IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NORTH CAROLINA WESTERN DIVISION CASE NO. 5:23-cv-354

DOUG PAUL; ALEXANDER BEKO, on behalf of themselves and all others similarly situated,

Plaintiffs,

VS.

BLUE CROSS BLUE SHIELD OF NORTH CAROLINA,

Defendant.	

CLASS ACTION COMPLAINT

Plaintiffs Doug Paul and Alexander Beko, individually and on behalf of all others similarly situated, file this Class Action Complaint (the "Complaint"), pursuant to Rule 23 of the Federal Rules of Civil Procedure, asserting causes of action in law and equity for relief against Defendant Blue Cross Blue Shield of North Carolina.

I. <u>INTRODUCTION</u>

- 1. This is a class action on behalf of participants and beneficiaries of health benefit plans administered by Blue Cross Blue Shield of North Carolina ("BCBSNC"), who were denied benefits for proton beam radiation therapy ("PBRT") to treat prostate cancer.
- 2. Plaintiffs allege that BCBSNC uniformly applied an arbitrary medical policy to deny claims for PBRT as experimental, investigational, and/or not medically necessary, despite PBRT being recognized for decades by the medical community as an established, safe, and effective standard of care for cancers, including prostate cancer.

II. PARTIES

- 3. Plaintiff Doug Paul is and was at all relevant times a resident of Apex, Wake County, North Carolina.
- 4. At all relevant times, Mr. Paul was and remains a participant in an employee group health benefit plan ("ERISA Plan") governed by the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. § 1001, et seq., and was entitled to health benefits pursuant to the ERISA Plan.
- 5. The ERISA Plan is administered by Defendant BCBSNC. Attached as **Exhibit A** is a true and correct copy of the applicable BCBSNC insurance policy for the Plan.
- 6. Plaintiff Alexander Beko is and was at all relevant times a resident of Raleigh, Wake County, North Carolina.
- 7. At all relevant times, Mr. Beko was and remains a participant in a non-ERISA health benefit plan, the State Health Plan for Teachers and State Employees ("State Plan"), administered by Defendant BCBSNC.
- 8. Attached as **Exhibit B** is a true and correct copy of the applicable State Health Plan for Teachers and State Employees.
- 9. Plaintiffs are informed and believe that Defendant BCBSNC is an insurance company with its principal place of business in Durham, North Carolina, authorized to transact business and transacting business in the Eastern District of North Carolina, and can be found in the Eastern District of North Carolina.

III. JURISDICTION AND VENUE

10. For ERISA governed plans such as Mr. Paul's, this action against Defendant arises under 29 U.S.C. §§1132(a), (c), (e), (f) and (g) of the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. §1001 et seq. This Court has jurisdiction over this action pursuant to 29 U.S.C. §1132(e)(1). Jurisdiction is predicated under these code sections as well as 28 U.S.C. §1331, as this action involved a federal question.

- 11. For non-ERISA governed plans such as Mr. Beko's under the State Plan, pendent or supplemental jurisdiction pursuant to 28 U.S.C. § 1367 applies to ERISA claims and state law claims because the claims arise from a nucleus of operative fact common to both claims and BCBSNC served as claims administrator for both ERISA Plans and non-ERISA plans such as the State Plan.¹
- 12. Venue is proper in this District and Division pursuant to 29 U.S.C. §1132(e)(2) because at all relevant times Plaintiffs were residents of Wake County, North Carolina, and some or all of the fiduciary breaches for which relief is sought occurred in this district. Defendant BCBSNC also maintains business activities in this district.

IV. GENERAL FACTUAL ALLEGATIONS

A. Proton Beam Radiation Therapy

- 13. Proton therapy is the most effective form of radiation therapy for many types of tumors. It destroys cancer cells by preventing them from dividing and growing, like conventional X-ray radiation. One of the major differences between proton therapy and conventional X-ray radiation is that protons deposit much of their radiation directly in the tumor and then stop. This allows patients to receive higher doses, which can be more effective, while reducing damage to healthy tissues that surround the tumor.
- 14. The physical properties of protons are different from the physical properties of X-rays. Protons are large, positively charged sub-atomic particles that penetrate matter to a finite depth. X-rays are electromagnetic radiation that penetrates completely through tissue. Protons can be conformed to release much of their energy at precise depths so they can target tumors inside the body, depositing much of their radiation exactly at the tumor site. X-rays release their

See Technibilt Grp. Ins. Plan v. Blue Cross & Blue Shield of N.C., No. 5:19-CV-00079-KDB-DCK, 2021 U.S. Dist. LEXIS 57003, at *8 n.4 (W.D.N.C. Mar. 25, 2021) (citing Salim v. Dahlberg, 170 F. Supp. 3d 897, 907 (E.D. Va. 2016) ("holding based on Supreme Court precedent that trial courts enjoy wide latitude in determining whether to exercise supplemental jurisdiction and are permitted to deal with pendent claims in the manner that most sensibly accommodates a range of concerns and values.")).

maximum dose of radiation quickly after penetrating the skin, damaging healthy tissue and organs on their way to the tumor and again as they pass through the body beyond the tumor.

- 15. One of the goals of treatment is to deliver the proper dose of radiation to the tumor while limiting the dose received by the surrounding healthy tissue. To deposit the proper amount of energy into the tumor, X-rays must irradiate much of the healthy tissue in front of it, known as an "entrance dose," and they continue to penetrate through the tumor and irradiate much of the healthy tissue behind it, known as an "exit dose." To deliver the proper dose to a tumor, a radiation oncologist must "work around" the tumor by using multiple X-ray beams, delivering the highest dose where the beams intersect, but delivering low to medium "entrance" and "exit" doses to surrounding healthy tissue. In contrast, protons enter the patient at a low dose, then, at a precise depth, they deliver a large burst of energy. Immediately after this burst, they stop completely. To treat the entire tumor, additional protons are sent in at lower doses. In this way, protons completely irradiate the tumor while limiting the dose to the nearby healthy tissue. Proton treatment delivers a dose in a more accurate, more efficient way and spares more of the surrounding healthy tissue. Since protons have a low "entrance dose" and essentially no "exit dose," the volume of normal tissue receiving radiation with proton therapy is typically reduced by a factor of 2-3 when compared to even the most modern X-ray treatment plan.
- 16. Proton therapy allows for effective treatment of prostate cancer, while minimizing the radiation dose to vital functions, such as the gastrointestinal system or urinary tract.
- 17. In the late 1970s, imaging advancements coupled with the development of sophisticated computers and improved accelerator and treatment delivery technology made proton therapy more viable for routine medical applications, such as cancer treatment.
- 18. Proton therapy has been approved by the Federal Drug Administration since 1988 for the treatment of localized tumors and other conditions susceptible to treatment by radiation.
- 19. The first hospital-based proton-beam center in the United States was at the Loma Linda University Medical Center in Southern California, which began operation in 1990.

- 20. Currently in the United States, there are 42 proton therapy centers among 24 states.² There are currently no proton therapy centers in North Carolina, although one is under construction in Charlotte, North Carolina. Each of the 42 proton therapy centers in the United States offer proton therapy treatment for prostate cancer.
- 21. Many respected cancer facilities and providers treat prostate cancer with proton therapy, including but not limited to, Johns Hopkins Proton Therapy Center (where Mr. Paul received treatment), University of Florida Proton Therapy Institute (where Mr. Beko received treatment), Harvard Medical School/Massachusetts General Hospital, Northwestern University, Baptist Hospital's Miami Cancer Institute, Loma Linda University, University of Maryland, Mayo Clinic, Emory University, Case Western Reserve University, Washington University in St. Louis, University of Washington, New York Proton Center, MD Anderson Cancer Center, Penn Medicine, and the Texas Center for Proton Therapy.
- 22. Five of the top ten cancer centers in the United States according to the annual U.S. News & World Report rankings of the top cancer hospitals either have a proton center or are building a proton center.³
- 23. Over 200,000 patients have been treated with proton therapy. Prostate cancer is the most treated cancer type for proton therapy.
- 24. Johns Hopkins Proton Therapy Center states that PBRT "can precisely target prostate tumors, while better sparing surrounding tissues and organs from radiation exposure," allowing "the right dose of radiation to different parts of the tumor to effectively kill prostate cancer."

