**Appendix B: Survey on Medical Coverage Decisions for** Lasers B

### **QUESTIONNAIRE ON MEDICAL POLICY**

### **SECTION 1: MEDICAL POLICY**

Three laser applications that are currently available in different fields of Each application is medicine are described on the following pages. followed by a series of identical questions. The data presented in these descriptions are as clinically accurate as possible. We would like you to read each description and answer the questions based on the information provided in each case. This section requires the most reflection; Sections II and III require less time.

All responses will be kept strictly confidential.

I have previously completed this survey. \_ (Please return in pre-addressed envelope.)

I am unable to complete the survey at this time.

(Please provide reason, if possible, and return in pre-addressed envelope. )

Would you like to receive a summary of results of this survey? -Yes - No

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2	Application I (C Percutaneous transluminal coronary angioplasty is per persons >=35 years of age per year). Laser angioplast coronary obstructions. According to the medical literal inadequate diameter of recanalization achieved, such the angioplasty in at least 70% of cases. Major complication coronary artery bypass grafting, may be similar to the complications such as dissection of the vessel can be vessel wall moderately higher (2.5%) when compared to using laser assisted-angioplasty are similar to convent appears to increase complications, to be less effective the expense to PTCA. Currently, this laser technique has not the general code, 72982 Percutaneous transluminal control of the	formed in selected patients (approximately 16/1 0, ty is a more recent non-invasive technique for treat ture, a significant obstacle to laser angioplasty is at there continues to be a need for subsequent balloons, such as death, myocardial infarction and need the more conventional balloon angioplasty. However substantially higher (up to 17%), and perforation of conventional angioplasty. In addition, restenosis rational balloon angioplasty. Therefore, laser angiopla han balloon angioplasty alone, and to add an increase ounique CPT code and would therefore be billed un	ing the con for ver, the ites isty
QUEST	<u>ions</u>		
Q-1	If the health care provider balls for this laser technique paid, would you know that this laser application is bei		nely
	— <sup>(1)</sup> Definitely not — <sup>(2)</sup> Probably not — <sup>(3)</sup> Prob	ably yes — <sup>@</sup> Definitely Yes	7
Q-2	Which of the following would be most likely to alert population by a health care provider? (Please <i>rank</i> top	three sources from the list provided below)	red
	01 Higher than average charge submitted by provider	07 Internet technology coverage committee  OS medical or trade publications	
	02 Provider queries about coverage policy	09 General public media	
	03 Patient queries about coverage policy	10 Manufacturers advertising	
	04 Manufacturers queries about coverage policy  05 Internally aware because our type of HMO initially approves the purchase of the laser	11 Informal discussions with your medical or insurance colleagues	
	06 Utilization review by medical record audit	12 Other	
Se	st likely source (enter number) cond likely source (enter number) ird likely source (enter number)  Once you are aware that this laser is being used, which medical coverage policy decision for this laser techniq (Please rank top three factors from the list provided be	ue versus simply covering the routine procedure?	.9,9 10,11 12.13 e a specific
	High potential number of insured population affected	5 Concern over covering a technique with more potential complications	
	2 High potential cost	6 Concern that coverage may represent a	
	3 Concern that this is an experimental procedure	liability risk	
	4 Technique is not considered a community standard		
Se	st important factor (enter number cond important factor (enter number ird important factor (enter number	·) —	14 15 16

4	conserve patients involving introduce 90% for the percuta approve for percutangement of the percutangement of	Application II (Orthopedical low back pain is a common and substantial rative and surgical interventions. Excision or destrict with a herniated disk, (approximately 17 cases/ ag an open procedure on the spine, general anesthed the conventional surgery. The use of a Ho:Yag or hablation of the diseased disk. The procedure uneously to a patient given local anesthesia, and sed, there is scarce clinical data on humans as to the cutaneous diskectomy. Currently, this laser technique code, 62287 Aspiration Procedure Percutaneous, for multiple levels, lumbar.	health problem, which is treated though a varie uction of the intervertebral disk is a therapy for sel- 10,000 persons >= 18 years of age per year) typ isia and a hospital stay. Percutaneous diskectomy us approach itself reported at 60-70 %, compared to the second of	ected sically was to 80- nique duced FDA ability er the
Q-1		ne health care provider bills for this laser technique on d, would you know that this laser application is bein		ly
	_	<sup>(1)</sup> Definitely not — <sup>(2)</sup> Probably not — <sup>(3)</sup> Proba	ably yes — <sup>(4)</sup> Definitely Yes	45
Q-2	you	this laser technology as described, how strongly or company's decision to recommend coverage or dease rank separately the top five considerations in fa	eny coverage?	e
		01 Medically acceptable, reasonable and necessary	12 Decreased complication rate	
		02 Experimental or investigational technique	13 Increased efficacy of this technique	
		03 Potential for increased cost of the procedure due to laser technique	14 Decreased efficacy of this technique	
		04 Potential for decreased cost of the procedure due to laser technique	15 Potential differences between clinical trials (efficacy) and community experience (effectiveness)	
		05 Potential for increased volume of this procedure due to new laser technique	16 FDA approval	
		06 Potential for decreased volume of this procedure due to new laser technique	17 Increased cost-effectiveness 18 Decreased cost-effectiveness	
		07 Concern that coverage will prompt inflow of new patients into insurance plan	19 Complications present a liability risk for the company	
		08 Benefits policy excludes procedure	20 Technique is outpatient rather than inpatient	
		09 Denial of coverage may be legally challenged in the court system	21 Technique is inpatient rather than outpatient	
		10 Alternate technique available which is clinically proven effective	22 Laser technique is potentially last resort 23 What other carriers are covering	
		11 Increased complication rate	24 Other	
	Most ii	mportant consideration in favor of coverage	(enter number)	46,47
	Third important consideration in favor of coverage		(enter number)	48,49
			(enter number)	50,51
			(enter number) (enter number)	52,53 54,55
	Most i	mportant consideration against coverage	(enter number)	56,57
		important consideration against coverage	(enter number)	58,59
		important consideration against coverage	(enter number)	60,61
		important consideration against coverage nportant consideration against coverage	(enter number) (enter number)	62,63 64,65
	From t	he list provided above, please record the two consi r of and against recommending coverage.	derations that would be of least importance	
	Least i	mportant considerations in favor of coverage	{enter number <u>)</u> (enter number <u>)</u>	66.67 68,69
	Least i	important considerations against coverage	(enter number) (enter number)	70,71 72,73

