UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2024

Argued: September 16, 2024 Decided: March 6, 2025

Docket No. 23-1231-cv

SAFE HAVEN HOME CARE, INC., ELIM HOME CARE AGENCY, LLC, SILVER LINING HOMECARE AGENCY, ANGEL CARE, INC.,

Plaintiffs-Appellants,

— v. —

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the United States Department of Health and Human Services, UNITED STATES CENTERS FOR MEDICARE & MEDICAID SERVICES, STEPHANIE CARLTON, in her official capacity as Administrator of the U.S. Centers for Medicare and Medicaid Services, NEW YORK STATE DEPARTMENT OF HEALTH, JAMES V. MCDONALD, in his official capacity as Commissioner of the New York State Department of Health, AMIR BASSIRI, in his official capacity as Medicaid Director of the New York State Department of Health,

Defendants-Appellees.[*]

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[*] The Clerk of Court is respectfully directed to amend the official caption in this case to conform to the caption above.

B e f o r e:

LYNCH, PÉREZ, and MERRIAM, *Circuit Judges*.

This appeal challenges the decision of the U.S. Centers for Medicare & Medicaid Services to approve the New York State Department of Health's application to pay $361.25 million to certain managed care organizations, which assist the State of New York in administering its Medicaid system. As detailed in the approved application, the managed care organizations were instructed to direct the money to the top one-third of revenue-generating licensed home care services agencies in New York's four rate regions that were willing to agree to use the funding in a particular manner. Appellants, licensed home care services agencies that did not satisfy the revenue threshold for eligibility to receive this funding from the New York State Department of Health, argue that the approval of the application was unlawful under federal law and regulations because the class of eligible licensed home care services agencies was improperly defined and the application was not assessed for actuarial soundness before pre-approval was granted.

The district court (Cronan, *J.*) dismissed the amended complaint against the State Appellees for failure to adequately allege a cause of action under *Ex parte Young*, 209 U.S. 123 (1908), and granted summary judgment to the Federal Appellees, concluding that the approval of the State's application did not violate the Administrative Procedure Act. In addition, the district court denied Appellants' motion for the admission of extra-record evidence. We agree that the decision to approve New York's distribution of the funds complied with federal law and conclude that that determination resolves Appellants' claims against both the Federal and State Appellees on the merits. We also conclude that the district court did not abuse its discretion in excluding Appellants' extra-record evidence. We therefore AFFIRM the judgment of the district court.

DEREK ADAMS (Susan Baldwin Hendrix, *on the briefs*), Potomac Law Group, PLLC, Washington, D.C., *for Plaintiffs-Appellants*.

MOLLIE KORNREICH (David E. Farber, Benjamin H. Torrance, *on the brief*), Assistant United States Attorneys, *for* Damian Williams, United States Attorney for the Southern District of New York, New York, NY, *for* United States Department of Health and Human Services, Xavier Becerra, United States Centers for Medicare & Medicaid Services, and Chiquita Brooks-Lasure.

BLAIR J. GREENWALD, Assistant Solicitor General (Barbara Underwood, Solicitor General, Judith N. Vale, Deputy Solicitor General, *on the brief*), *for* Letitia James, Attorney General of the State of New York, New York, NY, *for* New York State Department of Health, James V. McDonald, and Amir Bassiri.

GERARD E. LYNCH, *Circuit Judge*:

Plaintiffs-appellants Safe Haven Home Care, Inc., Elim Home Care Agency, LLC, Silver Lining Homecare Agency, and Angel Care, Inc. (together, "Appellants") are licensed home care services agencies ("LHCSAs") that did not receive funding when appellee the New York State Department of Health ("NYSDOH") disbursed $361.25 million in funds to the top one-third of revenue generating LHCSAs in New York, after obtaining the written pre-approval of appellee the U.S. Centers for Medicare & Medicaid Services ("CMS") to do so. In

this action, Appellants contend that CMS's decision to pre-approve NYSDOH's application to make this payment violated the Administrative Procedure Act ("APA"). The district court (John P. Cronan, *J.*) disagreed, holding that Appellants had failed to state a claim against the State Appellees and that the Federal Appellees were entitled to summary judgment. We agree and therefore AFFIRM the judgment of the district court.

BACKGROUND

On March 11, 2021, the American Rescue Plan Act of 2021 ("ARPA") was enacted to redress the harmful effects of the COVID-19 pandemic on the economy and the healthcare system. *See* American Rescue Plan Act of 2021, Pub. L. No. 117-2, 135 Stat. 4; *West Virginia ex rel. Morrisey v. U.S. Dep't of Treasury*, 59 F.4th 1124, 1132 (11th Cir. 2023). One feature of ARPA was increased federal matching for qualifying state Medicaid expenditures. *See* Pub. L. No. 117-2, §§ 9814–15, 9817, 135 Stat. at 215–17.

A particular aspect of that increased federal matching is at the heart of the instant appeal. Section 9817 of ARPA increased "the Federal medical assistance percentage . . . by 10 percentage points with respect to expenditures of the State under the State Medicaid program for home and community-based services"

provided between April 1, 2021 and March 31, 2022. *Id.* § 9817(a), 135 Stat. at 216. In turn, Section 9817(b) imposed two restrictions on how States were to utilize this increased funding: (1) the State was required to "use the Federal funds attributable to the increase under subsection (a) to supplement, and not supplant, the level of State funds expended for home and community-based services for eligible individuals through programs in effect as of April 1, 2021"; and (2) the State had to "implement, or supplement the implementation of, one or more activities to enhance, expand, or strengthen home and community-based services under the State Medicaid program." *Id.* § 9817(b), 135 Stat. at 217.

This appeal originates from NYSDOH's decision to use this increased federal matching to direct approximately $361 million to certain providers of home and community-based services in New York known as LHCSAs.

I. Statutory and Regulatory Framework

Before turning to the particularities of the funding decision at issue in this appeal, it is necessary to understand how New York administers its Medicaid program through managed care organizations. Managed care organizations are "health insurance plans or health care systems." J. App'x 46, ¶ 38. The State of New York contracts with managed care organizations, and the managed care

organizations, in turn, contract with medical providers, who then provide medical care to Medicaid enrollees. *See Community Health Care Ass'n of New York v. Shah*, 770 F.3d 129, 137 (2d Cir. 2014). Simply put, managed care organizations act as middlemen between the State and the medical providers and Medicaid enrollees who benefit from the Medicaid program.