%20stop.

https://www.proton-therapy.org/map/

https://health.usnews.com/best-hospitals/rankings/cancer

https://www.hopkinsmedicine.org/health/conditions-and-diseases/prostate-cancer/proton-therapy-for-prostate-cancer#:~:text=Proton%20therapy%20can%20precisely%20target,into%20the%20tumor%20and

- 25. The University of Florida Health Proton Therapy Institute specifically lists prostate cancer as one of twelve identified cancers for which proton therapy is "a highly effective cancer treatment option."⁵
- 26. The medical community has found proton beam therapy radiation treatment to be a generally accepted standard of medical practice for the treatment of prostate cancer.
- 27. Other insurers, including Medicare, approve PBRT as a safe and effective prostate cancer treatment that is not "investigational."

B. BCBSNC is an ERISA Fiduciary

- 28. The majority of health plans underwritten and/or administered by BCBSNC, including the Plan providing coverage for Plaintiff Doug Paul, are employee group health benefit plans governed by ERISA ("ERISA Plans").
- 29. BCBSNC is an ERISA fiduciary, as defined by 29 U.S.C. § 1002(21)(A), with respect to Mr. Paul's ERISA Plan and the plans of all putative Class Members in that BCBSNC interprets and applies ERISA plan terms, makes coverage and benefit determinations under the ERISA plans within its discretion and may provide payment under the ERISA plans to participants, beneficiaries, and their providers. Accordingly, BCBSNC was required to comply with the requirements ERISA imposes on fiduciaries.
- 30. At all relevant times alleged herein, BCBSNC acted as both a named and functional fiduciary with respect to the specific issues alleged herein.
- 31. The ERISA health benefit plans administered by BCBSNC are either (1) insured by an insurance policy issued by BCBSNC, or (2) self-funded by the employer through a trust or assets.
- 32. With respect to insured plans, including Mr. Paul's, BCBSNC both administers the plan by making all benefit determinations and pays the benefits out of its own assets.

⁵ https://www.floridaproton.org/ppc/proton-top

- 33. With respect to self-funded plans, BCBSNC serves as claims administrator for the plan and the plan sponsor or employer is responsible for providing the funding for BCBSNC who issues the benefit payments.
- 34. When processing benefits for a self-funded plan, BCBSNC makes all benefit determinations and authorizes benefit payments to be issued out of bank accounts that BCBSNC controls and is fully responsible for processing the health claims and making the determination whether to issue the payment from these accounts.
- 35. Whether an ERISA plan is fully insured or self-funded, BCBSNC is the proper party for Plaintiff and the putative Class to seek relief from because BCBSNC made all the relevant benefit determinations for the ERISA plans.

C. BCBSNC is Fiduciary under North Carolina State Law

- 36. BCBSNC is a fiduciary under North Carolina state law as it undertakes to act for the benefit of another, thus causing the participants and beneficiaries of the State Plan and other non-ERISA plans it administers to place special faith, confidence, and trust in BCBSNC.
- 37. BCBSNC's conduct in administering health plans, including the State Plan, creates a fiduciary relationship between it and the State Plan, as well as between it and the participants and beneficiaries of the State Plan and other non-ERISA plans that it administers.
- 38. BCBSNC has a fiduciary relationship with the participants and beneficiaries of the State Plan and other non-ERISA plans it administers because confidence has been reposed in it such that it results in domination and influence over the participants and beneficiaries of the State Plan and the other non-ERISA plans it administers.
- 39. A fiduciary relationship between BCBSNC and the participants and beneficiaries of the State Plan and other non-ERISA plans it administers further exists because BCBSNC has all the financial power and technical information and asserts complete control over the decision to approve or deny medical claims, including specifically for PBRT treatment of prostate cancer, and the rights of the participants and beneficiaries of the State Plan and other non-ERISA plans it administers are directly and substantially impacted.

- 40. BCBSNC is in equity and good conscience required to act honestly, in good faith, and in the best interests of participants and beneficiaries of the plans it administers.
- 41. BCBSNC has been reposed with special faith, confidence, and trust to represent the best interests of the participants and beneficiaries of the State Plan and the other non-ERISA plans it administers.
- 42. At all relevant times alleged herein, BCBSNC acted as either a named or functional fiduciary, or both, with respect to the specific issues alleged herein.
- 43. At all relevant times alleged herein, BCBSNC had either a *de jure* fiduciary relationship with the participants and beneficiaries of the State Plan and the other non-ERISA plans it administers, a *de facto* fiduciary relationship with the participants and beneficiaries of the State Plan and the other non-ERISA plans it administers, or both, with respect to the general conduct and the specific issues alleged herein.
- 44. BCBSNC serves as clams administrator for the State Plan and other non-ERISA plans and the plan sponsor or employer is responsible for providing the funding for BCBSNC who issues the benefit payments. BCBSNC also serves as the claims administrator and insurer for other non-ERISA plans.
- 45. When processing benefits for a non-ERISA plans, such as the State Plan, BCBSNC makes all benefit determinations and authorizes benefit payments to be issued out of bank accounts that BCBSNC controls and is fully responsible for processing the health claims and making the determination whether to issue the payment from these accounts.
- 46. When processing benefits for a non-ERISA plan it insures, BCBSNC makes all benefit determinations and benefit payments are issued out of bank accounts that BCBSNC owns and is fully responsible for processing the health claims and making the determination whether to issue the payment from its account.

D. BCBSNC's Charged Particle Radiotherapy Medical Policy

- 47. BCBSNC drafted, adopted, applied, and continues to apply, Charged Particle Radiotherapy Medical Policy ("BCBSNC Medical Policy") to requests for coverage, requests for prior approval, and claims for benefits for proton beam therapy.
- 48. The BCBSNC Medical Policy was most recently reviewed in May 2022 before BCBSNC denied Plaintiffs' claims in June and August 2022.
- 49. The BCBSNC Medical Policy cites a single source a 2010 TEC Assessment regarding prostate cancer. The BCBSNC Medical Policy claims the 2010 TEC ("Blue Cross and Blue Shield Association Technical Evaluation Center") Assessment concluded that "it has not yet been established whether PBT improves outcomes in any setting for clinically localized prostate cancer" and that no data published since 2010 would alter the conclusions of the TEC Assessment. No external medical sources are cited.
- 50. The BCBSNC Medical Policy was updated in June 2010 to include the following language: "When not covered section: C. "In patients with clinically localized prostate cancer, because the clinical outcomes with this treatment have not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT) or conformal radiation therapy, yet proton beam therapy is generally more costly than these alternatives."
- 51. The BCBSNC Medical Policy states that PBRT is considered investigational for prostate cancer.
- 52. The BCBSNC Medical Policy is unsupported by the standard of care for treatment of prostate cancer in the medical community.
- 53. BCBSNC denied Plaintiffs' claims for PBRT based upon the BCBSNC Medical Policy.

E. BCBSNC Definition of Investigational

54. The ERISA Plan and State Plan both provide the following identical definition of Investigational:

INVESTIGATIONAL (EXPERIMENTAL)

The use of a service or supply including, but not limited to, treatment, procedure, facility, equipment, drug, or device that Blue Cross NC⁶ does not recognize as standard medical care of the condition, disease, illness, or injury being treated. The following criteria are the basis for Blue Cross NC's⁷ determination that a service or supply is investigational:

- a) Services or supplies requiring federal or other governmental body approval, such as drugs and devices that do not have unrestricted market approval from the U.S. Food and Drug Administration (FDA) or final approval from any other governmental regulatory body for use in treatment of a specified condition. Any approval that is granted as an interim step in the regulatory process is not a substitute for final or unrestricted market approval.
- b) There is insufficient or inconclusive scientific evidence in peer-reviewed medical literature to permit Blue Cross NC's evaluation of the therapeutic value of the service or supply.
- c) There is inconclusive evidence that the service or supply has a beneficial effect on health outcomes.
- d) The service or supply under consideration is not as beneficial as any established alternatives.

