Public Comments Summary
TKR/THR Warranty

We appreciate the many valuable and constructive comments by over 60 respondents during our public comment period. As a result of these comments we have removed accountability of providers for failure of the implantable device from the warranty.

While we anticipate that some provisions of the bundle and warranty remain areas in which there are differences of opinion, each comment has been carefully reviewed by our committee and weighed against available evidence medical evidence. Finally, the warranty was approved by the provider, purchaser, health plan, and quality organizations that comprise the Bree Collaborative in July 2013.

Public Comment Survey for Draft Total Knee and Total Hip Replacement (TKR and THR) Warranty

SurveyMonkey

1. What sector do you represent? Choose the option that is the best fit.

	Response Percent	Response Count
Orthopedic surgeons	**37.7%**	**23**
Other health care providers (primary care physicians, physical therapists, nurses, etc.)	16.4%	10
Hospitals	4.9%	3
Government/Public Purchasers	3.3%	2
Employers	3.3%	2
Health Plans	3.3%	2
Health Plans with Integrated Delivery Systems	1.6%	1
Quality Improvement Organization	4.9%	3
Consumers/Patients	8.2%	5
Self	6.6%	4
Other (please specify)	9.8%	6
	answered question	**61**
	skipped question	**1**

2. Many of the definitions in this warranty are clinical or technical in nature. Would you like to provide comments about the specific definitions, or would you prefer to just provide general feedback?

	Response Percent	Response Count
I would like to review the specific definitions AND provide general feedback.	**72.5%**	**29**
I would like to only provide general feedback.	27.5%	11
	answered question	**40**
	skipped question	**22**

3. Do you agree with this definition?

	Response Percent	Response Count
Yes	**73.5%**	**36**
No	6.1%	3
Neutral/No opinion	20.4%	10
	answered question	**49**
	skipped question	**13**

4. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	3
answered question	**3**
skipped question	**59**

5. Do you agree with this definition?

		Response Percent	Response Count
Yes		**64.4%**	**29**
No		2.2%	1
Neutral/No opinion		33.3%	15
		answered question	**45**
		skipped question	**17**

6. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	1
answered question	**1**
skipped question	**61**

7. Do you agree with this definition?

		Response Percent	Response Count
Yes		**80.0%**	**36**
No		13.3%	6
Neutral/No opinion		6.7%	3
		answered question	**45**
		skipped question	**17**

8. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	6
answered question	**6**
skipped question	**56**

9. Do you agree that death attributable to TKR and THR surgery should be included in the warranty?

		Response Percent	Response Count
Yes		40.9%	18
No		**45.5%**	**20**
Neutral/No opinion		13.6%	6
	answered question		**44**
	skipped question		**18**

10. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	19
answered question	**19**
skipped question	**43**

11. Do you agree that mechanical complications attributable to TKR and THR surgery should be included in the warranty?

	Response Percent	Response Count
Yes	**58.5%**	**24**
No	36.6%	15
Neutral/No opinion	4.9%	2
	answered question	**41**
	skipped question	**21**

12. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	15
answered question	**15**
skipped question	**47**

13. Do you agree that periprosthetic joint infection should be included in the warranty?

	Response Percent	Response Count
Yes	**51.2%**	**21**
No	43.9%	18
Neutral/No opinion	4.9%	2
	answered question	**41**
	skipped question	**21**

14. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	18
answered question	**18**
skipped question	**44**

15. Do you agree that wound infection should be included in the warranty?

		Response Percent	Response Count
Yes		**48.8%**	**20**
No		46.3%	19
Neutral/No opinion		4.9%	2
	answered question		**41**
	skipped question		**21**

16. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	19
answered question	**19**
skipped question	**43**

17. Do you agree that surgical site bleeding should be included in the warranty?

	Response Percent	Response Count
Yes	**60.0%**	**24**
No	30.0%	12
Neutral/No opinion	10.0%	4
answered question		**40**
skipped question		**22**

18. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	12
answered question	**12**
skipped question	**50**

19. Do you agree that pulmonary embolism should be included in the warranty?

	Response Percent	Response Count
Yes	45.0%	18
No	**47.5%**	**19**
Neutral/No opinion	7.5%	3
answered question		**40**
skipped question		**22**

20. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	19
answered question	**19**
skipped question	**43**

21. Do you agree that acute myocardial infarction (MI) should be included in the warranty?

		Response Percent	Response Count
Yes		30.0%	12
No		**55.0%**	**22**
Neutral/No opinion		15.0%	6
	answered question		**40**
	skipped question		**22**

22. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	22
answered question	**22**
skipped question	**40**

23. Do you agree that pneumonia should be included in the warranty?

		Response Percent	Response Count
Yes		37.5%	15
No		**47.5%**	**19**
Neutral/No opinion		15.0%	6
		answered question	**40**
		skipped question	**22**

24. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	19
answered question	**19**
skipped question	**43**

25. Do you agree that sepsis should be included in the warranty?

		Response Percent	Response Count
Yes		**47.5%**	**19**
No		42.5%	17
Neutral/No opinion		10.0%	4
		answered question	**40**
		skipped question	**22**

26. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	18
answered question	**18**
skipped question	**44**

27. Are there any other complications that you believe should be added to this list? If so, why?

	Response Count
	18
answered question	**18**
skipped question	**44**

28. Do you agree with the warranty periods in the first 90 days?

		Response Percent	Response Count
Yes		**52.5%**	**21**
No		40.0%	16
Neutral/No Opinion		7.5%	3
	answered question		**40**
	skipped question		**22**

29. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	16
answered question	**16**
skipped question	**46**

30. Do you agree with the warranty period for failure of the implant (10 years)?

		Response Percent	Response Count
Yes		37.5%	15
No		**52.5%**	**21**
Neutral/No Opinion		10.0%	4
	answered question		**40**
	skipped question		**22**

31. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	21
answered question	**21**
skipped question	**41**

32. Do you agree with these two proposed terms?

		Response Percent	Response Count
Yes		**47.5%**	**19**
No		42.5%	17
Neutral/No Opinion		10.0%	4
		answered question	**40**
		skipped question	**22**

33. If no, why? Please provide citations for evidence to support your opinion if possible.

	Response Count
	17
answered question	**17**
skipped question	**45**

34. If you have any other comments about the definitions or the warranty more broadly please provide them here.

	Response Count
	20
answered question	**20**
skipped question	**42**

35. Name:

	Response Count
	30
answered question	30
skipped question	32

36. Email address:

	Response Count
	29
answered question	29
skipped question	33

37. Organization:

	Response Count
	28
answered question	28
skipped question	34

Page 1, Q1. What sector do you represent? Choose the option that is the best fit.		
1	Medical Device Manufacturers	Jul 3, 2013 9:48 AM
2	Health Policy Consultant for Minimally Invasive Surgery	Jul 2, 2013 2:01 PM
3	Home health agencies	Jul 2, 2013 7:13 AM
4	Integrated Health Care Delivery System	Jun 21, 2013 7:12 AM
5	Manufacturer	Jun 20, 2013 1:25 PM
6	Tribal benefit plan	Jun 19, 2013 1:06 PM

Page 3, Q4. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	xx	Jul 3, 2013 7:44 AM
2	Arthritis implies acute inflammation, which should include inflammatory arthritis. Most joint replacements are done for artthrosis or degenerative conditions which are affected by repetitive traumatic events.	Jul 1, 2013 2:40 PM
3	it should include those other things	Jun 20, 2013 7:09 AM

Page 5, Q6. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	xx	Jul 3, 2013 7:45 AM

Page 7, Q8. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	Trauma. Tumor. Infection. Congenital.	Jul 1, 2013 2:41 PM
2	Advanced elderly are more prone to complications and may not be able to travel to facility/provider that did the original surgery. Suggest you provide an upper age limit	Jul 1, 2013 11:00 AM
3	We believe an upper limit should be in place due to the increased co-morbidity of the upper age geriatric population (>80).	Jun 21, 2013 7:14 AM
4	There are unusual occasions where up and knee replacement may be indicated for those under 18. This would not be for osteoarthritis but for things like avascular necrosis, Trevor's disease, Legg Calve Perthes disease, juvenile rheumatoid arthritis, slipped capital femoral epiphysis, to name a few. These indications would be rare.	Jun 20, 2013 6:39 PM
5	youth trauma may require joint replacement, prostheses	Jun 20, 2013 1:00 PM
6	This is entirely arbitrary. Young patients are the least likely to have a diagnosis code of osteoarthritis.	Jun 20, 2013 8:13 AM