The manner in which New York may contractually compensate managed care organizations is subject to limitations imposed by federal law. Generally speaking, States compensate managed care organizations via capitation payments, which are fixed periodic payments that a managed care organization receives per enrolled individual regardless of whether or how much that enrolled individual utilizes medical services during the relevant payment period. *See* 42 C.F.R. § 438.2 (2021). To be eligible to receive federal reimbursement for those expenditures, the State must make capitation payments that are "actuarially sound." 42 U.S.C. § 1396b(m)(2)(A)(iii). That means the capitation payment must be "projected to provide for all reasonable, appropriate, and attainable costs that are required under the terms of the contract and for the operation of the [managed care organization] . . . for the time period and the population covered under the terms of the contract." 42 C.F.R. § 438.4(a) (2021).

Federal regulations generally prohibit a State from "direct[ing]" a managed care organization's "expenditures under the [relevant] contract" between the State and the managed care organization. 42 C.F.R. § 438.6(c)(1) (2021).[1] There are, however, exceptions to this general prohibition that permit the State to direct the expenditures of managed care organizations, which are known as state-directed payments. *See id.* § 438.6(c)(1)(i)–(iii). One of those exceptions is relevant here. A State is permitted to require a managed care organization to "[p]rovide a uniform dollar or percentage increase for network providers that provide a particular service under the contract." *Id.* § 438.6(c)(1)(iii)(C).

Before directing a managed care organization to disburse such a state-directed payment, the State must prepare an application, submit that application to CMS, and receive CMS's written pre-approval. *See id.* § 438.6(c)(2)(ii). Federal regulations delineate the scope of CMS's review of such applications. Section 438.6(c)(2) provides, *inter alia*, that

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[1] Section 438.6 was substantially amended as of July 9, 2024. *See* Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality, 89 Fed Reg. 41002 (May 10, 2024). Neither party has argued that the amended regulation should be given retroactive effect in this case. Accordingly, this Court's decision relies exclusively on the version of the federal regulations that were in effect at the time CMS granted pre-approval to NYSDOH's application.

> (i) All contract arrangements that direct the [managed care organization's] . . . expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices.
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> (ii) Contract arrangements that direct the [managed care organization's] . . . expenditures under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(B) through (D) of this section must have written approval prior to implementation. . . . To obtain written approval, a State must demonstrate, in writing, that the arrangement—
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> (A) Is based on the utilization and delivery of services;
> (B) Directs expenditures equally, and using the same terms of performance, for a class of providers providing the service under the contract;
> (C) Expects to advance at least one of the goals and objectives in the quality strategy in § 438.340;
> (D) Has an evaluation plan that measures the degree to which the arrangement advances at least one of the goals and objectives in the quality strategy in § 438.40;
> (E) Does not condition provider participation in contract arrangements under paragraphs (c)(1)(i) through (iii) of this section on the provider entering into or adhering to intergovernmental transfer arrangements; and
> (F) May not be renewed automatically.

In accordance with this regulation, during the time period relevant to this appeal, CMS reviewed applications for pre-approval to ensure compliance with the requirements of 42 C.F.R. § 438.6(c)(2)(ii) but did *not* evaluate the applications for actuarial soundness during the pre-approval process. Instead, actuarial soundness was evaluated as part of the separate periodic review of the State's

rate certifications.

II. Administrative Proceedings

With that regulatory background in mind, we turn to the specifics of the state-directed payment at issue in this appeal. On December 23, 2021, NYSDOH sought pre-approval from CMS to make a state-directed payment under 42 C.F.R. § 438.6(c)(1)(iii)(C) in connection with utilizing the increased federal matching provided under Section 9817 of ARPA.[2] The application indicated that the State of New York was seeking approval to make a payment totaling $361.25 million to two specific types of managed care organizations: Managed Long-Term Capitation Plans ("MLTCP") and Medicaid Advantage Plus Plans ("MAP"), which, in turn, would be required to pay that money to qualifying LHCSAs. The increased funding was structured to be a "[u]niform [d]ollar or [p]ercentage [i]ncrease," meaning that the qualifying LHCSAs would receive an additional "$3.69 per hour of service" provided during the relevant time period. J. App'x 298–99.

The application indicated, however, that not all LHCSAs in New York

[2] That application is the operative application at issue in this case. NYSDOH had submitted an incomplete version of the application on November 15, 2021.

would qualify to receive that increase. Instead, the eligible class of providers was limited to those LHCSAs "whose 2019 managed care revenue received from MLTCP and MAP plans falls in the top third of providers in their designated . . . rate regions and that attest to using the funding on State-directed programs and/or services in SFY 2022 (April 1, 2021 through March 31, 2022) and 2023 (April 1, 2022 through March 31, 2023)." *Id.* at 293. In total, 212 LHCSAs across four different rate regions (the "NYC Area," the "Mid-Hudson/Northern Metro," the "Northeast/Western," and the "Rest of State" regions) met those eligibility criteria. *Id.* at 343–44.

NYSDOH's application provided a justification for this limitation on eligible LHCSAs. NYSDOH explained that its central goal in making the state-directed payment was to "increas[e] the quality and capacity of the [Medicaid home and community-based services] workforce, such that the [LHCSAs] are able to implement evidence-based care interventions, promote quality, and prepare to participate effectively in value-based payment . . . arrangements." *Id.* at 300. NYSDOH argued that providing funding only to the highest-revenue-generating LHCSAs would best further that goal because those agencies account for "92% of managed care revenue from MLTCP and MAP plans"; therefore,

targeting those agencies would lead to "greater, more targeted and meaningful investments" as compared to spreading the funding across all LHCSAs in New York. *Id.*

After NYSDOH's application was submitted for CMS's review, some New York-based LHCSAs lodged an objection to NYSDOH's proposed limitations on the eligible class of providers. On January 19, 2022, the Potomac Law Group, on behalf of a group of LHCSAs, sent a letter to CMS requesting that CMS withhold approval of NYSDOH's application, contending that defining a class of eligible providers based on a revenue threshold is inconsistent with federal regulations. After receiving that objection, CMS asked NYSDOH follow-up questions about the definition of the provider class, which NYSDOH then answered in a revised application submitted on February 1, 2022.[3]

In response to CMS's questions, NYSDOH explained that it had limited the provider class to the top one-third of revenue generating LHCSAs "to maximize

