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No. 90394-8

SUPREME COURT
OF THE STATE OF WASHINGTON

BRUCE PLEASANT AND KIMBERLY PLEASANT,
a marital community,

Appellants,

v.

REGENCE BLUESHIELD, a Washington Corporation,

Respondent.

RESPONDENT'S OPPOSITION TO PETITION FOR REVIEW

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I. INTRODUCTION

This case involves the terms of an individual health care plan purchased by Appellant Bruce Pleasant ("Pleasant") and issued by respondent Regence BlueShield ("Regence"). Both the trial court and the Court of Appeals properly held that the terms of the plan, which exclude coverage for investigational services and limit coverage for an inpatient rehabilitation admission to $4,000, are clear and unambiguous. On the parties' cross-motions for summary judgment, the undisputed evidence established that Pleasant was aware of the limitations in his plan, and he received all of the benefits to which he was entitled under the plan. The rulings below, which merely enforce the explicit terms of the plan, do not present an issue of substantial public interest warranting discretionary review by this Court.

II. COUNTER-STATEMENT OF THE CASE

A. The Health Care Plan.

At times material to this case, Bruce Pleasant subscribed to an individual health care plan with Regence. CP 155-226. Services are covered under the plan if they are "Medically Necessary,"[1] identified as a covered service, and not excluded. CP 197, 206.

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[1] *See* CP 209, ¶ 8.5 ("All services and supplies must be Medically Necessary as defined in Article 1, except as provided in this Article for preventive care services."). "Medically necessary" services are those provided "for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms." CP 170.

Services identified as covered include professional, inpatient hospital, and inpatient skilled nursing facility, described as follows:

> SECTION 8.6 PROFESSIONAL. The services of a provider who is not a facility that provides Inpatient services, will be provided for the diagnosis and treatment of illness, accidental injury, or physical disability ....
>
> SECTION 8.7 HOSPITAL FACILITY.
>
> 8.7.1 INPATIENT BENEFITS. When the member is confined as an **Inpatient**,[2] Benefits will be provided for services and supplies provided by a Hospital ....
>
> * * *
>
> SECTION 8.30 SKILLED NURSING FACILITY. **Inpatient** services and supplies by a skilled nursing facility will be provided for illness, accidental injury, or physical disability, limited to 30 days per Year ....

CP 209, 221 (emphasis supplied for defined terms).

The plan excludes coverage for "Investigational Services or Supplies, as defined in Article 1." CP 199, ¶ 6.1.17. "Investigational Services or Supplies" are services or supplies that are classified as such either by the national Blue Cross Blue Shield Association or by Regence, using five specifically identified criteria:

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[2] An "Inpatient" is defined as: "A person confined to overnight in a Hospital or other facility as a regularly admitted bed patient to whom a charge for room and board is made in accordance with the Hospital's or facility's standard practice." CP 168, ¶ 1.13.

SECTION 1.15 INVESTIGATIONAL SERTICE OR SUPPLY. A service or supply ... that is determined by the Company to meet any one of the following:

1.15.1 Any service or supply classified as experimental and/or investigational by the national Blue Cross Blue Shield Association ... as adopted by the Company. The national Blue Cross Blue Shield Association's determination is based on the following criteria:

a. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes (which means significant measurable improvement in length of life, ability to function, or quality of life);

b. The technology must improve the net health outcome (as defined above);

c. The technology must be as beneficial as any established alternatives;

d. The improvement must be attainable outside the laboratory or clinical research setting; and

e. Items must have been approved by the U.S. Food and Drug Administration (FDA) as being safe and efficacious for general marketing, and permission must have been granted by the FDA for commercial distribution; or

1.15.2 Any service or supply classified as experimental or investigational by the Company. The Company's determination is based on the criteria specified under Paragraph 1.15.1 ....

CP 169.

In addition, the plan excludes "[t]reatment for rehabilitative care, including speech therapy, physical therapy, or occupational therapy, <u>except as specified in the Home Health, Hospice, and Rehabilitation Benefits of Article 8</u>." CP 200, ¶ 6.1.34 (emphasis added). Article 8 provides limited coverage for an inpatient rehabilitation admission as follows:

> SECTION 8.29 REHABILITATION. The Benefits described below will be provided when Medically Necessary to restore and improve function that was previously normal but lost following a documented injury or illness:
>
> 8.29.1 INPATIENT. The Professional, Inpatient Hospital, and Skilled Nursing Facility Benefits of this Article will be provided to an Inpatient for an **Inpatient Rehabilitation Admission** for physical therapy, speech therapy, and occupational therapy, to a maximum of $4,000 per Year.