Page 9, Q10. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	Death is from comorbidities not the joint replacement	Jul 3, 2013 4:29 PM
2	Although very uncommon, death can happen, usually from cardiac, metabolic, or other underlying systemic issues that cannot be fully controlled by the surgeon or hospital. If they were, then why not warranty the medical physician's preoperatve medical clearance?	Jul 3, 2013 12:28 PM
3	cc	Jul 3, 2013 7:46 AM
4	xx	Jul 3, 2013 7:42 AM
5	Death can occur after any surgery and should not be included in a "warranty"	Jul 2, 2013 1:36 PM
6	Intraoperative and postoperative deaths are a known risk of surgery, regardless of type of surgery	Jul 1, 2013 2:44 PM
7	How are you determining whether or not the death was the results of the THA/TKA? Bleeding from VTE Prophylaxis, Sepsis, PN etc that results in death will be attributed ultimately to the THA/TKA? What about elderly patients with high comorbidity?	Jul 1, 2013 11:02 AM
8	Physicians and hospitals are not fully able to control all patient factors to prevent death	Jun 30, 2013 12:06 PM
9	What are parameters to assure that death was related to the replacements? There are deaths related to an unknown/underlying cardiac event that can occur during ANY surgery.	Jun 28, 2013 12:12 PM
10	Death is not a never event in some cases. If the pre operative work up was thorough and no error was made people will still die just as they do every day.	Jun 25, 2013 2:32 PM
11	People undergoing TJA are often elderly and may die. Determining that death occurred BECAUSE of TJA would be nearly impossible, and would be prone to debatable attribution of cause.	Jun 24, 2013 8:11 PM
12	If a patient passes following a total knee or hip surgery there were most likely other risk factors that lead to the patients passing that were unrelated to the surgerical procedure.	Jun 21, 2013 6:59 PM
13	Death as a complication of total joint replacement Is a very uncommon, and typically not related to the procedure (with the exception of fatal pulmonary embolism). For example, I don't see how a fatal MI can be blamed on the surgeon or hospital. Including this in the definition will have the unintended consequence higher risk patients being turned down for surgery. Cherry picking, anyone?	Jun 20, 2013 6:44 PM
14	"Attribution" will be very difficult. Death is rare after elective TJA but who gets to decide that the death is "attributable" to the surgery versus other comorbidities. This will make it impossible for anyone with comorbidities to have TJA as the risk to the facility and surgeon is unacceptable.	Jun 20, 2013 8:15 AM
15	A warranty that includes an incident that may occur without any ability on the part of the physician to prevent the incident is not reasonable for all stakeholders	Jun 19, 2013 5:20 PM

Page 9, Q10. If no, why? Please provide citations for evidence to support your opinion if possible.		
16	Stroke and death are complications that are unpredictable and rare. The control of these outcomes may not be always possible.	Jun 19, 2013 3:02 PM
17	Complications are unavoidable in arthroplasty surgery. There should not be a penalty for unavoidable complications!	Jun 19, 2013 12:23 PM
18	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total joint arthroplasties are older with medical comorbidities and are at a significantly increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not completely preventable events. In summary, the proposed warranty appears to be a mechanism for the State of Washington to avoid paying for between 4/10 of a percent and 2% of all total joint replacements. The consequence for patients would be that patients in a higher risk group would find receiving treatment to be increasingly difficult and many patients with medical comorbidities would probably find that care was not available because these events are only predictable in a statistical manner. The financial margin for joint replacement is low enough that even a small percentage loss makes the procedure impossible to perform. The question then becomes which statistical marker is used to reduce the risk of surgery. If you are 5 pounds over weight should you be excluded? Or perhaps being over age 60 or having diabetes will prevent a joint replacement. In spite of the variability of risks joint replacement surgery has	Jun 19, 2013 11:18 AM

Page 9, Q10. If no, why? Please provide citations for evidence to support your opinion if possible.		
	been demonstrated to improve the quality of life in all age groups and disease states that result in joint destruction. Certain specialty facilities that were only providing care to low risk patients would be unaffected and in fact, they are to some degree cherry picking already. The proposed criteria for warranty would also encourage increased invasive testing and evaluation in an attempt to avoid being penalized for what are otherwise virtually unpredictable medical events. The last problem is that physicians may find that practicing in Washington state is so onerous that they won't choose to provide care here. We certainly have seen other businesses leave states that have become hostile work places. I think that the goal of improving medical care is laudable; however, there is no cheap and easy fix. Three hundred years of scientific medicine has led to greater improvement than 5,000 years of tradition and magical thinking. Improvement in medicine requires continuous effort, measurement and reassessment, not superficial reflex action. While this process is expensive in the short term, the long term benefits have been proven for 3 centuries. If the state insists on reimbursement for these medical events they should buy insurance to cover the costs and pay for high quality research to improve the quality of care.	
19	Death, as with any complication, may occur despite no flaws in care. Penalizing providers who provide care or attempt to resuscitate a patient in extremis is essentially making a demand for free care.	Jun 19, 2013 11:00 AM

Page 11, Q12. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	Rare, but can happen.	Jul 3, 2013 12:29 PM
2	cc	Jul 3, 2013 7:46 AM
3	xx	Jul 3, 2013 7:42 AM
4	These can occur after any surgery and should not be included in a "warranty"	Jul 2, 2013 1:37 PM
5	There is always some risk of poor result.	Jul 1, 2013 2:45 PM
6	Yes if MD related. No if patient related (not following post-op instructions)	Jun 28, 2013 12:13 PM
7	I&D in the early post op period to drain a hematoma or a superficial infection can be necessary to prevent a deep infection later. This will occur in a small but definite percentage of patients. While I would not strongly object to withholding pay for the I&D, it should not prevent payment for the original procedure.	Jun 24, 2013 8:16 PM
8	mechanical complications may be due to the components provided by the vendors. hospitals, surgeons, anesthesiologists should not be penalized for that.	Jun 24, 2013 7:40 AM
9	There are always risks related to surgical procedures.	Jun 21, 2013 7:01 PM
10	An obese patient puts more stress on a component. This would limit access to obese patients.	Jun 20, 2013 8:16 AM
11	Mechanical complications is too broad if the purpose of the "warranty" is to not pay a surgeon if a patient has a mechanical complication. Accidents can and do happen despite proper medical care and clinical best practices being followed so the mechanical complications needs to be more clearly defined. IF a pt after THA falls and sustains a fracture that requires treatment ,the physician should expect to be paid for those services, however, if a patient dislocates due to component placement or the physician fractures the bone during insertion of a component, then the surgeon should correct the technical error and not expect full payment, under the 90 day global fee period	Jun 19, 2013 10:00 PM
12	***	Jun 19, 2013 5:21 PM
13	I think that mechanical complications may be attributable to the implant manufacturer not the surgeon or hospital.	Jun 19, 2013 3:02 PM
14	Complications occur in all surgeries - they are not eliminatable.	Jun 19, 2013 12:24 PM
15	Mechanical complications such as dislocation, as with any complication, may occur despite no flaws in care. for example, a patient who refuses to comply with precautions, and subsequently dislocates a hip, would be the responsible party, rather than the clinician. Penalizing providers who provide care is essentially making a demand for free care.	Jun 19, 2013 11:02 AM

Page 13, Q14. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	Rare, but can happen due to reasons outside the control of surgeon or hospital.	Jul 3, 2013 12:30 PM
2	xx	Jul 3, 2013 7:42 AM
3	Infection can occur after any surgery despite all prophylactic measures and should not be included in a "warranty"	Jul 2, 2013 1:37 PM
4	This is medicine not an automobile	Jul 1, 2013 2:46 PM
5	Surgical site infection is often caused by patient factors not under our control.	Jun 30, 2013 2:26 PM
6	Yes if MD/facility related. No if patient behavior related.	Jun 28, 2013 12:13 PM
7	You are going to create a situation where many people will be denied access to care because of the fear of an infection. Even if you do everyting perfectly there will still be infections so infection is not a never event. I suspect the unintended consequence of this will be many people will not have access to joint replacement.	Jun 25, 2013 2:36 PM
8	Infection occurs in a small but definite % of patients in every large series. While careful protocols to minimize this risk are important, there can be no guarantee that this will not occur in any individual, especially if they are at increased risk.	Jun 24, 2013 8:20 PM
9	Risk of infections are a part of any surgical procedure. Physicians and Hospital's with higher than average infection rates chould be subject to a financial penalty.	Jun 21, 2013 7:03 PM
10	Infection is not entirely preventable by the surgeon and may not be due to his or her actions. Infection above a certain rate would be something that could be fair.	Jun 20, 2013 5:08 PM
11	Some classes of patients are at increased risk for infection including those with Diabetes, poor dentition, prior history of infection. These patients would no longer have access to TJA.	Jun 20, 2013 8:17 AM
12	it depends, if the infection is due to an unrelated medical complication, ie, patient gets pneumonia after the 7 day global and that pneumonia leads to sepsis that then secondarily infects the prosthetic joint, the surgeon and hospital should expect to be paid for services in an effort to irradicate the infection.	Jun 19, 2013 10:05 PM
13	Infection can occur despite all the best practices and best work by the doctors and the hospital and can be influenced by patient behavior. The warranty should not include infections	Jun 19, 2013 5:24 PM
14	While the purpose and goals of the warranty are aimed in the right direction, including events that occur even in the best case of care, creates unfair burdens on the hospitals and physicians. Every surgeon who has performed large numbers of replacements experiences some cases of bleeding, infection, and emboli, that occur despite extensive pre-op workup, and prevention, correct surgical technique, and approiate aftercare. Yet these events still occur as described in the litature to a certain degree. Having consequences for these events does steer health care toward correct and common goals, but the reality is that there is still some occurence. Instead of defining these as never events, the criteria should be an allowable number that matches national data. For example if infection after TKA is 1%, then the hosptal of physcian should be	Jun 19, 2013 3:15 PM

