

No. 95449-6

No. 74600-6-I

DIVISION I, COURT OF APPEALS
OF THE STATE OF WASHINGTON

JOHN STRAUSS and MICHELLE STRAUSS,
husband and wife, and their marital community,

Appellants,

v.

PREMERA BLUE CROSS,

Respondent.

APPEAL FROM THE SUPERIOR COURT FOR KING COUNTY
(Hon. Monica J. Benton)

BRIEF OF RESPONDENT

Gwendolyn Payton
WSBA No. 26752
Ryan P. McBride
WSBA No. 33280
Jessica N. Walder
WSBA No. 47676
*Attorneys for Respondent
Premera Blue Cross*

LANE POWELL PC
1420 Fifth Avenue, Suite 4200
P.O. Box 91302
Seattle, WA 98111-9402
Telephone: 206.223.7000
Facsimile: 206.223.7107

2015 AUG 10 PM 1:02
DIVISION I
COURT OF APPEALS
STATE OF WASHINGTON
CR

TABLE OF CONTENTS

I.	INTRODUCTION	1
II.	COUNTERSTATEMENT OF THE ISSUES	2
III.	COUNTERSTATEMENT OF THE CASE.....	2
A.	Factual Background.....	2
1.	IMRT Is The Standard Of Care For Radiation Therapy To Treat Prostate Cancer; There Is No Clinical Evidence That PBT Is Superior To IMRT.....	2
a.	Prostate Cancer And Radiation Therapy Generally	2
b.	No Clinical Guidelines Recognize PBT As Superior to IMRT For The Treatment of Prostate Cancer	4
c.	There Are No Head-To-Head Randomized Trials Or Studies Showing PBT To Be Superior To IMRT	7
2.	Strauss Chooses PBT Based On The Advice Of Friends, His Own Research And The Proximity Of Loma Linda University Medical Center To His Home In California.....	8

3.	Strauss’s Health Plan Covers Only Medically Necessary Services; Premera’s Medical Policy States That PBT Is Not Medically Necessary Because There Is No Reliable Evidence Showing That PBT Is Superior To IMRT	11
4.	Expert Radiation Oncologists At Two Independent Review Organizations Affirm Premera’s Determination That Strauss’s PBT Was Not Medically Necessary.....	13
B.	Procedural Background.....	17
IV.	ARGUMENT	18
A.	Strauss’s Breach Of Contract Claim Was Properly Dismissed As A Matter Of Law Because Strauss Did Not Satisfy His Burden Of Demonstrating That PBT Was “Medically Necessary”	19
1.	There Is No Clinical Evidence That PBT Is Superior To IMRT In Reducing Side-Effects	21
2.	The Opinion Testimony Of Bush And Laramore Do Not Raise A Genuine Issue Of Material Fact On Whether PBT Is Superior To IMRT.....	28
B.	The Trial Court Properly Dismissed Strauss’s Bad Faith And CPA Claims Because Premera Acted Reasonably And Followed Washington Law In Reviewing His Initial Claim And Appeals	30
1.	Premera’s Good Faith Denial Of Strauss’s Claim Was Based On A Reasonable Interpretation Of The Plan.....	32

2.	Premera’s Good Faith Handling Of Strauss’s Claim And Appeals Strictly Complied With OIC’s Regulations And Was Reasonable At All Levels Of Review.....	33
C.	Strauss Is Not Entitled To Attorney Fees On Appeal.....	36
V.	Conclusion.....	36

TABLE OF AUTHORITIES

Page

Cases

<i>Baxter v. MBA Group Ins. Trust Health and Welfare Plan</i> , 958 F. Supp. 2d 1223 (W.D. Wash 2013)	18, 22, 26, 27, 28
<i>Coventry Assocs. v. Am. States Ins. Co.</i> , 136 Wn.2d 269, 961 P.2d 933 (1998)	33
<i>Hardy v. Pemco Mut. Ins. Co.</i> , 115 Wn. App. 151, 61 P.3d 380 (2003)	36
<i>Hearst Commc'ns, Inc. v. Seattle Times Co.</i> , 154 Wn.2d 493, 115 P.3d 262 (2005)	19
<i>In re Real Estate Brokerage Antitrust Litig.</i> , 95 Wn.2d 297, 622 P.2d 1185 (1980)	35
<i>Kirk v. Mt. Airy Ins. Co.</i> , 134 Wn.2d 558, 951 P.2d 1124 (1998)	31, 33
<i>Leingang v. Pierce County Med. Bur., Inc.</i> , 131 Wn.2d 133, 930 P.2d 288 (1997)	31
<i>Lucas v. Texas Intern. Life Ins. Co.</i> , 2012 WL 6000306 (E.D.Ok. Nov. 30, 2012)	4
<i>Pleasant v. Regence Blue Shield</i> , 181 Wn. App. 252, 325 P.3d 237 (2014)	19, 30
<i>Quadrant Corp. v. Am. States Ins. Co.</i> , 154 Wn.2d 165, 110 P.3d 733 (2005)	19
<i>Smith v. Safeco Ins. Co.</i> , 150 Wn.2d 478, 78 P.3d 1274 (2003)	31

<i>State Farm Mut. Auto. Ins. Co. v. Ruiz</i> , 134 Wn.2d 713, 952 P.2d 157 (1998)	19
<i>Tank v. State Farm Fire & Cas. Co.</i> , 105 Wn.2d 381, 715 P.2d 1133 (1986)	30, 31
<i>Transcon. Ins. Co. v. Wash. Pub. Utils. Dists. Util. Sys.</i> , 111 Wn.2d 452, 760 P.2d 337 (1988)	32
<i>Villella v. Pub. Employees Mut. Ins. Co.</i> , 106 Wn.2d 806, 725 P.2d 957 (1986)	31
<i>Zeneca Inc. v. Eli Lilly & Co.</i> , 1999 WL 509471 (S.D.N.Y. July 19, 1999).....	4

Statutes and Regulations

RCW 48.43.535(6).....	33
RCW 48.44.020	35
RCW 48.44.020(1).....	30
RCW 48.44.040	35
WAC 284-30 <i>et seq.</i>	31
WAC 284-30-320.....	31
WAC 284-43 <i>et. seq.</i>	34
WAC 284-43-160(15).....	34
WAC 284-43-2000.....	34
WAC 284-43-3070.....	35
WAC 284-43-3110(6).....	35
WAC 284-43-5440.....	34

WAC 284-44 <i>et seq.</i>	34
WAC 284-44-010.....	34
<i>Former</i> WAC 284-43-130	34
<i>Former</i> WAC 284-43-130(14).....	34
<i>Former</i> WAC 284-43-535	15
<i>Former</i> WAC 284-43-410	34
<i>Former</i> WAC 284-43-620	34
<i>Former</i> WAC 284-43-620(4).....	35
<i>Former</i> WAC 284-43-860	34
WSR 13-15-025	34

Rules

RAP 2.5(a)	34
RAP 9.12.....	34
CR 56(c).....	19

I. INTRODUCTION

After Appellant John Strauss was diagnosed with prostate cancer, he became convinced after talking to friends and doing research on the internet that he needed something called proton beam therapy (“PBT”), a form of radiation treatment, from a facility in California. While his doctors agreed that radiation was an appropriate form of treatment, none prescribed PBT. At the time, no national association of cancer specialists recommended PBT to treat prostate cancer, and PBT was not recognized as superior to other forms of radiation therapy. Rather, the national association guidelines and the radiation oncologist community uniformly considered intensity-modulated radiation technique, or “IMRT,” to be the generally accepted standard of care for radiation therapy to treat prostate cancer. The same is still true today.

