(d)(1)(B). Taking the second criterion first—the baseline functional assessment—it does not in any way exclude or restrict coverage for Exondys as a new prescription. That criterion does not require a patient to be ambulatory, as asserted by petitioner; it only requires the patient to take a

to deny coverage for a covered drug"); *In re Vioxx Products Liability Litigation*, MDL No 1657, 2010 WL 2649513, at *10, *13-14 (ED La June 29, 2010) (addressing a state claim "that had it known that Vioxx presented cardiovascular risks it would not have approved reimbursement under the State's Medicaid program," and concluding that the state could not have denied coverage for Vioxx while it was on the market because Louisiana law did not provide a mechanism under which the state could deny coverage of Vioxx during that time).

Petitioner also cites to an Arkansas appellate court decision. We also find that decision unpersuasive, because the court did not engage in statutory construction of the Medicaid Act. *Arkansas Dept. of Human Services v. Sarepta Therapeutics, Inc.*, 2021 Ark App 330, 2021 WL 4186665 (Ark App 2021) (addressing a claim where the state denied coverage of Exondys for a patient based on an agency rule that "[a]ll services must be medically necessary," the court stated without engaging in statutory construction that "[p]rior authorization is a time-limited, administrative process for ensuring that a doctor has prescribed the covered outpatient drug for a medically accepted indication").

[10] As explained above, since July 2020, the PA Criteria have included in this criterion "or have documented contraindication to steroids."

baseline functional assessment. On the face of the rule, that assessment is used solely for comparison purposes to evaluate whether continued coverage of Exondys is medically appropriate under the renewal criterion—a criterion that petitioner *does not* challenge. At most, that criterion could minimally delay coverage until an assessment is completed, but it does not exclude or restrict coverage of Exondys.

Returning to the first criterion—six months on a stable dose of corticosteroids—we also conclude that it does not on its face exclude or restrict coverage of Exondys on a drug-wide basis. That criterion, in a particular case, could delay coverage for up to six months if the individual patient had not started such treatment before seeking coverage of Exondys, but it is not an exclusion or restriction under 42 USC section 1396r-8(d)(1)(B), as we understand that section. It is a patient-specific criterion and does not, on its face, exclude or restrict coverage of Exondys for its indicated use—treatment of patients diagnosed with Duchenne muscular dystrophy amenable to exon 51 skipping. And, in this facial rule challenge, we are not permitted to use hypothetical individual facts as a basis on which to invalidate a rule.[11] *See, e.g.*, *AFSCME Local 2632*, 315 Or at 79 ("Numerous individual fact situations can arise under any rule, but judicial review of the rule as applied to each of those situations is reserved to other forums."). We are not persuaded by petitioner's argument that the criteria used by OHA are an impermissible exclusion or restriction of coverage under 42 USC section 1396r-8(d)(1)(B).

We also note that petitioner does not assert that the PA Criteria for Exondys do not otherwise conform to other parts of the Medicaid Act or to the regulations that allow for "appropriate limits" based on medical necessity or utilization control. The stated goals, on the face of the rule, appear to be generally consistent with those requirements, although we do not decide that issue as it is not currently

[11] To the extent this PA Criteria could, in a particular case, result in a complete denial of coverage for Exondys, such a possibility is beyond the scope of a facial rule challenge, and we therefore decline to address it. And, in all events, we would decline to address it here under our discretion to address moot cases because the current PA Criteria allows an exception for a "documented contraindication to steroids."

before us. Moreover, our scope of review does not permit us to look beyond the face of the rule to address what appears to be largely a fact-based issue.

Our limited scope of review does not permit us to do more here. The Oregon Supreme Court has cautioned that our scope of review on a facial rule challenge must remain limited and cannot extend to any documents beyond the text of the rule and applicable statutory provisions. *Wolf v. Oregon Lottery Commission*, 344 Or 345, 355, 182 P3d 180 (2008) ("The record on review *** consists of two things only: the wording of the rule itself (read in context) and the statutory provisions authorizing the rule."); *see also Walter v. Oregon Board of Education*, 301 Or App 516, 532, 457 P3d 288 (2019) ("[I]n this rule challenge, there *is* no evidentiary record." (Emphasis in original.)). Given our narrow scope of review, we cannot examine the documents cited by petitioner, including the FDA approval for Exondys, or consider potential fact scenarios under which the PA Criteria might exclude or restrict coverage for a medically indicated use. Nor can we look behind the face of the rule to consider whether the criteria, in fact, are appropriately based on medical necessity and utilization controls. We do not suggest by our holding in this facial rule challenge that petitioner, or others, could not in the future seek relief under another procedure that permits consideration of such information.

Motion to dismiss as moot denied. OAR 410-121-0040(3) (Jan 1, 2018) held valid.