Page 13, Q14. If no, why? Please provide citations for evidence to support your opinion if possible.		
	required to practice in this range. If greater than the average then additional rembersment should be limited, similar to your description. However if the facility or physician has occurances in line with that described in the litature and national data, then they would be exempt. This seems the proper way to achieve your goals and practice in the real world. As the data does not support zero.	
15	I would modify this to allow payment for periprosthetic infection at a reasonable incidence level (0.5-1%) since it is not proven or possible at this point to get to zero infections.	Jun 19, 2013 3:02 PM
16	Can never reduce infection risk to zero.	Jun 19, 2013 12:24 PM
17	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total joint arthroplasties are older with medical comorbidities and are at a significantly increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not completely preventable events. In summary, the proposed warranty appears to be a mechanism for the State of Washington to avoid paying for between 4/10 of a percent and 2% of all total joint replacements. The consequence for patients would be that patients in a higher risk group would find receiving treatment to be increasingly difficult and many patients with medical comorbidities would	Jun 19, 2013 11:19 AM

Page 13, Q14. If no, why? Please provide citations for evidence to support your opinion if possible.		
	probably find that care was not available because these events are only predictable in a statistical manner. The financial margin for joint replacement is low enough that even a small percentage loss makes the procedure impossible to perform. The question then becomes which statistical marker is used to reduce the risk of surgery. If you are 5 pounds over weight should you be excluded? Or perhaps being over age 60 or having diabetes will prevent a joint replacement. In spite of the variability of risks joint replacement surgery has been demonstrated to improve the quality of life in all age groups and disease states that result in joint destruction. Certain specialty facilities that were only providing care to low risk patients would be unaffected and in fact, they are to some degree cherry picking already. The proposed criteria for warranty would also encourage increased invasive testing and evaluation in an attempt to avoid being penalized for what are otherwise virtually unpredictable medical events. The last problem is that physicians may find that practicing in Washington state is so onerous that they won't choose to provide care here. We certainly have seen other businesses leave states that have become hostile work places. I think that the goal of improving medical care is laudable; however, there is no cheap and easy fix. Three hundred years of scientific medicine has led to greater improvement than 5,000 years of tradition and magical thinking. Improvement in medicine requires continuous effort, measurement and reassessment, not superficial reflex action. While this process is expensive in the short term, the long term benefits have been proven for 3 centuries. If the state insists on reimbursement for these medical events they should buy insurance to cover the costs and pay for high quality research to improve the quality of care.	
18	Infection is a multi-factorial event. Again, penalizing providers for this does not address factors out of the clinician's control, such as smoking, BMI, living environment, level of personal hygiene.	Jun 19, 2013 11:04 AM

Page 15, Q16. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	cc	Jul 3, 2013 7:46 AM
2	xx	Jul 3, 2013 7:42 AM
3	Infection can occur after any surgery and should not be included in a "warranty"	Jul 2, 2013 1:37 PM
4	Wound infections are a known risk of surgery	Jul 1, 2013 2:47 PM
5	Not all surgical site infections are under surgeons control. We can be ultraselective and avoid high risk patients. Insurers can defer patient denials to doctors. If we have to warranty patients from infection then very few patients will get treatment. It is a clever form of rationing in my opinion	Jun 30, 2013 2:30 PM
6	Yes if MD/facility related No if patient related (IV drug use as one extreme example, poor post-op care)	Jun 28, 2013 12:14 PM
7	See my previous answer. The unintended consequence will be many patients will lose access to TJR. A better solution is to publish infection rates of hospitals and doctors	Jun 25, 2013 2:37 PM
8	Infection occurs in a small but definite % of patients in every large series. While careful protocols to minimize this risk are important, there can be no guarantee that this will not occur in any individual, especially if they are at increased risk.	Jun 24, 2013 8:21 PM
9	wound infection may be due to multiple factors NOT under the control of the hospital, surgeon, and anesthesiologist, e.g. wound care after surgery (including self-care at home, or at a nursing facility post-discharge from the hospital)	Jun 24, 2013 7:42 AM
10	Too much outside the control of the physician, hospital. Too many unkn	Jun 22, 2013 6:22 AM
11	no comment	Jun 21, 2013 7:04 PM
12	Infection is not entirely preventable by the surgeon and may not be due to his or her actions. Infection above a certain rate would be something that could be fair.	Jun 20, 2013 5:08 PM
13	See previous response	Jun 20, 2013 8:17 AM
14	wound infections are often caused by patient behavior and habitus which are unable to be controlled by the physician and hospital. A warranty may exclude these patients from the ability to obtain a joint replacement	Jun 19, 2013 5:25 PM
15	While the purpose and goals of the warranty are aimed in the right direction, including events that occur even in the best case of care, creates unfair burdens on the hospitals and physicians. Every surgeon who has performed large numbers of replacements experiences some cases of bleeding, infection, and emboli, that occur despite extensive pre-op workup, and prevention, correct surgical technique, and approiate aftercare. Yet these events still occur as described in the litature to a certain degree. Having consequences for these events does steer health care toward correct and common goals, but the reality is that there is still some occurence. Instead of defining these as never events, the criteria should be an allowable number that matches national data. For example if infection after TKA is 1%, then the hosptal of physcian should be required to practice in this range. If greater than the average then additional rembersment should be limited, similar to your description. However if the	Jun 19, 2013 3:15 PM

Page 15, Q16. If no, why? Please provide citations for evidence to support your opinion if possible.		
	facility or physician has occurances in line with that described in the litature and national data, then they would be exempt. This seems the proper way to achieve your goals and practice in the real world. As the data does not support zero.	
16	I would once again qualify the level of incidence that is acceptable to be paid for since we cannot, as yet, achieve zero wound infections. Also, if a patient falls down at home, or a physical therapist manipulates and extremity leading to a wound complication as an outpatient, should this be covered by the warranty?	Jun 19, 2013 3:02 PM
17	Can never prevent all wound infections	Jun 19, 2013 12:24 PM
18	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total joint arthroplasties are older with medical comorbidities and are at a significantly increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not completely preventable events. In summary, the proposed warranty appears to be a mechanism for the State of Washington to avoid paying for between 4/10 of a percent and 2% of all total joint replacements. The consequence for patients would be that patients in a higher risk group would find receiving treatment to be increasingly difficult and many patients with medical comorbidities would probably find that care was not available because these events are only	Jun 19, 2013 11:19 AM

Page 15, Q16. If no, why? Please provide citations for evidence to support your opinion if possible.		
	predictable in a statistical manner. The financial margin for joint replacement is low enough that even a small percentage loss makes the procedure impossible to perform. The question then becomes which statistical marker is used to reduce the risk of surgery. If you are 5 pounds over weight should you be excluded? Or perhaps being over age 60 or having diabetes will prevent a joint replacement. In spite of the variability of risks joint replacement surgery has been demonstrated to improve the quality of life in all age groups and disease states that result in joint destruction. Certain specialty facilities that were only providing care to low risk patients would be unaffected and in fact, they are to some degree cherry picking already. The proposed criteria for warranty would also encourage increased invasive testing and evaluation in an attempt to avoid being penalized for what are otherwise virtually unpredictable medical events. The last problem is that physicians may find that practicing in Washington state is so onerous that they won't choose to provide care here. We certainly have seen other businesses leave states that have become hostile work places. I think that the goal of improving medical care is laudable; however, there is no cheap and easy fix. Three hundred years of scientific medicine has led to greater improvement than 5,000 years of tradition and magical thinking. Improvement in medicine requires continuous effort, measurement and reassessment, not superficial reflex action. While this process is expensive in the short term, the long term benefits have been proven for 3 centuries. If the state insists on reimbursement for these medical events they should buy insurance to cover the costs and pay for high quality research to improve the quality of care.	
19	Infection is a multi-factorial event. Again, penalizing providers for this does not address factors out of the clinician's control, such as smoking, BMI, living environment, level of personal hygiene.	Jun 19, 2013 11:04 AM