[3] NYSDOH answered CMS's questions in a document appended to the end of the revised application. Otherwise, the revised application was largely identical to the application submitted on December 21, 2021, with the exception of a revised calculation indicating that the uniform dollar increase would result in an additional "$3.80 per hour of service" being paid to qualifying LHCSAs for services performed between April 1, 2021, and September 30, 2021. J. App'x 353, 359.

the impact of these funds in achieving the goals of the [application]—specifically, to improve the quality of care for Medicaid members by ensuring that the funds are adequate to enable meaningful and innovative workforce recruitment and retention initiatives." *Id.* at 375. NYSDOH backed this proposition up with quantitative reasoning:

> The top third of LHCSAs—as included in this preprint—comprise the *vast* majority of Medicaid service delivery at 92% of total Medicaid spend for personal care services provided by LHCSAs. Because there is a large volume of small LHCSAs with de minimis Medicaid service delivery hours and reimbursement, funding all LHCSAs that participate in Medicaid would result in the receipt of funding by hundreds of very small providers in the bottom two-thirds, whose revenue only total 8% of Medicaid spend for personal care services provided by LHCSAs. To that end, if the State were to include all LHCSAs in the provider class, about 350 LHCSAs would receive less than $1,000. Based on the approved purposes of this funding, it is unlikely that such small award amounts would have a meaningful impact on workforce development and [value-based payment] readiness for the personal care sector. Accordingly, by limiting the provider class to LHCSAs that have greater engagement with the Medicaid program, the State can distribute larger amounts of funding to each provider that will result in real, long-term change for the personal care sector, consistent with the direction and purposes of Section 9817 of ARPA.

Id. (emphasis in original).

NYSDOH then submitted another revised application on February 23, 2022, which was identical to the February 1, 2022 application in all respects relevant to this appeal. Finally, on March 4, 2022, CMS granted written approval

to NYSDOH's application. In so doing, CMS indicated that its approval "only satisfie[d] the regulatory requirement pursuant to 42 CFR 438.6(c)(2) for written approval prior to implementation of any payment arrangement described in 42 CFR 438.6(c)(1)" and thus did "not constitute approval of any Medicaid managed care plan contracts or rate certifications for the aforementioned rating period." *Id.* at 405. In other words, it remained necessary for NYSDOH to submit rate certifications, which incorporate state-directed payments, for CMS to review for compliance with the applicable statutory and regulatory requirements governing New York's payments to managed care organizations, including actuarial soundness. *See* 42 C.F.R. §§ 438.4(b), 438.7 (2021).

This lawsuit followed shortly thereafter.

III. Procedural History

On March 18, 2022, six LHCSAs that had been excluded from eligibility for funding as a result of the revenue threshold sued CMS, the United States Department of Health and Human Services ("HHS"), NYSDOH, and various officials of those agencies.[4] Soon thereafter, the LHCSAs sought to enjoin

[4] The specific officials sued were Xavier Becerra in his official capacity as Secretary of HHS, Chiquita Brooks-Lasure in her official capacity as Administrator of CMS, Mary Bassett in her official capacity as Commissioner of

NYSDOH from making the scheduled disbursement of the pre-approved state-directed payment on March 31, 2022. After a full evidentiary hearing, the district court denied the LHCSAs' motion for a preliminary injunction. The LHCSAs promptly filed an interlocutory appeal on April 4, 2022; however, that appeal was withdrawn after this Court denied their motion for an injunction pending appeal.

On June 1, 2022, Appellants, a subset of the original plaintiff LHCSAs, filed an amended complaint, suing the same defendants for injunctive and declaratory relief. Appellants averred that CMS's approval of NYSDOH's application was unlawful because the state-directed payment was not actuarially sound and the class of providers was improperly defined. The amended complaint accordingly asserted that the APA had been violated because, in approving NYSDOH's application, CMS exceeded its statutory authority, did not act in accordance with law, and acted arbitrarily and capriciously.

On September 2, 2022, the Federal Appellees moved to dismiss the amended complaint and, in the alternative, for summary judgment based on the

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NYSDOH, and Brett Friedman in his official capacity as Medicaid Director of NYSDOH. For the sake of brevity, this Opinion refers to the federal agencies and officials sued as the "Federal Appellees" and to the state agency and officials sued as the "State Appellees."

certified administrative record. That same day, the State Appellees moved to dismiss the amended complaint. Appellants opposed both motions and moved for the admission of extra-record evidence. On July 10, 2023, the district court granted summary judgment to the Federal Appellees, dismissed the amended complaint against the State Appellees, and denied Appellants' motion for the admission of extra-record evidence. *See Safe Haven Home Care, Inc. v. U.S. Dep't of Health and Human Servs.*, 681 F. Supp. 3d 195 (S.D.N.Y. 2023).

With respect to the Federal Appellees, the district court held that CMS's approval of NYSDOH's application complied with federal law. As most relevant to this appeal, the district court first concluded that the provider class was properly defined, under 42 C.F.R. § 438.6(c)(2)(ii)(B), because the plain text of the regulation permitted CMS to approve a provider class that is defined based on a revenue threshold. *Safe Haven Home Care*, 681 F. Supp. 3d at 219. The district court then held that CMS was not required to assess actuarial soundness as part of the pre-approval process; accordingly, CMS's approval decision was not rendered unlawful by its failure to analyze NYSDOH's application for actuarial soundness. *Id.* at 220–22. Finally, the district court held that CMS did not otherwise act arbitrarily or capriciously when it approved NYSDOH's application, as CMS did

not fail to consider any factors it was required to evaluate under federal law. *Id.* at 222–25.

Ancillary to its decision on the merits of the Federal Appellees' summary judgment motion, the district court denied Appellants' motion for the admission of extra-record evidence. *Id.* at 225–26. The district court reasoned that because CMS was not required to assess actuarial soundness during the pre-approval process, it would be improper to admit Appellants' extra-record evidence, which pertained only to actuarial soundness. *Id.*

Finally, with respect to the State Appellees, the district court dismissed the amended complaint, with leave to amend, because it failed to adequately allege a cause of action under *Ex Parte Young*, 209 U.S. 123 (1908). *Safe Haven Home Care*, 681 F. Supp. 3d at 207–12. Instead of amending their complaint, Appellants took the instant appeal.