Strauss’s health plan with Respondent Premera Blue Cross covers “medically necessary” services, including IMRT. Premera does not consider PBT to be medically necessary to treat prostate cancer, however, because—while PBT is more expensive than IMRT—there is no evidence that it leads to better results in terms of efficacy or reduced side effects. After Premera denied Strauss’s claim, he appealed and expert radiation oncologists at two external and independent review organizations both agreed with Premera that PBT is not medically necessary. In a separate action, a federal court came to the same conclusion on identical facts. The trial court properly recognized

that there are no genuine issues of fact on either Strauss's breach of contract claim or his secondary bad faith and CPA claims. This Court should affirm.

II. COUNTERSTATEMENT OF THE ISSUES

1. Did the trial court properly conclude as a matter of law that PBT is not "medically necessary" as defined by Strauss's Plan because it is undisputed that there is no clinical evidence that PBT is superior to IMRT as a treatment for prostate cancer? **Yes.**

2. Did the trial court properly conclude as a matter of law that Premera did not violate its duty of good faith, the CPA or any Washington statute or regulation in handling Strauss's claim and appeals? **Yes.**

III. COUNTERSTATEMENT OF THE CASE

A. Factual Background

1. IMRT Is The Standard Of Care For Radiation Therapy To Treat Prostate Cancer; There Is No Clinical Evidence That PBT Is Superior To IMRT.

a. Prostate Cancer And Radiation Therapy Generally.

Prostate cancer is the most common form of cancer in men, and is typically treated by surgery or radiation therapy. CP 416 (Beer Report); CP 451. Radiation therapy uses high-energy radiation to shrink tumors and kill cancer cells. Standard radiation therapy uses x-rays, and is most often administered using the intensity-modulated radiation technique (IMRT) or 3D-conformal technique. CP 417 (Beer Report). The standard for radiation

therapy for prostate cancer has evolved over the years, from older poorly aimed 4-field radiation, to 3D conformal, then to IMRT, and now to image-guided IMRT radiation therapy. *Id.*; CP 663 (Russell Depo at 30).

These technological advances enable greater focus of radiation on the target area, allowing a safe administration of higher doses (increasing efficacy) and, at the same time, reducing exposure to surrounding tissues (decreasing toxicity). CP 417-18 (Beer Report). IMRT achieves this by splitting the radiation dose into a large number of beams all of which “cross” on the target, but are beamed from different angles around the body. This approach limits dose delivery to any area outside of the prostate. Image guidance further improves the reliability of IMRT. *Id.*

Proton beam therapy (PBT) relies on the delivery of a different type of radiation, protons instead of x-rays, the energy level of which can be adjusted so that they penetrate to the target but then lose most of their energy there. CP 419 (Beer Report). PBT is complicated in its delivery and requires precise patient positioning, patient-specific range-shifting filters, scattering foils and tissue-compensating filters. *Id.* Because PBT is susceptible to day-to-day variations in patient position and beam angle, it may result in less precise delivery. *Id.* Advocates of PBT, however, suggest that it is superior to standard x-ray radiation therapy because it results in less exposure to surrounding tissues and, thus, theoretically at least, fewer side effects. *Id.*

b. No Clinical Guidelines Recognize PBT As Superior To IMRT For The Treatment Of Prostate Cancer.

Widely-accepted guidelines for prostate cancer treatment uniformly agree that IMRT, not PBT, is the standard of care for the treatment of prostate cancer through radiation therapy. CP 416 (Beer Report). The National Comprehensive Cancer Network (NCCN) is an alliance of the leading cancer centers and the authoritative source of evidence-based guidelines for the treatment of cancer, including the field of radiation oncology. CP 416-18, 420. Its “guidelines are developed based on testing, and evidence through panels of expert physicians in the field of cancer treatments and reflect a consensus reached by these physicians on current approaches and standards for the treatment of cancer. These guidelines are the standard of care for the treatment of cancer.” *Lucas v. Texas Intern. Life Ins. Co.*, 2012 WL 6000306, *2 (E.D.Ok. Nov. 30, 2012); also *Zeneca Inc. v. Eli Lilly & Co.*, 1999 WL 509471, *23 (S.D.N.Y. July 19, 1999) (NCCN is “an expert body in the field of clinical oncology” and its guidelines “are authoritative in the field”).¹

NCCN publishes Clinical Practice Guidelines in Oncology for Prostate Cancer (NCCN Guidelines), CP 315-412, and those guidelines—which are used by oncologists in their practice—compare various forms of

¹ See generally, <https://www.nccn.org/about/default.aspx>.

radiation therapy, including IMRT and PBT. CP 367-68. The current NCCN Guidelines conclude, based on peer-reviewed studies and trials, as follows:

The NCCN panel believes there is no clear evidence supporting a benefit or decrement to proton therapy over IMRT for either treatment efficacy or long-term toxicity.

CP 368. NCCN's guidelines for patients similarly explains, "[t]o date, research hasn't shown that proton treatment is any better or worse for treating cancer or causing side effects." CP 482. Indeed, when Strauss considered options for radiation therapy to treat his prostate cancer, and later appealed Premera's coverage decision, the NCCN Guidelines did not even mention PBT. CP 554-99 (2009 guidelines); CP 601-24 (2010 guidelines).²

NCCN is not alone. Other medical organizations also recognize that IMRT is the standard of care because there is insufficient evidence regarding PBT's efficacy or effects. For example, the American Society for Radiation Oncology (ASTRO), publishes a model policy on PBT. CP 626-44.³ As it relates to the treatment for prostate cancer, ASTRO concludes:

There is no clear evidence that proton beam therapy for prostate cancer offers any clinical advantage over other forms

² Strauss's urologist similarly testified that NCCN is the "governing body of cancer treatment protocols" and its guidelines the "go-to resource for most practicing cancer physicians." CP 446-47 (Lin Depo at 29-30).

³ "ASTRO is the premier radiation oncology society in the world, with more than 10,500 members who are physicians, nurses, biologist, physicists, radiation therapists, dosimetrists and other health care professionals who specialize in treating patients with radiation therapies." See <https://www.astro.org/About-ASTRO.aspx>.

of definitive radiation therapy. Clinical trials are necessary to establish a possible advantage of this expensive therapy.

CP 642. ASTRO explains that there can be no “informed consensus” on how PBT “compares to other radiation therapy modalities such as IMRT” until there are “well-designed registries and studies with sizable comparator cohorts to help accelerate data collection.” CP 630. Thus, ASTRO recommends PBT serve as a primary treatment for prostate cancer “only . . . within the context of a prospective clinical trial or registry.” *Id.*

The Agency for Healthcare Research and Quality (AHRQ), an agency of the U.S. Department of Health and Human Services, likewise publishes guidelines on PBT for cancer treatment. CP 646-50. The guidelines—which are a “synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature”—state:

Members of the working group do not currently recommend that patients with prostate cancer . . . be referred for proton beam radiotherapy, due to an insufficient evidence base.

CP 648. In sum, as Strauss’s own radiation oncologists conceded, all nationally recognized medical guidelines for prostate cancer treatment identify IMRT—not PBT—as the standard of care, and no guidelines conclude that PBT is superior to IMRT. CP 439-40 (Bush Depo at 185-87); CP 940 (Bush Depo at 203-04); CP 663 (Russell Depo at 30).

c. There Are No Head-To-Head Randomized Trials Or Studies Showing PBT To Be Superior To IMRT.