Page 17, Q18. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	Patients with cardiac related issues, pacemakers, stents, prior DVT or PE, may require heavy anticoagulation use post op, such as Lovenox. This can allow joints to bleed through no fault of surgeon or hospital.	Jul 3, 2013 12:31 PM
2	xx	Jul 3, 2013 7:42 AM
3	Bleeding is normal at a surgical site postoperatively and should not be included under a warranty	Jul 2, 2013 1:38 PM
4	Surgical bleeding is almost always guaranteed. If it is really surgery	Jul 1, 2013 2:48 PM
5	Surgical site bleeding occurs in every total joint replacement. It is problematic in a small percentage. A large part of this is affected by patient factors. While careful hemostasis is important, factors under the surgeon's control are only one part of cause of potential surgical site bleeding.	Jun 24, 2013 8:25 PM
6	nocomment	Jun 21, 2013 7:04 PM
7	Bleeding risk is directly proportional to the aggressiveness of anti-coagulation. Anti-coagulation regulations are mandated by CMS and thus would increase the risk of bleeding especially with THA where aggressive injection anti-coagulation is mandated unless a spinal anesthetic is done. In addition, no one will operate on anyone with a prior history or family history of bleeding, coagulation disorders or chronic anticoagulation such as after a stroke.	Jun 20, 2013 8:19 AM
8	While the purpose and goals of the warranty are aimed in the right direction, including events that occur even in the best case of care, creates unfair burdens on the hospitals and physicians. Every surgeon who has performed large numbers of replacements experiences some cases of bleeding, infection, and emboli, that occur despite extensive pre-op workup, and prevention, correct surgical technique, and approiate aftercare. Yet these events still occur as described in the litature to a certain degree. Having consequences for these events does steer health care toward correct and common goals, but the reality is that there is still some occurence. Instead of defining these as never events, the criteria should be an allowable number that matches national data. For example if infection after TKA is 1%, then the hosptal of physcian should be required to practice in this range. If greater than the average then additional rembersment should be limited, similar to your description. However if the facility or physician has occurances in line with that described in the litature and national data, then they would be exempt. This seems the proper way to achieve your goals and practice in the real world. As the data does not support zero.	Jun 19, 2013 3:15 PM
9	There should be a reasonable level of coverage for a reasonable incidence, since DVT prophylaxis results in a baseline incidence of bleeding complications that may be unavoidable.	Jun 19, 2013 3:02 PM
10	Can never prevent all bleeding	Jun 19, 2013 12:25 PM
11	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general,	Jun 19, 2013 11:20 AM

Page 17, Q18. If no, why? Please provide citations for evidence to support your opinion if possible.

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Page 17, Q18. If no, why? Please provide citations for evidence to support your opinion if possible.		
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12	Surgical bleeding is an inevitable possible consequence of aggressive anticoagulation. You cannot insist on 100% adherence to VTE prophylaxis, and not expect up to a 4% incidence of major bleeding; the most recent Chest physician guidelines note that the risk of bleeding approximates the risk of VTE.	Jun 19, 2013 11:07 AM

Page 19, Q20. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	Can happen. Not in complete control. Too many patient variables.	Jul 3, 2013 12:33 PM
2	xx	Jul 3, 2013 7:41 AM
3	PE can occur after a surgery such as TKA and THA and should not be included in a "warranty"	Jul 2, 2013 1:39 PM
4	There is good data that shows no matter what we use as chemical DVT prophylaxis the rate of symptomatic PE after THA/TKA surgery remains the same (roughly 0.3 to 1% based on what study you read). Since this is a known possible complication with a very low incidence that virtually impossible to eliminate as a possibility then why should physicians and hospitals have to treat it "for free" in the postop phase. In other words, no matter how fastidious we may be in selecting patients pre-op and treating patients peri-op with DVT prophylaxis meds this postop complication cannot always be prevented.	Jul 2, 2013 7:15 AM
5	It is a known risk of surgery	Jul 1, 2013 2:49 PM
6	Even with prophylaxis, there is a small probability of PE. Some patients are too high risk of bleeding to prophylax	Jun 30, 2013 10:02 PM
7	Not MD or facility controllable	Jun 28, 2013 12:14 PM
8	Pulmonary embolism occurs in a very tiny percentage of patients even with the best possible VTE prophylaxis measures. Why should the surgeon be penalized for results that are outside of his control?	Jun 24, 2013 8:28 PM
9	All measures are to "REDUCE" such complications, NOTHING guarantees "PREVENTIONS". Thus to be penalized for these complications when they will occur no matter what, is unreasonable.	Jun 24, 2013 7:44 AM
10	These are generally unrelated to the surgical procedure.	Jun 21, 2013 7:05 PM
11	Pulmonary embolism is not entirely preventable by the surgeon and may not be due to his or her actions.PE above a certain rate would be something that could be fair.	Jun 20, 2013 5:09 PM
12	Some patients are at increased risk due to family or personal history of PE, coaguation disorders. These patients would not have access to TJA. Additionally, efforts to decrease the risk of PE directly increase the risk of bleeding complications. So which complication are you going to have try the hardest to avoid? All patients with the least bit of increased risk would be avoided by hospitals and surgeons and they would not have access to TJA.	Jun 20, 2013 8:43 AM
13	only in cases where dvt prophylaxis regimens were not followed nor documented	Jun 19, 2013 10:06 PM
14	s	Jun 19, 2013 5:26 PM
15	While the purpose and goals of the warranty are aimed in the right direction, including events that occur even in the best case of care, creates unfair burdens on the hospitals and physicians. Every surgeon who has performed large numbers of replacements experiences some cases of bleeding, infection, and emboli, that occur despite extensive pre-op workup, and prevention, correct surgical technique, and approiate aftercare. Yet these events still occur as	Jun 19, 2013 3:15 PM

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16	Since the incidence of this complication is not zero in the best practices, there should be payment coverage for treatment below some level of predictable incidence.	Jun 19, 2013 3:02 PM
17	PE's happen even in setting of apprpriate prophylaxis use	Jun 19, 2013 12:25 PM
18	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total joint arthroplasties are older with medical comorbidities and are at a significantly increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not	Jun 19, 2013 11:20 AM

Page 19, Q20. If no, why? Please provide citations for evidence to support your opinion if possible.

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19	simply demanding that PEs never happen is not a realistic viewpoint. Even in the face of full compliance with VTE prophylaxis, a certain number of patients will suffer an event - 4% according to the most recent Chest guidelines	Jun 19, 2013 11:08 AM

Page 21, Q22. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	same as prior question	Jul 3, 2013 12:37 PM
2	xx	Jul 3, 2013 7:41 AM
3	AMI is a known complication around the time of surgery.	Jul 2, 2013 1:39 PM
4	same reasoning i have included for PE. unless a physician fails to get appropriate pre-op medical/cardiac clearance then why should we be penalized for something that is unpredictable and cannot be totally eliminated as a postop risk.	Jul 2, 2013 7:16 AM
5	Known risk	Jul 1, 2013 2:49 PM
6	Concern on how this will be worded- does patient have prior HX of cardiovascular disease? Same with PE- does the patient have prior hx and was the recommended treatment for prophylaxis followed?	Jul 1, 2013 11:04 AM
7	MI risk exists even with proper management	Jun 30, 2013 10:03 PM
8	Not MD/facility controllable	Jun 28, 2013 12:14 PM
9	Acute MI occurs in a population of patients in the age group for TJA whether they undergo surgery or not. Appropriate pre-op screening is important, but its occurrence cannot always be predicted even then. Even if related to the surgery, the anesthesiologist probably has a greater influence on the hemodynamic factors likely to precipitate an MI than the surgeon does.	Jun 24, 2013 8:32 PM
10	All measures are to "REDUCE" such complications, NOTHING guarantees "PREVENTIONS", so to be penalized for these complications when they will occur no matter what, is unreasonable.	Jun 24, 2013 7:44 AM
11	Physicians would not perform surgeries on patient's with heart problems if they were penalized if the patient had a MI.	Jun 21, 2013 7:06 PM
12	Unless proper preventive care has not been utilized (beta blockers, for example) then I don't see this as an "avoidable" complication. Same with DVT and PE.	Jun 20, 2013 6:47 PM
13	Myocardial infarction cannot be held against the surgeon in most cases, and would force surgeons to turn away certain patients. In addition some practices see sicker patients than others and there would have to be risk adjustment.	Jun 20, 2013 5:11 PM
14	AMI most likely complication of preexisting condition	Jun 20, 2013 1:03 PM
15	MI is secondary to pre-existing condition ie CAD	Jun 20, 2013 11:22 AM
16	Patients with any history of CAD, HTN or a family history of such would be an unacceptable risk for TJA. If you have had a prior MI or stent you would no longer be a candidate for TJA. Too bad for you. Sorry your knee hurts.	Jun 20, 2013 8:45 AM
17	pts can and will have cardiopulmonary complications despite being "cleared" for surgery and considered medically suitable by their cardiologist prior to undergoing TKR/THR	Jun 19, 2013 10:08 PM
18	0*	Jun 19, 2013 5:26 PM