For the State Plan, the phrase "Blue Cross NC" is replaced with "the State Health Plan or its representative."

For the State Plan, the phrase "Blue Cross NC" is omitted and not replaced.

e) There is insufficient information or inconclusive scientific evidence that, when utilized in a non-investigational setting, the service or supply has a beneficial effect on health outcomes and is as beneficial as any established alternatives.

If a service or supply meets one or more of the criteria, it is deemed investigational except for clinical trials as described under this health benefit plan. Determinations are made solely by Blue Cross NC after independent review of scientific data. Opinions of experts in a particular field and/or opinions and assessments of nationally recognized review organizations may also be considered by Blue Cross NC but are not determinative or conclusive.

- 55. BCBSNC's application of its BCBSNC Medical Policy resulted in the denial of PBRT coverage for Plaintiffs and Members of the Class they seek to represent (as defined below), violated the terms of the relevant plans and BCBSNC's fiduciary obligations under ERISA and state law, and breached the contract of health benefits.
- 56. The Plans' definition of an investigational treatment is in conflict with the BCBSNC Medical Policy. The BCBSNC Medical Policy imposes an additional requirement for coverage by requiring that the requested treatment must be superior to an alternative treatment.
- 57. BCBSNC systematically relied upon its internally developed BCBSNC Medical Policy to inappropriately justify applying more restrictive coverage guidelines than allowed for under the plain language of the applicable health plans.
- 58. Plaintiffs' health plans both required that BCBSNC cover treatment that is "[w]ithin generally accepted standards of medical care in the community." Plaintiffs clearly established that PBRT is within the generally accepted standards of medical care in the community for their medical conditions, *i.e.*, prostate cancer, and therefore BCBSNC's decision to deny benefits for PBRT was contradictory to the Plans' language.

V. PLAINTIFF DOUG PAUL'S INDIVIDUAL FACTUAL ALLEGATIONS

A. Plaintiff Doug Paul's Claims for PBRT and BCBSNC's Denials

- 59. Plaintiff Doug Paul was diagnosed with prostate cancer in May 2021 at age 52. He consulted with physicians at John Hopkins Proton Therapy Center, including Dr. Curtiland Deville, for treatment recommendations.
- 60. Dr. Deville recommended that Mr. Paul undergo PBRT for treatment of his prostate cancer.
- 61. On June 20, 2022, Dr. Deville requested benefits from BCBSNC for Mr. Paul's PBRT and provided medical records and wrote a letter of medical necessity explaining the reasons why PBRT was the most advantageous treatment option for Plaintiff:
 - The advantage of PBRT is the precision of the proton beam and improved control of the radiation dose prescribed to the gross tumor and areas at risk for microscopic disease. The proton therapy fields can be designed to deliver dose directly to the tumor bed with significantly reduced entrance dose and essentially no exit dose, thus reducing the risk of damage to the surrounding health tissue and organs, specifically the rectum, bladder, bowel, femoral heads, penile bulb, and adjacent normal tissues.
 - For Mr. Paul, considering his removed prostate and current urinary symptoms
 and continued recovery, all of the organs at risk including the bladder, bowel,
 sigmoid, and rectum are better spared in the scanning beam proton therapy
 plan. Dr. Deville provided a dose color wash scans for comparison between
 proton and photon beams.
 - PBRT was the preferrable option to IMRT because it reduced the risk of treatment related secondary malignancy. Dr. Deville cited a medical study which found that prostate cancer patients undergoing proton therapy were at least four times less likely to have subsequent secondary malignancy compared to IMRT.

- PBRT provides lower cumulative doses to normal tissues and critical adjacent organs at risk.
- The 2021 NCCN Clinical Practice Guidelines in Oncology v. 2, Guidelines for Radiation Therapy in Prostate Cancer indicate that proton therapy is an effective and acceptable form of external beam radiation.
- Proton therapy has been used to treat prostate cancer for several decades with low incidence of side effects.
- Proton therapy is non-invasive, completely outpatient, extremely well tolerated, and should have little to no impact on patient energy level with minimal recovery necessary.
- Dr. Deville provided citations to six medical studies and articles supporting
 PBRT based on clinical outcomes of prostate cancer patients.

In summary, Dr. Deville wrote that proton therapy will provide the best chance for Mr. Paul to reduce his risk of future and secondary malignancy compared to photon therapy.

- 62. In a June 27, 2022 letter, BCBSNC denied benefits for Mr. Paul's PBRT, claiming it "considers this therapy investigation [sic] for your condition, prostate cancer. This means Blue Cross NC does not have enough scientific proof that this therapy will benefit you."
- 63. BCBSNC cited its "Blue Cross NC Corporate Medical Policies: Charged Particle Radiotherapy, Investigational (Experimental) Services" and determined that PBRT "is investigational per guidelines outlined in the policies."
 - 64. Mr. Paul requested a second level appeal.
- 65. In a July 8, 2022 letter, BCBSNC wrote to inform Mr. Paul that the Level II Appeal panel meeting for review of his case taking place **the same day the letter was mailed, July 8, 2022,** at 12:15 pm EST. BCBSNC advised Mr. Paul of the right to participate in the second level appeal hearing. However, Mr. Paul did not receive the mailed letter until days after the second level appeal hearing took place.

- 66. On August 4, 2022, Mr. Paul submitted a written appeal and external review request disputing BCBSNC's denial. Mr. Paul wrote that PBRT is the standard of care for many types of cancer and Medicare covers PBRT for prostate cancer.
- 67. On August 5, 2022, BHM Healthcare Solutions, a medical review company, provided a medical review of Mr. Paul's request for PBRT. The review upheld the BCBSNC denial. The review stated that "proton radiation is not proven to yield superior clinical outcomes as compared to standard of care photon-based IMRT" and the review concluded that PBRT is considered investigational. The review did not reference, refute, or acknowledge the medical literature provided by Dr. Deville and cited just three studies. The review did not identify the documents that were considered on appeal.
- 68. Notwithstanding BCBSNC's denial of coverage, Mr. Paul proceeded to have PBRT, with very positive results, and paid out-of-pocket for the cost of treatment.
- 69. Mr. Paul exhausted all administrative remedies required under ERISA and performed all duties and obligations on his part to be performed, and this claim is ripe for judicial review pursuant to 29 U.S.C. § 1132.

B. BCBSNC's Violations of ERISA

- 70. As the claims administrator responsible for interpreting and administering the ERISA Plan and similar BCBSNC plans issued nationwide, and vested with responsibility for making final benefit determinations, BCBSNC is an ERISA fiduciary.
- 71. As an ERISA fiduciary, BCBSNC was required to discharge its duties consistent with 29 U.S.C. § 1104, which requires (among other things) that it do so "solely in the interest of the participants and beneficiaries" and for the "exclusive purpose" of "providing benefits to participants and their beneficiaries" and paying reasonable expenses of administering the plan. It must do so with "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers. BCBSNC did not satisfy these requirements of a fiduciary.
- 72. BCBSNC failed to satisfy its duties when it prepared and applied the BCBSNC Medical Policy because it relied on incomplete and outdated medical evidence, ignored medical

evidence supporting PBRT as a standard of care for treatment of prostate cancer, and unreasonably concluded that PBRT was investigational.