CP 220.

An "Inpatient Rehabilitation Admission" is defined as: "An inpatient admission to a Company approved facility specifically for the purpose of receiving speech, physical, or occupational therapy in an inpatient setting." CP 169, ¶ 1.14.

B. Pleasant's Medical History.

1. Inpatient Hospital Admission to Swedish Medical Center (3/18/10 to 4/5/10).

On March 18, 2010, while or shortly after undergoing knee surgery, Bruce Pleasant suffered a stroke, for which he received extensive medical care. He was admitted to Swedish Medical Center as a regularly admitted patient, where he received inpatient medical care for approximately three weeks to stabilize his condition. CP 229-30.

During Pleasant's hospitalization, Pleasant and his family discussed with Pleasant's caregivers options for Pleasant's continuing treatment following his discharge from the hospital and how to optimize use of the various benefits available to him under his Regence plan. CP 240. The various options included admission to a rehabilitation unit, admission to a skilled nursing facility, or a combination of the two. *Id.* After having specific conversations with Regence about the fact that the plan provided a limited benefit of $4,000 for inpatient rehabilitation, CP 232-35, 240, Pleasant decided to first enter a skilled nursing facility, then transfer to a rehabilitation facility. Pleasant recognized that this option would allow him to maximize both his 30-day skilled nursing facility benefit and the $4,000 benefit for inpatient rehabilitation. CP 245 (recommending that Pleasant "use at least 3-4 weeks of that [SNF[3]] benefit prior to paying privately for ARU[4]"); *see also* CP 247 (Swedish

[3] SNF means Skilled Nursing Facility.
[4] ARU means Acute Rehabilitation Unit.

Care Manager noting Pleasant will "utilize SNF benefit first" then "pay privately at ARU when ARU benefit has been exhausted").

2. Admission to Skilled Nursing Facility (4/5/10 to 5/5/10).

Accordingly, on April 5, 2010, Pleasant transferred to a skilled nursing facility, where he stayed for 30 days.

3. Inpatient Rehabilitation Admission to Swedish Cherry Hill's Inpatient Acute Rehabilitation Unit (5/5/10 to 5/31/10).

On May 5, 2010, with full knowledge of his limited inpatient rehabilitation benefit and having made private pay arrangements, Pleasant was admitted to Swedish Cherry Hill's Inpatient Acute Rehabilitation Unit. Pleasant's admitting provider, Dr. Clawson, is a physician specializing in rehabilitation. CP 257. Pleasant was pre-authorized by Swedish Cherry Hill for admission to the Rehabilitation Unit,[5] and his admission record confirms this was an "elective" admission for the sole

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[5] Rehabilitation Units have preadmission screening procedures to evaluate and determine a patient's eligibility for inpatient admission, which require that the patient have suffered a new or recent onset of certain medical conditions (including a stroke), be "medically stable and show evidence of physical and cognitive readiness to participate in the rehabilitation program," and be "willing and capable" of participating in the program for at least three hours daily. WAC 182-550-2551; 182-550-2561. Accordingly, in order to qualify Pleasant for benefits, Swedish Cherry Hill completed an Inpatient Rehabilitation Facility – Patient Assessment Instrument ("IRF-PAI") for him on May 5, 2010. CP 254-56. The IRF-PAI is also used to determine the facility's reimbursement.

purpose of receiving rehabilitative care.[6] Pleasant received intensive physical, occupational, and speech therapy every day during his rehabilitation admission. CP 257-493. Although he was not admitted as a regular patient hospitalized because of a need for medical care, as would be expected due to his previous stroke, Pleasant also received medical services and drugs during his inpatient rehabilitation admission.[7] He was discharged to his home on May 31, 2010. CP 493.