Page 21, Q22. If no, why? Please provide citations for evidence to support your opinion if possible.		
19	The incidence of this is low, and standard screening for cardiac disease may not prevent this. Again there is some baseline incidence that we have no control over.	Jun 19, 2013 3:02 PM
20	Cant eliminate all MI risk	Jun 19, 2013 12:26 PM
21	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total joint arthroplasties are older with medical comorbidities and are at a significantly increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not completely preventable events. In summary, the proposed warranty appears to be a mechanism for the State of Washington to avoid paying for between 4/10 of a percent and 2% of all total joint replacements. The consequence for patients would be that patients in a higher risk group would find receiving treatment to be increasingly difficult and many patients with medical comorbidities would probably find that care was not available because these events are only predictable in a statistical manner. The financial margin for joint replacement is low enough that even a small percentage loss makes the procedure impossible to perform. The question then becomes which statistical marker is used to reduce the risk of surgery. If you are 5 pounds over weight should you be excluded? Or perhaps being over age 60 or having diabetes will prevent a joint replacement. In spite of the variability of risks joint replacement surgery has	Jun 19, 2013 11:21 AM

Page 21, Q22. If no, why? Please provide citations for evidence to support your opinion if possible.		
	been demonstrated to improve the quality of life in all age groups and disease states that result in joint destruction. Certain specialty facilities that were only providing care to low risk patients would be unaffected and in fact, they are to some degree cherry picking already. The proposed criteria for warranty would also encourage increased invasive testing and evaluation in an attempt to avoid being penalized for what are otherwise virtually unpredictable medical events. The last problem is that physicians may find that practicing in Washington state is so onerous that they won't choose to provide care here. We certainly have seen other businesses leave states that have become hostile work places. I think that the goal of improving medical care is laudable; however, there is no cheap and easy fix. Three hundred years of scientific medicine has led to greater improvement than 5,000 years of tradition and magical thinking. Improvement in medicine requires continuous effort, measurement and reassessment, not superficial reflex action. While this process is expensive in the short term, the long term benefits have been proven for 3 centuries. If the state insists on reimbursement for these medical events they should buy insurance to cover the costs and pay for high quality research to improve the quality of care.	
22	Major complications such as AMI are essentially black swan events, and cannot be predicted.	Jun 19, 2013 11:09 AM

Page 23, Q24. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	same as prior	Jul 3, 2013 12:37 PM
2	xx	Jul 3, 2013 7:57 AM
3	xx	Jul 3, 2013 7:41 AM
4	Pneumonia should not be included in a warranty and is a known complication	Jul 2, 2013 1:39 PM
5	Known risk	Jul 1, 2013 2:50 PM
6	Not MD/facility controllable all the time If you continue to make these items under the warranty, sicker patients will simply be denied care as they will be too risky for the MD/facility to treat.	Jun 28, 2013 12:15 PM
7	ff	Jun 28, 2013 8:54 AM
8	Pneumonia would not usually be related to a TJA but to other factors related to the patient's medical condition, unless the patient were left in bed for an extended and inappropriate period of time.	Jun 24, 2013 8:35 PM
9	All measures are to "REDUCE" such complications, NOTHING guarantees "PREVENTIONS", so to be penalized for these complications when they will occur no matter what, is unreasonable.	Jun 24, 2013 7:44 AM
10	No comment.	Jun 21, 2013 7:07 PM
11	As 3 a , or as a result of of other factors not associated with the procedure or implant	Jun 20, 2013 1:05 PM
12	Too distant - not really related	Jun 20, 2013 11:22 AM
13	Again, anyone with risk factors for pneumonia such as prior history or prior lung injury would be screened out and not offered TJA.	Jun 20, 2013 8:46 AM
14	Seems wrong	Jun 20, 2013 7:12 AM
15	*	Jun 19, 2013 5:26 PM
16	Pneumonia may result from aspiration during induction and may be more related to anesthesia practice rather than complication related to the surgical procedure/delay in mobilizing after surgical procedure	Jun 19, 2013 1:45 PM
17	Cannot eliminate all risk	Jun 19, 2013 12:26 PM
18	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free	Jun 19, 2013 11:21 AM

Page 23, Q24. If no, why? Please provide citations for evidence to support your opinion if possible.

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Page 23, Q24. If no, why? Please provide citations for evidence to support your opinion if possible.		
	insurance to cover the costs and pay for high quality research to improve the quality of care.	
19	Complications such as pneumonia can occur despite flawless care.	Jun 19, 2013 11:10 AM

Page 25, Q26. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	same as prior	Jul 3, 2013 12:37 PM
2	xx	Jul 3, 2013 7:41 AM
3	Sepsis can occur after any surgery and should not be included in a "warranty"	Jul 2, 2013 1:40 PM
4	same reasoning as PE and MI	Jul 2, 2013 7:16 AM
5	Known risk	Jul 1, 2013 2:50 PM
6	Only sepsis clearly attributable to lack of appropriate f/u of a SSI	Jul 1, 2013 11:06 AM
7	See prior comments.	Jun 28, 2013 12:15 PM
8	See my answer to 11 and 12	Jun 25, 2013 2:38 PM
9	Sepsis would not usually be related to a TJA but to other factors related to the patient's medical condition.	Jun 24, 2013 8:36 PM
10	same reason for "wound infections"	Jun 24, 2013 7:47 AM
11	no comment	Jun 21, 2013 7:08 PM
12	As 3b	Jun 20, 2013 1:06 PM
13	see above	Jun 20, 2013 8:47 AM
14	*	Jun 19, 2013 5:27 PM
15	This consideration affects immunocompromised patients at higher risk, such as patients with HIV. If it is included then their care must be handled outside of a bundle.	Jun 19, 2013 2:52 PM
16	Cannot eliminate all risk	Jun 19, 2013 12:26 PM
17	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total joint arthroplasties are older with medical comorbidities and are at a significantly	Jun 19, 2013 11:21 AM

Page 25, Q26. If no, why? Please provide citations for evidence to support your opinion if possible.		
	increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not completely preventable events. In summary, the proposed warranty appears to be a mechanism for the State of Washington to avoid paying for between 4/10 of a percent and 2% of all total joint replacements. The consequence for patients would be that patients in a higher risk group would find receiving treatment to be increasingly difficult and many patients with medical comorbidities would probably find that care was not available because these events are only predictable in a statistical manner. The financial margin for joint replacement is low enough that even a small percentage loss makes the procedure impossible to perform. The question then becomes which statistical marker is used to reduce the risk of surgery. If you are 5 pounds over weight should you be excluded? Or perhaps being over age 60 or having diabetes will prevent a joint replacement. In spite of the variability of risks joint replacement surgery has been demonstrated to improve the quality of life in all age groups and disease states that result in joint destruction. Certain specialty facilities that were only providing care to low risk patients would be unaffected and in fact, they are to some degree cherry picking already. The proposed criteria for warranty would also encourage increased invasive testing and evaluation in an attempt to avoid being penalized for what are otherwise virtually unpredictable medical events. The last problem is that physicians may find that practicing in Washington state is so onerous that they won't choose to provide care here. We certainly have seen other businesses leave states that have become hostile work places. I think that the goal of improving medical care is laudable; however, there is no cheap and easy fix. Three hundred years of scientific medicine has led to greater improvement than 5,000 years of tradition and magical thinking. Improvement in medicine requires continuous effort, measurement and reassessment, not superficial reflex action. While this process is expensive in the short term, the long term benefits have been proven for 3 centuries. If the state insists on reimbursement for these medical events they should buy insurance to cover the costs and pay for high quality research to improve the quality of care.	
18	Major complications are rare and unpredictable events.	Jun 19, 2013 11:10 AM

Page 26, Q27. Are there any other complications that you believe should be added to this list? If so, why?		
1	no	Jul 3, 2013 12:38 PM
2	xx	Jul 3, 2013 8:00 AM
3	no	Jul 3, 2013 7:41 AM
4	No	Jun 30, 2013 10:08 PM
5	mm	Jun 28, 2013 8:54 AM
6	Stroke	Jun 23, 2013 4:08 PM
7	none	Jun 21, 2013 7:08 PM
8	I would remove medical complications as too broad and undefined.	Jun 21, 2013 7:16 AM
9	no	Jun 20, 2013 5:11 PM
10	DVT without PE	Jun 20, 2013 1:06 PM
11	There should be an 'out' clause for a patient induced complication for instance refusing to do rehab etc	Jun 20, 2013 11:23 AM
12	No	Jun 20, 2013 8:47 AM
13	device rejection	Jun 20, 2013 7:12 AM
14	no, surgery even in the best of circumstances, all precautions being, taken, and with the most conservative selection criteria will have complications. Surgery has risks and the collaborative can not set the expectation or bar to be one of perfection or zero tolerance for complications as that will reduce access to care for the sickest patients and those who need care the most for fear of financial retribution should anything unforseen happen despite best intentions	Jun 19, 2013 10:11 PM
15	none	Jun 19, 2013 5:27 PM
16	No	Jun 19, 2013 3:16 PM
17	no - complications happen and you cant eliminate all risk associated with surgery	Jun 19, 2013 12:27 PM
18	I think that the only things can can be warranteed are controllable events that can be eliminated by the actions of the individual or group that has the financial liability. Including problems that are not preventable is just a scam to avoid paying for service rendered and will like serve to prevent people who could benefit from joint replacement, but who have medical co-morbidities from receiving surgery. Most of the medical complications listed are more of a reflection the the patients primary care than the joint replacement.	Jun 19, 2013 11:26 AM