As these national guidelines recognize, IMRT is generally accepted by radiation oncologists as the standard of care because there is not yet any clinical evidence demonstrating that PBT is superior to IMRT in terms of efficacy or reduced side-effects. Although PBT pre-dates IMRT by decades, there has not been a single randomized trial—which is the only definitive means for comparing different treatment types—involving PBT and IMRT. CP 419-21 (Beer Report); CP 686 (Stewart Depo at 110, 113); CP 653, 680, 902 (Bush Depo at 29, 55, 61); CP 657, 660 (Laramore Depo at 62-63, 65, 174); CP 691 (“there has not been any direct randomized trial comparing the different options”). In other words, PBT “has never been compared head to head to conventional radiation therapy.” CP 420 (Beer Report).

As a result, and as discussed more below, those claiming that PBT leads to fewer side-effects than IMRT (often, doctors working at hospitals that sell PBT) rely exclusively on predictions and assumptions derived from mathematical models, dosimetric studies (studies that compare treatment plans) and retrospective cross-study comparisons (comparing the results of separate studies). CP 419, 424 (Beer Report); CP 683, 901-03 (Bush Depo at 51-52, 54, 55, 58, 59-60, 68-69); CP 657, 778-79, 787 (Laramore Depo at 57-58, 62-64, 93); CP 691 (Laramore Report). And, ironically, many of these

limited studies actually suggest that PBT will have the same or worse side-effect profile as IMRT and other forms of radiation therapy. CP 421, 428-31 (Beer Report). In short, “[c]laims of clinical superiority are basically claims based on hope, and not evidence.” CP 422 (Beer Report).

2. Strauss Chooses PBT Based On The Advice Of Friends, His Own Research And The Proximity Of Loma Linda University Medical Center To His Home In California.

Strauss was diagnosed with intermediate risk prostate cancer in October 2008. CP 69. Upon diagnosis, Strauss’s urologist, Dr. Lin, went over treatment options, which included “radiation and surgical management of the disease.” *Id.* Strauss told Dr. Lin that he was particularly interested in radiation due to the positive experience of some of his “golf buddies” and other friends, and that he had heard about PBT treatment at the Loma Linda University Medical Center (Loma Linda) in Southern California. *Id.*; CP 94 (Strauss Depo at 28); CP 110 (Lin Depo at 44). Dr. Lin, however, did not recommend PBT over any other radiation treatment option. CP 84, 110 (Lin Depo at 44, 64); CP 94 (Strauss Depo at 27).

Dr. Lin referred Strauss to Dr. Russell, a radiation oncologist, to go over radiation treatment options later that month. CP 72; CP 88 (Russell Depo at 31); CP 94 (Strauss Depo at 28). Strauss conceded that even before he saw Dr. Russell, he was “leaning pretty heavily toward” PBT based on the advice of his friends, his own internet research, and the fact that his winter

home was only 45 minutes away from Loma Linda. CP 94 (Strauss Depo at 28-29); CP 1020. Like Dr. Lin, Dr. Russell did not recommend PBT to Strauss. CP 88 (Russell Depo at 32-33). On the contrary, Dr. Russell told Strauss of the “lack of clear, long-term evidence showing improved side effect profile for patients who undergo proton therapy versus [IMRT] therapy.” CP 1020. Still, Strauss told Dr. Russell he was “most interested in seeking proton therapy since [Loma Linda] is near his family.” *Id.*

Strauss did not have surgery or begin radiation therapy any time soon. Indeed, more than six months after his diagnosis, in May 2009, Dr. Lin called Strauss to follow up on his choice of treatment. CP 96. Strauss told Dr. Lin that he was still “leaning toward” radiation, and reported that “he would like to have [PBT] since he lives close to Loma Linda during a portion of the year.” *Id.*; CP 100 (Lin Depo at 79). Notwithstanding Dr. Lin’s encouragement to Strauss “strongly again to seek out primary therapy,” Strauss indicated “he would probably want to wait until after the summer to proceed with some form of radiation, particularly if it is [PBT].” CP 96.

Strauss did wait. CP 118-19. In July, 2009, three months after seeing Dr. Russell, and nine months after his diagnosis, Strauss and his wife visited Dr. Lin. *Id.*; CP 100 (Lin Depo at 79-81). During the visit, Dr. Lin “encouraged [Strauss] that he should think about some aggressive primary curative treatment,” either surgery or radiation. *Id.* Strauss told Dr. Lin that

he wanted to “proceed with [PBT] at Loma Linda which is near his winter residence in Palm Desert, California. He has several friends and colleagues who have undergone [PBT] at Loma Linda and his is encouraged by the results.” CP 118. Dr. Lin recommended that Strauss begin treatment in the “immediate term,” but Strauss “was adamant about starting in the fall.” *Id.*⁴

Strauss saw Dr. Lin again in October 2009, three months later. CP 121-22. Strauss still had not begun treatment. This time, Strauss “was very adamant about proceeding with radiation therapy in the winter and preferably after the beginning of the new year.” *Id.* Dr. Lin stressed the need to receive some form of treatment soon, but Strauss “desired to merely schedule his Loma Linda proton beam therapy in January.” *Id.* Two months later, when Strauss saw his cardiologist, Dr. Stewart, he similarly told Dr. Stewart that he wanted PBT due to “his own research.” CP 76-78; CP 91 (Stewart Depo at 102). Like Dr. Lin and Dr. Russell, Dr. Stewart did not recommend PBT either. CP 91 (Stewart Depo at 103-04).

Strauss finally scheduled an evaluation at Loma Linda in January 2010 and began PBT treatment there a month later—more than a year and four months after diagnosis. CP 115, 127-31. Dr. Bush, who treated Strauss

⁴ Strauss’s failure to follow the medical advice of his doctors was nothing new. Strauss suffers from a heart condition, and the record is full of examples where—because he thought he knew better or otherwise—Strauss ignored his prescribed medical treatment. CP 53-56 (¶ 25); CP 145-67.

at Loma Linda, noted that Strauss had met with oncologists in Washington “who both offered definitive treatment options, but [Strauss] stated he wanted time to explore his options and wanted to learn more about proton radiation therapy.” CP 127. Strauss received PBT at Loma Linda for approximately two months, ending in April 2010. CP 133. According to Strauss and his doctors, the treatment was successful. CP 137 (Jenson Depo at 104); CP 140 (Lin Depo at 92); CP 143 (Strauss Depo at 107).

3. Strauss’s Health Plan Covers Only Medically Necessary Services; Premera’s Medical Policy States That PBT Is Not Medically Necessary Because There Is No Reliable Evidence Showing That PBT Is Superior To IMRT.

At the time of his prostate cancer and diagnosis, Strauss was insured under Premera’s Heritage Preferred Plus 20 Plan (hereinafter, the Plan). CP 4 (¶ 3.1); CP 169-206. The Plan covers radiation therapy services, CP 186, but only if such services are, in Premera’s judgment, “medically necessary.” CP 177. The Plan defines “medically necessary” as follows:

Those covered services . . . that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- In accordance with generally accepted standards of medical practice;
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient’s illness, injury or disease; and

- Not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service . . . at least likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient’s illness, injury or disease.

For these purposes, “generally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the view of physicians practicing in the relevant clinical areas and any other relevant factors.

