IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ZING HEALTH, INC., ZING HEALTH MICHIGAN, INC., AND ZING HEALTH CONSOLIDATOR, INC., *Plaintiffs,* v. DEPARTMENT OF HEALTH AND HUMAN SERVICES et al., *Defendants.*	Case No. 1:24-cv-00855 (RBW)

FIRST AMENDED COMPLAINT

Plaintiffs Zing Health, Inc. ("Zing"), Zing Health of Michigan, Inc. ("Zing Michigan"), and Zing Health Consolidator, Inc. ("ZHC," collectively, "Zing Health" or "Plaintiffs"), submit the following First Amended Complaint for declaratory and injunctive relief against Defendants Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS"), Xavier Becerra, in his official capacity as Secretary of HHS, and Chiquita Brooks-LaSure, in her official capacity as Administrator of CMS (collectively, "Defendants" or "CMS"), and allege as follows:

INTRODUCTION

1. This is a case in which CMS has added insult to injury by applying its regulations in a flagrantly unlawful manner and then, once two courts rightly rejected that move, responding with limited corrective action that again unlawfully failed to redress the massive and ongoing harm its earlier unlawful action caused Plaintiffs, whose situation is quite unique and remains

significantly harmed by CMS's actions as the only Medicare Advantage plan that was terminated for 2024 and reinstated no less than 6 months after that inappropriate termination.

2. Zing initially brought this action to challenge a serious error that CMS made in calculating Zing's 2024 Star Ratings, which, if uncorrected, would have caused Zing to be unfairly terminated from participating in the Medicare Advantage program, thereby precluding it from serving low-income minority and disadvantaged beneficiaries and undermining its mission of addressing inadequacies in the healthcare system as well as suffering substantial, ongoing, and irreparable harms.

3. That erroneous calculation and CMS's refusal to address it in compliance with its own regulation are a disturbing, if textbook, example of unreasonable agency decision-making that is arbitrary, capricious, and contrary to law. It should be set aside.

4. As two courts in this District have recently held, CMS improperly disregarded and contradicted the plain text of its own regulation and adopted an "implied" approach, obscured within regulatory preamble and commentary, to calculate the 2024 Star Ratings for MA-PD plans, including Zing.

5. That new methodology, which was never the subject of any proper rulemaking, improperly reduced Zing's 2024 Star Ratings. That result is directly contrary to the entire purpose of the regulation that CMS misapplied, which is to stabilize Star Ratings and thereby reduce wild, year-over-year ratings swings through use of explicit "guardrails." All told, CMS's unlawful conduct toward Zing has substantially and irreparably harmed Zing Health as well.

6. Indeed, despite Zing highlighting the erroneous calculations, the significant impact it would have on Zing's plan, Zing Health and its mission, and the significant progress the company was making in its Star Ratings, CMS willfully chose to terminate Zing's contract.

The termination, enabled by CMS's erroneous calculation, was made despite CMS having the regulatory discretion not to impose this penalty. These two arbitrary actions – the cancelation of the contract, enabled by the arbitrary change in calculation methodology – made Zing the *sole* Medicare health plan out of 976 plans to be terminated and reinstated on the basis of this calculation error.

7. Zing Health was founded in 2019 by physician entrepreneurs and a healthcare executive with the mission to address healthcare disparities among historically underserved populations. In fact, 83% of the Medicare beneficiaries enrolled across all of Zing Health's MA-PD plans are Black or Hispanic and between 65% and 75% of beneficiaries receive low-income subsidies for the Medicare Part D coverage.

8. Moreover, Zing Health offers two of only seven available MA-PD HMO plans with Cook County Hospital System that provide important healthcare services to minority, underserved beneficiaries, of whom 75% receive low-income subsidies, with $0 premiums and deductibles, low maximum out-of-pocket costs, and Part D coverage gap coverage.

9. Zing Health's stated mission is to "drastically improve health outcomes in diverse populations that have been chronically underserved."[1]

10. Zing Health maintains several MA-PD contracts, including Zing Michigan's H4624 contract, which also provide quality healthcare to underserved communities. Zing Michigan has the same geographic footprint and coverage as Zing, meaning they share the same administrative and risk-based capital burdens.

11. MA-PD plans, like Zing and Zing Michigan, receive annual Star Ratings from CMS based on "health and drug plan quality and performance measures." Medicare

[1] *See About Us*, Zing Health, https://www.myzinghealth.com/about-us (last visited July 11, 2024).

beneficiaries use CMS's Star Ratings of plans to evaluate and compare plans' quality performance, as assessed by CMS, when they shop for a Medicare Advantage plan. Such ratings are intended to be true reflections of a plan's quality. As such, Star Ratings are an important indicator that shoppers rely on in comparing and selecting among plans.

12. CMS also relies on the Star Ratings to determine MA-PD plans' eligibility to receive quality bonus payments and rebates that fund additional benefits for plans' Medicare members.

13. CMS must calculate the Star Ratings based on a clear and unambiguous methodology that includes the calculation of measure-specific "cut points." Cut points are the dividing lines between one Star Rating and the next higher or lower Star Rating.

14. In 2020, CMS promulgated regulations that revised its Star Ratings methodology to include "guardrails" that provide stability and predictability for MA-PD plans by reducing the fluctuation in the cut points used to calculate annual Star Ratings. *See* 42 C.F.R. §§ 422.162, 422.166, 423.182, 423.186.

15. CMS is required to use actual cut points from the prior year to determine the appropriate cut points that are used to calculate an MA-PD plan's Star Ratings.

16. But in calculating the 2024 Star Ratings for Zing, CMS applied an entirely different and new methodology that was not subject to any formal notice and comment rulemaking, and that directly contradicted the plain text of its own regulation.

17. Instead of using *actual* plan performance data from 2023 to calculate 2024 cut points in accordance with the established guardrails for Star Ratings, CMS recalculated the 2023 cut points, creating *simulated* cut points, by prematurely applying the Tukey outlier deletion

method to eliminate extreme outliers on the high and low ends of a data set, inconsistent with its own clearly-written regulations.

18. When Zing confronted the agency about its use of recalculated data, CMS merely asserted it did not agree with Zing and doggedly refused to abide by its own regulation in the face of the obvious and widespread harms its unlawful approach would have on plans and beneficiaries.

19. The result was unsurprising – and catastrophic. Zing's 2024 Part D Star Rating remained low, and became the third and last data point used by CMS immediately to prohibit Zing from marketing and enrolling beneficiaries into its MA-PD plans and *terminate* Zing's contract from the Medicare Advantage program effective December 31, 2024, threatening Zing current members' continued access to comprehensive healthcare coverage and continuity in their relationships with their physicians and other care providers, depriving other similarly situated, very vulnerable Medicare beneficiaries of the opportunity to choose Zing for access to healthcare for all of 2024, and depriving Zing Health of millions of dollars in revenues.

20. CMS terminated Zing's contract without even providing Zing Health with an opportunity to develop and implement a corrective action plan and imposed sanctions based on 2024 Star Ratings that CMS miscalculated *in violation of its own regulation*.

21. Besides depriving Zing of critical revenue from participating in the Medicare Advantage program, CMS's sanctions prohibited Zing from marketing and enrolling members effective January 12, 2024. That foreclosed new enrollments into Zing's MA-PD plans for the remainder of 2024.

22. Because of the disruption caused by Zing flawed 2024 Star Ratings, ZHC suffered harms that impacted its ability to maintain services for Zing Michigan's contract.

23. Among other harms, a national pharmacy benefit manager ("PBM") firm terminated negotiations with Zing Health because of CMS's adverse actions. The negotiation was intended to improve drug pricing, which is critical to Zing Health's ability to offer best in class drug pricing to members therefore reducing barriers to care and improving health outcomes.

24. Of note, CMS's termination notice was provided to Zing during a recapitalization of the enterprise that would enable it to sustainably operate for years to come. Zing Health notified CMS that the potential termination could endanger Zing Health's ability to continue serving vulnerable Medicare beneficiaries across all its markets.

25. Though Zing Health was ultimately able to obtain capital, CMS's termination based on its flawed, unlawful Star Ratings calculations nearly caused the enterprise to lose financing, and the capital that was finally obtained came at a much greater long-term financial cost to Zing Health.

26. CMS's improper termination and sanctions against Zing have remained in place and been reported publicly on CMS's website as well as nationally in publications and are naturally imputed to Zing Health, causing irreparable harm to Zing Health's reputation, goodwill, and competitive position.

27. Indeed, despite CMS's stated goal to "further advance health equity, expand coverage, and improve health outcomes for the more than 170 million individuals supported by CMS programs," terminating Zing's contract and sanctioning it – and effectively making the plan not viable – as well as irreparably harming Zing Health's reputation and goodwill and operations in the process, are clearly inconsistent with CMS's alleged strategic focus on health equity.