#### Application III (Oncology)

Photodynamic therapy is an experimental cancer therapy which is being studied for its effectiveness in transitional ceil carcinoma of the bladder. This therapy is currently undergoing evaluation for formal FDA approval for this cancer, but is not approved to date. For some stages of this tumor, no alternative, curative therapy exists. The therapy involves injecting a photosensitizing agent, usually a porphyrin-based compound into the patient, which is selectively taken up by the malignant tissue. The tumor is then exposed to a non-thermal appropriate wavelength of laser light from a tunable-dye laser. The molecule of the photosensitizing agent is excited, releasing a cytotoxic singlet oxygen species, which destroys the malignant tissue. Current literature suggests that photodynamic therapy is an important therapeutic intervention for refractor carcinoma-in-situ and prophylaxis of recurrent superficial transitional-cell carcinoma of the bladder. The reported complete response rates for carcinoma-in-situ to photodynamic therapy have consistently been 80-100%. There is also data to support prophylaxis through a single photodynamic session for recurrent cancers which have failed previous interventions, providing 12 to 20 months of disease-free intervals. No deaths have been reported due to photodynamic therapy. Complications include permanent bladder contracture which was reported in 10% of earlier patients. Patients also experience temporary urinary frequency, urgency and nocturia of variable severity. The photosensitizing agent is relatively non-toxic, except the patient must avoid sunlight and bright indoor lighting for a period of time. Therefore, although not yet FDA approved, photodynamic laser therapy for bladder cancer appears to have no significant complications, has unclear cost implications, but has increased efficacy over more conventional therapies.

Q-1	If the health care provider bills for this laser technique using the general CPT procedure code that is routinely
	paid, would you know that this laser application is being used? (Check one below)

— "Definitely not — "Probably not — "Probably yes — "Definitely yes

Q-2 For this laser technology as described, how strongly would each of the following considerations influence your company's decision to recommend coverage or deny coverage? (Please rank separately the top five considerations in favor of, and against, recommending coverage)

01 Medically accentable reasonable and necessary 12 Decreased complication rate

of Medically acceptable, reasonable and necessary	12 Decreased complication rate
02 Experimental or investigational technique	13 Increased efficacy of this technique
03 Potential for increased cost of the procedure due to laser technique	14 Decreased efficacy of this technique
04 Potential for decreased cost of the procedure due to laser technique	15 Potential differences between clinical trials (efficacy) and community experience (effectiveness)
05 Potential for increased volume of this procedure due to new laser technique	16 FDA approval
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06 Potential for decreased volume of this procedure due to new laser technique	18 Decreased cost-effectiveness
07 Concern that coverage will prompt influx of new patients into insurance plan	19 Complications present a liability risk for the company
08 Benefits policy excludes procedure	20 Technique is outpatient rather than inpatient
09 Denial of coverage may be legally challenged in the court system	21 Technique is inpatient rather than outpatient
the court system	22 Laser technique is potentially last resort
10 Alternate technique available which is	
clinically proven effective	23 What other carriers are covering
11 increased complication rate	24 Other

Most important consideration in favor of coverage Second important consideration in favor of coverage Third important consideration in favor of coverage Fourth important consideration in favor of coverage Fifth important consideration in favor of coverage

Most important consideration against coverage Second important consideration against coverage Third important consideration against coverage Fourth important consideration against coverage Fifth important consideration against coverage