CP 212. Premera publishes a Corporate Medical Policy concerning PBT, which is used to evaluate medical necessity based on peer-reviewed medical literature, national guidelines and local standards. CP 216-22. The Medical Policy—consistent with NCCN’s and ASTRO’s guidelines for radiotherapy treatment of prostate cancer—states that PBT is not medically necessary “because the outcomes have not shown to be superior to other approaches including intensity modulated radiation therapy (IMRT) . . . yet proton beam therapy is generally more costly than these alternatives.” CP 217.

The Medical Policy cites to more than a dozen sources, and notes the conclusion of one author that “[i]n terms of [PBT] leading to reduced side-effects, . . . that work is just beginning. The author comments that we do not know if there would be gains by treating with [PBT] to the doses currently used in IMRT therapy . . . and this is a topic where studies are needed.” CP

220. The policy was updated twice during the relevant period. A January 2010 update stated that “a systematic review of published peer-reviewed literature reported previously and updated here is devoid of any clinical data demonstrating benefit in terms of survival, tumor control, or toxicity in comparison with best conventional treatment for . . . prostate cancer.” CP 224-30. An April 2010 update cites the lack of “randomized trials of charged particle radiation therapy for cancer.” CP 232-39.

4. Expert Radiation Oncologists At Two Independent Review Organizations Affirm Premera’s Determination That Strauss’s PBT Was Not Medically Necessary.

Strauss finally sought treatment in late 2009, and asked Loma Linda to obtain pre-authorization from Premera for PBT therapy in November 2009—over a year after his diagnosis. CP 241. Premera responded just six days later. CP 243. Relying on Premera’s Medical Policy, one of Premera’s assistant medical directors, Dr. Kaneshiro, denied the request for pre-authorization as not “medically necessary” because PBT has “not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT) . . . yet [PBT] is generally more costly than these alternatives.” *Id.*; CP 1366 (Kaneshiro Depo at 35). The letter informed Strauss that if he did “not agree with our decision, you or someone you choose may file an appeal.” CP 243. The letter enclosed a copy of the appeal

process, and informed him that he “may want to provide more information or materials that might help the panel reach a decision.” CP 244-45.

The appeals process for Strauss’s health plan was regulated by Washington law and provided two levels of internal appeals and an external review by an Independent Review Organization (IRO). Strauss filed a Level I Appeal on December 30, 2009. CP 247-52. In addition to threats of a lawsuit and eagerness to depose Premera’s staff, *id.*, Strauss included a half-page letter from Dr. Stewart, his cardiologist, in which Dr. Stewart asked that Strauss be approved for PBT. CP 253. In the letter, Dr. Stewart admits that “[c]omparative studies are not yet available,” but that “there is strong preliminary evidence that the side effects associated with [PBT] are significantly lower.” *Id.* Dr. Stewart was hesitant to write the letter because he knew there was no evidence that PBT was superior to IMRT. CP 260 (Stewart Depo at 111-13). Dr. Stewart admitted he wrote the letter for Strauss based on the “hope” that PBT had fewer side effects. *Id.*

Premera referred Strauss’s Level I Appeal to Medical Review Institute of America (MRIoA), an external review organization, for a “Same Specialty Review.” CP 272-73.⁵ On January 8, 2010, MRIoA’s radiation

⁵ Under Washington law, a plan member is entitled to an internal review of an adverse benefit decision by “health care providers or staff who were not involved in the initial decision,” “who are not subordinates of the persons involved in the initial decision,” and if the decision involves medical

oncologist upheld Premera's initial coverage decision. In finding that PBT was not "medically necessary," the reviewer concluded:

Although there has been increased interest in the use of protons for definitive treatment of prostate cancer recently, there is no evidence in the recent peer-reviewed literature of improved efficacy or reduced toxicity with the use of protons compared to photons. As protons are significantly more expensive, the treatment is defined as not medically necessary in this particular case according to the plan language.

CP 274. The radiation oncologist also found that "most experts recommend further study of safety and efficacy of proton treatment for prostate cancer at this time." CP 273.⁶ Based on MRIoA's independent review, Premera denied Strauss's Level I Appeal on February 1, 2010. CP 277-78.

judgment, "the reviewer must be or must consult with a health care professional who has appropriate training and experience in the field of medicine encompassing the appellant's condition or disease." WAC 284-43-3110 (formerly WAC 284-43-535). Although the Plan permitted Premera to conduct an internal review of Strauss's Level I Appeal, CP 200, Premera referred it to an external review organization for a Same Specialty Review to ensure that it was reviewed by a radiation oncologist.

⁶ The reviewer's identity is confidential in order to insure objectivity, but his credentials were impressive. "The reviewer is a member of the American Society for Therapeutic Radiation and Oncology, the American College of Radiation Oncology, the American College of Radiology and their state medical association. The reviewer has served as a clinical lecturer, assistant professor of radiology, and staff radiologist. The reviewer has served as the representative for radiation oncology for his state Carrier Advisory Committee. The reviewer does stereotactic radiosurgery at an institution that treats over 200 patients a year. The reviewer holds privileges at three hospitals and has been in active practice since 2002." CP 274.

Strauss filed a Level II Appeal on March 2, 2010, CP 280-81, again accompanied by a volley of threats. CP 299-300 (“Premera . . . is going to learn a very expensive lesson”) (emphasis in original). During the course of the Level II Appeal, Premera learned that MRIOA had inadvertently used an outdated definition of “medically necessary” during the Level I Appeal. CP 288. After Premera re-submitted the Plan language to MRIOA, its radiation oncologist again reached the same conclusion, adding “there is considerable controversy in the radiation oncology community as to whether [PBT] should be considered a medically necessary treatment option for patients with localized prostate cancer, and it is therefore not in accordance with generally accepted standards of medical practice at this time.” CP 292-95. Premera’s 3-person appeal panel then denied the Level II Appeal, and informed Strauss that if he thought Premera was wrong he could request review by an IRO “for a coverage decision that will be binding on us.” CP 288-90.

Strauss requested external review of the Level II Appeal decision by an IRO (along with more litigation threats). CP 297. As required by Washington law, Premera requested a random IRO selection from the Office of the Insurance Commissioner (OIC), which assigned Managing Care Managing Claims (MCMC). CP 302-06. On August 3, 2010, MCMC’s

reviewer, also a radiation oncologist, upheld Premera's denial. CP 308-13.⁷

MCMC's reviewer found, among other things:

[T]he Proton therapy is not medically necessary in this case.

There are other standard treatment options available to the patient [for] which he is a good candidate. These standard treatment options include radical prostatectomy either open or robotic (this was offered by patient's urologist), external beam radiotherapy either IMRT or 3D conformal therapy and brachytherapy either LDR or HDR. There is an abundance of medical data and experience to support these treatment options with known efficacy, toxicity, and quality of life. In contrast, clinical evidence to support proton therapy for prostate cancer is limited in terms of efficacy, toxicity and effects on quality of life.

CP 312. The reviewer noted that the NCCN-recommended treatments for prostate cancer "include 3D conformal therapy, IMRT and brachytherapy. There is no consensus or mentioning of Proton therapy." CP 312.