C. Regence's Coverage Determinations.

Regence provided full coverage for Pleasant's inpatient hospital admission in March 2010, for which Swedish charged approximately $250,000.[8] CP 585-600. Regence also fully covered Pleasant's 30-day stay at the skilled nursing facility. CP 236. In this case, Pleasant contests only Regence's coverage determinations for a mechanical embolectomy procedure and for his inpatient rehabilitation admission.

[6] The "Primary Service" is identified as "Rehab" and "Secondary Service" is identified as "None." CP 257; *see also* CP 259 (Swedish discharge summary stating reason for ARU admission: "Admitted for rehabilitation for deficits related to Right MCA embolic CVA related to patent foramen ovale following knee surgery.").

[7] Every rehabilitation patient must have an underlying medical illness or injury in order to qualify for rehabilitative care, and thus every rehabilitation patient has medical needs. WAC 182-550-2551; WAC 182-550-2561. In order to be admitted for rehabilitation, however, the patient's medical condition must be "medically stable." *Id.* Thus, by definition, an inpatient rehabilitation patient has a medical condition but does not need to be hospitalized for his or her condition.

[8] All of the hospital's charges for Pleasant's inpatient stay as a "regularly admitted bed patient" were covered under the inpatient hospital benefit of Pleasant's plan. CP 168, 209. This coverage included incidental rehabilitation services provided during his hospital admission, which were not applied to the limited benefit for an Inpatient Rehabilitation Admission, since Pleasant was not hospitalized "for the purpose of receiving ... therapy"). CP 168-69, 209.

1. Mechanical Embolectomy Procedure.

One of the many medical procedures Pleasant received on the day of his stroke is called "mechanical embolectomy." Both Regence and the Blue Cross Blue Shield Association classify mechanical embolectomy as an investigational procedure when used for the treatment of acute ischemic stroke. CP 789-96.[9] As detailed in the medical literature cited in Regence's Medical Policy, studies and medical trials conducted to date on the use of mechanical embolectomy for stroke patients are inconclusive on whether the procedure is safe, effective, or preferable to alternative treatments.[10] *Id.* Regence's Medical Policy also relies in part on the American Heart Association's opinion that the usefulness and effectiveness of mechanical embolectomy devices is "uncertain," and "the utility of the device in improving outcomes after stroke remains unclear." *Id.* In addition to the American Heart Association, the American Journal of Radiology, studies funded by the United States Department of Health and Human Services, and numerous other public and private health

[9] Regence's Medical Policy, including citations to the medical publications and studies that are cited in the policy, is published for the public at http://blue.regence.com/trgmedpol/surgery/sur158.html (last accessed 6/15/12).
[10] In fact, mechanical embolectomy did not improve Pleasant's condition. CP 1193-95.

carriers agree that the safety and efficacy of mechanical embolectomy for the treatment of acute ischemic stroke is unproven.[11] *See infra,* pp. 18-19.

In accordance with Pleasant's plan, Regence denied coverage for the physician's charge of $415 to perform a mechanical embolectomy procedure. Regence sent an Explanation of Benefits ("EOB") informing Pleasant of the basis for denial of the charge. CP 1192 (EOB stating "investigational or experimental services and supplies are not covered"). The EOB also described the procedure to appeal the denial and offered "a free explanation of our scientific or clinical judgment, applying the terms of the plan to your medical circumstances, is available upon request." *Id.* Regence followed up with a letter to Pleasant repeating the basis for the claim denial and providing the specific URL for the publication of Regence's Medical Policy on mechanical embolectomy. CP 1305-08.[12]

2. Inpatient Rehabilitation Admission.

Pleasant's May 5, 2010, admission to Swedish Cherry Hill's Rehabilitation Unit qualified as an Inpatient Rehabilitation Admission under the contract, defined as an admission "specifically for the purpose of receiving speech, physical, or occupational therapy in an inpatient

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[11] Pleasant's representation that "Regence's own reviewing neurosurgeon, Dr. Maurice Collada" disagreed with the Medical Policy on mechanical embolectomy is false and misstates the record. *See Appellants' Amended Petition for Review*, p. 11. Dr. Collada is not and never has been an employee or agent of Regence. CP 1552 (28:18-24). His comments were received by Regence in response to the company's practice of soliciting public comments on draft policies, and they merely reflect that one doctor out of the thousands in this state disagrees with the Medical Policy. *Id.*

[12] Pleasant's contention that the denial was "unexplained" clearly is inaccurate. *See Appellants' Amended Petition for Review*, p. 10.

setting." CP 169, ¶ 1.14. The "admitting diagnosis" is "the medical condition responsible for a hospital admission, as defined by ICD-9-M diagnostic code." WAC 182-531-0050. Pleasant's "admitting diagnosis" was "rehabilitation procedure" (coded as V57.89). CP 494.