77.78

81,82

83 84

87,88

99.90

91,92

93.94

6			
Q-2	Please record the two considerations that would be of I coverage.	east importance in favor of or	against recommending
	Least important considerations in favor of coverage	(enter number) (enter number)	95,96 97,98
	Least important considerations against coverage	(enter number) (enter number)	99,100 101,102
Q-3	Does your company currently cover the use of a lasar for the	ne following conditions? (Check  (1) Yes (Covered)	yes or no)  (2)No (Not covered)
	Ablation of tatoos	V 7 (Covereu)	103
	Ablation of basal cell carcinoma of the skin		104
	Diabetic retinopathy		105
	Removal of colonic adenomas	_	106
	Percutaneous coronary angioplasty		107
	Percutaneous diskectomy		108
	Photodynamic therapy for bladder carcinoma		
	Ablation of inoperable endobronchial carcinoma		110
	Upper gastrointestinal hemorrhage		111
	Ablation of carcinoma-in-situ of the cervix		112
	Hemorrhoidectomy		113
	Endometriosis		114
	Stapedotomy		116
	Removal of tonsils and adenoids	-	118
	Ablation of urethral strictures		117

7	
SECTION II: MEDICAL COVERAGE DECISION PROCESS	
The following section contains a selection of questions covering the process for making medical coverage decisions within your company. There are also questions about the sources of information you utilize when making coverage decisions. Please read and answer these questions.	

4

8		
Q-1	What is your company's review process for making medical policy coverage decisions for a technology such as a laser?	
	"Reviewed by medical director alone  "Initially reviewed by medical director, but then always referred to another individual  "Initially reviewed by medical director, but then always referred to a Committee  - "Initially reviewed by medical director, who then, at his/her discretion refers to another individual  "Initially reviewed by medical director, who then, at his/her discretion refers to a committee  - "Other"  "Other"	118
	If referred to a committee, approximately how many members does it have? (enter number).	110,120
	Who are the members?	
	<ul> <li>Chief executive officer or president</li> <li>Benefits director or designee</li> <li>Claims director or designee</li> <li>Medical director</li> <li>Medical director staff</li> <li>Attorney</li> <li>Medical Ethicist</li> <li>Community physician</li> <li>Utilization review representative(s)</li> <li>Marketing representative(s)</li> <li>Financial representative(s)</li> <li>Other</li> </ul>	121 122 123 124 125 126 127 128 129 130 131
Q-2	Who is responsible in your company for making medical policy coverage decisions for a technology such as a laser?	
	"MediCal director alone  - (2) A committee  - (9) Other	133
Q-3	Who should optimally be responsible for making medical policy decisions relative to new technologies being used and reviewed for coverage?  "Medical director alone	134
Q-4	Are the majority of medical coverage policy decisions made in a: (choose one)  _ "Retrospective fashion     (after claims submitted or paid for)  _ "Prospective fashion	136
Q-5	(before claims submitted or paid for)  What do you consider the optimal timing for making medical policy decisions relative to new technologies being used and reviewed for coverage?  "Retrospective fashion (after claims submitted or paid for)  "Prospective fashion (before claims submitted or paid for)	136

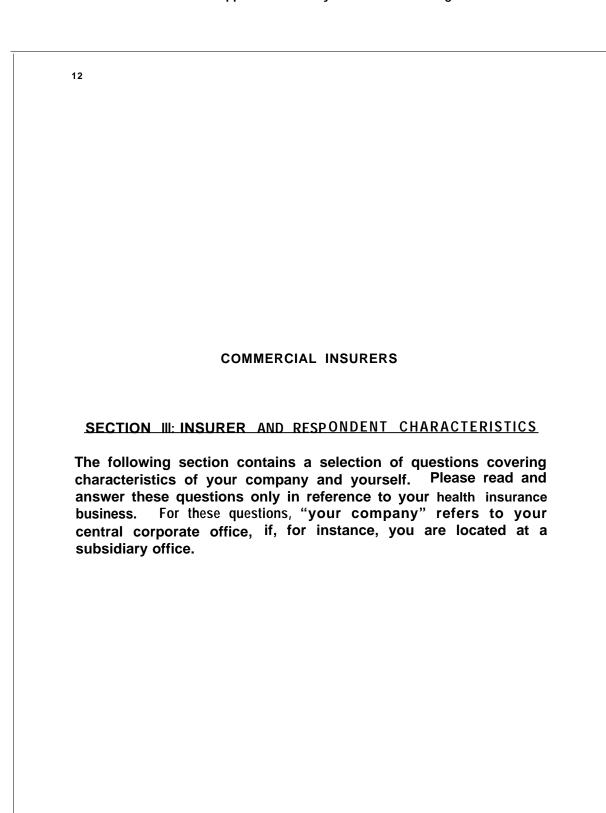
# 28 Coverage of Laser Technology By Health Insurers