- 73. BCBSNC compounded its fiduciary breach by relying upon the BCBSNC Medical Policy to deny health claims submitted by Mr. Paul and Class Members in contravention of the terms of their BCBSNC plans.
- 74. BCBSNC did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT as investigational when the evidence submitted to BCBSNC demonstrated that PBRT is not investigational for treatment of prostate cancer and is a standard of care in the medical community.
- 75. In violating its fiduciary duties, BCBSNC elevated its own interests above the interests of plan participants and beneficiaries, reflecting its conflict of interest when determining whether to cover PBRT for prostate cancer. By promulgating and applying its Medical Policy, BCBSNC sacrificed the interests of insureds like Mr. Paul and the Class Members so that it could artificially decrease the number and value of claims both that it was forced to pay out of its own assets and that it asked its self-funded employer-sponsor customers to pay and prioritized the assets of its employer-sponsor customer. BCBSNC also advanced its own interests in retaining and expanding its business with such customers.
- 76. BCBSNC's breach of its fiduciary duties by improperly denying benefits for PBRT resulted in Mr. Paul paying \$267,825.00 to receive the PBRT prescribed to him by his treating radiation oncologists. Because PBRT provided the best, safest, and most effective course of treatment for Mr. Paul and many others, he now brings this action on behalf of the Class Members, as well.
- 77. BCBSNC has unqualified medical directors with no experience or training in the context of radiation oncology, PBRT, and/or who are not board certified in the requisite medical specialty, adjudicate Members' claims and render boilerplate adverse benefit determinations.
- 78. BCBSNC's use of unqualified medical reviewers is a systemic, institutional abdication of its duty to screen, conduct background checks, review available public records

through state medical licensing boards, and conduct meaningful interviews of qualified candidates before employing candidates as medical directors who are charged with rendering life and death decisions for members, participants, and beneficiaries who seek life-saving treatment under their respective plans, and violates ERISA regulations and case precedent.

79. By placing this Medical Policy into the hands of medical directors who are not qualified to render opinions as to the medical necessity of PBRT, who lack the education, training and experience to appreciate factors in a given case that indicate the medical necessity for PBRT, who are unaware of contemporary medical evidence in the requisite specialty indicating the medical necessity for PBRT, and who follow the inadequate policies and procedures for clinical review, BCBSNC categorically wrongfully denies all prior approval requests and claims for PBRT for prostate cancer.

VI. PLAINTIFF ALEXANDER BEKO'S INDIVIDUAL FACTUAL ALLEGATIONS

A. Plaintiff Alexander Beko's Claims for PBRT and BCBSNC's Denials

- 80. Plaintiff Alexander Beko was diagnosed with prostate cancer in May 2022. He consulted with physicians at the University of Florida Proton Therapy Institute, including Dr. Randall Henderson, M.D., for treatment recommendations.⁸
- 81. Dr. Henderson recommended that Mr. Beko undergo PBRT as an alternative to IMRT for many reasons, including but not limited to his young age of 51, his ongoing medical history risks, and because PBRT reduces the probability of long-term side effects (*i.e.*, incontinence, bleeding/irritation, obstruction, strictures) and post-treatment complications.
- 82. Mr. Beko requested BCBSNC approve benefits for his PBRT at the University of Florida Proton Therapy Institute.
- 83. In an August 16, 2022 letter, BCBSNC denied benefits for Mr. Beko's PBRT, claiming treatment was "investigational when used to treat prostate cancer, non-small cell lung

Mr. Beko also consulted with other cancer facilities, such as Johns Hopkins, who all rendered the same professional opinion that PBRT was most medically appropriate for his cancer presentation.

cancer, tumors of the head and neck other than skull-based chordoma or chondrosarcoma, or any other tumors not listed in the medical policy." BCBSNC cited "Blue Cross NC Corporate Medical Policy: Charged Particle Radiotherapy; Investigational (Experimental) Services" (aka "BCBSNC Medical Policy").

- 84. Dr. Henderson filed an "Urgent Request for FIRST APPEAL; life threatening diagnosis" on Mr. Beko's behalf with BCBSNC on August 17, 2022.
- 85. In a letter dated August 19, 2022, BCBSNC again found that PBRT was investigational and upheld its "denial as investigational under CMP Charged Particle Radiotherapy (Proton or Helium Ion)," stating that "there is not enough scientific proof to show proton beam therapy improves health compared to other modalities of radiation therapy."
- 86. Dr. Henderson filed an "Urgent Request for SECOND LEVEL; life threatening diagnosis" appeal on Mr. Beko's behalf with BCBSNC on August 22, 2022.
 - 87. Dr. Henderson wrote that PBRT is recommended because:
 - Mr. Beko is a very young gentleman of 51 years and has an ongoing history of nocturia.
 - Acute and late urinary toxicity is a key risk for Mr. Beko. These adverse
 events are caused by inflammation of the prostate glade or urethra while
 treating intact prostate tissue.
 - PBT reduces the amount of normal tissue exposure around the prostate, including dose to the bladder.
 - Given his young age, minimizing normal tissue exposure reduces probability
 of acute and chronic complication including reducing the chance of
 secondary malignancies later in life.
 - PBT will minimize unnecessary exposure to Mr. Beko 's bladder and penile bulb.
 - PBT also reduces the probability of additional long-term side effects such as:

 1) incontinence, 2) bleeding/irritation, 3) obstruction, and 4) strictures.

- Mr. Beko is a healthy and functional male. Long-term complications from treatment should be avoided at all costs.
- BCBSNC is not considering the long-term consequences of not treating Mr.
 Beko with the best available care options. PBT provides the best chance of reducing post-treatment complications all reasons for approving PBT, especially with a favorable prognosis with treatment.
- 88. Dr. Henderson also provided the following evidence in support of PBRT:
 - BCBSNC's medical policy is incomplete because it lists 53 references
 regarding proton therapy and ZERO pertain to prostate cancer. Dr. Henderson
 provided 79 references to trials and case studies which support PBRT for
 prostate cancer.
 - Evidence showing the superiority of PBRT versus IMRT. Dr. Henderson
 provided comparisons between PBRT and IMRT for various structures (*i.e.*,
 bladder, rectum, small bowel) with each comparison showing PBRT as the
 better plan.
 - PBRT has decreased mortality compared to photon therapy by 24.4%.
 - PBRT prevents grade 3 and 4 toxicities and complications by targeting the
 prostate alone with minimal exit dose thus reducing unnecessary radiation by
 10% to his bowel and 15-35% to his bladder, causing a decreased chance of
 incontinence, bleeding/irritation, obstruction, and strictures in both early and
 late periods.
 - IMRT would put Mr. Beko at risk of potential complications leading to additional management and cost periods in the future.
 - PBRT prevents hip fractures and radiation to the femur which would be in the
 path of the treatment fields. With PBRT, unnecessary irradiation and
 weakening of the femur is minimized.
 - ASTRO Model Policy supports the medical necessity of PBRT to prevent

complications and toxicities. ASTRO Medical Policy for PBRT states that PBRT is medically necessary to spare the surrounding normal tissue when it cannot be effectively achieved with photon-based radiotherapy. A photon based technique would increase the probability of clinically significant normal tissue toxicity by exceeding the dose to Mr. Beko's large and small bowel, bladder, and rectum.

- 89. Dr. Henderson concluded that PBRT "is medically necessary and the superior care for Mr. Beko's prostate cancer for several reasons:
 - 1. Reduce the probability of acute and late urinary toxicity associated with intact prostate radiation therapy.
 - 2. Proton beam therapy will decrease Mr. Beko's risks of gastrointestinal (GI) toxicities such as diarrhea, by sparing his rectum by 10%.
 - Proton beam therapy will reduce urinary toxicity rates for Mr. Beko by 15-35%, thereby alleviating the potential for additional urinary symptoms aside from nocturia.
 - 4. Proton beam therapy will minimize irradiation to Mr. Beko's femur, and as a result, may potentially prevent radiation-induced hip fractures that could lead to catastrophic outcomes.
 - 5. Proton therapy will sustain Mr. Beko's life given his young age of 51 years."
- 90. Mr. Beko received notice of a Level II Appeal panel meeting for review of his case and his right to participate from BCBSNC in the mail when he got home from work on the same day the meeting was scheduled to take place.
- 91. In a letter dated August 25, 2022, BCBSNC again found that PBRT was investigational and upheld its denial following the external medical panel meeting on August 24, 2022, stating that "Blue Cross NC Corporate Medical Policy CMP Charged Particle Radiotherapy states that charged particle irradiation is considered investigational for clinically

localized prostate cancer, as in this member's condition of intermediate risk stage T2aN0M0 prostate cancer" and that "the requested proton beam therapy would not be considered medically necessary for Alexander Beko's clinical condition." This letter constituted BCBSNC and the North Carolina State Health Plan's "Notice of Final Internal Adverse Benefit Determination."