In the health care industry, inpatient rehabilitation admissions are paid differently than and separately from inpatient hospital admissions.[13] Swedish Cherry Hill's Rehabilitation Unit, which is separate from the hospital facility, submitted an invoice for Pleasant's inpatient rehabilitation admission.[14] Regence paid benefits for the inpatient rehabilitation admission up to the contract's limit of $4,000. CP 220, ¶ 8.29.1.

Pleasant was fully informed in advance that his Regence plan would provide a limited benefit of $4,000 for the admission. CP 238 (confirming on 3/24/10: "Your benefits for your stay on the inpatient rehabilitation unit are: Covered at 80%. Limit $4,000 per 12 months.").

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[13] The Centers for Medicare and Medicaid Services ("CMS") has established various Prospective Payment Systems (or "PPSs") as methods to reimburse medical services. CP 500-01. Separate PPSs apply for reimbursement to acute inpatient hospitals, hospice, hospital outpatient, inpatient psychiatric facilities, inpatient rehabilitation facilities, and skilled nursing facilities; and facilities are prohibited from billing one patient under different categories for the same admission. *Id.*; *see also* WAC 182-550-2598(14)(b) (noting that the Washington Health Department "uses the per diem payment method to pay for services provided in ... distinct rehabilitation units").

[14] In accordance with federal regulations, Swedish Cherry Hill bills its 36-bed rehabilitation unit separately from its 385-bed acute care hospital. CP 503; *see* 42 CFR §412.105(b) (excluding beds located in a hospital's rehabilitation unit from the number of beds used to calculate hospital inpatient reimbursement amount). The invoice for Pleasant's inpatient rehabilitation admission invoice uses NPI number 1427103589, which is the NPI number for Swedish's Rehabilitation Unit. CP 494, 496. (An NPI number is a "unique identifier for health care providers" established by CMS. CP 495.) Swedish's general acute care hospital operates under a different NPI number. CP 498.

D. Procedural History.

Pleasant filed the instant action on February 9, 2011, based on Regence's enforcement of the plan's $4,000 limit on an inpatient rehabilitation admission. The parties agreed the facts of the case were undisputed and cross-moved for summary judgment. Pleasant argued the limitation should not apply because his May 2010 admission was not actually an "inpatient rehabilitation admission" as defined by the plan.[15] CP 11-19. Regence pointed out that based on Pleasant's medical records, he was admitted to the Rehabilitation Unit for the purpose of receiving rehabilitative therapy and, therefore, his admission was an "inpatient rehabilitation admission" as defined by the plan. CP 1682-1700. Following two separate days of oral argument, the Honorable Mary Yu denied Pleasant's motion for summary judgment and granted summary judgment to Regence, finding that Regence properly enforced the terms of Pleasant's heath care plan limiting benefits for an "inpatient rehabilitation admission" to $4,000 per year. CP 602-03; CP 1707-09.

However, Judge Yu also permitted the Pleasants to assert a new claim based on Regence's denial of the $415 charge for a mechanical embolectomy procedure performed on March 18, 2010. CP 1707-09. On subsequent cross-motions for summary judgment on this claim, Judge Yu

[15] Pleasant argued that the benefit limitation is unenforceable under Washington public policy but, as recognized by the Court of Appeals, he failed to address the argument in his briefing and provided no authority to support the argument; accordingly, it was not considered by the Court of Appeals. *Pleasant v. Regence BlueShield*, -- Wn. App. --, 325 P.3d 237, 242, fn. 5 (2014) (citing RAP 10.3(a)(6)).

ruled that Regence properly denied the mechanical embolectomy claim as an investigational procedure and dismissed the remainder of the lawsuit. CP 1512-13. The trial court denied Pleasant's motion for reconsideration, CP 1647, and Pleasant appealed to Division I of the Court of Appeals.