07 Other larger insurers 08 Opinions of local expert physicians 09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 11 Other  OPT Of the larger insurers 08 Opinions of local expert physicians 09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 11 Other  OPT Opinions of national expert physicians  Most used source (enter number)  OPT Of Covernment documents, i.e., OHTA 01 Government documents, i.e., OHTA 02 FDA clearance document 03 Medicar policies 04 Medical journals 05 Insurer association information, i.e., HIM, TEC (BCBS) 10 Nint consensus conferences 11 Other  OPT Of Covernment documents, i.e., OHTA 09 FDA clearance document 09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 10 Nint consensus conferences 11 Other larger insurers 11 Other larger insurers 12 Opinions of local expert physicians 13 Medicare policies 14 Medical journals 15 Insurer association information, i.e., HIM, TEC (BCBS) 16 Opinions of national expert physicians  Most optimal source (enter number)  FIRST type (enter number) 1 Testimony or theory 2 Randomized, controlled trial 3 Non-randomized, controlled trial 4 Case series 9 Observational cohort study of patients receiving different theraples  First type (enter number)  Genter number)  (enter number) (enter number)  9 Observational cohort study of patients receiving different theraples	02 FDA clearance document 03 Medicar policies 04 Medical journals 05 Insurer association information, i.e., HIAA, 1EC (BCBS) 06 Opinions of national expert physicians  07 Other larger insurers 08 Opinions of local expert physicians  09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 10 NIH consensus conferences 11 Other  11 Other  12 Other  13 Other  14 Other  15 Other  16 Opinions of national expert physicians  17 Other making medical policy decisions for a netechnology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below of the provided below	
O. P. P. Cestantice counters  O. Medicar policies  O. Medicar policies  O. Medical journals  O. Insurer association information, i.e., HIAA, TEC (BCBS)  O. Opinions of national expert physicians  Most used source (enter number)  Second used source (enter number)  Third used source (enter number)  O. What do you consider the optimal sources of information for making medical policy decisions for a new technology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below)  O. Other larger insurers  O. Opinions of local expert physicians  O. Medical journals  O. Insurer association information, i.e., HIM, TEC (BCBS)  O. Insurer association information, i.e., HIM, TEC (BCBS)  O. Opinions of national expert physicians  Most optimal source (enter number)  Second optimal source (enter number)  C. Second optimal source (enter number)  C. When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following to evidence? (Please rank the top three types from the list below)  O. Observational cohort study of patients receiving different therapies  First type (enter number)  O. Observational cohort study of patients receiving different therapies  First type  O. Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  O. Other larger insurers  O. Other larg	03 Medicare policies  04 Medical journals  05 Insurer association information, i.e., HIAA,  TEC (BCBS)  06 Opinions of national expert Physicians  Most used source (enter number)  Third used source (enter number)  07 What do you consider the optimal sources of information for making medical policy decisions for a netechnology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below  07 Other larger insurers  08 Opinions of local expert physicians  09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  07 Other larger insurers 08 Opinions of local expert physicians  09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  10 NIH consensus conferences  11 Other  11 Other  12 Other larger insurers 13 Medicare policies 14 Medical journals 15 Insurer association information, i.e., HIM, TEC (BCBS) 16 Opinions of national expert physicians  17 Other larger insurers 18 Opinions of local expert physicians  19 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  10 NIH consensus conferences 11 Other  11 Other  12 Other larger insurers 13 Opinions of local expert physicians 14 Medical journals 15 Insurer association information, i.e., HIM, Insurer larger insurers 16 Opinions of national expert physicians  18 Opinions of local expert physicians 19 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 10 NIH consensus conferences 11 Other larger insurers 10 Opinions of local expert physicians 11 Other larger insurers 12 Opinions of local expert physicians 13 Opinions of local expert physicians 14 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 16 Opinions of local expert physicians 17 Opinions of local expert physicians 18 Opinions of local expert physicians 19 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 19 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 19 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 10 NIH consensu	139, 141,
O4 Medical journals os Insurer association information, i.e., HIAA, TEC (BCBS)  —66 Opinions of national expert physicians  Most used source (enter number)  Second used source (enter number)  Third used source (enter number)  O1 Government documents, i.e., OHTA O2 FDA clearance document O3 Medicare policies O4 Medical journals O5 Insurer association information, i.e., HIM, TEC (BCBS)  Model are policies O4 Medical journals O5 Insurer association information, i.e., HIM, TEC (BCBS)  Most optimal source (enter number)  Most optimal source (enter number)  Second optimal source (enter number)  Most optimal source (enter number)  Second optimal source (enter number)  First type  (enter number)  O NINH consensus conferences  11 Other  10 NIH consensus conferences 11 Other larger insurers 08 Opinions of local expert physicians 09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 10 NIH consensus conferences 11 Other  11 Other  12 Randomized, controlled trial 13 Non-randomized, control lad trial 34 Case series 9 Observational cohort study of patients 15 Case reports/anecdotes  First type (enter number)  (enter number)  O5 Opinions of local expert physicians  O7 Other larger insurers 09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP 10 NIH consensus conferences 11 Other  11 Other  12 Testimony or national expert physicians  Most optimal source (enter number)  13 Non-randomized, controlled trial 14 Case series 9 Observational cohort study of patients 15 Case reports/anecdotes	Od Medical journals  os Insurer association information, i.e., HIAA,  TEC (BCBS)  -08 Opinions of national expert Physicians  Most used source (enter number) Second used source (enter number) Third used source (enter number)  Of Government documents, i.e., OHTA  Of SPA clearance document  Of Medical journals  Of Medical journals  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  Of Medical journals  Most used source (enter number)  Of Government documents, i.e., OHTA  Of Other larger insurers  Of Opinions of local expert physicians  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  In Other larger insurers  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  In Other larger insurers  Of Opinions of local expert physicians  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  In Other larger insurers  Of Opinions of local expert physicians  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  In Other larger insurers  Of Opinions of local expert physicians  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  In Other larger insurers  Of Opinions of local expert physicians  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  In Other larger insurers  Of Opinions of local expert physicians  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  In Other larger insurers  Of Opinions of local expert physicians  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  Of Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  Of Medical society statements or practice guidelines, i.e.,	139, 141,
os Insurer association information, i.e., HIAA, TEC (BCBS)  -06 - Opinions of national expert physicians  Most used source (enter number) Third used source (enter number)  Other insurer association information for making medical policy decisions for a new technology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below)  Other larger insurers Other larg	os Insurer association information, i.e., HIAA,  11 Other    Other	139, 141,
Most used source (enter number) Second used source (enter number) Third used source (enter number)  Of What do you consider the optimal sources of information for making medical policy decisions for a new technology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below)  Of Government documents, i.e., OHTA Of SPA clearance document Of Medical journals Of Insurer association information, i.e., HIM, the consensus conferences TEC (BCBS)  Of Opinions of national expert physicians  Most optimal source Foecond optimal source Center number) Center number)  Of Traditional review article Third optimal source (enter number)  Of Traditional review article Third optimal source (enter number)  Of Traditional review article Third optimal source (enter number)  Of Traditional review article The stimony or theory  Of Traditional cohort study of patients receiving different therapies  First type  Of Traditional cohort study of patients receiving different therapies	Most used source (enter number)  Second used source (enter number)  Third used source (enter number)  Third used source (enter number)  What do you consider the optimal sources of information for making medical policy decisions for a net technology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below 01 Government documents, i.e., OHTA	139, 141,
Most used source (enter number)	Most used source (enter number)  Second used source (enter number)  (enter number)  Third used source (enter number)  (enter number)  (enter number)  Third used source (enter number)  (enter number)  (enter number)  Of the larger insurers  Of Other larger insurers  Of	139, 141,
Second used source (enter number)	Second used source Third used source (enter number)	139, 141,
technology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below)    01 Government documents, i.e., OHTA	technology, such as a laser, being reviewed for coverage? (Please rank top three from list provided below    01 Government documents, i.e., OHTA   07 Other larger insurers   08 Opinions of local expert physicians   09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP   10 NIH consensus conferences   11 Other   11 Other   11 Other   12 Other   13 Other   14 Other   14 Other   15 Other	
02 FDA clearance document 03 Medicare policies 04 Medical journals 05 Insurer association information, i.e., HIM, TEC (BCBS) 06 Opinions of national expert physicians  Most optimal source Second optimal source (enter number) Third optimal source (enter number) Third optimal source (enter number) Third optimal source (enter number)  2 When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following ty evidence? (Please rank the top three types from the list below)  1 Testimony or theory 2 Randomized, controlled trial 3 Non-randomized, controlled trial 4 Case series 5 Case reports/anecdotes  6 Opinions of local expert physicians  09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  10 NIH consensus conferences 11 Other  1 Other  6 Traditional review article 7 Formal meta-analysis 8 Retrospective, case-control study 9 Observational cohort study of patients receiving different therapies 5 Case reports/anecdotes	02 FDA clearance document 03 Medicare policies 04 Medical journals 05 Insurer association information, i.e., HIM, TEC (BCBS) 06 Opinions of national expert physicians  Most optimal source Second optimal source Third optimal source (enter number)	
02 FDA clearance document 03 Medicare policies 04 Medical journals 05 Insurer association information, i.e., HIM, TEC (BCBS)  06 Opinions of national expert physicians  Most optimal source Second optimal source Third optimal source (enter number) (enter number) (enter number)  2  When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following to evidence? (Please rank the top three types from the list below)  1 Testimony or theory 2 Randomized, controlled trial 3 Non-randomized, controlled trial 4 Case series 5 Case reports/anecdotes  6 Opinions of local expert physicians  09 Medical society statements or practice guidelines, i.e., AMA, ACS, ACP  10 NIH consensus conferences  11 Other  ——  (enter number) ——  6 Traditional review article 7 Formal meta-analysis 8 Retrospective, case-control study 9 Observational cohort study of patients receiving different therapies  5 Case reports/anecdotes	02 FDA clearance document 03 Medicare policies 04 Medical journals 05 Insurer association information, i.e., HIM, TEC (BCBS) 06 Opinions of national expert physicians  Most optimal source (enter number) Second optimal source (enter number) Third optimal source (enter number)  Q-8 When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following evidence? (Please rank the top three types from the list below)  1 Testimony or theory  6 Traditional review article	
03 Medical policies 04 Medical journals 05 Insurer association information, i.e., HIM, TEC (BCBS)  06 Opinions of national expert physicians  Most optimal source (enter number) Second optimal source (enter number) Third optimal source (enter number) Third optimal source (enter number)  10 NIH consensus conferences 11 Other	03 Medicar policies 04 Medical journals 05 Insurer association information, i.e., HIM, TEC (BCBS) 06 Opinions of national expert physicians  Most optimal source Second optimal source Third optimal source (enter number) Third optimal source (enter number) (enter number) Third optimal source (enter number) (enter number)  Q-8 When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following evidence? (Please rank the top three types from the list below)  1 Testimony or theory  6 Traditional review article 7 Formal meta-analysis	
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Most optimal source Second optimal source Third optimal source  When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following ty evidence? (Please rank the top three types from the list below)  1 Testimony or theory 2 Randomized, controlled trial 3 Non-randomized, control lad trial 4 Case series 5 Case reports/anecdotes  First type  (enter number)  (enter number)  6 Traditional review article 7 Formal meta-analysis 8 Retrospective, case-control study 9 Observational cohort study of patients receiving different therapies	Most optimal source (enter number) Second optimal source (enter number) Third optimal source (enter number)  Q-8 When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following evidence? (Please rank the top three types from the list below)  1 Testimony or theory  6 Traditional review article 7 Formal meta-analysis	
Second optimal source (enter number)  Third optimal source (enter number)  When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following ty evidence? (Please rank the top three types from the list below)  1 Testimony or theory 6 Traditional review article 2 Randomized, controlled trial 7 Formal meta-analysis 3 Non-randomized, control lad trial 8 Retrospective, case-control study 4 Case series 9 Observational cohort study of patients receiving different therapies  5 Case reports/anecdotes	Second optimal source (enter number)  Third optimal source (enter number)  When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following evidence? (Please rank the top three types from the list below)  1 Testimony or theory  6 Traditional review article 7 Formal meta-analysis	
Third optimal source  (enter number)  When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following ty evidence? (Please rank the top three types from the list below)  1 Testimony or theory 2 Randomized, controlled trial 3 Non-randomized, control lad trial 4 Case series 5 Case reports/anecdotes  First type  (enter number)  (enter number)  (enter number)	Third optimal source (enter number)  Q-8 When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following evidence? (Please rank the top three types from the list below)  1 Testimony or theory  6 Traditional review article 7 Formal meta-analysis	143, 146.
When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following to evidence? (Please rank the top three types from the list below)  1 Testimony or theory 6 Traditional review article 2 Randomized, controlled trial 7 Formal meta-analysis 3 Non-randomized, control lad trial 8 Retrospective, case-control study 4 Case series 9 Observational cohort study of patients receiving different therapies  5 Case reports/anecdotes	Q-8 When reviewing the current evidence for a laser therapy, what hierarchy would you assign the following evidence? (Please rank the top three types from the list below)  1 Testimony or theory  6 Traditional review article	147,
evidence? (Please rank the top three types from the list below)  1 Testimony or theory 6 Traditional review article 2 Randomized, controlled trial 7 Formal meta-analysis 3 Non-randomized, control lad trial 8 Retrospective, case-control study 4 Case series 9 Observational cohort study of patients receiving different therapies  5 Case reports/anecdotes	evidence? (Please rank the top three types from the list below)  1 Testimony or theory  6 Traditional review article  7 Formal meta-analysis	
2 Randomized, controlled trial 7 Formal meta-analysis 3 Non-randomized, control lad trial 8 Retrospective, case-control study 4 Case series 9 Observational cohort study of patients receiving different therapies  First type (enter number)	7 Formal meta-analysis	j types
2 Randomized, controlled trial 7 Formal meta-analysis  3 Non-randomized, control lad trial 8 Retrospective, case-control study  4 Case series 9 Observational cohort study of patients receiving different therapies  First type (enter number)	7 Formal meta-analysis	
3 Non-randomized, control lad trial 4 Case series 5 Case reports/anecdotes  8 Retrospective, case-control study 9 Observational cohort study of patients receiving different therapies  First type (enter number)		
4 Case series  5 Case reports/anecdotes  9 Observational cohort study of patients receiving different therapies  First type (enter number)	a Petrospective case-control study	
First type (enter number)	4 Case series 9 Observational cohort study of patients	
(anter mumber)	receiving universit therapies	
(anter mumber)		
Second type (enter number)	· · · · · · · · · · · · · · · · · · ·	149
Third type (enter number)	Second type	161
Third type (enter number)	Third type (************************************	