- 92. Mr. Beko timely sought independent external review through the North Carolina Department of Insurance ("Health Insurance Smart NC").
- 93. Health Insurance Smart NC assigned Mr. Beko's claim to independent review organization iMPROve Health on or about September 27, 2022.
- 94. In a letter dated September 29, 2022, iMPROve Health denied the expedited external appeal, claiming treatment "was not medically necessary and was experimental and/or investigational."
- 95. Notwithstanding BCBSNC's denial of coverage, Mr. Beko proceeded to have PBRT, with very positive results, and paid out-of-pocket for the cost of treatment.
- 96. Mr. Beko exhausted all levels of internal and external administrative remedies required or permitted under the North Carolina State Health Plan and performed all duties and obligations on his part to be performed, and this claim is ripe for judicial review.

B. BCBSNC's Violations of Its Duties to Alexander Beko

- 97. As the claims administrator responsible for interpreting and administering the State Plan and similar BCBSNC plans issued nationwide, and vested with responsibility for making final benefit determinations, BCBSNC is a fiduciary.
- 98. As a fiduciary, BCBSNC was required in equity and good conscience to discharge its duties honestly, in good faith, and in the best interests of the participants and beneficiaries of the plans it administers. BCBSNC did not satisfy these requirements of a fiduciary.
- 99. BCBSNC failed to satisfy its duties when it prepared and applied the BCBSNC Medical Policy because it relied on incomplete and outdated medical evidence, ignored medical evidence supporting PBRT as a standard of care for treatment of prostate cancer, and unreasonably concluded that PBRT was investigational.

- 100. BCBSNC compounded its breaches by relying upon the BCBSNC Medical Policy to deny health claims submitted by Mr. Beko and Class Members in contravention of the terms of their BCBSNC plans.
- 101. BCBSNC breached its duties when it denied coverage for PBRT as investigational when the evidence submitted to BCBSNC demonstrated that PBRT is not investigational for treatment of prostate cancer and is a standard of care in the medical community.
- 102. In violating its fiduciary duties, BCBSNC elevated its own interests above the interests of plan participants and beneficiaries, reflecting its conflict of interest when determining whether to cover PBRT for prostate cancer. By promulgating and applying its Medical Policy, BCBSNC sacrificed the interests of insureds like Mr. Beko and the Class Members so that it could artificially decrease the number and value of claims both that it was forced to pay out of its own assets and that it asked its self-funded employer-sponsor customers to pay and prioritized the assets of its employer-sponsor customer. BCBSNC also advanced its own interests in retaining and expanding its business with such customers.
- 103. BCBSNC improperly denying benefits for PBRT, resulted in Mr. Beko paying \$40,039.00 to receive the PBRT prescribed to him by his treating radiation oncologists. Because PBRT provided the best, safest, and most effective course of treatment for Mr. Beko and many others, he now brings this action on behalf of the Class Members, as well.
- 104. BCBSNC has unqualified medical directors with no experience or training in the context of radiation oncology, PBRT, and/or who are not board certified in the requisite medical specialty, adjudicate Members' claims and render boilerplate adverse benefit determinations.
- 105. BCBSNC's use of unqualified medical reviewers is a systemic, institutional abdication of its duty to screen, conduct background checks, review available public records through state medical licensing boards, and conduct meaningful interviews of qualified candidates before employing candidates as medical directors who are charged with rendering life

and death decisions for Members who seek life-saving treatment under their respective plans, and violates ERISA regulations and case precedent.

106. By placing this Medical Policy into the hands of medical directors who are not qualified to render opinions as to the medical necessity of PBRT, who lack the education, training and experience to appreciate factors in a given case that indicate the medical necessity for PBRT, who are unaware of contemporary medical evidence in the requisite specialty indicating the medical necessity for PBRT, and who follow the inadequate policies and procedures for clinical review, BCBSNC categorically wrongfully denies all prior approval requests and claims for PBRT for prostate cancer.

VII. <u>CLASS ACTION ALLEGATIONS</u>

- 107. Plaintiffs bring this action individually and on behalf of all others similarly situated as a Class Action pursuant to Federal Rules of Civil Procedure Rule 23.
- 108. Pursuant to Rule 23(b)(1) and (b)(2), Plaintiffs seek certification of a "PBRT Class," defined as follows:

All persons covered under health plans that are administered by BCBSNC, whose pre-service or post-service requests to BCBSNC for benefits for proton beam radiation therapy for the treatment of prostate cancer were denied at any time within the applicable statute of limitations, or whose requests to BCBSNC for PBRT will be denied in the future, based upon a determination by BCBSNC that PBRT is not medically necessary or is experimental, investigational, or unproven.

- 109. The definition of "investigational" contained in Plaintiffs' plans, and relied upon by BCBSNC in denying coverage for Plaintiffs for PBRT, is the same or substantially similar to, and is interpreted by BCBSNC as having the same meaning as, comparable definitions and exclusions included in the BCBSNC plans applicable to all Class Members.
- 110. The PBRT Class excludes (a) BCBSNC, including any entity or division in which BCBSNC has a controlling interest, as well as its agents, representatives, officers, directors,

employees, trustees, and other entities related to, or affiliated with BCBSNC, (b) Class Counsel, and (c) the Judge to whom this case is assigned and any Members of the Judge's staff or immediate family.

- 111. Plaintiffs and the Class Members reserve the right under Federal Rules of Civil Procedure Rule 23(c)(l)(C) to amend or modify the class to include greater specificity, by further division into subclasses, or by limitation to particular issues.
- 112. This action has been brought and may be properly maintained as a Class Action under the provisions of Federal Rules of Civil Procedure Rule 23 because there is a well-defined community of interest in the litigation and the proposed class is ascertainable.

A. Numerosity

- 113. The potential Members of the proposed class as defined are so numerous that joinder of all the Members of the proposed class is impracticable.
- 114. While the precise number of proposed Class Members has not been determined at this time, Plaintiffs are informed and believe that there are a substantial number of individuals covered under plans administered by BCBSNC who have been similarly affected.
- 115. Prostate cancer accounts for more than 25% of new cancer cases diagnosed in men with an estimated 248,530 new cases of prostate cancer diagnosed in 2021.⁹
 - 116. Breast cancer and prostate cancer are most frequently treated with PBRT. 10
- 117. BCBSNC reports a total of 3,861,722 members in 2020, including 584,308 members through the State of North Carolina.¹¹
- 118. The PBRT Class is ascertainable because its Members can be readily identified using BCBSNC's claims data. PBRT therapy is described with a discrete set of procedure codes under the Current Procedural Terminology ("CPT") promulgated by the American Medical

Siegel RL, Miller KD, Fuchs HE, Jemal A. Cancer Statistics, 2021. *CA Cancer J Clin*. 2021;71(1):7–33.

https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2791568

https://www.bluecrossnc.com/2020-corporate-report/our-customers

Association. Accordingly, Class Members can be readily and objectively ascertained through use of records maintained by BCBSNC.

119. Finally, PBRT Class Members are dispersed geographically throughout the United States such that joinder of all Members is impracticable.