DISCUSSION

I. Federal Appellees

We start with the grant of summary judgment to the Federal Appellees. On appeal, Appellants argue that the district court failed to recognize that the Federal Appellees acted unlawfully in two principal ways: first, by approving an

improperly defined provider class, and second, by failing to assess actuarial soundness before granting pre-approval. Appellants also argue that the district court improperly denied their motion for the admission of extra-record evidence.[5] For the reasons discussed below, we find that CMS's approval of NYSDOH's application complied with federal law and that Appellants' extra-record evidence was properly excluded. We therefore affirm the grant of summary judgment to the Federal Appellees.

A. Standard of Review

"On appeal from a grant of summary judgment involving a claim brought under the [APA], we review the administrative record *de novo* without according deference to the decision of the district court." *New York v. Raimondo*, 84 F.4th 102, 106 (2d Cir. 2023) (alteration in original), quoting *Town of Southold v. Wheeler*, 48 F.4th 67, 77 (2d Cir. 2022). We also review any questions of statutory

[5] The district court also held that the state-directed payment complied with the regulatory requirement that it be "based on the utilization and delivery of services," 42 C.F.R. § 438.6(c)(2)(ii)(A), because "the amount of money paid to each LHCSA depends on the number of hours of home-care services provided during the relevant period," *Safe Haven Home Care*, 681 F. Supp. 3d at 218. Appellants did not challenge that holding until their reply brief. Accordingly, we decline to consider it. *See EDP Medical Computer Sys., Inc. v. United States*, 480 F.3d 621, 625 n.1 (2d Cir. 2007); *FTC v. Verity Int'l, Ltd.*, 443 F.3d 48, 65 (2d Cir. 2006).

interpretation *de novo*. *See Power Auth. v. M/V Ellen S. Bouchard*, 968 F.3d 165, 170 (2d Cir. 2020). However, our "review of agency actions under the Administrative Procedure Act is narrow and deferential." *American Cruise Lines v. United States*, 96 F.4th 283, 286 (2d Cir. 2024) (internal quotation marks omitted). We will "only set aside an agency action" if it "is arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with the law." *Id.* (internal quotation marks omitted).

B. Provider Class

Appellants contend that the Federal Appellees violated the APA because CMS regulations prohibit defining a provider class based upon a revenue threshold. We disagree.

The validity of Appellants' challenge hinges on the meaning of "a class of providers" in 42 C.F.R. § 438.6(c)(2)(ii)(B). To interpret that key phrase, we start with "the traditional tools" of statutory interpretation: "the text, structure, history, and purpose of [the] regulation." *Kisor v. Wilkie*, 588 U.S. 558, 575 (2019) (internal quotation marks omitted). If, after deploying those traditional tools, we find that the meaning of the regulation is unambiguous, our task is completed, and we need not defer to the agency's interpretation of its own regulation. *Walsh v. Walmart, Inc.*, 49 F.4th 821, 827–28 (2d Cir. 2022). Here, those traditional tools of

statutory interpretation foreclose Appellants' position.

We first look at the relevant text. In order to obtain CMS's written pre-approval, the "State must demonstrate, in writing, that the arrangement," *inter alia*, "[d]irects expenditures equally, and using the same terms of performance, *for a class of providers* providing the service under the contract." 42 C.F.R. § 438.6(c)(2)(ii) (emphasis added). The relevant dictionary definition of a "class" is "[a] set or category of things having some related properties or attributes in common, grouped together, and differentiated from others under a general name or description; a kind, a sort." *Class*, OXFORD ENGLISH DICTIONARY, https://www.oed.com/dictionary/class_n?tl=true#9303200 (last visited Jan. 17, 2025); *see also Class*, MERRIAM-WEBSTER'S UNABRIDGED DICTIONARY, https://unabridged.merriam-webster.com/unabridged/class (last visited Dec. 9, 2024) ("a group, set, or kind marked by common attributes or a common attribute"). Accordingly, the plain text of the regulation requires that a State define its provider class based on an identifiable, shared characteristic that distinguishes the providers in the class from providers outside the class.

If we stopped there, as the district court did, the regulation would seem to permit the State to propose, and CMS to approve, a class of providers as long as

those medical providers share *any* identifiable characteristic. *See Safe Haven Home Care*, 681 F. Supp. 3d at 219. We recognize, as the district court did implicitly, that the dictionary definition of "class" is extremely broad. Indeed, providers may be divided into classes in any number of ways, and the directive to act with reference to *classes* of providers, rather than directing funds to providers on an individual basis, does not appear to give preference to any particular method of categorization. Accordingly, absent any contextual reference to a specific scheme of classification, we are skeptical of Appellants' contention that the instruction to treat "a class of providers" equally, 42 C.F.R. § 438.6(c)(2)(ii)(B), somehow means that the proper class here is all LHCSAs.

Nevertheless, the district court's conclusion that the regulation permits *any* kind of classification by reference to *any* common characteristic would render the requirement meaningless, as such an interpretation inherently lacks content or limiting principles. It would permit CMS to approve a class defined by characteristics that are completely irrelevant to the permissible purposes for making state-directed payments. For example, if we accepted the district court's interpretation of the regulation, then CMS could approve a state-directed payment to a class of all dental practices accepting Medicaid in New York City

that employ a dentist named Smith. That is certainly a group of providers that share a common characteristic, but one might reasonably question whether such a class is crafted to further permissible objectives in directing the expenditures of managed care organizations, the particular context that is relevant here.

That is exactly why we must not "construe words 'in a vacuum.'" *Gundy v. United States*, 588 U.S. 128, 141 (2019), quoting *Davis v. Michigan Dep't of Treasury*, 489 U.S. 803, 809 (1989). Instead, it is critical that we look to the broader regulatory context to discern the meaning of the regulation. *See Rock of Ages Corp. v. Secretary of Labor*, 170 F.3d 148, 155 (2d Cir. 1999). To do so, we need look no further than Section 438.6 itself as a whole.