On March 31, 2014, the Court of Appeals issued a decision affirming the trial court's orders finding that the terms of the health care plan are unambiguous, that those unambiguous terms and the undisputed record "do not support Pleasant's argument that he was entitled to coverage for nonrehabilitative expenses he incurred while an inpatient at the ARU at Swedish," and that Regence's denial of the mechanical embolectomy claim complied with Washington law and was based on reasonable grounds as a matter of law. *Pleasant v. Regence BlueShield*, -- Wn. App. --, 325 P.3d 237, 244, 247 (2014).

III. ARGUMENT WHY REVIEW SHOULD BE DENIED

A. Pleasant Fails to State a Basis for Review.

Pleasant seeks review under RAP 13.4(b)(4), arguing that this case presents "an issue of substantial public interest that should be determined by the Supreme Court." However, he fails to establish a basis for review.

As explained more fully below, the Court of Appeals properly held that the terms of the health care plan are unambiguous, that Regence fully and accurately communicated with Pleasant regarding the limitations on the plan, and that Regence acted properly in enforcing the unambiguous terms of the plan. On both the inpatient rehabilitation and mechanical embolectomy issues, the parties filed cross-motions for summary

judgment, agreeing that the facts were undisputed. The undisputed evidence proved that Pleasant's May 2010 admission was an "inpatient rehabilitation admission" for which the contract provides a benefit of $4,000, and that Pleasant was fully aware of the scope of benefits in his chosen plan before he obtained the services. The undisputed evidence also established that mechanical embolectomy is an investigative procedure based on the criteria set forth in the contract, and Regence properly denied coverage for the procedure. Contrary to Pleasant's position, nothing in Washington law or expressed public policy requires a health carrier to provide unlimited benefits for all services, and Pleasant's petition for review of the decisions below should be denied.[16]

B. The Courts Below Properly Enforced the Plan's Limited Benefit for Pleasant's Inpatient Rehabilitation Admission.

Pleasant's health care plan provides benefits for an Inpatient Rehabilitation Admission[17] to a maximum of $4,000 per year. CP 220, ¶ 8.29.1. The evidence before the trial court was undisputed that Pleasant's May 2010 admission was an Inpatient Rehabilitation Admission. He was admitted on an "elective" basis to the Swedish Cherry Hill ARU for the specific purpose of receiving rehabilitative care.

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[16] In fact, even the recently-adopted Affordable Care Act does not provide unlimited Inpatient Rehabilitation benefits. *See, e.g.,* WAC 284-43-878(7)(b)(ii) and (7)(e) (limiting "inpatient rehabilitation facility and professional services delivered in those facilities" to 30 days per year).

[17] An Inpatient Rehabilitation Admission is defined as "[a]An inpatient admission to a Company approved facility specifically for the purpose of receiving speech, physical, or occupational therapy in an inpatient setting." CP 169, ¶ 1.14.

CP 254-57. His admitting diagnosis was "rehabilitation procedure" with no other diagnosis, CP 494, and he received intensive rehabilitation services during each day of his admission. Of course, since all rehabilitation admissions are precipitated by an underlying medical condition, it is to be expected that patients such as Pleasant also will receive prescription drugs and medical services. *See* WAC 182-550-2501 (acute physical medicine and rehabilitation "is a twenty-four-hour inpatient comprehensive program of integrated medical and rehabilitative services provided during the acute phase of a client's rehabilitation") (emphasis added). Under the Regence contract, however, it is the purpose of the admission that determines coverage, and there is no evidence that Pleasant was or needed to be hospitalized as an inpatient in May 2010.[18] Furthermore, Pleasant was fully aware of the terms of his contract with Regence and he, his family and his medical providers made certain decisions regarding his care based on their understanding that the contract provided a benefit of $4,000 for an inpatient rehabilitation admission.