Page 28, Q29. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	this is flat out crazy. we are talking about human beings and surgery...not auto mechanics.	Jul 3, 2013 12:39 PM
2	cc	Jul 3, 2013 8:01 AM
3	xx	Jul 3, 2013 7:41 AM
4	Patients are not buying a vehicle here. This is medicine and while every effort can be taken to minimize risk, complications can occur at any stage postoperatively. A warranty period does nothing to change the known risk of surgery and only makes it more difficult for patients to access care.	Jul 2, 2013 1:43 PM
5	No warranty has been implied	Jul 1, 2013 2:52 PM
6	What responsibility does the patient have to properly follow directions postop to prevent infection or dislocation?	Jun 30, 2013 10:18 PM
7	My problem as stated in 11 12 and perhaps 18 is with infection	Jun 25, 2013 2:39 PM
8	Mechanical complications related to malposition of the components might be appropriately covered. As previously noted, even with the very best of practices, infections can not be entirely prevented.	Jun 24, 2013 8:43 PM
9	Believe that 7 days should also include death and several of those that are listed in the 30 day period (i.e.,surgical site bleeding, wound infection, pulmonary embolism) What type of warranty is given between 90 days and 10 years. It seems that mechanical complications should be covered from 90 days to 10 years. Think that Loosening should be part of the mechanical complications and be part of the warranty.	Jun 23, 2013 4:13 PM
10	no comment	Jun 21, 2013 7:09 PM
11	I disagree with all of this. This does not make any sense. The risk for PE, for example, extends beyond 30 days. I treat patients for 6 weeks after TJA to reduce the risk of PE. I disagree with the entire concept but 30 days is arbitrary. The risk for periprosthetic joint infection is life-long. I suspect there will be a spike in "late" periprosthetic joint infections that occur just after 90 days ... this system provides a disincentive to aggressively diagnosis and treat an infection as soon as possible.	Jun 20, 2013 8:51 AM
12	12 month	Jun 20, 2013 7:13 AM
13	For the first trial of the warranty, a shorter time frame may induce more buy in.	Jun 19, 2013 3:03 PM
14	Cannot eliminate the risks, period.	Jun 19, 2013 12:27 PM
15	Mechanical is the only preventable hence warantable event. Infectipon is not preventable and represents a scam.	Jun 19, 2013 11:27 AM
16	Other than reimbursement issues, there is nothing particularly magical about a 90 day period.	Jun 19, 2013 11:11 AM

Page 30, Q31. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	This is crazy too. patients have a huge range of variables including body habitus and activity leve. there are no garantees on performance of implants.	Jul 3, 2013 12:41 PM
2	cc	Jul 3, 2013 8:01 AM
3	xx	Jul 3, 2013 7:41 AM
4	previously stated	Jul 2, 2013 1:44 PM
5	over 10 years we know there is a risk of implant failure that cannot always be attributed to surgical technique. what about patients who are involved in unavoidable accidents (MVA's, falls, or other trauma) within 10 years who need revision surgery - how can we as surgeons possibly foresee or predict those cases? of course i see the goal for being very stringent with patient selection pre-op but complete warranty for 10 years is excessive.	Jul 2, 2013 7:19 AM
6	No implied warrantee.	Jul 1, 2013 2:52 PM
7	Why should the physician and hospital have responsibility for a design or manufacturing defect or mechanical mistake	Jun 30, 2013 10:21 PM
8	Need more evidence from vendors on longitudial use prior to commenting.	Jun 28, 2013 12:16 PM
9	1. Difficulty in assigning fault to the provider. 2. How would you collect on the warranty 10 years later?? 3. "Disruption?" Do you mean fracture? That should certainly NOT be covered. 4. Loosening is probably related to design. This actually IS at least partly in the control of the surgeon, at least in some cases. * LOOSENING should be warrantied by the manufacturer as they continue to provide high cost "new idea" prosthetics which are more expensive, and frequently show inferior wear and loosening characteristics.	Jun 24, 2013 8:49 PM
10	I don't know what the implant manufactures guarantee? This should be standard to what the suppliers can stand up to.	Jun 24, 2013 7:48 AM
11	Failure can occur prior to 10 years and I also believe that hardware loosening should be included in the warranty. The loosening could be situational dependent but does impact the patient in terms of reliability against complete failure. I would think it would be stressful to think it could lead to a fall,etc.	Jun 23, 2013 4:16 PM
12	Implants wear our just like healty knees and hips.	Jun 21, 2013 7:09 PM
13	The surgeon can't control what activities that the patient may undertake that would be outside of the normal limits of a joint replacement	Jun 21, 2013 10:45 AM
14	10 years, especially in the elderly constitutes a prolonged period that may have other issues associated with the failure.	Jun 21, 2013 7:17 AM
15	current materials, materials science, and surgical procedures should provide at least 20 years	Jun 20, 2013 1:08 PM
16	Why is the surgeon being held responsible for mechanical failure of the implant? Is the surgeon able to control manufacturing quality or issues? If the surgeon does not assemble something correctly and it fails we have a tort system to address it.	Jun 20, 2013 8:53 AM

Page 30, Q31. If no, why? Please provide citations for evidence to support your opinion if possible.		
17	physical disruption should exclude wear of the bearing requiring liner exchange as this occurrence is typically dependent on patient compliace with activity restrictions after TKR, THR, otherwise 10 yr warranty for actual implant failure, ie breakage of the implant seems reasonable, but why doesn't this financial burden fall back to the implant manufactuer to issue a warranty against this failure and share the fiscal and moral responsibility to ensure patient safety	Jun 19, 2013 10:15 PM
18	This will slow use of new devices or procedures, if concern for future treatment of complications is a factor in medical decision making. Again while the aim of having implants last longer than 10 years is a common and realistic goal. Lets not create barriers to inovation.	Jun 19, 2013 3:19 PM
19	We dont understand all the causes for failure, so there shouldn't be a penalty for failure	Jun 19, 2013 12:28 PM
20	The warrantee does not account for patient behaviors. There is a low level of prosthetic failure unrelated to poor design, poor implantation or other controllable event.	Jun 19, 2013 11:29 AM
21	Disregards potential design flaws in implants, disregards patient activity, disregards potential idiosyncratic reactions such as ALVAL/ALTR	Jun 19, 2013 11:12 AM

Page 32, Q33. If no, why? Please provide citations for evidence to support your opinion if possible.		
1	agree with #2, but this doesn't always work.	Jul 3, 2013 12:42 PM
2	dc	Jul 3, 2013 8:02 AM
3	If a patient has surgery at hospital A, then at some point notices that their wound is infected or they got acutely ill and is then brought to hospital B, and appropriate care is initiated, why should hospital A pay the financial expenses for care at hospital B?	Jul 2, 2013 1:49 PM
4	this will be impossible to administer between hospitals and/or surgeons. hoping that we would "negotiate" an agreement is overly optimistic. even if there are guidelines for penalties i doubt that surgeons and hospitals will agree to make payments and will argue why their case is an exception.	Jul 2, 2013 7:20 AM
5	The patient is free to seek care wherever they think is best for them	Jul 1, 2013 2:54 PM
6	Very difficult to force one hospital to "pay" for care at another facility when the cost of care isn't the same at the two facilities. It also limits patient choice. Are we holding the manufacturer of the implant liable or just the hospitals/surgeons?	Jul 1, 2013 11:09 AM
7	I can't see how a referring hospital will be able to manage the costs of care at another facility with their cost shifting mechanisms which may work with insurance companies that can level costs by disallowing expenses or establishing write offs. I don't know how a regional facility can stay in business if it must be financially responsible	Jul 1, 2013 7:43 AM
8	We can advise the patient to call us, go to their index hospital, etc...but often they will not follow this information. The patient needs to understand that the warranty is applicable only if they go to the index hospital.	Jun 28, 2013 12:17 PM
9	What if the second hospital performs a surgery that though not malpractice is something at the edge of acceptable and wouldn't have been performed at the first institution and believe me this occurs	Jun 25, 2013 2:40 PM
10	Agree with 2. 3 would be a nightmare.	Jun 24, 2013 8:51 PM
11	No comment	Jun 21, 2013 7:10 PM
12	The initial hospital involved should have first opportunity in these situations to deal with the complications - it should be mutual agreement between the facility and patient on seeking care with another institution outside of the system.	Jun 21, 2013 7:19 AM
13	I have had to take care of complications from other surgeons. I usually make an attempt to get the patients back to their original surgeon but this is not always possible or safe. This sounds like a recipe for dumping patients or refusing care. This is not safe or ethical. In addition, if a patient from another facility shows up at my hospital I will be incentivized to be sure to blame the other surgeon or facility so that I will be protected and paid. Additionally, blaming someone else is a great way to punish competition. What a great way to incite hatred amongst surgeons and hospitals!	Jun 20, 2013 8:56 AM
14	If there is a warranty then the patient should be required to go to the hospital that provides the warranty or the warranty is voided	Jun 19, 2013 5:29 PM