B. Procedural Background

MCMC's independent review was Strauss's last internal appeal under the Plan. Strauss sued Premera nearly three years later, asserting claims for

⁷ Like MRIOA's reviewer, the identity of MCMC's reviewer is confidential, but no less impressive: "I am board certified in Radiation Oncology. My areas of expertise include breast cancer, prostate cancer, lung cancer, prostate seed implant, gamma knife stereotactic radiosurgery, linac based stereotactic radiosurgery, radiation therapy, and high dose brachytherapy. I am published in the peer reviewed medical literature and member of the American Society for Therapeutic Radiology and Oncology, American Society of Clinical Oncology, American College of Radiology, and the American College of Radiation Oncology." CP 310.

breach of contract, bad faith and violation of the CPA. CP 3-9. Approximately one week before Strauss filed suit, the federal district court for the Western District of Washington (Zilly, J.) issued a published opinion in *Baxter v. MBA Group Ins. Trust Health and Welfare Plan*, 958 F. Supp. 2d 1223 (W.D. Wash 2013), in which the court held—on summary judgment and notwithstanding expert opinion to the contrary—that PBT was not “medically necessary” for the treatment of prostate cancer under an identical plan definition. *Id.* at 1237.

Premera moved for summary judgment. CP 18-43. Like the defendant in *Baxter*, Premera argued that PBT was not “medically necessary” under the terms of the Plan because it is not generally accepted in the radiation oncologist community that PBT results in fewer side effects than IMRT. *Id.* At argument, Strauss’s counsel agreed that the “case comes down to side effect differences.” VRP at 14. “We lose if there’s not less. It’s just that simple.” *Id.* at 17. The trial court agreed. On December 18, 2015, the trial court granted Premera’s motion, and dismissed all of Strauss’s claims as a matter of law. CP 1467-68. Strauss timely appealed. CP 1469.

IV. ARGUMENT

The trial court properly granted Premera’s motion for summary judgment. This Court reviews summary judgment *de novo*, engaging in the same inquiry as the trial court and viewing the facts and all reasonable

inferences in the light most favorable to the nonmoving party. *Hearst Commc'ns, Inc. v. Seattle Times Co.*, 154 Wn.2d 493, 501, 115 P.3d 262 (2005). Summary judgment is proper if, as here, the pleadings, depositions, answers to interrogatories, admissions, and affidavits show that there is no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. CR 56(c); *Hearst*, 154 Wn.2d at 501.

A. Strauss's Breach Of Contract Claim Was Properly Dismissed As A Matter Of Law Because Strauss Did Not Satisfy His Burden Of Demonstrating That PBT Was "Medically Necessary."

The trial court properly granted Premera summary judgment on Strauss's breach of contract claim because PBT is not "medically necessary." Interpretation of a health plan is a question of law that this Court reviews *de novo*. *Pleasant v. Regence Blue Shield*, 181 Wn. App. 252, 261, 325 P.3d 237 (2014). Because a health plan is a contract, principles of contract interpretation apply. *Id.* (citing *Quadrant Corp. v. Am. States Ins. Co.*, 154 Wn.2d 165, 171, 110 P.3d 733 (2005)). If a plan is unambiguous, a court must enforce it as written and may not modify the contract or create ambiguity where none exists. *Id.* (citing *State Farm Mut. Auto. Ins. Co. v. Ruiz*, 134 Wn.2d 713, 721, 952 P.2d 157 (1998)). The plan member bears the burden of showing that coverage exists and, only if it does, does the plan provider bear the burden of establishing an exclusion. *Id.* (citation omitted).

The only issue here is one of coverage, not exclusion. Strauss's Plan states that, "[b]enefits are available for a service . . . when it meets all of these requirements: . . . It must be, in our judgment, medically necessary." CP 177. "Medically necessary," in turn, is defined as those "covered services . . . that a physician, exercising prudent clinical judgment, would provide to a patient" for the treatment of a disease, and that are:

- In accordance with generally accepted standards of medical practice;
- Clinically appropriate, in terms of type, frequency, extent, site and duration, and considered effective for the patient's illness, injury or disease; and
- Not primarily for the convenience of the patient, physician, or other health care provider, and not more costly than an alternative service . . . at least likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "generally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the view of physicians practicing in the relevant clinical areas and any other relevant factors.

CP 212. The parties did not dispute that PBT and IMRT offer equivalent results in controlling prostate cancer, and that PBT is more expensive than IMRT. Thus, PBT is "medically necessary" only if Strauss can carry his burden of proving that PBT leads to fewer side-effects. Op. Br. at 19; *see*

also CP 19; CP 748.⁸ He can't. For the reasons explained below, Strauss fails to raise a genuine issue of material fact that PBT is superior to IMRT.

1. There Is No Clinical Evidence That PBT Is Superior To IMRT In Reducing Side-Effects.

The trial court did not use the “wrong criteria” to interpret the Plan. Op. Br. at 22. It correctly concluded that Strauss did not carry his burden of demonstrating coverage because PBT is not “medically necessary” under the Plan’s plain meaning. There is no evidence that PBT results in fewer side-effects than IMRT. It is undisputed that the alleged superiority of PBT is theoretical and has not been proven in head-to-head trials, has not been recognized by any national medical association, and is not generally accepted as superior in the radiation oncology community. If that were not enough, and it is, both Premera’s and the trial court’s determination that PBT was not “medically necessary” within the meaning of the Plan was confirmed by two

⁸ In denying coverage, Premera relied on the definition’s third-prong—*i.e.*, whether PBT was “not more costly than an alternative service . . . at least likely to produce equivalent therapeutic or diagnostic results”—not the definition’s first prong, *see* CP 1477-78 & n. 4—and, thus, Strauss’s sojourn into why PBT is a “generally accepted standard of medical practice” is besides the point. *See* Op. Br. at 22-23. In any event, even if PBT is generally accepted as an effective means of treating prostate cancer, for all the reasons set forth herein, it is not generally accepted that it leads to fewer side effects: there is no “credible scientific evidence” of that fact; no “physician specialty society” recommends PBT; and “physicians practicing in the relevant clinical area” consider IMRT the standard of care.

independent and external medical experts and was entirely consistent with the district court's thorough decision in *Baxter* on indistinguishable facts.

First, it is undisputed that there are no head-to-head "randomized" clinical trials comparing PBT to IMRT, in which the side-effects of the two treatments were measured by the same researchers using the same scoring methodology among a single cohort of patients. CP 420 (Beer Report); CP 691 (Laramore Report); CP 657, 787 (Laramore Depo at 62, 93); CP 653, 680 (Bush Depo at 29, 61). Strauss's experts agree; randomized trials are the "gold standard" for an evidence-based comparison of different treatment methods. CP 660 (Laramore Depo at 174). As Dr. Bush, who treated Strauss at Loma Linda, put it: "in today's world, [it] is what most people point to as being kind of definitive data for scientific folks." CP 902 (Bush Depo at 55).

It is widely accepted in the medical community that a randomized trial is the only conclusive way to compare treatment methods because such a trial eliminates the variables and "sampling bias" that render modeling and cross-study comparisons (articles comparing the results of separate studies) unreliable—*i.e.*, different patient pools, testing methods, grading scales, frequency and completeness in patient follow up. CP 424 (Beer Report); CP 901-03 (Bush at 54, 55, 58). Again, Strauss's experts agree: absent a randomized trial, "you're grabbing two groups of patients who, of course, you try to make as similar as you can, but there may be differences between

the groups that you can't control." CP 901 (Bush Depo at 52); CP 657 (Laramore Depo at 63: "And so there may be a mismatch in the patient cohorts under the study. This is the purpose of doing a randomized trial.").