28. CMS's termination and sanctions eliminated a critically needed MA-PD plan option for 2024 that is specifically tailored to meet the unique health needs of high risk/low income beneficiaries.

29. CMS's failure to adhere to its articulated methodology to calculate Zing's Star Ratings constitutes an unexplained and unreasonable departure from its own regulation, which carries dire consequences for Zing Health and other Medicare Advantage plans.

30. CMS's actions are a textbook example of arbitrary and capricious agency action that is unlawful and may be set aside under Section 706 of the Administrative Procedure Act ("APA"). So far, two courts in this District have squarely addressed CMS's calculation of the 2024 Star Ratings and held that CMS unlawfully failed to abide by its regulation in doing so.[2]

31. In response to those decisions, CMS issued a memorandum on June 13, 2024 ("CMS Memorandum"), supposedly to address its unlawful conduct and the resultant harms but that in reality is not competitively neutral and fails to remediate the substantial and ongoing harms suffered by Zing Health as a result of CMS's now-conceded unlawful action.

32. The CMS Memorandum states "we have recalculated the 2024 Star Ratings using the published 2023 Star Ratings cut points to determine the guardrails for the 2024 Star Ratings (i.e., Tukey outliers were not removed from the 2023 Star Ratings). We have assigned all contracts the recalculated 2024 overall and/or summary Star Ratings if those recalculated ratings result in higher QBP Ratings than what was previously assigned based on the contract's overall and/or summary 2024 Star Ratings that were released in October 2023."

33. Under the memorandum, CMS did not implement a change to MA plans' QBP ratings if the recalculation resulted in a decreased QBP rating compared to the ratings previously

[2] *SCAN Health Plan v. Department of Health & Human Services*, Civ. A. No. 23-3910 (CJN) (D.D.C. June 3, 2024); *Elevance Health, Inc. v. Becerra*, Civ. A. No. 23-3902 (RDM) (D.D.C. June 7, 2024).

assigned (*i.e.*, such plans were held harmless in the recalculation). MA plans with increases in their QBP or rebate percentages were given a time-limited opportunity to resubmit their contract bids for 2025.

34. To date, CMS's remedial action to correct the improper termination of Zing's MA-PD plan has been limited to a notice that CMS is reversing its improper termination of Zing's contract and is allowing Zing Health to submit a bid for the plan for 2025. This reversal notice was provided to Zing Health six months after CMS issued the initial termination and sanctions based on its flawed, unlawful Star Ratings calculation and *months* after existing members believed they would no longer have access to the plan for 2025.

35. This limited relief is, in short, too little too late. It does nothing to address the marketing and enrollment sanctions that CMS applied to Zing, which rendered the terminated MA-PD plan commercially unviable and therefore have caused substantial and irreparable harms to Zing Health as a result of its unlawful conduct.

36. Nor does CMS's supposed remedy address the operational disruptions and resulting impacts on Zing Health's value as a result of CMS's arbitrary and capricious actions taken against Zing Health. And in no way does CMS's supposed solution addresses the unique and irreparable harms that Zing has suffered from being the only plan that, because of CMS's unlawful actions, had a termination imposed and belatedly rescinded.

37. CMS's refusal to follow its own promulgated methodology and reliance on flawed data are arbitrary and capricious agency actions that must be set aside under Section 706 of the APA.

38. CMS's 2024 Star Ratings for Zing should be vacated, and this matter should be remanded to CMS to adjust Zing's 2024 Star Ratings based on a proper application of its regulation and use of data that is not inherently flawed.

39. CMS should further be enjoined from relying on its improper Part D Star Ratings to terminate Zing's contract with CMS and impose sanctions on Zing.

40. CMS should be ordered to issue a public notice of its error and the correction of Zing's 2024 Star Ratings, to be posted both on the CMS website and in one or more newspapers of general circulation in each community or county located in the service area of Zing's improperly terminated contract.

41. CMS also should be ordered to engage in specific outreach to current enrollees of Zing's improperly terminated contract, and those who disenrolled with an effective date of January 1, 2024, through the release of CMS's correction notice.

42. CMS should further be directed to treat Zing Michigan's H4624 contract as a new contract for the 2025 contract year to lessen the adverse financial impact on Zing Health and competitive harms it has suffered as a result of CMS's unlawful ratings calculations and the limited relief afforded to certain plans to address certain (but not all) impacts of its unlawful action.

43. Fundamentally, CMS must be ordered to take all actions necessary to ensure that Zing Health is not competitively disadvantaged as a result of CMS's corrective actions to cure its unlawful star ratings calculations, including, but not limited to, treat Zing Michigan's H4624 contract as a new plan for the 2025 contract year.

44. To prevent Zing Health from suffering additional and ongoing irreparable harm from CMS's improper rating, and limited relief that favors some competitors over Zing Health,

the Court should issue the foregoing injunctive relief and expedite the resolution of this matter on the merits.

PARTIES

45. Plaintiff Zing Health Consolidator, Inc. is the parent organization of Zing Health, Inc., and Zing Health of Michigan, Inc.

46. Plaintiff Zing Health, Inc., is a for-profit corporation incorporated in Illinois, duly licensed as a health maintenance organization in Illinois, and with its principal place of business in Chicago, Illinois.

47. Plaintiff Zing Health of Michigan, Inc., is a for-profit corporation incorporated in Michigan, duly licensed as a health maintenance organization in Michigan and Illinois, and with its principal place of business in Chicago, Illinois.

48. Defendant HHS is the department of the federal government ultimately responsible for the federal Medicare and Medicaid programs.

49. HHS has delegated its authority to administer the Medicare and Medicaid programs to CMS. *See* 66 Fed. Reg. 35437.

50. Defendant CMS is a federal agency within HHS with the primary oversight responsibility for the Medicare program and the federal portion of the Medicaid program. It was created by the Reorganization Act of March 9, 1977. *See* 66 Fed. Reg. 35437.

51. Defendant Xavier Becerra is named in his official capacity as the Secretary of HHS. *See* 42 C.F.R. § 405.1136(d)(1).

52. Defendant Chiquita Brooks-LaSure is named in her official capacity as Administrator of CMS. The CMS Administrator is responsible for the administration of the Medicare program, including the Star Ratings for Medicare Advantage plans. *Id.*

JURISDICTION & VENUE

53. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331 because this action arises under the APA, 5 U.S.C. §§ 701 *et seq.*, and 42 U.S.C. §§ 1395 *et seq.*

54. Venue is proper in this Court under 28 U.S.C. § 1391(e) because this is an action against officers and agencies of the United States and a substantial part of the events giving rise to Zing Health's claims occurred in this District.

55. The Complaint is timely under 28 U.S.C. § 2401(a).

REGULATORY AND FACTUAL BACKGROUND

The Medicare Program And Star Ratings

56. The Medicare program, authorized under Title XVIII of the Social Security Act ("SSA"), is a federal program that provides health insurance benefits for Americans aged 65 years and older and certain disabled persons. *See* 42 U.S.C. §§ 1395 *et seq.*

57. CMS is the federal agency responsible for administering the Medicare program.

58. As part of its strategic plan, CMS has announced its commitment to expanding "access to quality, affordable health coverage and care" by advancing "health equity and addressing the health disparities that underlie" the health system.[3]

59. Individuals enrolled in Medicare may elect to receive their benefits under Part C of the Medicare program, commonly referred to as the "Medicare Advantage" program, as an alternative to original Medicare.

60. Under Part C, CMS contracts with private insurance payors, commonly known as Medicare Advantage Plans ("MA Plans"), to provide and arrange for Medicare-covered benefits for Medicare beneficiaries who enroll in their benefit plan. *See* 42 C.F.R. § 422.4.

[3] *See* CMS Strategic Plan, Centers for Medicare and Medicaid Services, https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan (last visited on July 11, 2024).

61. Most MA Plans also provide Medicare Part D prescription drug coverage. *See* 42 C.F.R. § 422.4(c)(1).

62. MA Plans that offer Part D coverage are referred to as MA-PD plans. *See* 42 C.F.R. § 423.4.

63. Besides arranging and paying for Medicare-covered benefits of Medicare beneficiaries, MA Plans typically provide supplemental benefits as well as lower co-payments and other cost sharing, which further reduce the cost of covered services for beneficiaries.

64. The Medicare Advantage program is intended to shift the financial risk of providing health care to beneficiaries from the federal government to the privately run MA Plans in exchange for a per-member, per-month payment.

65. MA Plans that are better at keeping their members healthy, by effectively managing their care and providing important related services, receive higher ratings, and overall, perform better in the marketplace. *See generally* 42 C.F.R. § 422.160.

66. By providing additional benefits beyond those covered by Medicare, MA Plans compete with original Medicare and with one another to convince beneficiaries to select their plan.