This Court previously rejected the argument, made by Pleasant in this case, that a health care contract cannot define benefits based on the

[18] The fact that Pleasant did not need to be hospitalized distinguishes his example of a patient who trips and suffers a traumatic brain injury. *See Amended Petition for Review*, p. 14. Furthermore, although not material to coverage as it is defined under the Regence plan, there also was no evidence before the trial court that any services received by Pleasant during his May 2010 admission to the ARU were not in fact related to rehabilitation.

location of the services or the type of inpatient admission.[19] Specifically, in the case of *Rew v. Beneficial Standard Life Ins. Co.*, 41 Wn.2d 577, 578-83, 250 P.2d 956 (1953), the Court held that the plaintiff was not entitled to health care benefits for an inpatient stay at a convalescent home under a policy that covered "confine[ment] as a resident bed patient within any hospital," regardless of the fact that "respondent wife secured in the convalescent home the same care she would have received at the Deaconess Hospital, had she remained there," and remanded with instructions to enter judgment for the insurer. *See also Taylor v. Phoenix Mut. Life Ins. Co.*, 453 F. Supp. 372, 374-75 (E.D. Penn. 1978) (granting insurer's motion for summary judgment and holding that when a patient is admitted to a facility "primarily for rehabilitative care," even though he or she may receive "incidental medical attention" during the admission, coverage is properly denied under a policy that limits coverage to "[c]harges made by a hospital").

The Court of Appeals properly held that both of the out-of-state cases cited by Pleasant are inapposite. In *National Family v. Kuykandall*,

[19] Pleasant contends that he received some "non-rehabilitative care which is ordinarily covered under the policy of insurance." *Amended Petition for Review*, p. 13. This contention presupposes coverage without any explanation. The Regence plan defines benefits based both on the location of services and the type of admission. For example, services received by Pleasant while he was a hospital inpatient – including incidental rehabilitation services, non-prescription drugs, etc. – were covered without a limit under the plan's inpatient hospital benefit section. CP 209. These services would have been subject to different provisions of the plan if they had been provided while in a different facility or if Pleasant received the services as an out-patient, and they may or may not have been covered, depending on the applicable plan provisions. (For example, prescription drugs not received while a hospital inpatient are subject to an annual maximum of $2,000. CP 216 (¶ 8.25.1).

705 S.W.2d 267 (Tex. App. 1986), the only issue was whether a contract covering hospitalization in an "Intensive Care Unit" covered hospitalization in a unit "designated as the Coronary Care Unit." Plaintiff's physician testified that the Coronary Care Unit was essentially the same as an Intensive Care Unit, and the Court affirmed a jury finding on this issue. The *Kuykandall* case does not support Pleasant's argument that a plan cannot limit benefits based on the type of facility or type of admission; only that the terms of the contract at issue in that case did not do so. The other case cited by Pleasant, *Dobias v. Service Life Ins. Co. of Omaha*, 469 N.W.2d 143 (Neb. 1991), is similarly distinguishable because it relied on the fact that the plaintiff received primarily acute medical care, the facility providing the care was not a rehabilitation facility (but only "coincidentally … named a 'rehabilitation center'"), and, more importantly, that plaintiff had been misled about the terms of the policy. As the Court of Appeals found: "Here, unlike in *Dobias* and *Kuykandall*, the health care plan is not ambiguous." *Pleasant*, 325 P.3d at 245.

Pleasant's physician ordered that he be placed into a rehabilitation facility specifically for the purpose of receiving rehabilitative care, the contract expressly defines the scope of an Inpatient Rehabilitation Admission, Pleasant in fact received primarily rehabilitative care, and he was fully aware of the terms of his contract before the admission. Although the contract excludes rehabilitative care, it provides a limited benefit of $4,000 for an Inpatient Rehabilitation Admission. Regence appropriately paid for Pleasant's Inpatient Rehabilitation Admission under

this limited benefit, summary judgment was correctly granted on this issue, and discretionary review is not warranted.

C. Pleasant's Claim for Mechanical Embolectomy Also Was Properly Dismissed.

The courts below also correctly ruled that the $415 charge for mechanical embolectomy was not covered under the Regence plan, which excludes coverage for services classified as investigational. CP 199, ¶ 6.1.17. Mechanical embolectomy is a controversial procedure that to date, has not been proved as a safe or effective treatment of acute stroke.

Under WAC 284-44-043, health carriers may exclude coverage for investigational services. Either the health carrier "or an affiliated entity" is authorized to "make [the] determination of which services will be considered to be experimental or investigational," provided that "the criteria it will utilize to determine whether a service is experimental or investigational [is] set forth in the contract and any certificate of coverage issued thereunder." WAC 284-44-043(2).