Page 32, Q33. If no, why? Please provide citations for evidence to support your opinion if possible.		
15	I would recommend requiring any further treatment at the index hospital, unless it is an urgent or emergent problem.	Jun 19, 2013 3:04 PM
16	I dont agree with the concept of a warranty	Jun 19, 2013 12:29 PM
17	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total joint arthroplasties are older with medical comorbidities and are at a significantly increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not completely preventable events. In summary, the proposed warranty appears to be a mechanism for the State of Washington to avoid paying for between 4/10 of a percent and 2% of all total joint replacements. The consequence for patients would be that patients in a higher risk group would find receiving treatment to be increasingly difficult and many patients with medical comorbidities would probably find that care was not available because these events are only predictable in a statistical manner. The financial margin for joint replacement is low enough that even a small percentage loss makes the procedure impossible to perform. The question then becomes which statistical marker is used to reduce the risk of surgery. If you are 5 pounds over weight should you be excluded? Or perhaps being over age 60 or having diabetes will prevent a joint replacement. In spite of the variability of risks joint replacement surgery has been demonstrated to improve the quality of life in all age groups and disease	Jun 19, 2013 11:30 AM

Page 32, Q33. If no, why? Please provide citations for evidence to support your opinion if possible.

states that result in joint destruction. Certain specialty facilities that were only providing care to low risk patients would be unaffected and in fact, they are to some degree cherry picking already. The proposed criteria for warranty would also encourage increased invasive testing and evaluation in an attempt to avoid being penalized for what are otherwise virtually unpredictable medical events. The last problem is that physicians may find that practicing in Washington state is so onerous that they won't choose to provide care here. We certainly have seen other businesses leave states that have become hostile work places. I think that the goal of improving medical care is laudable; however, there is no cheap and easy fix. Three hundred years of scientific medicine has led to greater improvement than 5,000 years of tradition and magical thinking. Improvement in medicine requires continuous effort, measurement and reassessment, not superficial reflex action. While this process is expensive in the short term, the long term benefits have been proven for 3 centuries. If the state insists on reimbursement for these medical events they should buy insurance to cover the costs and pay for high quality research to improve the quality of care.

Page 33, Q34. If you have any other comments about the definitions or the warranty more broadly please provide them here.

1	THIS WHOLE IDEA IS IDIOTIC AND FOCUSED IN THE WRONG DIRECTION. THERE ARE MUCH BETTER WAYS TO SAVE HEALTH CARE DOLLARS.	Jul 3, 2013 12:43 PM
2	Product warranties are guarantees that some defined aspect of a product will conform to certain specifications or standards, or that a product will perform in a certain manner and/or produce a certain result. A manufacturer would only extend a warranty to the extent that the manufacturer could reasonably expect to control the outcome being warranted. In orthopedics, many factors contribute to the outcome of a procedure. The design and manufacturing quality of an orthopedic product do play a role in the outcome. But at least as important to the outcome of a procedure are surgical, hospital, and patient-specific factors. A surgeon's independent medical judgment and operating skill have extremely significant roles to play in the outcome of every orthopedic procedure. He or she determines surgical technique and implant positioning utilized during any individual procedure and brings his or her own skill and experience to the procedure. Hospital-related factors that can affect the outcome of an orthopedic procedure include infection control procedures before, during, and after the surgical procedure; nursing care; therapists' skill; as well as other factors related to care received by the patient while in one or more facilities. A number of patient-specific factors also influence an orthopedic surgery's outcome. Patient-specific factors include pre-operative clinical condition, anatomy, bone quality, weight (particularly important for lower extremity procedures such as hip and knee replacements), activity levels, site to which a patient is discharged following a procedure, compliance with post-operative restrictions on activities, and compliance with post-operative skilled nursing and physical therapy. Companies may determine, based on post-market data, that a particular orthopedic implant product has unacceptable patient outcomes. These may be related to, for example, manufacturing issues, design, or inadequate training of physicians, and may result in a manufacturer recalling the product. Although it may be possible to pinpoint a cause of failure in certain cases, given the interplay and complexity of the factors mentioned above (surgical, hospital, patient, and device factors), assessing the exact cause – or even predominant cause – of the failure of a procedure involving orthopedic implants can be difficult in most cases. Due to the nature of the procedures, if a "failure" occurs, it is likely to occur months or years later. Recreating the surgery episode would be challenging, and homing in on which of the myriad potential surgical, hospital, and patient-specific pre-operative or post-operative factors could be at play would be no easier. Identifying the most probable cause of many orthopedic device failures is extremely difficult, making the enforcement of a manufacturer warranty legally problematic. Even in instances where higher than anticipated failures are observed clustered around an individual product, it is difficult to assign responsibility for the failure proportionally in each individual case. For example, a five-year revision rate of 15% may be higher than anticipated. However, in this example, 85% of the implants did not fail. If failure rates are clustered around particular hospitals, surgeons, patient, and/or device factors, it is not clear that the product is the source of the problem. Establishing a uniform standard of performance applicable to all patients would not capture the complex factors that impact outcomes. For example, the level of expected or intended performance for a young, active male would be different than for an elderly, obese smoker. This is a vivid illustration of patient specific factors and how they contribute to the analysis of suitable "outcomes" in orthopedics. Identifying a single, acceptable standard for purposes of drafting a warranty is very difficult	Jul 3, 2013 9:50 AM

Page 33, Q34. If you have any other comments about the definitions or the warranty more broadly please provide them here.

	because each patient has unique attributes. A manufacturer's warranty that an orthopedic product conforms to particular manufacturing specifications would be "within the control" of the manufacturer. However, determining whether or not a non-conformance actually contributed to the failure of the product in vivo would carry the same challenges as described above. Certain non-conformances could be immaterial to the performance of the device, and others could be material but unrelated to a particular failure. Defining materiality and relation to causation in such a way as to measure whether the product's performance conformed to the warranty is challenging because of the many different factors at play in the outcome of orthopedic procedures. Manufacturers of orthopedic implants should not be required to provide warranties, for the reasons stated above. A warranty is appropriate if it properly and fairly allocates risk to the party in control of the outcome of a particular risk. The outcomes of orthopedic procedures are simply not susceptible to this kind of risk and responsibility allocation. All the factors discussed above making it difficult to determine the cause of an orthopedic implant procedure failure in the U.S. apply as well to procedures in Europe. However, a very different health care delivery system, as well as a very different legal system in Europe that limits punitive and non-economic damages and generally prohibits contingency fees, allow some companies to offer warranties for their products used there.	
3	Post Acute rehab in the client's home as covered by medicare if client is homebound is beneficial in the following areas: 1. Client who have comorbidties requiring additonal multidiscipline oversight to achieve goals of previous function. Prevents rehospitalization or ED visit due to exacerbation of these conditons, CHF, Pain Management, Constipation, Redness or drainage at the incision site. Clinician works in collaboration with either PCP and the Orthopedic surgeon to manage symptoms as described above 2. Early discharge programs possible from the acute with additional resources at home once certain discharge criteria are met.(which is dependent on Ortho surgeon protocols i.e discharge with PT daily with an aide for personal care. This promotes continuim of rehab in the home and if appropriate transition to ourpatient within in the week if client is no longer homebound, or continued care until goals of ambulation and strenghtening are met. 3. Viable option for clients living alone with no ability to access outpatient rehab.	Jul 2, 2013 2:44 PM
4	This is all about off-loading the financial responsibility of insurers to the care providers- hospitals and individuals. A warranty will do nothing to improve care and will only hurt access to those who need care. A more practical way to acheive cost reduction is through standardization of care pathways, infection protocols, DVT prophylaxis protocols that are already in use in most hospitals.	Jul 2, 2013 1:52 PM
5	I would like to promote use of home health in post acute care of joint patients. Per the September 2012 Avalere Health LLC Home Health Chartbook, it has been reported that 30 day rehosp rates after major joint rplcmt for Home health users is 4.33%; SNF rate 8.29%	Jul 2, 2013 7:23 AM
6	I agree with the intent of a "warranty" but i strongly object to the complete inclusion of work for complications under the surgical payment. i think that a discount would be far more appropriate. In other words, we as surgeons are not looking to operate on people postop for complications, but if surgery needs to be done it should be done promptly. i would suggest that preserving the fee-for-	Jul 2, 2013 7:22 AM