67. CMS intended the Medicare Advantage program to be "competitive" which would "level the playing field between all options available to Medicare beneficiaries."[4]

68. In an effort to encourage MA Plans to offer high quality plans and to assist Medicare beneficiaries in selecting a competitive Part C plan, CMS studies and surveys MA Plans for quality, compliance, and other metrics to develop numerical ratings for each MA Plan ("Star Ratings").

[4] *See* Conference Report on Medicare Modernization Act of 2003, available at https://www.congress.gov/108/crpt/hrpt391/CRPT-108hrpt391.pdf.

69. The Star Ratings are based on a five-star scale, with 1 star being the lowest rating and 5 stars being the highest. *See* 42 C.F.R. § 422.162(b); 42 C.F.R. § 422.166(h)(1)(ii).

70. MA Plans that also provide Part D coverage receive a separate Part D Star Rating. *See* 42 C.F.R. § 422.162(b).

71. The Star Ratings are designed to be "a true reflection of the plan's quality" and must be based on data that is "complete, accurate, reliable, and valid." 83 Fed. Reg. 16440, 16521 (Apr. 16, 2018).

72. Star Ratings information is widely available to Medicare beneficiaries to consider when choosing to enroll in an MA Plan. These measures are particularly important, as they allow beneficiaries to compare health plans based on quality.

73. CMS prominently and publicly displays Star Ratings in its online and print resources on available MA Plans as required under the SSA. *See* 42 U.S.C. § 1395w–21.

74. Indeed, through the online Medicare Plan Finder tool, CMS displays MA Plans in highest to lowest Star Ratings order to prospective members, with the express purpose of guiding beneficiaries to higher-rated plans first.

75. The Star Ratings also impact the amount of funds CMS will pay to each MA Plan.

76. Under Section 1853(o) of the SSA, CMS allocates quality payment bonuses to MA Plans based on their Star Ratings and awards additional funds to MA Plans rated at or above 4 stars. *See* 42 U.S.C. § 1395w–23(o).

77. MA Plans use these bonuses, which are often in the tens, if not hundreds of millions of dollars, to provide additional benefits and services to improve care to their members.

78. Conversely, MA Plans that consistently receive Star Ratings below 3 stars may be terminated from the Medicare Advantage program altogether. *See* 42 C.F.R. § 422.510(a)(4)(xi); 42 C.F.R. § 423.509(a)(4)(x).

79. Before being terminated from the Medicare Advantage program, CMS must provide the MA Plan with notice and an opportunity to develop and implement a corrective action plan. 42 U.S.C. § 1395w-27(h).

80. When CMS may terminate an MA Plan's contract for low Star Ratings, it may also impose intermediate sanctions to bar marketing and prevent the MA Plan from enrolling additional beneficiaries into the plan. *See* 42 C.F.R. § 423.752(b).

81. As CMS has recognized, termination and sanctions are "severe consequences" given the substantial investments MA Plans must make to participate and operate in the Medicare business as well as the reputational and market harms that may result.[5]

82. Thus, the Star Ratings have tremendous value to and impact on MA Plans to provide quality care and benefits to their members, compete in the marketplace, receive compensation, and even remain eligible to continue to participate in the Medicare Advantage program.

Calculation Of Star Ratings Generally

83. To calculate Star Ratings, CMS must use clear and unambiguous calculations established in its regulations. *See* 42 C.F.R. § 422.162(b); 42 C.F.R. § 422.166(h)(1)(ii); 42 C.F.R. § 423.182(b); 42 C.F.R. § 423.186(h)(1)(ii).

[5] *See United Healthcare Ins. Co.*, Hearing Officer Docket No. 2011 C/D App 1-10 (2011), at 14, *available at* https://www.cms.gov/regulations-and-guidance/review-boards/medicare-advantage-prescription-drug-plan-decisions/downloads/2011_cd_app_01_through_10.pdf (last visited July 11, 2024).

84. Star Ratings for MA Plans are based on a calculation of numerous performance measures designed to assess member services and care, including but not limited to preventative health services, management of long-term conditions, member experiences with the health plan, member complaints, and customer service. *See Medicare 2024 Part C & D Star Ratings Technical Notes* at 26-100, CENTERS FOR MEDICARE AND MEDICAID SERVICES, https://www.cms.gov/files/document/2024technotes20230929.pdf.

85. CMS publishes these measures and the specifications that it uses to develop its Star Ratings. MA Plans (including Zing and Zing Michigan) use them to target areas of improvement and investment to ensure they are maximizing their care and services for beneficiaries, and in turn, earn higher Star Ratings.

86. Any changes to the Star Ratings calculations can have serious, and sometimes catastrophic, impacts on MA Plans.

87. When MA Plans' Star Ratings decrease, MA Plans may be disqualified from receiving quality bonus payments and can even be removed from the Medicare Advantage program altogether, resulting in devastating financial and coverage consequences for MA Plans and beneficiaries.

88. Therefore, in developing each MA Plan's Star Ratings, CMS must treat each MA Plan "fairly and equally," judging them only on matters that are "under the control of the health or drug plan," in a system that will "minimize unintended consequences" adopted through a "process of developing [a ratings methodology that] is transparent and allows for multi-stakeholder input." 83 Fed. Reg. 16440, 16521.

89. CMS calculates Star Ratings based on a rigid methodology – set forth in its own regulations – that focuses on "health and drug plan quality and performance measures." 42 C.F.R. § 422.166; Medicare 2024 Part C & D Star Ratings Technical Notes at 2 & 26-100.

90. Measures used to calculate Star Ratings can be grouped into two categories: those from the Consumer Assessment of Healthcare Providers and Systems surveys ("CAHPS"), and those from "non-CAHPS" sources. Medicare 2024 Part C & D Star Ratings Technical Notes, at 2 & 26-73.

91. CAHPS measures relate to member experience with healthcare providers, services, and plans deriving data from "surveys that ask consumers and patients to evaluate the interpersonal aspects of health care." 42 C.F.R. § 422.162(a). In other words, they measure the member experience.

92. Non-CAHPS measures derive data from sources other than CAHPS surveys. *See* Medicare 2024 Part C & D Star Ratings Technical Notes, at 4. Non-CAHPS measures consist of data from, among other sources, the Healthcare Effectiveness Data and Information Set[6] and CMS's Part C and D reporting requirements. *Id.* at i.

93. Each CAHPS and non-CAHPs measure is given a numeric score. *Id.* at 2.

94. The agency then determines the "cut point" for each measure – that is, the range of scores that correspond with particular Star Ratings and separates one Star Rating from the Star Rating above or below it.[7]

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[6] The Healthcare Effectiveness Data and Information Set ("HEDIS") is a tool used by more than 90 percent of U.S. health plans to measure performance on important dimensions of care and service. More than 190 million people are enrolled in health plans that report quality results using HEDIS. *See* Healthcare Effectiveness Data and Information Set (HEDIS) - Healthy People 2030 | health.gov (last visited July 11, 2024).

[7] For instance, the 2023 cut points for measure C11 (Controlling Blood Pressure) – which is measured as a percentage – were the following: below 39% for 1 Star, between 39% and 62% for 2 Stars, between 62% and 75%

95. The statistical method used to calculate the cut points differs for CAHPS and non-CAHPS measures. *Id.* at 8.

96. CAHPS measures employ a relative distribution and significance testing method,[8] while non-CAHPS measures are subject to a clustering sampling method. *Id.*

97. Together, the CAHPS and non-CAHPS measure scores and cut points are combined to develop each MA Plan's Star Ratings.

CMS Adopts Guardrail Requirements As Part Of The Star Ratings Methodology

98. On June 2, 2020, CMS promulgated a final rule establishing a new methodology for the calculation of Star Ratings. *See* 85 Fed. Reg. 33796. The timeline for implementation of the new methodology was delayed because of the COVID-19 pandemic.

99. The final rule modified the methodology for non-CAHPS measures in two critical ways.

100. *First*, the final rule explained that, starting in 2024, the Tukey outlier deletion method would be used in developing the cut points for non-CAHPS measures. *See* 42 C.F.R. § 422.166(a)(2).

101. Tukey outlier deletion is a "standard statistical methodology for removing outliers, to increase the stability and predictability of the star measure cut points." 85 Fed. Reg. 33798.

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for 3 Stars, between 75% and 83% for 4 Stars, and above 83% for 5 Stars. *See* Medicare 2023 Part C & D Star Ratings Technical Notes, at 45-47.

[8] Clustering sampling is defined by CMS as a "variety of techniques used to partition data into distinct groups such that the observations within a group are as similar as possible to each other, and as dissimilar as possible to observations in any other group." 42 C.F.R. § 422.162(a). Clustering of the measure-specific scores means "that gaps that exist within the distribution of the scores are identified to create groups (clusters) that are then used to identify the four cut points resulting in the creation of five levels (one for each Star Rating), such that the scores in the same Star Rating level are as similar as possible and the scores in different Star Rating levels are as different as possible." *Id.*

102. *Second*, and most importantly, the final rule implemented "guardrails" or "bi-directional caps that restrict upward and downward movement of a measure's cut points" from one year to the next. *Id.*

103. A guardrail is defined by CMS as "a bidirectional cap that restricts both upward and downward movement of a measure threshold-specific cut point for the current year's measure-level Star Ratings as compared to the prior year's measure-threshold-specific cut point." 42 C.F.R. § 422.162(a).