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Q-9	For each type of evidence listed below, do you consider it: a) adequal b) sufficient alone, to use when making a medical policy decision? (I	Please check either or both Adequate, used in combination?	) Sufficient alone?
		(¹)YES (²)NO	(1)YES (2)N 0
	Testimony or theory	162	161
	Randomized, controlled trial	163	182
	Non-randomized, controlled trial	164	163
	Case series	165	164
	Case reports/anecdotes	166	165
	Traditional review article	167	166
	Formal meta-analysis	168	167
	Retrospective, case-control study	169	168
	Observational cohort study of patients receiving different therapies	160	169
Q-10	If cost-effectiveness data is available comparing the new laser thera you consider necessary characteristics of the sources for the clinic		
(v	Primary data in a clinical trial s secondary data analysis, e.g., decision analysis)		170
,	Multi-site study (vs single site study)		171
	Published data (vs unpublished data)		172
	Published in a US journal (vs published in a non-US journal)		173
	Study conducted in the US (vs study conducted outside of the US)		
Q-1	If cost-effectiveness data is available comparing the new laser the you consider necessary characteristics of the sources for the cost		
(	Primary data in a clinical trial vs secondary data analysis, e.g., decision analysis)		_ 175
,	Multi-site study (vs single site study)		176
	Published data (vs unpublished data)		_ 177
	Published in a US journal		
	(vs published in a non-US journal)		_ 17
	Study conducted in the US (vs study conducted outside of the US)		_ 17