B. Commonality

- 120. This action satisfies the requirements of Fed. R. Civ. P. 23(a)(2) and 23(b)(3) because questions of law and fact that have common answers predominate over questions affecting only individual Class Members. These include, without limitation:
 - a. Whether PBRT therapy is an "investigational" service or treatment for prostate cancer under health plans insured and/or administered by BCBSNC;
 - Whether BCBSNC categorically applied its BCBSNC Medical Policy to deny coverage to PBRT Class Members;
 - c. Whether PBRT Class Members' claim denials were based in whole or in part on the BCBSNC Medical Policy;
 - d. Whether the criteria set out in the BCBSNC Medical Policy conflicts with Class Members' Plans;
 - e. Whether the application of the BCBSNC Medical Policy to Class Members' claims was a breach of BCBSNC's fiduciary duties;
 - f. Whether PBRT Class Members are entitled to the relief sought if Plaintiffs establish liability.

C. Typicality

121. Plaintiffs' claims are typical of the claims of PBRT Class Members because Plaintiffs are participants in health plans that are administered by BCBSNC, submitted claims for coverage of PBRT for treatment of their prostate cancer, and, like other PBRT Class Members, BCBSNC denied their claims for PBRT based on the flawed, out-of-date, and artificially restrictive BCBSNC Medical Policy.

D. Adequacy of Representation

122. Plaintiffs will fairly and adequately protect the interests of the Class. Plaintiffs' interests do not conflict with the interests of the Members of the Class. Further, Plaintiffs have retained counsel who are competent and experienced in complex class action litigation, and Plaintiffs and their counsel intend to prosecute this action vigorously on behalf of the Class Members and have the financial resources to do so. Neither Plaintiffs nor their counsel have any interest adverse to those of the Class Members.

E. Superiority

- 123. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(l) because the prosecution of separate actions by individual Class Members would create a risk of inconsistent or varying adjudications that could establish incompatible standards of conduct for BCBSNC.
- 124. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(2) because by applying a uniform Medical Policy treating PBRT as investigational, BCBSNC has acted and refused to act on grounds that apply generally to the Class, thereby requiring the Court's imposition of uniform relief to ensure compatible standards of conduct towards Class Members, and making final injunctive relief or corresponding declaratory relief appropriate respecting the proposed Class as a whole.
- 125. This action satisfies the requirements of Fed. R. Civ. P. 23(b)(3) because a class action is superior to other available methods for the fair and efficient adjudication of this controversy. Questions of law and fact common to the Class Members predominate over any questions affecting only individual Members.
- 126. A class action is superior to other available methods for the fair and efficient adjudication of this controversy because joinder of all Class Members is impracticable.
- 127. Further, because the unpaid benefits denied Class Members are small relative to the expense and burden of individual litigation, it would be impossible for the Members of the Class to redress individually the harm done to them, such that most or all Class Members would have no rational economic interest in individually controlling the prosecution of specific actions,

and the burden imposed on the judicial system by individual litigation by even a small fraction of the Class would be enormous, making class adjudication the superior alternative under Fed. R. Civ. P. 23(b)(3)(A).

128. The conduct of this action as a class action presents far fewer management difficulties, far better conserves judicial resources and the parties' resources, and far more effectively protects the rights of each Class Member than would piecemeal litigation. Compared to the expense, burdens, inconsistencies, economic infeasibility, and inefficiencies of individualized litigation, the challenges of managing this action as a class action are substantially outweighed by the benefits to the legitimate interests of the parties, the court, and the public of class treatment in this court, making class adjudication superior to other alternatives, under Fed. R. Civ. P. 23(b)(3)(D).

VIII. FIRST CLAIM FOR RELIEF

For Denial of Benefits on Behalf of Plaintiff Doug Paul and the Class

- 129. Plaintiff Doug Paul, individually and on behalf of the Class members, repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.
 - 130. This count is brought pursuant to 29 U.S.C. § 1132(a)(1)(B).
- 131. BCBSNC wrongfully denied Mr. Paul and the Class Members' claims for PBRT at a time when BCBSNC knew, or should have known, that Mr. Paul and the Class Members were due those benefits under the terms of their respective plans.
- 132. BCBSNC wrongfully denied Mr. Paul and the Class Members' claims for PBRT by unreasonably relying upon its BCBSNC Medical Policy that was flawed, out-of-date, and artificially restrictive.
- 133. BCBSNC failed to provide prompt and reasonable explanations of the bases relied upon under the terms of the plan documents, in relation to the applicable facts and plan provisions, for the denial of Mr. Paul and the Class Members' claims for medical benefits.

- 134. BCBSNC failed to properly and adequately investigate the merits of Mr. Paul and the Class Members' medical claims and failed to provide them with a full and fair review pursuant to 29 C.F.R.§2560.503-1 (h)(3)(iii) by failing to consult with health care professionals who have appropriate training and experience in the field of medicine involved in the medical judgment.
- 135. BCBSNC failed to thoroughly and independently evaluate both Mr. Paul's and the Class Members' medical records prior to issuing their denials of their claims and their appeals and failed to provide them with a copy of the internal guidelines relied upon in making the adverse benefit determination, in violation of 29 C.F.R.§2560.503-1 (g)(v)(A).
- 136. Mr. Paul is informed and believes that BCBSNC wrongfully denied his claims for health benefits by other acts or omissions of which he is presently unaware, but which may be discovered in this future litigation and which he will immediately make BCBSNC aware of once said acts or omissions are discovered by him.
- 137. Following the denial of Mr. Paul's claims for medical benefits under the Plan, he exhausted all administrative remedies required under ERISA, and he performed all duties and obligations on his part to be performed.
- 138. Mr. Paul and Class Members have been harmed by BCBSNC's improper benefit denials because they were deprived of health benefits they were owed.
 - 139. Mr. Paul and Class Members seek the relief identified below to remedy this claim.

IX. SECOND CLAIM FOR RELIEF

For Declaratory, Injunctive, and Other Equitable Relief, and Attorneys' Fees Pursuant to ERISA 29 U.S.C. §§ 1132(a)(3), (g) on Behalf of Plaintiff Doug Paul and the Class

- 140. Plaintiff Doug Paul, individually and on behalf of the Class members, repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.
- 141. BCBSNC acts as an ERISA fiduciary with respect to the administration and claims decisions of the group health plans within the meaning of 29 U.S.C. §§ 1109(a) and

- 1002(21)(A). With respect to these plans, BCBSNC exercises discretionary authority or control respecting management of the plans, or exercise authority or control respecting management or disposition of the plans' assets. BCBSNC has the authority, and actually exercised the authority, to fund the plans, make decisions on claims for benefits and appeals thereof, and write checks for benefits.
- 142. BCBSNC has categorically and improperly denied requests for PBRT to treat prostate cancer, as alleged above.
- 143. In acting and failing to act as described above, BCBSNC has breached its fiduciary duty.
- 144. 29 U.S.C. § 1109(a) provides that "[a]ny person who is a fiduciary with respect to a plan who breaches any of the responsibilities, obligations, or duties imposed upon fiduciaries by this subchapter shall be personally liable."
- 145. As an ERISA fiduciary, and pursuant to 29 U.S.C. § 1104(a), BCBSNC is required to discharge its duties "solely in the interests of the participants and beneficiaries" and for the "exclusive purpose of providing benefits to participants and their beneficiaries," and pay "reasonable expenses of administering the plan."
- 146. BCBSNC must do so with reasonable "care, skill, prudence, and diligence" and in accordance with the terms of the plans it administers.
- 147. BCBSNC must conform its conduct to a fiduciary duty of loyalty and may not make misrepresentations to the participants and beneficiaries of the plans it administers.
- 148. BCBSNC violated these duties by adopting and implementing a Medical Policy to deny coverage for PBRT based on investigational exclusions under its plans, when such a finding was contrary to generally accepted practices and to the terms of the plans. BCBSNC ignored current scientific evidence and widespread acceptance of PBRT as a safe and effective treatment for prostate cancer in improperly applying the investigational exclusion to PBRT.
- 149. In doing so, BCBSNC did not act "solely in the interests of the participants and beneficiaries" for the "exclusive purpose" of "providing benefits." BCBSNC did not utilize the

"care, skill, prudence, and diligence" of a "prudent man" acting in a similar capacity. BCBSNC did not act in accordance with the terms of the ERISA Plan and other BCBSNC plans it administers, all of which contain such an investigational exclusion.