Here, in accordance with Washington law, Regence adopted a Medical Policy on mechanical embolectomy, determining that the procedure is investigational when used in the treatment of acute ischemic stroke, and Pleasant's plan sets forth the criteria the company used to make this determination.[20] Specifically, the contract states that a service is excluded from coverage if it is classified as investigational either by the

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[20] All Regence plans are submitted to the Office of the Insurance Commissioner for review and approval before marketing. RCW 48.44.020, 48.44.040; WAC 284-43-920.

national Blue Cross Blue Shield Association or by Regence. CP 169, ¶ 1.15. The contract also sets forth the five specific criteria these entities use to make this determination.[21] CP 169 (¶ 1.15.1, as quoted *supra* p. 3).

Using these criteria, the Medical Policies of both the national Blue Cross Blue Shield Association and Regence classify mechanical embolectomy as investigational. CP 789-96. Regence's determination is based on the lack of scientific evidence to prove that mechanical embolectomy is effective, beneficial and safe for acute stroke patients, or that the procedure is preferable to alternative treatments. *Id.* Regence's Medical Policy relies in part on a recommendation by the American Heart Association that the usefulness and effectiveness of mechanical embolectomy devices is "uncertain," and "the utility of the device in improving outcomes after stroke remains unclear." *Id.* Pleasant failed to provide any contrary medical evidence.[22]

Pleasant's claim for coverage of the mechanical embolectomy procedure was properly dismissed, and discretionary review of this decision should be denied.

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[21] Regence's Medical Director, Richard Rainey, M.D., confirmed that the Medical Policy is based on the five criteria identified in Pleasant's plan document. CP 789-91.

[22] All of the evidence submitted to the trial court questioned use of the procedure for stroke patients. For example, according to the American Journal of Radiology, although two devices that can be used for mechanical embolectomy have been "cleared" by the Food & Drug Administration (FDA) for marketing, neither of these devices "has demonstrated efficacy for the improvement of patient outcomes."[22] CP 1491. A 2011 review funded by the United States Department of Health and Human Services notes the "lack [of] randomized trials to document that the [procedure] improve[s] patient outcomes." CP 1497. In fact, patient trials of mechanical embolectomy were suspended in April 2012 because the trials failed to indicate that the procedure improves patient outcomes. CP 1501.

IV. CONCLUSION

The courts below properly ruled to enforce the terms of Pleasant's contract, which excludes coverage for an investigational procedure, such as mechanical embolectomy, and limits benefits for an inpatient rehabilitation admission to $4,000. This case does not present an issue of substantial public interest warranting review, and Regence asks the Court to deny Pleasant's Petition for Review.

RESPECTFULLY SUBMITTED this 21st day of July, 2014.

LANE POWELL PC
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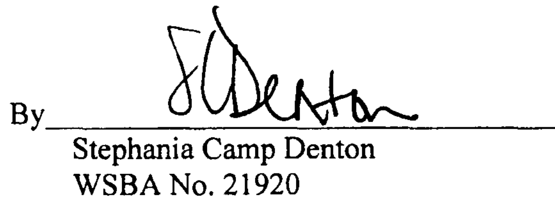
Regence BlueShield

By 

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CERTIFICATE OF FILING AND SERVICE

I, Helen Van Buren, hereby certify under penalty of perjury that I served the foregoing by email and U.S. Mail upon the following counsel of record:

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DATED this 21st day of July 2014.

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From: Van Buren, Helen [mailto:VanBurenH@LanePowell.com]
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To: OFFICE RECEPTIONIST, CLERK
Cc: rwathen@cwlhlaw.com; Denton, Stephania
Subject: Pleasant v. Regence Blueshield/No. 90394-8/Respondent's Opposition to Petition for Review

Dear Clerk: Attached for filing is the following document:

Case Name: Pleasant v. Regence Blueshield
No. 90394-8
Document Name: Respondent's Opposition to Petition for Review
Filing Party: Stephania C. Denton/21920

A hard copy will follow via U.S. Mail to counsel of record. Thank you.

Helen Van Buren

Legal Assistant for Stephania C. Denton
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