Because there are no randomized trials comparing PBT to IMRT, there is no clinical evidence that PBT is superior. Rather, all researchers have done and all they can do is predict that PBT may cause fewer side-effects based on models, dosimetric studies (studies that compare treatment plans) and cross-study comparisons. CP 419 (Beer Report). Indeed, every single study cited by Strauss's experts (many of which do not involve IMRT at all) suffer from this defect.⁹ Strauss's expert, Dr. Laramore, was candid on this point. He admitted that PBT's alleged superiority over IMRT is "theoretical," and based on "assumptions" and "inferences" drawn from the literature. *Id.*; CP 657, 778-79, 787 (Laramore Depo at 57-58, 62-64, 93); *see also* CP 691

⁹ *See, e.g.*, CP 901-03, 909, 920, 922-23, 925 (Bush Depo at 51-52, 59-60, 63, 82-83, 128, 134, 137-39, 147); CP 779, 782, 791-92, 794, 797, 800, 805-06 (Laramore Depo at 58, 74, 109-110, 120, 132-33, 143-44, 165, 167); *see also* CP 716-22 (Grimm Report). Strauss repeatedly implies that at least one of the studies cited by Dr. Bush was a "prospective, randomized" trial comparing PBT and IMRT. *See Op. Br.* at 11 & n. 4, 20. Even a cursory glance at Dr. Bush's letter, however, reveals that he compared two, separate studies—one using PBT and another using IMRT. CP 1126. When asked if the PBT study "confirms that proton beam would be superior to IMRT," Dr. Bush replied: "Well, that wasn't what was tested, right, so it doesn't speak to that. . . . No." CP 924 (Bush Depo at 142).

(Laramore Report: “there have not been direct randomized trials . . . but rather one must review the literature to infer the advantages and disadvantages”).

More than that, even these non-controlled studies offer highly mixed conclusions on the theoretical benefit of PBT—another point that Strauss’s own experts concede. CP 683 (Bush Depo at 68: “[t]here’s data, I think, to support both sides.”). Indeed, a significant number of dosimetric and comparative studies suggest that IMRT results in the same or fewer side-effects than PBT. For example, as NCCN noted:

The largest retrospective comparative effective analysis to date comparing IMRT to proton therapy has been performed using SEER-Medicare claims data With follow-up as mature as 80 months and using both propensity scoring and instrumental variable analysis, the authors concluded that men receiving IMRT therapy had statistically lower gastrointestinal morbidity than patients receiving proton therapy, whereas rates of urinary incontinence, non-incontinence urinary morbidity, sexual dysfunction, hip fractures, and additional cancer therapies were statistically indistinguishable between the cohorts.

CP 368. Many other studies have reached the same conclusion. CP 421, 428-31 (Beer Report); *also* CP 1300 (“there was no advantage of protons over photons.”). In sum, Strauss cannot show that PBT is superior to IMRT as a matter of law when there is no direct clinical evidence establishing that fact, and even the predictive and comparative literature disputes it.

Second, and because there is no evidence showing that PBT is superior, the medical community considers IMRT the standard of care for

radiation therapy to treat prostate cancer—and, indeed, no recognized national association of radiologists or oncologists recommends PBT. CP 416 (Beer Report); CP 827 (Laramore Depo at 248-49); CP 439-40, 940 (Bush Depo at 185-86, 202-05); CP 663 (Russell Depo at 30). On the contrary, NCCN's and ASTRO's guidelines, which reflect the generally accepted consensus among experts in this field, uniformly state that there is “no clear evidence” that PBT offers any clinical advantage over IMRT. CP 368, 482 (NCCN Guidelines); CP 642 (ASTRO). Strauss's expert, Dr. Laramore, agreed with that statement. CP 827 (Laramore Depo at 247-48).

It is not surprising, therefore, that Strauss's Washington doctors did not recommend PBT (and only Dr. Bush at Loma Linda did). CP 84, 110 (Lin Depo at 44, 64); CP 88 (Russell Depo at 32-33); CP 91 (Stewart Depo at 103-04); CP 81 (Jensen Depo at 88-89).¹⁰ In fact, Dr. Russell told Strauss about the “lack of clear, long-term evidence showing improved side effect profile for patients who undergo proton therapy versus [IMRT] therapy.” CP 1020. Strauss wrongly claims the trial court upheld Premera's decision on the grounds that Strauss's doctors did not recommend PBT, Op. Br. at 21-22,

¹⁰ Strauss argues that Dr. Lin, Strauss's urologist, told Strauss that either IMRT or PBT would be an appropriate treatment. See Op. Br. at 24. Dr. Lin said no such thing; he discussed the comparative benefits of radiotherapy generally versus surgery. CP 84 (Lin Depo at 63-65). Indeed, it was Strauss who raised the topic of PBT with Dr. Lin. *Id.*; CP 69.

24, but this fact is not referenced in any of Premera's (or the IRO reviewers') determinations, *see* CP 243-45, 272-75, 277-78, 288-90, 292-95, 308-13, or the trial court's summary judgment order. CP 1467-68. In any event, that none of Strauss's financially disinterested providers viewed PBT as superior to IMRT only confirms Premera's interpretation of the Plan's plain meaning.

The same, of course, is even more true with respect to the two IRO determinations Strauss received. Strauss's claim that PBT was "medically necessary" under the Plan was separately reviewed by experienced and expert radiation oncologists at MRIoA and MCMC, *see* CP 272-75, 292-95, 308-15, and both agreed there was no evidence that PBT was superior to IMRT in reducing side-effects. MRIoA's radiation oncologist found:

Although there has been increased interest in the use of protons for the definitive treatment of prostate cancer recently, there is no evidence in the recent peer-reviewed medical literature of improved efficacy or reduced toxicity with the use of protons compared to photons.

CP 294; *see also* CP 312 ("clinical evidence to support proton therapy for prostate cancer is limited in terms of efficacy, toxicity and effects on quality of life"). Here, too, the IROs' decisions mirrored Premera's and, while not binding on the Court, likewise demonstrate the absence of a disputed issue of material fact on PBT's alleged superiority over IMRT.

Third, and finally, the trial court was not working on clean slate. In *Baxter*, the federal district court considered the same issue raised here:

whether PBT was a “medically necessary” treatment for prostate cancer under the terms of a health care plan. And, not just that, but under an identical definition of “medically necessary.” *Compare* 958 F. Supp. 2d at 1228-29, 1233 to CP 212. Like Strauss, the plaintiff in *Baxter* concluded that receiving PBT at Loma Linda was “the best option” for him, and like here, his claim, internal appeals and IRO were denied on the basis of the plan’s “medically necessary” term—specifically because the “clinical outcomes with this treatment have not been shown to be superior to other approaches including intensity modulated radiation therapy (IMRT).” *Id.* at 1225-26. Notably, the plaintiff submitted letters from his treating physician at Loma Linda and Dr. Laramore—the same expert who testified for Strauss in this case—extolling the supposed superiority of PBT to IMRT. *Id.* at 1226.

On review, the district court concluded as a matter of law that PBT was not “medically necessary” under the plan because the plaintiff did not meet “his burden to show that there is a genuine issue of material fact whether proton therapy is superior to IMRT.” *Id.* at 1237. In reaching its conclusion, the court held that the issue of superiority “must be answered based on clinical outcomes of patient treatment”—specifically, randomized clinical trials—because, among other reasons, the “inconsistencies in the current observational studies [cross-study comparisons] comparing proton therapy with other modalities of treatment for prostate cancer are consistent with

NCCN’s conclusion that . . . clinical trials have not yet yielded data that demonstrates superiority to, or equivalence of, proton beam and conventional external beam for treatment of prostate cancer.” *Id.* at 1234, 37-38.