As we have already explained, Section 438.6 generally prohibits States from "direct[ing] the [managed care organization's] . . . expenditures under the contract," 42 C.F.R. § 438.6(c)(1), but does include specific exceptions that permit the State to direct expenditures under limited circumstances as long as the State obtains written pre-approval from CMS before making such an expenditure "under paragraphs (c)(1)(i) and (ii) and (c)(1)(iii)(B) through (D)," 42 C.F.R. § 438.6(c)(1)(i)–(2). The regulation is structured that way for a reason. The general prohibition on directing expenditures bans the use of what are known as "pass-

through" payments, because a State's contract with a managed care organization is supposed to "define[] the comprehensive cost for the delivery of services under the contract, and . . . the [managed care organization] . . . , as [a] risk-bearing organization[]," is supposed to be able to "maintain the ability to fully utilize the payment under that contract for the delivery of services." Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, and Revisions Related to Third Party Liability ("Final 2016 Rule"), 81 Fed. Reg. 27498, 27582, 27589, 27591 (May 6, 2016).[6]

The regulation, however, provided carve-outs, because CMS recognized that there may be circumstances in which permitting the State to direct expenditures would further permissible Medicaid-related goals. Specifically, the carve-outs were designed so as "to encourage states to use health plans as partners to assist the states in achieving overall delivery system and payment reform and performance improvements," and to give states the ability "to

[6] The regulation in effect at the time CMS rendered its decision in this case laid out a schedule pursuant to which the States' use of "pass-through" payments would be phased out over time. *See* 42 C.F.R. § 438.6(d); Final 2016 Rule, 81 Fed. Reg. at 27588, 27590.

incentivize and retain certain types of providers to participate in the delivery of care to Medicaid beneficiaries under a managed care arrangement." Medicaid and Children's Health Insurance Program (CHIP) Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies, and Revisions Related to Third Party Liability ("Proposed 2015 Rule"), 80 Fed. Reg. 31098, 31124 (proposed June 1, 2015); *see also* Final 2016 Rule, 81 Fed. Reg. at 27582. Notably, CMS intentionally chose *not* to promulgate an exception permitting states to direct payments to "specific providers" without any tie "to delivered services or the outcomes of those services" because such payments would constitute prohibited, actuarially unsound, "pass-through" payments. Final 2016 Rule, 81 Fed. Reg. at 27587–89. Rather than provide such an exception, CMS chose to give the States flexibility through the class-of-providers requirement in 42 C.F.R. § 438.6(c)(2), which was designed to be "a tool through which states and managed care plans can support payment rates that are directly tied to services" while still "direct[ing]" payments "toward specific classes of providers." *Id.* at 27590.

With that context in mind, we read 42 C.F.R. § 438.6(c)(2)(ii)(B) to require that the shared, identifiable characteristics that the State uses to define a provider

class plausibly further some permissible Medicaid-related goal, such as "enhancing services and ensuring access" to care. Final 2016 Rule, 81 Fed. Reg. at 27583; *see also* Proposed 2015 Rule, 80 Fed. Reg. at 31124. To interpret the provision otherwise -- to permit States to propose, and CMS to pre-approve, any provider class as long as the providers shared some identifiable characteristic -- would do violence to the regulatory scheme, which is centered on permitting States to direct expenditures only if doing so will further permissible Medicaid-related goals.

That, however, is where the limitations on the States' ability to craft provider classes end. But Appellants' arguments on appeal do not stop there. Instead, relying on CMS's sub-regulatory guidance and the application form itself, Appellants urge this Court to interpret the regulation to require the State to direct a payment to *all* providers of a service under the managed care organization's contract and not just to a smaller subset of such providers. If that rule were adopted and applied to this case, it would require NYSDOH to direct funding to all LHCSAs, not just those that are top revenue-earners. The problem for Appellants is that there is no textual or contextual hook to support such a limitation.

To start, the sub-regulatory guidance upon which Appellants rely is unavailing. Appellants point to a CMS bulletin which states that "CMS has deferred to states in defining the provider class for purposes of state directed payment arrangements, as long as the provider class is reasonable and identifiable, such as the provider class being defined in the state's Medicaid State Plan." Centers for Medicare & Medicaid Services, *Medicaid Managed Care Options in Responding to COVID-19*, at 6 (May 14, 2020), https://www.medicaid.gov/federal-policy-guidance/downloads/cib051420.pdf ("2020 CMS Bulletin"). The bulletin then elaborates that "[e]xamples of state directed payments for a target class or classes of providers providing services under the contract could include dental, behavioral health, home health and personal care, pediatric, federally-qualified health centers, and safety-net hospitals." *Id.*

But the extrapolation that Appellants seek to draw from this guidance (that the proper provider class here is all LHCSAs, because LHCSAs are a provider class recognized under New York law and New York's Medicaid State plan) is unfounded. First, the plain text of the bulletin provides illustrative, rather than exhaustive, "[e]xamples" of permissible provider classes. *Id.*; *see also Samantar v.*

Yousuf, 560 U.S. 305, 317 (2010) (noting that the "use of the word 'include' can signal that the list that follows is meant to be illustrative rather than exhaustive"); *Bragdon v. Abbott*, 524 U.S. 624, 639 (1998) ("As the use of the term 'such as' confirms, the list is illustrative, not exhaustive.").

Second, to the extent that the bulletin is treated, as Appellants would treat it, as limiting or guiding our interpretation of the term "class of providers,"42 C.F.R. § 438.6(c)(2)(ii)(B), its text points us in a direction opposite to Appellants' assertion. The bulletin, rather than incorporating some specified classificatory scheme, expressly announces CMS's intention to permit any State definition of a class that is "reasonable and identifiable." 2020 CMS Bulletin, at 6. In other words, CMS interprets the regulation that requires States to treat classes of providers equally to permit States to direct payments to classes that are defined *reasonably*, that is, in ways that plausibly further the goals of the Medicaid program. In sum, CMS's sub-regulatory guidance is a dead end for Appellants.

Even less persuasive is Appellants' attempt to infer a limitation from the application form itself. Appellants appear to believe that the fact that the application form requires States to select a "general class of providers [that] would be affected by the state directed payment" (here, "HCBS/personal care

services") means that any further limitation on a class of providers must be improper. J. App'x 414. But even if we could draw inferences about the meaning of the regulation from the application form, the form itself undermines the very inference that Appellants ask us to draw. That is because the next page of the application form asks States to "define the provider class(es) (*if further narrowed from the general classes indicated above*)." *Id.* at 415 (emphasis added). Accordingly, CMS plainly thought it was permissible for States to further limit a provider class beyond the general provider classes laid out earlier in the application form. Moreover, Appellants' own classification, which demands that New York treat all *LHCSAs* equally, fails their own test, since LHCSAs are themselves a limited subset of "HCBS/personal care services." *Id.* at 414. Appellants' argument therefore fails on its own terms.