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	ing that a new therapy is eq	ually safe compared	to a standard therap	y, ıs your company likely	•
tilera	by willen shows.		<sup>(1)</sup> Yes		<sup>(2)</sup> N o
Equal eff	ectiveness for equal cost?				180
Equal effe	ectiveness for greater cost?				181
Equal eff	ectiveness for lesser cost?				182
Less eff	ectiveness for equal cost?	•			183
Less effe	ctiveness for greater cost?				184
Less effectiveness for lesser cost?					185
Greater effectiveness for equal cost?		-			186
Greater eff	fectiveness for greater cost?	•			187
Greater et	fectiveness for lesser cost?				188
	of the following considerational way? (Please rank the top			ng medical coverage po	licy in an
Г	1 Lack of timely effectivenes	ss data	5 External regulat	ory harriers	
	2 Lack of timely cost-effecti		6 Legal barriers	ory barriers	
	3 Lack of timely safety data			on/lack of support for	
	Internal administrative ba		coverage policy 8 Other		
_			o one		<u>-</u>
First barı Second l		ımber) — ımber) —			188 190
Third ba	•	ımber) —			191
	at degree should the followin		nsibility for assuring	that technology used in	medical practice
yleid	s reasonable benefits at reas No	Little	Some	Moderate	Great deal of
	Respo nsibility	<u>Responsibility</u>	Responsibility	Respo nsibility	Respo nsibility
Federa Government	1 1	2	3	4	5102
Stat	e				
Government	1	2	3	4	<b>5</b> <sub>193</sub>
Health Car	e 1	2	3	4	<b>5</b> <sub>194</sub>
Insurers	1	2	3	4	5195
Practicin	g				
Physicians	1	2	3	4	<b>5</b> <sub>196</sub>
Patients	1	2	3	4	<b>5</b> <sub>197</sub>
Court Syster	m 1	2	3	4	<b>5</b> 198
Manufacture	r 1	2	3	4	5 199