104. Specifically, the guardrail prevents each measure's cut points from fluctuating more than 5% (upward or downward) from that of the previous year, thereby promoting stability in Star Ratings year over year. *See generally* 85 Fed. Reg. 33796–33911.

105. CMS thus adopted the guardrail requirement to provide stability and predictability from year-to-year. *See generally id.*

106. According to the regulation, CMS is supposed to "add a guardrail so that the measure-threshold-specific cut points for non-CAHPS measures do not increase or decrease more than the value of the cap from 1 year to the next." *See* 42 C.F.R. § 422.166(a)(2)(i).

107. CMS must rely on the actual measure cut points from the prior year's Star Ratings to determine and calculate the measure cut points for the current year's Star Ratings based on the application of the appropriate guardrails to each measure for the purpose of mitigating the shift in measure cut points that can occur from 1 year to the next. *Id.*

108. Under the final rule, therefore, to calculate the 2024 Star Ratings cut points, CMS is required to remove Tukey outliers from its methodology and then apply the guardrail caps for each measure's cut points compared to the actual 2023 cut points. *See* 42 C.F.R. § 422.166(a)(2)(i).

109. Doing so is supposed to prevent the 2024 cut points from deviating more than 5% from the 2023 cut points, thereby bringing stability to the calculations and process for MA Plans and Star Ratings. *Id.*

CMS's Arbitrary Rejection Of Its Own Methodology To Develop The 2024 Star Ratings Caused Zing To Receive A Lower Star Ratings

110. As a new MA-PD plan, Zing has struggled to receive high Star Ratings, receiving a 2.5 in 2022 and 2023.

111. As previously noted, due to the COVID-19 pandemic, CMS delayed implementing the Tukey outer fence outlier methodology for two years until 2023, when it was supposed to use that methodology to establish the 2024 Star Ratings. *See* 87 Fed. Reg. 22776.

112. Thus, 2023 was the first time that CMS implemented the Tukey outer fence outlier methodology along with the application of the guardrail requirement, when it established its 2024 Star Ratings. *See id.*

113. Zing's 2024 Part D Star Ratings came in at 2.5 Stars – far lower than its expected 3 Star Rating.

114. CMS may terminate an MA Plan contract when the Plan does not comply with the regulatory requirements of the Medicare Advantage program, including if a plan achieves less than a 3-Star rating on Part C or Part D for three years in a row. *See* 42 C.F.R. §§ 422.510(a)(4)(xi), 423.509(a)(4)(x).

115. Because of Zing's 2024 Part D Star Rating, Zing received three Part D Star Ratings below the 3-Star threshold. Accordingly, CMS initiated termination of Zing's contract.

116. CMS also imposed intermediate sanctions on Zing, prohibiting it from marketing and enrolling beneficiaries as of January 2024.

117. The termination and sanctions were also publicly reported and disclosed across the United States in major publications, trade journals, and websites.[9]

118. Zing timely reached out to CMS relating to the procedures it failed to adhere to, including the calculation of its 2024 Star Ratings.

119. In response to Zing's challenge, CMS advised that "the 2023 Star Ratings cut points were rerun . . . and [t]hese *rerun* 2023 Star Ratings cut points serve as the basis for the guardrails for the 2024 Star Ratings." *See* Exhibit ("Ex.") 1, CMS Letter to Zing on Jan. 26, 2024.

120. CMS did not rerun the 2023 Star Ratings using the actual cut points as required by regulation; instead, in computing Zing's 2024 Star Ratings, CMS used rerun simulated 2023 cut points data in which Tukey outliers had been removed.

121. CMS had no authority to do so because its own regulation requires it to rely on the previous year's *actual* cut points and data – not simulated, rerun data. *See* 42 C.F.R. § 422.166(a)(2).

122. Nevertheless, CMS rejected the methodology set forth in the regulation, and refused to consider actual cut points for the prior year.

123. The results were just as dire as expected: MA Plans' Star Ratings fluctuated wildly, and well-beyond the 5% caps on cut point swings that the guardrails are supposed to impose.[10]

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[9] *See, e.g.*, CMS, *Notice of Termination and Intermediate Sanctions (Suspension of Enrollment and Marketing) for Medicare Advantage-Prescription Drug Contract Number: H7330* (Dec. 27, 2023), *available at https://www.cms.gov/files/document/zing-health-termination-sanction-12272023.pdf* (last visited July 11, 2024); Jakob Emerson, *CMS to terminate Illinois insurer's Medicare Advantage drug plan following low stars*, Becker's Payer Issues (Jan. 8, 2024), *available at* https://www.beckerspayer.com/payer/cms-terminates-illinois-insurers-medicare-advantage-drug-plan-following-low-star-ratings.html (last visited July 11, 2024).

[10] *See* https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data (last visited July 11, 2024).

124. Thus, Zing's 2024 Part D Star Rating was significantly lower than expected as a direct result of CMS's failure to properly apply its own regulation.

125. Had CMS followed the regulation as codified, Zing's Part D Star Rating would have been 3 stars – which would have precluded CMS from terminating Zing's contract.

126. CMS's failure to follow its own regulation resulted in the very thing that the guardrails were designed and intended to prevent: wild fluctuations in cut points that have outsized impacts on MA Plans' Star Ratings.

127. Zing alerted CMS to its flawed methodology, explaining that the regulation requires CMS to apply the guardrail to actual cut points from the prior year, not to rerun data that effectively amount to simulated data points. *See* Ex. 2, Zing Letter to CMS on Jan. 5, 2024.

128. Rerunning the 2023 data is inconsistent with the plain and express language of the regulation, which calls for comparison between the current and prior year's actual and measure-specific-threshold cut points. *See* 42 C.F.R. § 422.166(a)(2)(i).

129. It also frustrates the very purpose of CMS's guardrail regulation, which is to reduce risk and uncertainty for MA Plans by preventing dramatic swings in cut points and resulting ratings that can have massive adverse impacts on MA Plans and beneficiaries.

130. It also runs counter to CMS's goal of supporting competitive bidding to ensure an equal playing-field for all participants. *See* 70 Fed. Reg. 4588, 4639 (Jan. 28, 2005).

131. By its express terms, CMS's regulation does not permit the agency to recalculate the prior year's cut points for the purposes of generating and applying the guardrails. *See* Ex. 2.

132. When confronted with the flaws in its approach, CMS asserted that statements in its preamble to its final rule related to the use of Tukey outliers somehow permitted its departure from the regulation's actual text. Ex. 1; 85 Fed. Reg. 9044; 85 Fed. Reg. 33833.

133. Despite Zing's efforts to further discuss and resolve its concerns, CMS refused to engage meaningfully with Zing or reconsider its flawed approach and the grave impacts of it.

134. As such, CMS ultimately used this third flawed Star Ratings – a rating that is not "a true reflection of the plan's quality" – to justify terminating Zing's contract and imposing sanctions. 83 Fed. Reg. 16440, 16521 (Apr. 16, 2018).

135. Shortly after CMS terminated and imposed sanctions on Zing, other MA Plans sued CMS in this District under the Administrative Procedure Act ("APA") to address the exact same violation at issue here: CMS's flawed approach to calculating the 2024 Star Ratings.[11]

136. In two decisions issued only weeks ago, two judges in this District held that CMS violated the APA by using simulated cut points because "the text of the regulation leaves only one reasonable interpretation," that is, CMS must use "the *actual* cut points." *SCAN Health Plan v. Department of Health & Human Services, et al.*, Case No. 23-cv-3910 (D.D.C. June 3, 2024), Dkt. 33 at 9 & 13; *see id.* at 13 n.5; *see also Elevance Health, Inc. et al. v. Becerra et al*., Case No. 1:23-cv-03902 (D.D.C. June 7, 2024), Dkt. 30 at 39 (holding CMS's calculation of the 2024 Star Ratings with simulated cut point data "was contrary to the agency's own regulations and thus contrary to law and arbitrary and capricious.").

137. In each case, both judges ordered the 2024 Star Ratings for the plaintiff MA Plans to be set aside and recalculated by CMS in compliance with its regulation. *Id.*

138. In response, on June 13, 2024, CMS issued a memorandum announcing its intention to recalculate the 2024 Star Ratings for 2025 Quality Bonus Payment purposes ("CMS Memorandum"). *See* Ex. 3.

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[11] *SCAN Health Plan v. Department of Health & Human Services*, Civ. A. No. 23-3910 (CJN) (D.D.C. 2024); *Elevance Health, Inc. v. Becerra*, Civ. A. No. 23-3902 (RDM) (D.D.C. 2024).