Appellants' argument, however, suffers from an even more fatal flaw than the weakness of the regulatory indicia upon which it is built: the limitation that Appellants ask us to read into the regulation was one that CMS intentionally omitted. As initially proposed, the regulation would have required States to "demonstrate, in writing, that the arrangement . . . [d]irects expenditures equally, and using the same terms of performance, for *all public and private providers*

providing the service under the contract." 2015 Proposed Rule, 80 Fed. Reg. at 31259 (emphasis added). But CMS replaced "all public and private providers" with "a class of providers" in the final rule after receiving public comments urging "that states be permitted to direct payments to certain provider types within a service classification without having to include all providers of that same service under a singular payment initiative." 2016 Final Rule, 81 Fed. Reg. at 27586, 27860. CMS did so because it agreed with the public commenters that requiring state-directed payments to go to "all public and private providers" would be "unnecessarily restrictive and could have inhibited a state's policy goals for the Medicaid program." *Id.* at 27586. Appellants' position, that the payment must go to all LHCSAs in New York, would have this Court reimpose a limitation that CMS purposely removed from the regulation, thus requiring the State "to include all providers of that same service under a singular payment initiative." *Id*. We decline to do so.

In sum, Section 438.6(c)(2)(ii)(B) permits States to propose, and CMS to pre-approve, a state-directed payment that goes to a subset of providers that share an identifiable characteristic that plausibly furthers some permissible Medicaid-

related goal.[7]

Applying the proper standard, we agree with CMS that it acted in accordance with federal law in approving NYSDOH's proposed provider class. NYSDOH defined the provider class based on shared, identifiable characteristics: revenue and willingness to attest to using the state-directed payment in a particular way. Those criteria plausibly further a permissible purpose: to "increas[e] the quality and capacity of the [Medicaid home and community-based services] workforce, such that the [LHCSAs] are able to implement evidence-based care interventions, promote quality, and prepare to participate effectively in value-based payment . . . arrangements." J. App'x 300. Because the top one-third of revenue-generating LHCSAs provide "the *vast* majority" of "personal care services provided by LHCSAs," it is plausible that targeting those LHCSAs will lead to "greater, more targeted and meaningful investments." *Id.* at 300, 375 (emphasis in original). That is especially so when spreading the funding across

[7] We note that we do not here defer to CMS's interpretation of its own regulation; we have no need to defer because the regulation, in our view, is clear. *See Kisor*, 588 U.S. at 574; *Walsh*, 49 F.4th at 827–28. Instead, we simply note that our interpretation is fully consistent with CMS's interpretation of the class-of-providers requirement, and that Appellants' contention that *its* interpretation is supported by the 2020 CMS Bulletin is without merit. *See* 2020 CMS Bulletin, at 6.

all LHCSAs would result in many smaller LHCSAs receiving a payment that is so small that it would be "unlikely" to "have a meaningful impact on workforce development and [value-based payment] readiness for the personal care sector." *Id.* at 375.[8]

In sum, NYSDOH's proposed provider class was permissible under 42 C.F.R. § 438.6(c)(2)(ii)(B), and CMS did not act contrary to that provision by pre-approving that class.

C. Actuarial Soundness

We now turn to Appellants' argument that CMS's failure to consider actuarial soundness when pre-approving NYSDOH's application was contrary to law, arbitrary, and capricious. The validity of this argument hinges on whether CMS's regulations or the Medicaid statute impose an obligation on CMS to assess actuarial soundness during the pre-approval process. For the reasons explained below, we conclude that neither federal regulations nor federal statutory law

[8] We further note that we do not have to determine for ourselves that we agree with New York's policy judgments in this regard. That is because CMS's acceptance of New York's conclusions does not conflict with law for the reasons we have already explained and because Appellants have put forward no argument that CMS's approval of New York's proposed class of providers was arbitrary and capricious.

require that assessment, and Appellants' challenge therefore fails.

1. Contrary to Law

Appellants first argue that CMS's failure to assess actuarial soundness was contrary to law. Appellants contend that a subsection of CMS's regulations, 42 C.F.R. § 438.6(c)(2)(i), and a provision of the Medicaid statute, 42 U.S.C. § 1396b(m)(2)(A)(iii), require CMS to assess actuarial soundness when pre-approving a state-directed payment. We disagree.

Appellants' principal argument is that Section 438.6(c)(2)(i) of CMS's regulations requires an assessment of actuarial soundness during the pre-approval process. It does not.

We start with the text. Section 438.6(c)(2) is entitled "Process for approval." Two of its three subdivisions are relevant here. The first relevant subdivision, 438.6(c)(2)(i), is the textual hook for Appellants' theory. It provides that "[a]ll contract arrangements that direct the [managed care organization's] . . . expenditures under paragraphs (c)(1)(i) through (iii) of this section must be developed in accordance with § 438.4, the standards specified in § 438.5, and generally accepted actuarial principles and practices." 42 C.F.R. § 438.6(c)(2)(i). The two sections incorporated by reference, 438.4 and 438.5, respectively set the

standards that capitation payment rates must satisfy for CMS to approve them as actuarially sound and delineate the process that states must follow to meet those standards. *See* 42 C.F.R. §§ 438.4–438.5 (2021). The second relevant subdivision, 438.6(c)(2)(ii), then lays out the six criteria that the "State must demonstrate, in writing," in order "[t]o obtain written approval" from CMS. *Id.* § 438.6(c)(2)(ii).

The plain terms of the two relevant subdivisions undermine Appellants' position. To start, it is subdivision (ii), not subdivision (i), that governs what a State must show in writing to obtain CMS's pre-approval. By extension, then, it is Section 438.6(c)(2)(ii) that governs what CMS must review before granting pre-approval. Critically, none of the six criteria in Section 438.6(c)(2)(ii) requires the state-directed payment to be actuarially sound. Furthermore, the plain terms of Section 438.6(c)(2)(i) impose obligations only on the State, not on CMS. As the district court aptly pointed out, it is telling that subdivision (i) uses the term "developed,"42 C.F.R. § 438.6(c)(2)(i), as it is the State, not CMS, that is developing the state-directed payment, *see Safe Haven Home Care*, 681 F. Supp. 3d at 220. And the sections that 438.6(c)(2)(i) incorporates by reference do not oblige CMS to assess actuarial soundness *at the pre-approval stage*. *See* 42 C.F.R. §§ 438.4(b)–(c), 438.5(b). In sum, the plain terms of Section 438.6(c)(2) do not

require CMS to analyze actuarial soundness before granting pre-approval.