Page 33, Q34. If you have any other comments about the definitions or the warranty more broadly please provide them here.		
	service system with something like a 50% discount for postop infections/complications would be far more appropriate.	
7	The first read sounds all great- when you dig deeper and think about the ramifications of it, it sounds like an administrative nightmare for hospitals, providers and whomever is providing oversight for the program	Jul 1, 2013 11:10 AM
8	Interesting concept. I generally support this, would hope that the second hospital would treat and not make the patient return to the first hospital (in cases where the patient has moved for instance).	Jul 1, 2013 8:38 AM
9	This concept is novel and I have no problem driving efficiencies and quality in orthopedic work. However I see this as a scheme to defer denial of care from insurers to physicians and hospitals by only operating on healthy patients. It makes a flawed assumption that all risks and complications are controlled on the provider side when patients make unhealthy choices in life which we can not mitigate. Humans are not like machines or furniture for which warranties can be managed financially in an effective business plan. I wouldn't want to do this unless the money were substantially better. I also don't trust hospitals to share the income fairly if reimbursement is bundled to them	Jul 1, 2013 7:50 AM
10	1. The exact nature of the warranty can be stated more clearly right up front - for example, if a patient experiences one of the complications, what happens? Is the payer reimbursed somehow? Is the provider (hospital? surgeon?) not paid, or paid less? The meaning of 'warranty' needs to be laid out clearly. 2. Re the complications themselves: if a patient dies, what are the implications for the providers? Again, it is not clear what the existence of a warrantee actually means in concrete terms. 3. I appreciate the effort to identify complications that can be reasonably associated with the procedure and attributable to care. However, cause and effect are often difficult to determine. If the patient went home without an apparent wound infection, but developed one at home and was readmitted 2 days later, how can that be attributed to the hospital care? Did s/he use clean or sterile technique at home? Did the caregiver?	Jun 28, 2013 1:36 PM
11	It is a good beginning but feel that infections should be handled differently	Jun 25, 2013 2:41 PM
12	We should endeavor to provide best practices and have low rates of complications. This has already occurred in orthopedic surgery. "Warranties" provide a fallacy. Consents are provided precisely because we cannot guarantee results. Do you not realize how much pressure most surgeons place on themselves to do everything in their power to prevent complications? If it were humanly possible, by intelligence, force of will and effort to have no complications, there would already be none. This effort will only create more pressure, and will have little if any benefit.	Jun 24, 2013 8:59 PM
13	Therre always risks associated with surgical procedure and it often involves weak elderly patients. If physicians and hospital were penalized for poor outcoms they would only perform surgeries on relatively young patients not at risk for a bad outcome.	Jun 21, 2013 7:12 PM
14	No comments; criteria seem logical based on surgical procedure	Jun 21, 2013 2:36 PM

Page 33, Q34. If you have any other comments about the definitions or the warranty more broadly please provide them here.

15	There has been a tremendous amount of work on these types of warranties at the Harvard Business School - Value Measurement in Health Care, it is my hope that this collaborative has sought information and input from there large body of knowledge on these subjects. Richard Bennett	Jun 21, 2013 7:24 AM
16	This is an excellent effort. I wonder about holding the hospitals responsible for defects in protheses. Is there any way to get the manufacturers to accept responsibility for their devices?	Jun 21, 2013 7:16 AM
17	This is, quite possibly, the worst idea I have ever heard. This will change the face of orthopaedics forever and limit access to those who need it the most ... the elderly, the poor, those who have medical comorbities. I currently take all type of insurance including Medicaid and Medicare patients. I accept that some patients are higher risk but I do not deny them appropriate care. But if this system goes into practice I will not be able to offer care to patients at higher risk for complication. I already accept a significant loss of income for caring for a Medicaid patients (up to a 500% difference in reimbursement for some procedural codes compared to my best insurance plans). I do this as a service to my community in rural Washington. I accept that my least insured patients are also often the ones with the most comorbidities such as diabetes, obesity, poor hygiene, poor dentition, tobacco or drug abuse and neglected medication issues. I care for them because this is the morally appropriate thing to do. But if I am expected to take on additional financial risks and lose more money to care for these patients then I will be unable to continue to serve my community. The wealthy matrons of Bellevue will always have access to care but the poor folks of rural Washington will lose access to high quality orthopaedic care.	Jun 20, 2013 9:13 AM
18	I think that I have emphacized that where the baseline incidence in the best institutions in the country are not zero, then the limit of liability of warranty should be at that level.	Jun 19, 2013 3:07 PM
19	Since there is no way to reduce risks to zero, there should not be a warranty for no complications.	Jun 19, 2013 12:30 PM
20	I reviewed the proposed warranty for joint replacements that is currently under discussion. The warranty seems to be a guarantee kick-back scheme to place the risks of doing surgery on the provider and hospitals. The medical complications that are proposed for warranty coverage are, in general, unpredictable events that occur at low rates in association with all surgical procedures. Specifically, unless the patient's primary care provider has been ignoring symptoms of active cardiovascular disease, impending stroke or infection in the weeks or months leading up to this surgery these are unpredictable events. Including these events in the warranty would guarantee that several tenths of a percent of all total joints would be performed for free because there will undoubtedly be financial penalties associated with the warranty. I think that there is an opportunity for unintended consequences, including increased utilization of invasive cardiac diagnostic testing to minimize the risk of occurrence of these events. The 30 day warranty includes coverage for complications such as death, surgical site bleeding, wound infection and pulmonary embolism. Again, these problems are rarely caused by surgical misadventure or medical mismanagement and are not completely avoidable even with optimal medical management. Many of the patients who receive total	Jun 19, 2013 11:30 AM

Page 33, Q34. If you have any other comments about the definitions or the warranty more broadly please provide them here.

joint arthroplasties are older with medical comorbidities and are at a significantly increased risk for death compared to young healthy individuals. Pulmonary embolism prevention and surgical site bleeding are related events. Appropriate treatment to minimize the risk of pulmonary embolism and venous thrombosis disease significantly increases the risk of postoperative bleeding. Conversely, treatments that minimize the risk of bleeding increases the risk of pulmonary embolism. Surgical site bleeding also increases the wound infection rates. The most aggressive guidelines for preventing pulmonary embolus were developed by the chest physicians which have been demonstrated to have a significant increased rate of bleeding and subsequent increases in infection. Absolute prevention of infection is virtually impossible. In fact, up to 80% of surgical site infections may be related to normal bacterial colonization of the patients. The infection rate following joint arthroplasty ranges between 1/2% and 2% nationwide, even with best practices being employed. The 90 day warranty for mechanical problems, is probably the only part of the warranty that hospitals and physicians have significant control over. Peri-prosthetic infections are not significantly different than surgical site infections as noted above. They are not completely preventable events. In summary, the proposed warranty appears to be a mechanism for the State of Washington to avoid paying for between 4/10 of a percent and 2% of all total joint replacements. The consequence for patients would be that patients in a higher risk group would find receiving treatment to be increasingly difficult and many patients with medical comorbidities would probably find that care was not available because these events are only predictable in a statistical manner. The financial margin for joint replacement is low enough that even a small percentage loss makes the procedure impossible to perform. The question then becomes which statistical marker is used to reduce the risk of surgery. If you are 5 pounds over weight should you be excluded? Or perhaps being over age 60 or having diabetes will prevent a joint replacement. In spite of the variability of risks joint replacement surgery has been demonstrated to improve the quality of life in all age groups and disease states that result in joint destruction. Certain specialty facilities that were only providing care to low risk patients would be unaffected and in fact, they are to some degree cherry picking already. The proposed criteria for warranty would also encourage increased invasive testing and evaluation in an attempt to avoid being penalized for what are otherwise virtually unpredictable medical events. The last problem is that physicians may find that practicing in Washington state is so onerous that they won't choose to provide care here. We certainly have seen other businesses leave states that have become hostile work places. I think that the goal of improving medical care is laudable; however, there is no cheap and easy fix. Three hundred years of scientific medicine has led to greater improvement than 5,000 years of tradition and magical thinking. Improvement in medicine requires continuous effort, measurement and reassessment, not superficial reflex action. While this process is expensive in the short term, the long term benefits have been proven for 3 centuries. If the state insists on reimbursement for these medical events they should buy insurance to cover the costs and pay for high quality research to improve the quality of care.

Pages 66-74 include the names and contact information for respondents and have therefore been removed from the publicly posted version.