139. Although CMS recalculated the 2024 Star Ratings using the published 2023 Star Ratings cut points, CMS did not commit to vacating past terminations, sanctions, or any other decisions made in reliance on the unlawful Star Ratings methodology imposed on MA Plans.

140. Rather, CMS only committed to allowing MA plans with increases in their QBP determinations after the recalculation of the 2024 Star Ratings to resubmit their bids for 2025. Ex. 3.

141. The CMS Memorandum thereby afforded only limited relief to certain plans to address certain problems and in doing so failed to address the full extent of damages caused by its unlawful actions in a fair and competitively neutral way.

142. Among other things, the CMS Memorandum thus provided no relief to address the loss of beneficiaries to other plans as a result of CMS's flawed Star Ratings, harms to reputation, goodwill, and the market position of impaired MA Plans, or the extensive financial harms caused by its unlawful conduct.

143. On July 1, 2024, CMS issued a second memorandum announcing it had implemented the general statement of policy announced in the CMS Memorandum. *See* Ex. 4, July 1 Memorandum. But CMS again failed to redress any other injury stemming from the erroneous past Star Ratings, or address the fact it arbitrarily acted to assist some but not all Plans in a fair and competitively neutral way.

CMS's Unlawful Conduct Has Harmed – And Continues To Harm – Zing Health

144. CMS's refusal to abide its own regulation has already caused, and threatens to continue to cause continuing severe and irreparable harm to Zing Health.

145. By applying some newfound "intrinsic" methodology to calculate guardrails, rather than applying the regulation as written, Defendants have used simulated, rerun data to calculate Zing's Star Ratings.

146. As a result, Defendants have published and relied upon fundamentally flawed Part D and overall Star Ratings for Zing of 2.5 stars.

147. The impact of Defendants' actions are serious and substantial and have irreparably harmed Zing Health in many ways.

148. CMS's issuance of a flawed 2024 Part D Star Rating for Zing's contract adversely impacted Zing Health by making the contract less attractive to Medicare beneficiaries who were choosing plans during the 2024 Annual Enrollment Period.

149. By issuing a flawed 2024 Part D Star Rating for Zing's contract, CMS also made Zing's contract eligible for termination and did in fact notify Zing Health that it was terminating Zing's contract effective December 31, 2024, which will cause Zing to cease operations and discontinue serving low socioeconomic and minority beneficiaries.

150. Terminating Zing's contract, as well as suspending Zing's marketing and enrollment with intermediate sanctions, has adversely impacted – and will continue to impact – a vulnerable, high-needs population of beneficiaries by making access to comprehensive healthcare benefits and care even more challenging for them.

151. Indeed, Zing Health offers *two of only seven* available MA-PD HMO plans within the Cook County Hospital System that specifically target low-income beneficiaries through $0 premiums and deductible, low maximum out of pocket costs, and Part D gap coverage.

152. Zing Health has also invested heavily in benefits relating to social determinants of health ("SDoH"), including monthly allowances toward healthy foods and/or utilities, in-home

support services, and unlimited transportation to dialysis centers – all of which will be discontinued because of CMS's actions.

153. Accordingly, as a result of CMS's flawed rating methodology, beneficiaries will lose their health coverage and be unable to access equivalent care. They will be forced to choose alternative plans that lack the prioritization of critical benefits to their members that Zing Health provides.

154. These actions run counter to CMS's stated strategic plan, which is dedicated to expanding health equity across diverse populations.

155. Indeed, as a result of CMS's arbitrary and capricious conduct, existing members whose current coverage they have entrusted to Zing Health will lose that coverage.

156. Moreover, other similarly situated Medicare beneficiaries who are not current Zing Health members will have to forego even having Zing as a choice, threatening their ability to achieve equity in access to healthcare, with harmful and devastating consequences to their health and well-being.

157. CMS's termination and marketing and enrollment sanctions, all of which derive from its flawed Star Ratings methodology, have further irreparably harmed Zing Health.

158. Because CMS issued improper sanctions and terminated Zing's contract, it has been prohibited from enrolling new beneficiaries in its MA-PD plans for the remainder of 2024, thereby depriving Zing Health of millions of dollars in revenue.

159. The intermediate sanctions were imposed without additional justification and without giving formal notice or affording Zing Health the opportunity to develop and implement a corrective action plan. *See* 42 C.F.R. § 423.509(c)(1)(i); *see also* 42 C.F.R. § 422.510(c)(1)(i).

160. Had CMS afforded Zing Health this opportunity, Zing Health would have met its burden by showing it had corrected the deficiencies and was conservatively projected based on the correct application of CMS's regulations to have a 3-star rating for both Part C and Part D for contract year 2024.

161. CMS's flawed Star Ratings, contract termination, sanctions, and publications have seriously undermined and irreparably harmed Zing's competitive position, reputation, and goodwill with beneficiaries and other market participants.

162. Upon information and belief, Zing was the only MA-PD plan that was terminated from and subsequently reinstated to the Medicare Advantage Program because of its erroneously-calculated Star Rating.

163. Moreover, because of the adverse effects upon Zing's contract, Zing Health has suffered substantial and ongoing disruptions that have impacted its ability to maintain services to other contracts, including the Zing Michigan contract (H4624).

164. Indeed, Zing Health has been forced to expend substantial resources and time to address the irreparable harms and fallout directly caused by CMS's unlaw actions, suffered tremendous harm to its competitive position and reputation, worked to repair shattered investor confidence, and suffered losses and harms that well exceed $200 million –which has disrupted Zing Health's operations and ability to remain a going concern.

165. Zing Health has tried to resolve the parties' dispute informally to no avail. Exs. 1-2. Even after its actions were deemed unlawful, CMS failed and refused to come to grips with the consequences of its unlawful action and address the full scope of the harms it caused Zing Health.

166. Left with no other option, Zing Health turns to this Court to require Defendants to comply with federal law, vacate the flawed Star Ratings assigned to Zing, to enjoin them from relying on that unlawful rating in connection with Zing's eligibility as a Medicare Advantage Plan, and to require them to take remedial action to level the competitive playing field and rectify the harm caused by their unlawful actions.

COUNT I
(Violation Of 5 U.S.C. § 706(2)(A) – Against All Defendants)
(Use Of Simulated And Rerun Cut Point Data)

167. Plaintiffs reallege the allegations set forth in Paragraphs 1 through 166 of this Complaint as if fully set forth herein.

168. CMS's decision – as approved and directed by Defendants – to use simulated and rerun 2023 cut point data to calculate Zing's 2024 Star Ratings rather than the actual cut points is a final agency action made reviewable by 5 U.S.C. § 706(2) and 42 C.F.R. § 422.260(c)(3).

169. Plaintiffs are adversely affected and aggrieved by Defendants' action.

170. Defendants' decision to use simulated and rerun cut point data for 2023 rather than the actual cut points is arbitrary and capricious and contrary to law.

171. Defendants failed to engage in reasoned decision-making; to reasonably (or at all) explain their departure from CMS's own regulation; and to provide an adequate and reasonable explanation for their decision.

172. Defendants' action flies in the face of the plain and unambiguous text of their own regulation and undermines the policy and purpose of that regulation to reduce Star Ratings swings that harm MA Plans and beneficiaries.

173. Defendants acted unreasonably and contrary to law by deploying a methodology that is inconsistent with the approach mandated by their regulation, and was never disclosed to regulated parties – let alone adopted pursuant to any proper rulemaking proceedings.

174. As a result, Defendants' decision is arbitrary, capricious, and otherwise not in accordance with the law in violation of 5 U.S.C. § 706(2)(A).

175. Plaintiffs have suffered and will continue to suffer irreparable harm as a result of Defendants' violations of 5 U.S.C. § 706(2)(A).

176. Plaintiffs are entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT II
(Violation Of 5 U.S.C. § 706(2)(A) – Against All Defendants)
(CMS Memorandum)

177. Plaintiffs reallege and incorporate Paragraphs 1 through 166 as if fully set forth herein.

178. CMS has relied on the methodology and final actions set forth in its CMS Memorandum to reissue its 2024 Star Ratings based on revised bids submitted by June 28, 2024.

179. The CMS Memorandum and its implementation are final agency actions made reviewable by 5 U.S.C. § 706(2). *See Arch Coal, Inc. v. Acosta*, 888 F.3d 493, 501 (D.C. Cir. 2018); *Sec. Indus. & Fin. Markets Ass'n v. U.S. Commodity Futures Trading Comm'n*, 67 F. Supp. 3d 373, 414 n.21 (D.D.C. 2014).