					13
Q-1	What is the approximate number	er of current covered liv	ves and/or claims processe	d last year by your company?	
	Covered Lives			Claims	
	() >1 million	- 500,000 0 - 1 million - 2 million n - 5 million		(") < 1 million (") > 1 million - 5 million (") > 5 million - 10 million (") > 10 million - 20 million (") > 20 million - 40 million (") > 40 million (") Data not available	201
Q-2	Approximately what percent of	of your covered lives a	re: (Estimate percentages,	0-100)	
			Percent		
	Children ( < 18	B years)		á	202-204
	Young Adults	(18-40 years)		á	205-207
	_	dults(41-64 years)			208-210
	Older Adults	(>65 years)	 100	2	211-213
	Data not avail	able			214
Q-3	What percent of the covered	lives are in each type	of health insurance listed I	below? (Estimate percentages,	
	Type of Insurance		Percent		
	Individual Inde	emnity, other t	ha <u>n HMO</u>		15-217
	Group Indemnity, oth	er than HMO			118-220 21-223
	НМО		100	•	.21-223
	If you offer HMO cove	erage, what percent of t	he covered lives are the fa	llowing? (Estimate percentages, 0-	-100)
	Type of HMO	!	Percent		
	Staff model‡			:	224-226
	Group model:	##		:	227-229
	IPA model‡‡				230-232
	Network mod	del‡‡‡‡	_ <u>_</u> _	•	233-236
Q-4	Does your company offer the	e following insurance p			
	Preferred provider o Point-of-service plar	• • •	(1)Yes (2)N o — — — — —		236 237
‡ An	organized prepaid health care system	n that delivers health servi	ces through a salaried physician	n group that is employed by the HMO.	
‡‡ An	organized prepaid health care system	m that contracts with one	or more group practices, b	ut primarily treats your HMO's enrolle	
	n organized prepaid health care syst re not your HMO's enrollees.	em that contracts with one	e or more group practices,	but the group provides care to pati	ents
#### associ	An organized prepaid health care ations of physicians in independer	system that contracts di nt practice , and/or with	rectly with physicians in indo one or more multi-speciality gr	ependent practice, with one or more oup practices to provide health service	s.
in retu	n product whereby a third-party payer urn for prompt payment and a certa product that offers the consumer a cl	in volume of patients.	·	rnish services at lower than usual fees rather than at the time of enrollm	ent.