- 150. BCBSNC elevated its own interests and those of its corporate affiliates above the interests of plan participants and beneficiaries. By adhering to an incomplete and outdated Medical Policy, BCBSNC artificially decreased the number and value of covered claims thereby benefiting itself and its corporate affiliates and clients at the expense of claimants.
- 151. BCBSNC did not act "solely in the interests of the participants and beneficiaries" when it denied coverage for PBRT. Rather, upon information and belief, BCBSNC denied coverage for PBRT to treat prostate cancer despite evidence establishing PBRT was not investigational for treatment of prostate cancer.
- 152. BCBSNC's decision to apply its Medical Policy without any recent clinical developments that acknowledge that PBRT is no longer investigational, demonstrates that BCBSNC arbitrarily applied the Medical Policy to Mr. Paul's claim and continues to arbitrarily apply the Medical Policy to Class claims.
- 153. Mr. Paul and Class Members have been harmed by BCBSNC's breaches of fiduciary duty because their claims have been subjected improperly to investigational exclusion, leading to denials of coverage for PBRT, when PBRT is a Covered Service within the definition of the BCBSNC plans.
- 154. Pursuant to 29 U.S.C. § 1132(a)(3), Mr. Paul and the Class Members seek equitable and remedial relief as follows:
 - a. An injunction compelling BCBSNC to: (1) retract their categorical denials of PBRT for the treatment of prostate cancer; (2) provide notice of said determinations in the form and manner required by ERISA to all BCBSNC subscribers/members who have had requests for PBRT to treat prostate cancer denied; (3) provide for the re-review of all such improperly denied claims; and

- (4) revise and update its Medical Policy to be consistent with current medical literature, research, studies, trials, and generally accepted standards of care.
- b. An accounting and disgorgement by BCBSNC of any profits made by BCBSNC from the monies representing the improperly denied claims and disgorgement of any profits accrued by BCBSNC by denying PBRT requests for the treatment of prostate cancer.
- c. Other appropriate equitable relief as permitted by law, equity, and the statutory provisions set forth herein, including but not limited to surcharge, constructive trust, restitution, equitable estoppel, and/or any other appropriate remedial relief.
- d. Such other equitable and remedial relief as the Court may deem appropriate.
- e. Attorneys' fees in an amount to be proven at the time of trial.

X. THIRD CLAIM FOR RELIEF

For Denial of Benefits on Behalf of Plaintiff Alexander Beko and the Class

- 155. Plaintiff Alexander Beko, individually and on behalf of the Class members, repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.
- 156. Mr. Beko entered into a health contract with BCBSNC pursuant to his employment with the State of North Carolina.
- 157. As a participant in the State Plan, Mr. Beko was and is entitled to healthcare coverage provided in the State Plan.
- 158. Mr. Beko has complied with all conditions precedent to entitle him to health benefits under the State Plan.
- 159. Despite Mr. Beko providing BCBSNC with adequate proof of his health claim under the State Plan, and despite his compliance with all conditions precedent to entitle him to health benefits under the State Plan, BCBSNC has failed and refused to provide benefits under the State Plan and have breached their contractual obligations owed to Mr. Beko.

- 160. BCBSNC's failure to provide healthcare coverage to Mr. Beko was and continues to be a breach of the State Plan.
- 161. As a proximate and direct result of the breach of contract by BCBSNC, Mr. Beko has suffered damages in an amount of approximately \$40,039.00, plus other incidental and consequential damages.
- 162. Mr. Beko is entitled to benefits under the State Plan and such additional consequential and incidental damages as he may prove as a result of BCBSNC's failure to pay the benefits due under the health contract.
- 163. Mr. Beko and Class Members have been harmed by BCBSNC's improper benefit denials because they were deprived of health benefits they were owed.
- 164. Following the denial of Mr. Beko's claim for medical benefits under the State Plan, he exhausted all administrative remedies required under the State Plan, and he performed all duties and obligations on his part to be performed.
- 165. Plaintiff Alexander Beko and Class Members are entitled to a trial by jury on this claim for relief.

XI. FOURTH CLAIM FOR RELIEF

For Breach of Fiduciary Duty on Behalf of Plaintiff Alexander Beko and the Class

- 166. Plaintiff Alexander Beko, individually and on behalf of the Class members, repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.
- 167. BCBSNC acts as a fiduciary with respect to the administration and claims decisions of health plans. With respect to these plans, BCBSNC exercises discretionary authority or control respecting management of the plans, or exercise authority or control respecting management or disposition of the plans' assets. BCBSNC has the authority, and actually exercised the authority, to fund the plans, to make decisions on claims for benefits and appeals thereof, and make payments for benefits.

- 168. BCBSNC has categorically and improperly denied requests for PBRT to treat prostate cancer, as alleged above.
- 169. In acting and failing to act as described above, BCBSNC has breached its fiduciary duty to Mr. Beko and Class Members.
- 170. As a fiduciary, BCBSNC was required in equity and good conscience to discharge its duties honestly, in good faith, and in the best interests of the participants and beneficiaries of the plans it administers.
- 171. BCBSNC violated these duties by adopting and implementing a Medical Policy to deny coverage for PBRT based on investigational exclusions under its plans, when such a finding was contrary to generally accepted practices and to the terms of the plans. BCBSNC ignored current scientific evidence and widespread acceptance of PBRT as a safe and effective treatment for prostate cancer in improperly applying the investigational exclusion to PBRT.
- 172. In doing so, BCBSNC did not act in the interests of the participants and beneficiaries and did not act in accordance with the terms of the State Plan and other BCBSNC plans it administers.
- 173. BCBSNC elevated its own interests and those of its corporate affiliates above the interests of plan participants and beneficiaries. By adhering to an incomplete and outdated Medical Policy, BCBSNC artificially decreased the number and value of covered claims thereby benefiting itself and its corporate affiliates and clients at the expense of claimants.
- 174. BCBSNC violated its fiduciary duties to provide coverage for PBRT to treat prostate cancer despite evidence establishing PBRT was not investigational for treatment of prostate cancer.
- 175. BCBSNC's decision to apply its Medical Policy without any recent clinical developments that acknowledge that PBRT is no longer investigational, demonstrates that BCBSNC arbitrarily applied the Medical Policy to Mr. Beko's claim and continues to arbitrarily apply the Medical Policy to Class claims.

- 176. Mr. Beko and Class Members have been harmed by BCBSNC's breaches of fiduciary duty because their claims have been subjected improperly to investigational exclusion, leading to denials of coverage for PBRT, when PBRT is a Covered Service within the definition of the BCBSNC plans.
 - 177. Mr. Beko and the Class Members seek equitable and remedial relief as follows:
 - a. An injunction compelling BCBSNC to: (1) retract their categorical denials of PBRT for the treatment of prostate cancer; (2) provide notice of said determinations to all BCBSNC subscribers/members who have had requests for PBRT to treat prostate cancer denied; (3) provide for the re-review of all such improperly denied claims; and (4) revise and update its Medical Policy to be consistent with current medical literature, research, studies, trials, and generally accepted standards of care.
 - b. An accounting and disgorgement by BCBSNC of any profits made by BCBSNC from the monies representing the improperly denied claims and disgorgement of any profits accrued by BCBSNC by denying PBRT requests for the treatment of prostate cancer.
 - c. Other appropriate equitable relief as permitted by law, equity, and the statutory provisions set forth herein, including but not limited to surcharge, constructive trust, restitution, equitable estoppel, and/or any other appropriate remedial relief.
 - d. Such other equitable and remedial relief as the Court may deem appropriate.
 - e. Attorneys' fees in an amount to be proven at the time of trial.
- 178. Plaintiff Alexander Beko and Class Members are entitled to a trial by jury on this claim for relief.