180. Zing Health is adversely affected and aggrieved by CMS's implementation of CMS Memorandum.

181. An actual controversy has arisen and exists between Zing Health and Defendants regarding the CMS Memorandum.

182. The CMS Memorandum affords only limited redress for the harms caused by its arbitrary and capricious calculations of 2024 Star Ratings by only reevaluating quality bonus payment eligibility for certain plans.

183. But Defendants fail to address the other harmful effects stemming from its flawed 2024 Star Ratings, including the termination and sanction decisions that harmed Plaintiffs.

184. And in adopting and implementing the CMS Memorandum, Defendants fail to treat all plans equally and on the same competitive playing field, instead addressing and benefitting some plans while arbitrarily excluding others from any redress or relief.

185. Plaintiffs are adversely affected and aggrieved by Defendants' CMS Memorandum.

186. Defendants' failure to address the harmful effects of its flawed 2024 Star Ratings is arbitrary and capricious and contrary to law.

187. Defendants' implementation of the CMS Memorandum failed to sufficiently remedy the harms its erroneous Star Ratings caused to Plaintiffs, including Zing Health's termination and sanctions decisions.

188. As a result, Defendants' decision is arbitrary, capricious, and otherwise not in accordance with the law in violation of 5 U.S.C. § 706(2)(A).

189. Plaintiffs have suffered and will continue to suffer irreparable harm as a result of Defendants' violations of 5 U.S.C. § 706(2)(A).

190. Plaintiffs are entitled to injunctive and declaratory relief to remedy Defendants' unlawful conduct, as well as all other relief as set forth in its Prayer for Relief. *See* 5 U.S.C. § 705.

COUNT III
Declaratory Judgment

191. Plaintiffs reallege and incorporate Paragraphs 1 through 166 as if fully set forth herein.

192. CMS's calculation of the 2024 Star Ratings is a final agency action made reviewable by 5 U.S.C. § 706(2).

193. Plaintiffs are adversely affected and aggrieved by the calculation of its Star Ratings.

194. An actual controversy has arisen and exists between Zing Health and Defendants regarding Defendants' calculation of Zing's 2024 Star Ratings using simulated and rerun 2023 data, decision to use these erroneous Star Ratings to make termination and sanctions decisions, and Defendants' implementation of the CMS Memorandum.

195. Zing Health requests a declaration from this Court under 28 U.S.C. § 2201 that Defendants' calculation is arbitrary and capricious; that Defendants must recalculate Zing's 2024 Star ratings; that Defendants' decision to terminate and impose sanctions upon Zing's contract is arbitrary and capricious; and that Defendants' implementation of the CMS Memorandum is arbitrary and capricious.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court vacate Zing's 2024 Star Ratings and remand this matter to the agency for further consideration. Additionally, Zing Health requests the Court to:

1. Adopt an expedited schedule to resolve the merits of this Complaint;

2. Declare that:

   - Defendants' rerunning of the 2023 cut points to calculate Zing's 2024 Star Ratings directly conflicts with CMS's regulatory requirements and is arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A);

   - Defendants must recalculate Zing's 2024 Star Ratings in compliance with CMS's final rule, specifically considering actual performance data;

   - Defendants' decision to terminate and impose intermediate sanctions upon Zing's contract was arbitrary and capricious in relying on erroneously calculated Star Ratings;

   - Defendants' implementation of the CMS Memorandum is arbitrary and capricious in violation of 5 U.S.C. § 706(2)(A).

3. Issue an injunction:

   - Preventing Defendants from terminating Zing's contract based on erroneously calculated 2024 Star Ratings;

   - Preventing Defendants from implementing Zing's contract intermediate sanction decisions related to CMS's erroneously calculated Star Ratings.

4. Require remedial action by Defendants to:

   - Issue a public statement of its error and the correction of Zing's 2024 Star Ratings, to be posted both on the CMS website and in one or more newspapers of general circulation in each community or county located in the service area of Zing's improperly terminated contract;

   - Engage in specific outreach to current enrollees of Zing's improperly terminated contract, and those who disenrolled with an effective date of January 1, 2024 through to the release of CMS's correction notice;

   - Take all actions necessary to ensure that Zing Health is not competitively disadvantaged as a result of CMS's corrective actions to cure its unlawful star

ratings calculations, including, but not limited to, treat Zing Michigan's H4624 contract as a new plan for the 2025 contract year; and

5. Award Zing Health its reasonable attorney's fees and costs, as permitted by law; and

6. Grant such other further relief as this Court deems just and proper.

Dated: July 11, 2024

By: _____

Paul Werner (D.C. Bar #482637)
Imad Matini (D.C. Bar # 1552312)
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Counsel for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on July 11, 2024, I electronically filed the foregoing document and the accompanying exhibits with the Clerk of the Court using the CM/ECF system, which will send notification of this filing to the attorneys of record and all registered participants.

/s/ Paul Werner
Paul Werner

Exhibit 1

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICARE

MEDICARE PARTS C & D OVERSIGHT AND ENFORCEMENT GROUP

January 26, 2024

Mr. Andrew Clifton
Chief Executive Officer
Zing Health, Inc.
225 West Washington Street, Suite 450
Chicago, IL 60606

Re: CMS Response to Zing Health, Inc.'s January 5, 2024 "Rebuttal to Intermediate Sanctions Contract H7330"

Dear Mr. Clifton:

Thank you for submitting your rebuttal on behalf of Zing Health, Inc. (Zing Health) dated January 5, 2024, in response to CMS's intermediate sanctions notice. We reviewed the additional information provided in your response but do not agree that it impacts the basis for the intermediate sanctions imposed by CMS on December 27, 2023. Your response did not present new information or evidence demonstrating that Zing Health was in compliance with Part D Star Ratings requirements.

In its rebuttal, Zing Health correctly states that these sanctions are discretionary. CMS exercises its discretion to issue sanctions to protect beneficiaries from enrolling in poor-performing plans. CMS established the Star Ratings system to provide both comparative information on plan quality and a means to evaluate compliance with regulatory and contract requirements. *See* 42 C.F.R. § 423.180(b). The basis for CMS's sanctions is that CMS determined that Zing Health failed to achieve a Part D summary Star Rating of at least three stars in three consecutive Star Rating periods. *See* 42 C.F.R. §§ 423.509(a)(4)(x) and 423.752(b). These ratings indicate poor performance by Zing Health through its inability to achieve at least an "average" star rating over an extended period. Therefore, CMS imposed sanctions to ensure beneficiaries can choose from plans that demonstrate the ability to offer a minimum level of quality to their enrollees.

Additionally, your rebuttal argues that imposing intermediate sanctions is arbitrary and capricious. Specifically, Zing Health argues that CMS's imposition of marketing and enrollment sanctions on H7330 constitutes inconsistent application of CMS's discretionary authority because when CMS issued a termination notice to Imperial Health Plan of California (H2793) due to that plan's low Part D Star Ratings, CMS did not impose these sanctions. However, the decision to impose intermediate sanctions in Zing Health's case was made pursuant to regulatory authority, and CMS has appropriately exercised its discretion based on the specific facts and circumstances and available information in each case. A different outcome in a previous case does not render CMS's decision arbitrary and capricious. Indeed, in *Kort v. Burwell*, 209 F.Supp.3d 98, 112 (D.D.C.

2016), cited in Zing Health's rebuttal, the court aptly noted that "the actions of [r]egulatory agencies do not establish rules of conduct to last forever, and an administrative agency is not disqualified from changing its mind." (citing *Am. Trucking Ass'ns, Inc. v. Atchison, T. & S.F.R. Co.*, 387 U.S. 397, 416 (1967); *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 417 (1993); internal quotations omitted). Moreover, CMS has consistently imposed intermediate sanctions on all other similarly situated contracts eligible for termination at the end of December 2024. As such, its decision was not arbitrary and capricious.

Zing Health also asserts that per the organization's current modeling, H7330 is on track to obtain a three-Star Part D rating for 2025. While we appreciate Zing Health's willingness to improve its rating, at this time, it is premature for any plan or CMS to predict 2025 Star Ratings, and also does not excuse the three previous years of low Star Ratings.

Furthermore, Zing Health states that it believes that its failure to achieve a 2024 Part D rating of three-Stars is, in part, due to CMS's premature application of the Tukey outlier deletion methodology and its use of recalculated cut points instead of actual plan performance data from 2023 to calculate 2024 cut points, in accordance with the established guardrails for Star Ratings. However, CMS does not agree with Zing Health's statements. CMS stated in the CY 2021 proposed rule (85 FR 9044) and final rule (CMS–4190–F) (85 FR 33833, 33835), for the first year that Tukey outlier deletion is implemented (2024 Star Ratings), we will rerun the prior year's thresholds using mean resampling and Tukey outlier deletion so that guardrails will be applied consistently between years. Thus, to calculate the guardrails for the 2024 Star Ratings, the 2023 Star Ratings cut points were rerun with mean resampling, Tukey outlier deletion, and no guardrails. These *rerun* 2023 Star Ratings cut points, not the 2023 cut points previously published in the Medicare 2023 Part C & D Star Ratings Technical Notes, serve as the basis for the guardrails for the 2024 Star Ratings, per the CY 2021 final rule.