That reading of the text is reinforced by the structure of Section 438.6(c)(2). Section 438.6(c)(2)(i) is a separate subdivision from Section 438.6(c)(2)(ii). That separation counsels in favor of not reading the regulation as if subdivision (i) were nested within subdivision (ii). But that is exactly what Appellants would have this Court do in order to find that the State must demonstrate, and CMS must therefore assess, actuarial soundness for pre-approval to be granted. We instead interpret the regulation as it is written and structured: that an assessment of actuarial soundness is not part of the pre-approval process.

That interpretation of the regulation also comports with the broader regulatory scheme governing the approval of capitation rates, laid out in Sections 438.4 and 438.7 of CMS's regulations. Section 438.4, which requires CMS to "review[] and approve[]" capitation rates "as actuarially sound," lists nine criteria that the State must meet to obtain CMS's approval. 42 C.F.R. § 438.4(b). Two of those criteria are that the capitation rates "[m]eet any applicable special contract provisions as specified in § 438.6" and "[b]e provided to CMS in a format and within a timeframe that meets requirements in § 438.7." *Id.* § 438.4(b)(7)–(8). Section 438.7, in turn, requires that the State submit its

capitation rates for managed care organizations, including all state-directed payments, to CMS in the State's periodic rate certification for "12-month rating period[s]," which CMS then reviews for actuarial soundness. *See* 42 C.F.R. § 438.7(a)–(b); Centers for Medicare & Medicaid Services, *2021-2022 Medicaid Managed Care Rate Development Guide*, at 2–5, 26–32 (June 2021), https://www.medicaid.gov/medicaid/managed-care/downloads/2021-2022-medicaid-rate-guide-11102021.pdf. Thus, CMS's regulations require that actuarial soundness, including the effect on actuarial soundness of state-directed payments, be assessed as part of the periodic rate certification process. It would therefore make no sense to interpret Section 438.6(c)(2) to separately require that assessment at the pre-approval stage.

Stripped of the ability to rely on Section 438.6(c)(2)(i), Appellants' argument collapses, because the other contextual and regulatory clues that Appellants point to are completely unpersuasive.

First, Appellants argue that the title of Section 438.6(c)(2), "Process for approval," indicates that Section 438.6(c)(2)(i) must impose an obligation on CMS to assess actuarial soundness because "[t]he approval referenced by this section is that of CMS for a State's [state-directed payment]." Appellants' Br. 29 (emphasis

omitted). But even assuming that such an inference can be drawn, it is well established that a title cannot "override" the plain meaning of the text. *Dubin v. United States*, 599 U.S. 110, 121 (2023) (internal quotation marks omitted); *see also Bhd. of R.R. Trainmen v. Baltimore & O.R. Co.*, 331 U.S. 519, 528–29 (1947). Here, the plain meaning of the regulation does not require CMS to assess actuarial soundness during the pre-approval process. Accordingly, any counter-indications from the title do not override that plain meaning and are thus of no help to Appellants.

Second, Appellants point out that CMS requests information relevant to actuarial soundness in the application form that States submit to seek pre-approval, which Appellants argue is evidence that CMS must assess actuarial soundness during the pre-approval stage. It is true that the application form requests such information. Specifically, the form requires the State to provide assurances that "all expenditures" for the state-directed payment "are developed in accordance with 42 C.F.R. § 438.4, the standards specified in 42 C.F.R. § 438.5, and generally accepted actuarial principles and practices." J. App'x 420. In addition, Table 2, entitled "Provider Payment Analysis," *id.* at 417, is included in the application form so that "states [can] demonstrate that the state directed

payments result in provider payment rates that are reasonable, appropriate, and attainable as part of the review of the preprint," Centers for Medicare & Medicaid Services, *SMD # 21-001 RE: Additional Guidance on State Directed Payments in Medicaid Managed Care*, at 5–6 (Jan. 8, 2021), https://www.medicaid.gov/Federal-Policy-Guidance/Downloads/smd21001.pdf. The fundamental problem for Appellants, however, is that the application form cannot alter what is required under the text of the regulation itself. As a policy matter, CMS is, of course, entitled to request information about actuarial soundness. But that CMS can seek information does not mean that it is required to make a particular assessment of that information determinative of approving the application.

Third and finally, Appellants recite statements from a 2023 proposed rule that indicate that CMS must review actuarial soundness during the pre-approval process. *See* Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality, 88 Fed. Reg. 28092 (proposed May 3, 2023). That argument too suffers from a fatal flaw: the 2023 proposed rule, which was promulgated as a final rule in 2024, *amended* Section 438.6(c) in order to require CMS to analyze actuarial soundness during the pre-

approval process. *Id.* at 28234–36; Medicaid Program; Medicaid and Children's Health Insurance Program (CHIP) Managed Care Access, Finance, and Quality, 89 Fed. Reg. 41002, 41268–69 (May 10, 2024). And as we have noted above, *see supra* note 1, neither party has argued that this version of the regulation should be given retroactive effect in this case. Accordingly, Appellants' reliance on commentary accompanying a 2023 proposed rule, which amended the regulation to adopt, for the future, Appellants' position on appeal, is totally misplaced.

In sum, the version of CMS's regulations in effect at the time the relevant decisions were made in this case does not require CMS to analyze actuarial soundness during the pre-approval stage.

In addition to their argument based on the regulation, Appellants also argue that a provision of the Medicaid statute, 42 U.S.C. § 1396b(m)(2)(A)(iii), independently requires CMS to assess actuarial soundness during the pre-approval process. Once again, we disagree.