Baxter is on-point. Strauss’s argument that this Court can ignore *Baxter* “because it involved an employee benefit plan covered by ERISA,” Op. Br. at 27, is baseless. The court’s analysis had nothing to do with ERISA, nor did it apply any unique principles of federal contract interpretation. There, like here, the plaintiff had the burden of proving coverage. *Baxter*, 958 F. Supp. 2d at 1230. Because the plan afforded the administrator no discretion, there, like here, the Court reviewed the plan’s denial of coverage “*de novo*.” *Id.* at 1227. There, like here, the court decided the issue under an identical summary judgment standard. *Id.* There, like here, the only issue was whether PBT satisfied the plan’s identical definition of “medically necessary.” *Id.* at 1228. *Baxter* is not binding, but its reasoning fully supports Premera’s denial and the trial court’s interpretation of the Plan.

2. The Opinion Testimony Of Bush And Laramore Do Not Raise A Genuine Issue Of Material Fact On Whether PBT Is Superior To IMRT.

Strauss’s argument that PBT is “medically necessary” under the Plan is premised almost entirely on the opinion of two doctors, his doctor at Loma Linda (Dr. Bush) and his paid expert (Dr. Laramore). Op. Br. at 19-21, 23-27. Strauss argues that because testimony regarding a “novel scientific theory

or principle” may be admissible under the *Frye* test if it “has achieved general acceptance in the relevant scientific community,” then such testimony necessarily raises an issue of fact on the question of “medically necessary.” *Id.* at 25. But the issue here is not the admissibility of expert testimony; it is one of contract interpretation—and, of course, the proper interpretation of a contract is a question of law for the Court, not expert opinion. *Kelly v. Aetna Cas. & Sur. Co.*, 100 Wn.2d 401, 407, 670 P.2d 267 (1983).

And, to the extent Dr. Bush and Dr. Laramore purported to opine on the factual basis of the Plan’s “medically necessary” definition—*i.e.*, whether PBT is superior to IMRT—the *Frye* test does not help Strauss either. “[S]cientific standards and legal standards do not always fit neatly together.” *Anderson v. Akzo Nobel Coatings, Inc.*, 172 Wn.2d 593, 607, 260 P.3d 857 (2011). Under *Frye*, a court first considers whether a particular theory is generally accepted and, if it is, then whether that theory would be helpful to the trier of fact under ER 702. *Id.* at 603. But theory is not the same thing as accepted fact. Under the general acceptance inquiry, a scientific theory passes muster under *Frye* so long as the “science and methods are widely accepted in the relevant scientific community . . . without separately requiring widespread acceptance of the plaintiff’s theory” itself. *Id.* at 609.

So, to say that Dr. Bush’s and Dr. Laramore’s opinion might qualify as a scientifically valid theory under *Frye* is far different from saying that

PBT's supposed superiority is a generally accepted fact. For all the reasons explained above, it is undisputedly not—something both experts readily conceded. CP 683 (Bush Depo at 68-69); CP 657, 660 (Laramore Depo at 62-64, 174). The Plan's definition of "medically necessary" is an objective standard; an alternative treatment is "at least likely to produce equivalent" results or it is not. CP 212. The trial court was rightly focused only on evidence of proven facts, not opinions on unproven theory—and, thus, correctly recognized that Dr. Bush's and Dr. Laramore's testimony did not satisfy Strauss's burden on summary judgment. Put differently, to the extent their testimony was admissible under ER 702 at all, the bases of their opinion only confirmed the absence of actual evidence showing PBT's superiority.

B. The Trial Court Properly Dismissed Strauss's Bad Faith And CPA Claims Because Premera Acted Reasonably And Followed Washington Law In Reviewing His Initial Claim And Appeals.

It is well known that insurers owe a duty of good faith to their insureds. *Tank v. State Farm Fire & Cas. Co.*, 105 Wn.2d 381, 386, 715 P.2d 1133 (1986). "[A]n insurer must deal fairly with an insured, giving equal consideration in all matters to the insured's interests." *Id.* Although Premera is a health care services contractor (HCSC), and not an insurer, *see* RCW 48.44.020(1) (HCSCs are "not . . . subject to the laws relating to insurance"), courts have applied this duty to HCSCs as well. *See Pleasant*, 181 Wn. App. at 270-71. An insurer—or, in this case, an HCSC—violates the duty of good

faith only if its conduct is “unreasonable, frivolous, or unfounded.” *Kirk v. Mt. Airy Ins. Co.*, 134 Wn.2d 558, 560, 951 P.2d 1124 (1998).

An insured also may bring a bad faith claim under the CPA. *Tank*, 105 Wn.2d at 394. The OIC promulgates regulations defining unfair or deceptive practices in the business of insurance, *see* WAC 284-30, but these regulations do not apply to HCSCs like Premera. *Leingang v. Pierce County Med. Bur., Inc.*, 131 Wn.2d 133, 151, 930 P.2d 288 (1997); WAC 284-30-320 (insurer “does not include health care service contractors”). Thus, to prevail, an insured must prove that the HCSC violated a regulation applicable to it, *see* WAC 284-43 & 284-44, or, alternatively, acted “without reasonable justification.” *Leingang*, 131 Wn.2d at 152-53, 155 (quoting *Villella v. Pub. Employees Mut. Ins. Co.*, 106 Wn.2d 806, 821, 725 P.2d 957 (1986)).

For both bad faith and CPA claims, when faced with a motion for summary judgment, “the insured must come forward with evidence that the insurer acted unreasonably. The policyholder has the burden of proof. The insurer is entitled to summary judgment if reasonable minds could not differ that its denial of coverage was based upon reasonable grounds.” *Smith v. Safeco Ins. Co.*, 150 Wn.2d 478, 486, 78 P.3d 1274 (2003). Reasonable minds could not differ here. Strauss failed to come forward with evidence that Premera acted unreasonably or violated any HCSC-specific regulation.

1. Premera’s Good Faith Denial Of Strauss’s Claim Was Based On A Reasonable Interpretation Of The Plan.

Strauss first claims Premera acted unreasonably in “failing to apply the plain language of its own policy” and denying coverage “entirely” upon the lack of randomized studies. Op. Br. at 32. This argument re-packages Strauss’s breach of contract claim, and must be rejected for all the reasons discussed above. Premera followed the Plan’s plain language and properly determined that PBT was not “medically necessary.” Premera did not deny coverage simply because there are no randomized trials. Rather, the lack of randomized trials is a key reason why Premera and two expert independent external reviewers concluded that PBT is not “medically necessary.”

A “denial of coverage based on a reasonable interpretation of the policy is not bad faith,” even if later determined to be incorrect. *Transcon. Ins. Co. v. Wash. Pub. Utils. Dists. Util. Sys.*, 111 Wn.2d 452, 470, 760 P.2d 337 (1988). Premera’s interpretation of “medically necessary” followed NCCN’s and ASTRO’s clinical guidelines—which, as Strauss’s own experts concede, set forth the generally accepted standard of care. CP 416-18; CP 439-40 (Bush Depo at 439-40); CP 827 (Laramore at Depo 248-49). Like Premera’s Medical Policy, these authoritative sources agree that PBT is not superior to IMRT. CP 368, 482, 630, 642. A denial of coverage based on the recognized standard of care is inherently reasonable as a matter of law.