Your rebuttal also contends that sanctioning H7330 will only harm the vulnerable, underserved, and high-needs populations of beneficiaries that Zing Health seeks to serve. CMS is aware that Zing Health has many members from vulnerable populations. CMS confirmed that there are other plan options with higher Part D Star Ratings available to serve the beneficiaries in H7330's service area.

Lastly, CMS's decision to terminate and impose intermediate sanctions on Zing Health for its low Part D Star Ratings is separate from CMS's communications with Zing Health about the organization's proposed contract novation and consolidation.

As always, if your team has any questions regarding the sanctions, please reach out to your Enforcement Lead who will be available to assist you.

Sincerely,

/s/

John A. Scott
Director
Medicare Parts C and D Oversight and Enforcement Group

cc: Kevin Stansbury, CMS/MOEG/DCE
Vanessa Duran, CMS/MDBG
Mark Newsom, CMS/MDBG
Linda Anders, CMS/MDBG
Michael Neuman, CMS/MDBG
Arianne Spaccarelli, CMS/MDBG
Elizabeth Goldstein, CMS/ MDBG
Kathryn Coleman, CMS/MCAG
Julie Uebersax, CMS/MCAG
Megan Mason, CMS/OPOLE
Raymond Swisher, CMS/OPOLE
Adams Solola, CMS/OPOLE
Avalon Gordon, CMS/OPOLE

Exhibit 2

SheppardMullin

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January 5, 2024

File Number: 77HD-344521

VIA E-MAIL AND U.S. MAIL

Kevin Stansbury
Director, Division of Compliance Enforcement
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244
Mail Stop: C1-22-06
E-Mail: kevin.stansbury@cms.hhs.gov

Re: Zing Health, Inc. Rebuttal to Intermediate Sanctions
Contract H7330

Dear Mr. Stansbury:

Pursuant to 42 C.F.R. § 422.756(a)(2), Zing Health, Inc. ("Zing") hereby submits this Rebuttal to the determination of the Centers for Medicare and Medicaid Services ("CMS") to impose intermediate sanctions on Zing's Medicare Advantage-Prescription Drug ("MA-PD") contract H7330. Sanctions are not warranted here where Zing has taken full accountability for its past performance, has been in close communication with CMS regarding its ongoing efforts to improve its performance, and has made significant investments in improving its performance on Part D star rating measures with positive results. Most importantly, imposing sanctions and terminating Zing will only harm the already underserved Medicare beneficiaries in the communities that Zing serves. Further, Zing hopes to novate H7330 and consolidate it with its higher-rated affiliate Zing Health of Michigan (H4624), which will alleviate the administrative and financial burden of operating two overlapping Medicare Advantage organizations and allow Zing to devote more resources to improving quality across the board. Finally, imposing intermediate sanctions is arbitrary and capricious because it constitutes inconsistent application of CMS's discretionary authority. For these reasons and as further detailed below, Zing respectfully requests that CMS reconsider its imposition of intermediate sanctions and withdraw them before they go into effect on January 12, 2024.

H7330 Will Achieve at least 3-Star Part D Rating in 2025

Zing takes full responsibility for its past performance and understands the importance of meeting the quality benchmarks CMS sets to protect Medicare beneficiaries. Since starting out in 2020, Zing has worked to improve its performance, and each year Zing's Part D rating has gone up accordingly. In 2022, CMS rated H7330 Part D at 2.483; in 2023, this rating improved to 2.594; and in 2024, H7330's Part D rating is 2.625. Zing achieved these gains through deliberate changes to its operations—including making changes in its leadership and migrating to a new pharmacy benefit manager—and seeking guidance from industry experts and consultants.

In fact, current modeling, which Zing shared with CMS during a meeting on December 15, 2023, conservatively predicts that H7330 is on track to obtain a 3-Star Part D rating for 2025. Zing's efforts to strategically engage members, physicians, and pharmacies is delivering improved Medication Adherence results. Provider partnership, data management, and information exchange have vastly improved HEDIS execution, and more than 50 percent of all HEDIS measures already exceed 2024 results. Further, Zing's targeted member engagement, care management, and coordinated care initiatives have improved raw scores and are expected to yield 4+ Stars across quality improvement measures.

Not only is Zing actively improving its performance on Part D measures, but Zing has also been transparent with CMS regarding its efforts and predictions for the future. Zing has met with CMS several times, including most recently on December 15, 2023, to assure CMS of its commitment and efforts to improve its Star Ratings. Notably, Zing also provided evidence of the positive results it is achieving. Zing is diligently working to improve its performance, and imposing intermediate sanctions only makes it more difficult for Zing to be successful.

While Zing acknowledges its responsibility for achieving a minimum 3-Star rating on Part C and Part D measures, Zing believes that its failure to achieve a 2024 Part D rating of 3-Stars is in part due to CMS's premature application of the Tukey outlier deletion methodology and use of recalculated cut points instead of actual plan performance data from 2023 to calculate 2024 cut points in accordance with the established guardrails for Star Ratings.

Sanctions Against Zing Harm the Beneficiaries CMS and Zing Serve

CMS states that its goals are to "further advance health equity, expand coverage, and improve health outcomes for the more than 170 million individuals supported by CMS programs . . . by identifying and working to eliminate barriers to CMS-supported benefits, services, and coverage."[1] Suspending marketing and enrollment for H7330 will adversely impact a vulnerable, high-needs population of beneficiaries by making access to benefits and care even more challenging.

Zing Health was founded in 2019 by two African American physician entrepreneurs, a seasoned healthcare executive, and Health2047 (the American Medical Association innovation subsidiary), to address inadequacies in the healthcare system by creating collaborative, community-based MA plans. Appellant's mission is to focus on Social Determinants of Health to reach and reduce healthcare disparities among those underserved populations who suffer from chronic conditions.

Zing offers two of only seven available MA-PD HMO plans with Cook County Hospital System that specifically target low-income beneficiaries through $0 premiums and deductible, low maximum out of pocket costs, and Part D gap coverage. These two plans are ranked #1 and #3 in total value-added benefits. The plans include benefits like monthly allowances toward healthy food and utilities, in-home support services, and transportation to dialysis centers. These plans

[1] *CMS Framework for Health Equity*, CMS.gov, https://www.cms.gov/priorities/health-equity/minority-health/equity-programs/framework (last visited Jan. 2, 2024).

make accessible to some of the neediest Medicare beneficiaries services that meaningfully improve their health and lives.

Thus, sanctioning and terminating H7330 is inconsistent with CMS's strategic focus on health equity. Therefore, Zing respectfully requests that the sanctions be withdrawn so it may continue to be available to serve the beneficiaries it was founded to reach.

Zing Plans to Novate H7330 to Combine with a Higher Rated Plan

Being new to the MA-PD program, as well as serving a historically underserved population of beneficiaries, have made it challenging for Zing to achieve a 3-star Part D rating to date. As detailed above, Zing is confident that H7330 will reach 3-stars by 2025, but regardless, it also hopes to novate H7330 to combine with the higher-rated contract held by Zing Health of Michigan - H4624.[2] H4624 overlaps the geographic footprint of H7330 except for three Chicago collar counties, and Zing intends to expand H4624 to include those counties in 2025.

Because of its coverage area and beneficiary population, H4624 does not face the same challenges as H7330, like high Unable to Reach rates. Combining the plans will eliminate the administrative and financial burdens of managing two separate plans, and will allow Zing to reallocate resources to continued quality improvement of H4624. Perhaps most importantly, novating H7330 to and consolidating that contract with H4624 will allow Zing to continue serving the vulnerable populations currently serviced by H7330.

Since Zing intends to novate H7330 to Zing Health of Michigan and consolidate that contract with H4624, CMS's imposition of enrollment sanctions on H7330 will eliminate a critically needed MA plan option for 2024 that is specifically tailored to meet the unique health and health-related needs of high risk/low income beneficiaries.

Importantly, if CMS proceeds with the planned termination of H7330, the novation and contract consolidation will ensure that members enrolled in H7330 will be able to continue in a plan for 2025 that is in the same parent organization as the plan they originally chose when they enrolled in Zing. This fact differentiates H7330 from other contracts that CMS has terminated due to low Star Ratings, and further underscores why the imposition of marketing and enrollment sanctions on H7330 is not warranted.

Applying Sanctions to H7330 Is Arbitrary and Capricious

CMS has discretion to impose intermediate sanctions—or not—in response to violations of the Medicare regulations.[3] However, CMS's discretionary authority is not limitless, and to be

[2] H4624 was rated 3.637 in 2023 and 2.868 in 2024.
[3] 42 C.F.R. § 422.752(a).