The relevant provision prohibits the federal government from making a payment "to a State with respect to expenditures incurred by it for payment (determined under a prepaid capitation basis or under any other risk basis) for services provided by" a managed care organization "unless . . . such services are

provided for the benefit of" Medicaid enrollees "in accordance with a contract between the State and [a managed care organization] under which prepaid payments to the [managed care organization] are made on an actuarially sound basis." 42 U.S.C. § 1396b(m)(2)(A). The problem for Appellants is simple: the plain language of this provision imposes no requirements on CMS's pre-approval of state-directed payments. Instead, it limits only when the federal government can reimburse the State for the State's expenditures on care provided by managed care organizations. In other words, it requires an assessment of whether the contracts with managed care organizations are actuarially sound *after* the State expends funds and seeks reimbursement; it says nothing about what CMS must do *before* approving a state-directed payment.[9]

Appellants protest that this is a distinction without a difference because the federal government provides matching funds for any state-directed payments that a State makes to a managed care organization. Appellants' position, however, overlooks that state-directed payments are assessed for actuarial

[9] Tellingly, Appellants do not allege or argue that the State was or should have been denied payment from the federal government for Medicaid expenditures in 2022 because the state-directed payment at issue here rendered the capitation rates actuarially unsound.

soundness during the rate certification process, at which point any issues with the state-directed payment must be reconciled. That review is sufficient to satisfy the requirements of 42 U.S.C. § 1396b(m)(2)(A)(iii), as nothing in the provision indicates that review for actuarial soundness must take place at the earlier pre-approval stage. We accordingly find Appellants' argument that 42 U.S.C. § 1396b(m)(2)(A)(iii) requires an assessment of actuarial soundness at the pre-approval stage is without merit.

In sum, because neither federal regulations nor federal law require CMS to analyze actuarial soundness before granting pre-approval to a state-directed payment, we find that CMS did not act contrary to law when it pre-approved NYSDOH's application without first conducting that analysis.

2. Arbitrary and Capricious

We next turn to Appellants' argument that CMS's failure to consider actuarial soundness during the pre-approval process was arbitrary and capricious. However, "[a]n agency's decision is arbitrary and capricious only if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency,

or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *American Cruise Lines*, 96 F.4th at 286 (internal quotation marks omitted). We have concluded above that CMS was authorized to grant pre-approval without first assessing the actuarial soundness of New York State's state-directed payment and to instead consider actuarial soundness as part of its review of the State's periodic rate certifications. It follows then that actuarial soundness was not "an important aspect of the problem" that CMS was tasked with addressing, at least at the pre-approval stage. *Id.*

In conclusion, CMS did not violate the APA by not considering actuarial soundness before granting pre-approval to NYSDOH's application.

D. Exclusion of Extra-Record Evidence

Finally, we turn to Appellants' contention that the district court erred in denying their motion for the admission of extra-record evidence. Appellants argue that the district court improperly excluded two expert declarations, one from Gregory G. Fann, who opined on whether the payment for which NYSDOH sought pre-approval was actuarially sound,[10] and another from John D. Inman,

[10] Appellants also characterize Fann's declaration as opining on whether NYSDOH's proposed payment was tied to the utilization and delivery of services. We disagree with that characterization because Fann's opinion about the

who provided general background about the relevant regulatory scheme and concluded that NYSDOH's proposed provider class was improper.

We review the district court's decision to exclude Appellants' extra-record evidence for abuse of discretion. *Nat'l Audubon Soc'y v. Hoffman*, 132 F.3d 7, 16 (2d Cir. 1997). "Generally, a court reviewing an agency decision is confined to the administrative record compiled by that agency when it made the decision." *Id.* at 14. There are, however, limited circumstances under which the admission of extra-record evidence "may be appropriate." *Id.* The first is "when there has been a strong showing in support of a claim of bad faith or improper behavior on the part of agency decisionmakers." *Id.* The second is "where the absence of formal administrative findings makes such investigation necessary in order to determine the reasons for the agency's choice." *Id.* The third is when "the district court need[s] to supplement the record with background information in order to determine whether the agency considered all of the relevant factors." *American*

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utilization and delivery of services is little more than a continued discussion of principles of actuarial soundness.

Wildlands v. Kempthorne, 530 F.3d 991, 1002 (D.C. Cir. 2008) (internal quotation marks omitted).[11]

The evidence that Appellants sought to admit does not fall within any of these exceptions. Fann's declaration, which focuses on actuarial soundness, was properly excluded because CMS was not required to assess actuarial soundness during the pre-approval process. Inman's declaration was properly excluded both because the background information he sought to offer is irrelevant, when the only issue before the district court was one of statutory and regulatory interpretation, and because his opinion about the permissibility of the proposed provider class is little more than improper second-guessing of CMS's decision on the merits. *See Ascaro, Inc. v. U.S. Env't Prot. Agency*, 616 F.2d 1153, 1160 (9th Cir. 1980) ("Consideration of [extra-record] evidence to determine the correctness or wisdom of the agency's decision is not permitted.").

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[11] The parties dispute whether extra-record evidence can be admitted when it "is alleged" that the agency "entirely failed to consider an important aspect of the problem." Appellants' Br. 35, quoting *Nat. Res. Def. Council, Inc. v. U.S. Food & Drug Admin.*, 598 F. Supp. 3d 98, 106 (S.D.N.Y. 2022). We need not decide this issue because the only evidence that Appellants appear to argue would be admissible under this rule is Fann's opinion on actuarial soundness, which was properly excluded for the independent reason that actuarial soundness is not a factor that CMS must consider before granting pre-approval.

In conclusion, we affirm the district court's denial of Appellants' motion for the admission of extra-record evidence. Given that the district court both properly concluded that CMS did not violate the APA by granting pre-approval to NYSDOH's application and properly excluded Appellants' extra-record evidence, we affirm the grant of summary judgment to the Federal Appellees.

II. State Appellees

Finally, we turn to the district court's decision to dismiss the amended complaint against the State Appellees. Appellants' claims against the State Appellees are entirely dependent on whether the Federal Appellees violated federal law by approving NYSDOH's application. Because we find that the Federal Appellees' decision to approve the application complied with federal law, all of Appellants' claims against the State Appellees necessarily fail on the merits. We accordingly affirm the dismissal of the amended complaint against the State Appellees.[12]

[12] We also note that Appellants did not challenge the merits of the district court's dismissal of the amended complaint against the State Appellees in its opening brief, so we decline to consider that issue. *See EDP Medical Computer,* 480 F.3d at 625 n.1; *Verity Int'l*, 443 F.3d at 65.

CONCLUSION

We have considered Appellants' remaining arguments and find them to be without merit. The district court properly granted summary judgment to the Federal Appellees, dismissed the amended complaint against the State Appellees, and denied Appellants' motion for the admission of extra-record evidence. Accordingly, we AFFIRM the judgment of the district court.