That is all the more obvious in light of the fact that medical experts with two independent review organizations, MRIoA and MCMC, agreed with Premera that Strauss's PBT was not "medically necessary." CP 272-74; 292-95; 308-13. IRO reviewers must make determinations "based upon their expert medical judgment, after consideration of relevant medical, scientific and cost-effectiveness evidence, and medical standards of practice in the state of Washington." RCW 48.43.535(6). Strauss does not argue that MRIoA and MCMC violated this standard and, of course, the evidence shows just the opposite. Indeed, an IRO may "override the health plan's medical necessity . . . standards" if they are "unreasonable or inconsistent with evidence-based medical practice," *id.*, but neither MRIoA nor MCMC chose to do so in Strauss's case. Here, too, a denial of coverage based on the opinion of two independent medical experts is inherently reasonable.

2. Premera's Good Faith Handling Of Strauss's Claim And Appeals Strictly Complied With OIC's Regulations And Was Reasonable At All Levels Of Review.

Strauss next argues that even if the Plan does not cover PBT, Premera acted in bad faith by "assigning a pediatrician" to the initial review. Op. Br. at 34. While there can be bad faith even in the absence of coverage, *Coventry Assocs. v. Am. States Ins. Co.*, 136 Wn.2d 269, 279, 961 P.2d 933 (1998), Strauss still must show that Premera's handling of his claim was "unreasonable, frivolous, or untenable." *Kirk*, 134 Wn.2d at 560. There can

be no dispute here, either. Strauss does not argue Premera violated the HCSC regulations governing benefit review and appeals. *See Former WAC 284-43-615 to 284-43-630; cf. WAC 284-43-3030 to 284-43-3210.*¹¹ The Plan's internal and external review process strictly complied with those regulations, and Premera carefully adhered to them and the Plan's terms as it shepherded Strauss's claim through four levels of review. *Id.*; CP 243-45 (initial review); CP 272-78; 292-95 (Level I Appeal-MRIoA); CP 288-90 (Level II Appeal); CP 302-13 (IRO-MCMC).¹² Strauss does not claim otherwise.

In fact, Strauss's complaint that Premera should have assigned a radiation oncologist to review his initial claim is contrary to Washington law. Dr. Kaneshiro's review was an adverse benefit determination, not an appeal. Under the regulations in effect at the time, and today, there is no requirement that an initial determination be made by a health care provider, much less an expert in the field. *Former WAC 284-43-410 & -620; cf. WAC 284-43-2000*

¹¹ WAC 284-44 applies exclusively to HCSCs. WAC 284-44-010. However, both during the relevant period and today, HCSCs are also defined as "health carriers," and, as such, WAC 284-43 also applies to HCSCs. *Former WAC 284-43-130(14); WAC 284-43-0160(15).*

¹² Strauss suggests that Premera's review somehow violated WAC 284-43-5440. Op. Br. at 34. This claim is baseless. Strauss never raised this issue below and, thus, it is waived on appeal. RAP 2.5(a); RAP 56(c). Even more fatal, WAC 284-43-5440 did not exist when Strauss made his claim and appeals 2009 and 2010; it was first codified as former WAC 284-43-860 in July 2013. *See WSR 13-15-025.* In any event, Premera's appeals process plainly satisfied both the former and current regulations.

& -3070. Only if a plan member “[a]ppeals” an initial determination must it “be evaluated by health care providers . . . who have appropriate expertise in the field[.]” *Former* WAC 284-43-620(4); *cf.* WAC 284-43-3110(6) (“the reviewer must be or must consult with a health care professional who has appropriate training and expertise in the field”).

There is no dispute that Strauss’s Plan complied with these regulations, CP 200-01, and the Plan’s terms were reviewed and approved by OIC. RCW 48.44.020; RCW 48.44.040. A finding that Premera acted unreasonably by not referring Strauss’s initial claim to a specialist would conflict with Washington law, and impermissibly interfere with OIC’s authority. *In re Real Estate Brokerage Antitrust Litig.*, 95 Wn.2d 297, 302-03, 622 P.2d 1185 (1980) (courts should defer to agency on “issues that fall within the scope of a pervasive regulatory scheme” because “a danger exists that judicial action would conflict with the regulatory scheme”). It would be unreasonable to expect Premera to have experts decide every initial claim when Washington law requires expert review at the appeal and IRO levels. This is especially true in Strauss’s case, where the initial determination was dictated by a Medical Policy that itself was prepared by experts in the field.

In any event, by myopically focusing only on Dr. Kaneshiro’s initial review, Strauss ignores entirely the two independent external reviews he received. Both MRIoA’s Level 1 Appeal review (twice) and MCMC’s IRO

review were conducted by board certified radiation oncologists and both considered whether PBT was “medically necessary” under the terms of the Plan—not just Premera’s Medical Policy. CP 272-75; CP 292-95; CP 308-14. Conspicuously, Strauss does not question the expertise or independence of those reviewers, nor does he claim that they made their decisions on incomplete information. Strauss’s bad faith claim must be viewed in light of Premera’s entire review and appeals process, and it cannot be disputed that the process was reasonable and impartial. For this reason too, the trial court properly dismissed Strauss’s bad faith and CPA claims as a matter of law.

C. Strauss Is Not Entitled To Attorney Fees On Appeal.

Strauss’s request for attorney fees should be denied. It is axiomatic that only the prevailing party is entitled to fees under *Olympic Steamship* or the CPA. Because he did not prevail below and will not prevail here, Strauss is not entitled to a fee award. *Hardy v. Pemco Mut. Ins. Co.*, 115 Wn. App. 151, 157, 61 P.3d 380 (2003) (“Because she did not prevail below or here, Ms. Hardy is not entitled to attorney fees.”). Moreover, even if this Court were to reverse and remand, it cannot award Strauss fees because he has not yet prevailed on the merits of his coverage or CPA claims.

V. CONCLUSION

Strauss did not satisfy his burden of proving coverage or resisting summary judgment because, in the absence of any evidence that PBT is

superior to IMRT, it is not “medically necessary” under the terms of the Plan. Strauss’s bad faith and CPA claims were also properly dismissed on summary judgment because there can be no dispute that Premera’s handling of Strauss’s claim was reasonable and strictly complied with Washington law.

RESPECTFULLY SUBMITTED this 10th day of August, 2016.

LANE POWELL PC

By 
Gwendolyn Payton, WSBA No. 26752
Ryan P. McBride, WSBA No. 33280
Jessica N. Walder, WSBA No. 47676
Attorneys for Respondent
Premera Blue Cross

CERTIFICATE OF SERVICE

I hereby certify under penalty of perjury of the laws of the State of Washington that on the 10th day of August, 2016, I caused to be served a copy of the foregoing Brief of Respondent on the following person(s) in the manner indicated below at the following address(es):

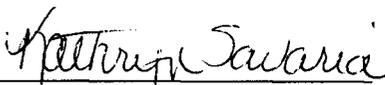
Howard M. Goodfriend
Victoria E. Ainsworth
SMITH GOODFRIEND, P.S.
1619 8th Avenue North
Seattle, WA 98109
howard@washingtonappeals.com
tori@washingtonappeals.com

- by Electronic Mail
- by Facsimile Transmission
- by First Class Mail
- by Hand Delivery
- by Overnight Delivery

Patrick A. Trudell
Kornfeld Trudell Bowen &
Lingenbrink, PLLC
3724 Lake Washington Blvd NE
Kirkland WA 98033-7802
patrick@ktblaw.com

- by Electronic Mail
- by Facsimile Transmission
- by First Class Mail
- by Hand Delivery
- by Overnight Delivery

SIGNED this 10th day of August, 2016, at Seattle, WA.


Kathryn Savaria

FILED
COURT OF APPEALS DIV 1
STATE OF WASHINGTON
2016 AUG 10 PM 1:02