XII. FIFTH CLAIM FOR RELIEF

For Unfair and Deceptive Trade Practices Pursuant to N.C.G.S. Chapter 75 and Chapter 58-63 on Behalf of Plaintiff Alexander Beko and the Class

- 179. Plaintiff Alexander Beko, individually and on behalf of the Class members, repeat and re-allege each and every allegation set forth in all of the foregoing paragraphs as is fully set forth herein.
- 180. The operation of BCBSNC involves or affects commerce as that term is used in N.C.G.S. § 75-1.1.
- 181. The action of BCBSNC in administering health plans generally is in or affecting commerce as defined by N.C.G.S. § 75-1.1.
- 182. The specific actions of BCBSNC as described herein were in and affecting commerce in the State of North Carolina and were unfair and deceptive trade practices as defined by N.C.G.S. § 75-1.1.
- 183. A trade practice is "unfair" and unlawful if it offends established public policy or is immoral, unethical, oppressive, unscrupulous, or substantially injurious to a consumer or consumers.
- 184. The actions of the BCBSNC as described herein also constitute unfair methods of competition and unfair or deceptive acts or practices as defined by N.C.G.S. Chapter 58-63-15.
- 185. BCBSNC knew or should have known that its actions in reliance upon its Medical Policy that relied upon incomplete and outdated medical evidence were unfair and deceptive.
- 186. BCBSNC failed to conduct a reasonable investigation into Plaintiff Alexander Beko's claim and the claims of Class Members, instead relying on an incomplete and outdated Medical Policy.
- 187. BCBSNC's failure to conduct a reasonable investigation caused it to deny Plaintiff Alexander Beko's claim for PBRT and the claims of Class Members.
- 188. BCBSNC refused to pay Mr. Beko's claim for PBRT and the claims of Class Members without conducting a reasonable investigation.

- 189. In denying Mr. Beko's claim for PBRT and the claims of Class Members in reliance upon the Medical Policy, BCBSNC failed to act in good faith.
- 190. In denying Mr. Beko's claim for PBRT and the claims of Class Members, BCBSNC misrepresented and misstated the terms of the plans, including but not limited to what coverage was provided.
- 191. BCBSNC elevated its own interests and those of its corporate affiliates above the interests of plan participants and beneficiaries. By adhering to an incomplete and outdated Medical Policy, BCBSNC artificially decreased the number and value of covered claims, thereby benefiting itself and its corporate affiliates and clients at the expense of claimants.
- 192. BCBSNC's decision to apply its Medical Policy without any recent clinical developments that acknowledge that PBRT is no longer investigational, demonstrates that BCBSNC arbitrarily applied the Medical Policy to Plaintiff Alexander Beko's claim and continues to arbitrarily apply the Medical Policy to Class claims.
- 193. Mr. Beko and Class Members have been harmed by BCBSNC's actions in this regard because their claims have been subjected improperly to investigational exclusion, leading to denials of coverage for PBRT, when PBRT is a Covered Service within the definition of the BCBSNC plans.
- 194. BCBSNC's denial letters to Mr. Beko and the Class Members, including any participants and beneficiaries of the plans it administers, denying coverage for PBRT for the treatment of prostate cancer and reflecting BCBSNC's position to that effect, in and of themselves and on their own establish actual injury proximately caused by BCBSNC sufficient to maintain an unfair and deceptive trade practices claim, irrespective of any of the other allegations alleged herein.
- 195. BCBSNC's failure to provide coverage for Mr. Beko's claim and Class Members' claims for PBRT to treat his prostate cancer diagnosis violated public policy and was immoral, unethical, oppressive, unscrupulous, or substantially injurious.

- 196. BCBSNC's actions as alleged herein misappropriated and/or misused its commercial advantage to the detriment of Mr. Beko and the Class Members.
- 197. BCBSNC's actions as alleged herein amounted to an inequitable assertion of its power or position.
- 198. BCBSNC's actions as alleged herein had a detrimental impact on Mr. Beko, the Class Members, and the marketplace.
- 199. Mr. Beko's claim for PBRT was denied, forcing him to pay out-of-pocket for his life-saving medical treatment.
- 200. As a direct and proximate result of BCBSNC's unfair and deceptive actions and omissions as described herein, Mr. Beko and Class Members incurred concrete and particularized, actual injury and damages.
- 201. Pursuant to N.C.G.S. § 75-16, Mr. Beko and Class Members are entitled to have and recover from BCBSNC damages in an amount to be proven at trial, which are to be trebled together with the costs of this action.
- 202. Pursuant to N.C.G.S. § 75-16.1, Mr. Beko and Class Members are entitled to have and recover of BCBSNC reasonable attorneys' fees and costs.
 - 203. Mr. Beko and Class Members are entitled to a trial by jury on this claim for relief.
 XIII. CLAIMS FOR ATTORNEYS' FEES & COSTS
- 204. Plaintiff Doug Paul seeks an award of his reasonable attorneys' fees incurred and to be incurred in the prosecution of this claim. He is entitled to recover those fees, together with his costs of court, pursuant to 29 U.S.C. §1132(g).
- 205. Plaintiff Alexander Beko seeks an award of his reasonable attorneys' fees incurred and to be incurred in the prosecution of this claim. He is entitled to recover those fees, together with his costs of court, under N.C.G.S § 75-16.1 and as otherwise provided under North Carolina state law.

XIV. PRAYERS FOR RELIEF

- 206. Plaintiffs individually and on behalf of the Class Members respectfully pray that upon trial of this matter or other final disposition, this Court find in their favor and against BCBSNC and issue judgment against BCBSNC as follows:
 - a. An Order certifying the proposed Class, appointing Plaintiffs to represent the proposed Class, designating Plaintiffs' counsel as Class Counsel, and approving a service award for Plaintiffs;
 - b. An Order finding that Plaintiffs and the proposed Class are entitled to recoupment of benefits due under the BCBSNC plans;
 - c. An Order declaring that BCBSNC's practices described herein violate ERISA and its ERISA-based fiduciary duties, responsibilities, and obligations;
 - d. An Order declaring that BCBSNC's practices described herein were a breach of the contract of health benefits provided to state employees and other non-ERISA participants and beneficiaries, and a breach of its fiduciary duties, responsibilities, and obligations under North Carolina state law, and constituted unfair and deceptive trade practices;
 - e. An Order requiring BCBSNC to reprocess Plaintiffs' and Class Members' claims for PBRT to treat prostate cancer in accordance with the health plans' respective requirements;
 - f. An Order requiring BCBSNC to revise and update its Medical Policy to be consistent with current medical literature, research, studies, trials, and generally accepted standards of medical care;
 - g. An Order requiring BCBSNC to create a common fund out of which it will make payment, with interest, of any unpaid benefits to Plaintiffs and the Member Class;

- h. Payment of health benefits due to Plaintiffs and the Member Class under BCBSNC's applicable plans;
- i. Injunctive relief, as described above;
- j. Monetary damages in an amount to be proved at trial;
- k. Disgorgement of all profits unjustly retained by BCBSNC as the result of its wrongful denials of PBRT for the treatment of prostate cancer;
- Other appropriate equitable relief as permitted by law, equity, and the statutory provisions set forth herein, including but not limited to surcharge, constructive trust, restitution, equitable estoppel, and/or any other appropriate remedial relief;
- m. Treble damages pursuant to N.C.G.S. § 75-16;
- n. Trial by jury on all eligible claims so authorized;
- o. Payment of all costs and attorneys' fees incurred in pursuing this action;
- p. Payment of prejudgment interest at a rate of at least the North Carolina legal rate of 8% and post-judgment interest as allowed for under ERISA; and
- q. For such other equitable, remedial, and further relief as the Court deems just and proper.

This the 27th day of June, 2023.

/s/Norris A. Adams, II

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