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reasonable, CMS must apply its discretion consistently across contractors.[4] In other words, CMS cannot treat two contractors disparately where their violations are identical or substantially similar.

On February 22, 2023, CMS terminated Imperial Health Plan of California Plan H2793.[5] In the termination letter, CMS cited Imperial's below 3-star Part D rating for three consecutive years as the sole reason for termination. Specifically, contract H2793 received Part D Summary Star Ratings of 2.5, 2.5, and 2, for years 2023, 2022, and 2021 respectively. Yet CMS did not impose any intermediate sanctions on Imperial. Like Imperial, CMS cited Zing's three consecutive years below a 3-star Part D rating as the sole reason for its termination. However, despite identical bases for termination, CMS imposed marketing and enrollment sanctions on Zing and none on Imperial. Indeed, Imperial's star ratings were lower than Zing's, and yet Zing suffered more severe repercussions. There is no basis for CMS's disparate treatment of Zing and Imperial, and thus imposing intermediate sanctions on Zing is arbitrary and capricious.

CONCLUSION

For the reasons stated above, Zing objects to CMS's imposition of intermediate sanctions and respectfully requests that they be withdrawn before they become effective on January 12, 2024. Zing intends to appeal the intermediate sanctions and termination and seek hearings on both issues.

Sincerely,

DocuSigned by:
Christine Clements
72437D5B8CB8407...

Christine M. Clements
for SHEPPARD, MULLIN, RICHTER & HAMPTON LLP

SMRH:4888-9446-3898.4

cc: Andrew Clifton

[4] See *Burlington N. & Santa Fe Ry. Co. v. Surface Transp. Bd.*, 403 F.3d 771, 777 (D.C. Cir. 2005) ("Where an agency applies different standards to similarly situated entities and fails to support this disparate treatment with a reasoned explanation and substantial evidence in the record, its action is arbitrary and capricious and cannot be upheld."); *see also Kort v. Burwell*, 209 F.Supp.3d 98, 112 (D.D.C. 2016) (finding that CMS's decision to allow Medicare coverage of one diagnostic test but not another similar test was arbitrary and capricious).

[5] *See* Termination Notice for Medicare Advantage-Prescription Drug Contract Number: H2793, *available at* https://www.cms.gov/files/document/imperialtermination02222023.pdf (last visited Jan. 1, 2024).

Exhibit 3

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
7500 SECURITY BOULEVARD
BALTIMORE, MARYLAND 21244-1850

DATE: June 13, 2024

TO: Medicare Advantage Organization Compliance Officers

FROM: Kathryn A. Coleman
Director, Medicare Drug & Health Plan Contract Administration Group, Center for Medicare

Vanessa S. Duran
Director, Medicare Drug Benefit and C & D Data Group, Center for Medicare

Jennifer Lazio
Director, Parts C & D Actuarial Group, Office of the Actuary

SUBJECT: Update to 2025 Quality Bonus Payment Determinations

In light of recent court decisions,[1] CMS is recalculating the 2024 Star Ratings for 2025 Quality Bonus Payment (QBP) purposes to address the application of Tukey outlier deletion and guardrails as codified at 42 C.F.R. §§ 422.166(a)(2)(i) and 423.186(a)(2)(i). CMS is not announcing here any policy or position with regard to the calculation of the 2025 Star Ratings, to be issued in October 2024.

Specifically, we have recalculated the 2024 Star Ratings using the published 2023 Star Ratings cut points to determine the guardrails for the 2024 Star Ratings (i.e., Tukey outliers were not removed from the 2023 Star Ratings). We have assigned all contracts the recalculated 2024 overall and/or summary Star Ratings if those recalculated ratings result in higher QBP Ratings than what was previously assigned based on the contract's overall and/or summary 2024 Star Ratings that were released in October 2023. If this recalculation would result in a contract's QBP Rating decreasing compared to the ratings previously assigned, CMS is not implementing

[1] The decisions in *SCAN Health Plan v. Department of Health & Human Services*, Civ. A. No. 23-3910 (CJN) (D.D.C.), and *Elevance Health, Inc. v. Becerra*, Civ. A. No. 23-3902 (RDM) (D.D.C.), were issued on June 3, 2024 and June 7, 2024 respectively. A decision whether to appeal those judgments has not yet been reached. CMS's decision to recalculate 2024 Star Ratings as described herein has no bearing on CMS's potential exercise of its right to appeal those decisions.

the change for those contracts and those contracts will be held harmless in this recalculation. A contract's QBP Rating will not be decreased by CMS as a result of this recalculation.

All MA contracts can view their updated 2025 QBP Ratings and Total Beneficiary Cost (TBC) data in the Health Plan Management System (HPMS). To access the recalculated QBP Ratings data, select Quality and Performance in the navigation bar and then Performance Metrics > Reports > Costs. Select MA QBP Rating as the "Report Type." Contracts should ensure that 2025 is selected as the "Contract Year" and then click "Create Report" to view their QBP Ratings. To access the TBC data, select Quality and Performance in the navigation bar and then Performance Metrics > Reports > Costs. Select Part C Total Beneficiary Costs as the "Report Type." Contracts should select 6/11/2024 as the "Report Period" and click "Create Report."

MA contracts with increases in their QBP Ratings as described above (i.e., only contracts that have an increase in their QBP Ratings from 3 to 3.5 stars, 3.5 to 4.0 stars, or 4.0 to 4.5 stars) will have a time-limited opportunity to resubmit their Contract Year 2025 bids, including bid pricing tools (BPTs), plan benefit packages (PBPs), and formularies. In an effort to minimize disruption to the overall formulary review process, including for those MA contracts without changes to their Star Ratings, affected contracts that plan to make changes to one or more formularies associated to their contracts must contact PartDFormularies@cms.hhs.gov by June 18, 2024 to confirm next steps.

In order for CMS to effectively and efficiently complete the bid review process consistent with its statutory obligations, revised bids and any formulary changes must be submitted no later than June 28, 2024, including the updated supporting documentation. CMS will open the gates in HPMS on June 26, 2024 for affected contracts to resubmit bids to reflect the change in their QBP Rating. MA organizations, including those that are Part D sponsors, should continue to respond to staged BPT, PBP, and formulary review communications that they receive. The actuarial certification for any bid resubmissions must be completed by July 3, 2024.

Questions regarding your QBP Rating should be sent to: PartCandDStarRatings@cms.hhs.gov. Questions regarding the TBC information posted in HPMS should be sent to: actuarial-bids@cms.hhs.gov. Questions related to the TBC policy should be submitted to: https://mabenefitsmailbox.lmi.org/MABenefitsMailbox/. Questions related to Part D benefits should be submitted to: PartDBenefits@cms.hhs.gov. Questions related to formularies should be sent to: PartDFormularies@cms.hhs.gov.

Additionally, we plan to update the 2024 Star Ratings information for all contracts on Medicare Plan Finder in the coming weeks.

Exhibit 4

DEPARTMENT OF HEALTH & HUMAN SERVICES
CENTERS FOR MEDICARE & MEDICAID SERVICES
7500 SECURITY BOULEVARD
BALTIMORE, MARYLAND 21244-1850

CENTER FOR MEDICARE

DATE: July 1, 2024

TO: All Medicare Advantage Organizations, Prescription Drug Plans, and Section 1876 Cost Plans

FROM: Kathryn A. Coleman
Director, Medicare Drug & Health Plan Contract Administration Group

Vanessa S. Duran
Director, Medicare Drug Benefit and C & D Data Group

SUBJECT: Availability of Updated 2024 Star Ratings Data

As noted in the June 13, 2024 HPMS memo titled "Update to 2025 Quality Bonus Payment Determinations," CMS has recalculated the 2024 Star Ratings using the published 2023 Star Ratings cut points to determine the guardrails for the 2024 Star Ratings.

After quality checks and providing flexibility to those MA organizations that have elected to retain the lower, original 2024 Star Ratings, the updated ratings are available in HPMS. To access the updated Part C and D Star Ratings data in HPMS, select: "Quality and Performance," then "Performance Metrics," then "Reports," then "Star Ratings and Display Measures," then "Star Ratings," and then select 2024 for the report period.

Updated ratings should be available on Medicare Plan Finder by the end of the day on July 2, 2024. Once Medicare Plan Finder is updated, Part C and D sponsors are able to update any communication materials to show the updated ratings. The updated 2024 Medicare Star Ratings marketing templates are also available in HPMS. Contracts that now receive 5 stars overall can market their continuous enrollment special election period (SEP). Additional guidance on the use of Star Ratings in marketing materials may be found at 42 CFR Parts 422 and 423 Subpart V.

The updated 2024 Star Ratings Data Tables will also be available at https://www.cms.gov/medicare/health-drug-plans/part-c-d-performance-data and landscape files at https://www.cms.gov/medicare/coverage/prescription-drug-coverage by the end of the day on July 2, 2024.