14					
Q-5	For what percent of the covered lives does you the case of self-funded employers, for white percentages. 0-100)	our company assume ch your company p	full or partial risk provides administr	versus assuming native services only	o risk, as in ? (Estimate
	paraeringes. e rec,	<u>Percent</u>			
	Full or partially insured				238-240
	Administrative Services Only (ASO/CSO)				241-243
Q-6	On what basis do the majority of your insura	nce policies have risl	k assessed? (Inclu	ide ASO with non-H	MO)
	Non-HMO	НМО			
	<sup>(1)</sup> Full community rated 244	(¹)Community rated (²)Community rated	hy class —		246
	<sup>∞</sup> Community rated by class _ <sup>∞</sup> Full experience rated	<sup>®</sup> Full experience rat	-		
0.7	For which plans and/or products offered do y	rou docido on modica	l policy coverage	dacisions?	
Q-7		ou decide on medica	i policy coverage (	uecisions :	2413
	<ul><li>Staff model</li><li>Group model</li></ul>				247
	— IPA model				248 249
	<ul><li>Network Model</li><li>PPO product</li></ul>				250
	Pro product      Open-ended product				251
	— Traditional indemnity pro	duct			252
Q-8	Are medical coverage decisions made similarl	y across the types of	insurance for which	ch you decide on me	dical policy?
	<sup>(1)</sup> Yes	, ,,		•	26:
	(²) <b>N</b> o				
	<b>4</b>				
	If no: For which types of insurance	do your responses in	n Section I and II a	apply?	
	— Staff model				254
	— Group model				255
	— IPA model				256 257
	<ul><li>Network Model</li><li>PPO product</li></ul>				258
	Open-ended product				259
	_ Traditional indemnity pro	oduct			260
Q-9	In which state(s) does your company have enrollment. )	its largest enrollment	? (Please rank the		argest
10	111AK 1081DC _ (15)IL _ (22	ME(29)N D	_ <sup>(36)</sup> O H	$-\frac{^{(43)}TN}{^{(44)}TX}$	(50) W V (51) W Y
_ <sub>10</sub>	$^{(2)}AL$ $^{(6)}DE$ $^{(16)}IN$ $^{(2)}$	)MI (30)NE	— (37) O K - (38) O R	(45)U T	_ ` ` <b>/VV</b> Y
	"AR _ "FL _ (18) K V _ (25	MO (32)NJ	- <sup>(39)</sup> РА	— <sub>(46)</sub> V А	
	- (26)	M S (33) N M	- (40) R I - (41) S C	- (47) <b>V</b> T - (48) <b>W</b> A	
	$^{(20)}$ CO $= ^{(13)}$ A $= ^{(20)}$ M A $= ^{(20)}$	"M T _ (34)N V _ (35)N Y	- (42) S D	— (49)W I	
«	POT		_	_	

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15
Q-10 How long has your company been in operation?
                                                                                                                                                  267
                                  (1)< 1 year
                                  (2)1 -2 years
                                  <sup>(3)</sup>3 -5 years
                                  (4)6 - 9 years
                                  <sup>(5)</sup>10 - 20 years
                                  <sup>(6)</sup>20 - 50 years
                                  <sup>(7)</sup>50 - 100 years
                                  <sup>(8)</sup> > 100 years
Q-1 1 is your company:
                                                                                                                                                  268
                                  <sup>(1)</sup>for profit
                                  (2)not for profit
Q-1 2 What are your professional/post-graduate degrees?
                                     __ <sup>(1)</sup>M. D., D.O. <sup>(2)</sup>Ph.D. or doctorate in biological science
                                                                                                                                               260-274
                                     " "Ph.D. of "Ph.D. of "Ph.D. of "Ph.D. of "Ph.P.H."
" "M.P.H."
" M.H.S."
" "M.B.A."
" "M. Sc."
" J. D."
" "M.P.A
                                          <sup>(3)</sup>Ph.D. or doctorate In social science
                                           <sup>(9)</sup>J. D.
<sup>(10)</sup>M.P.A.
                                           (11)R.N.P.
                                           (12)other
 Q-13 If you are an M.D. or D. O., what is your medical specialty and, if applicable, sub-specialty?
                                                                                                                                                   276
 Q-14 How long have you served in your current or a similar position for an insurance company?
                   (1) < 1 year

- (2) 1 -5 years

- (3) 6 -10 years
                                                                                                                                                   278
                   = (4)1 1 -15 years
                    __ ' -10 ,-

(5)15 - 20 years
                    __(6) > 20 years
 Q-1 5 What is your job title?
                                                                                                                                                   277
                                          THANK YOU FOR COMPLETING THIS QUESTIONNAIRE.
                                      PLEASE ADD ANY ADDITIONAL COMMENTS ON THE BACK.
     PLEASE RETURN THE QUESTIONNAIRE IN THE ACCOMPANYING PRE-ADDRESSED POSTAGE PAID ENVELOPE TO:
                                                      Neil R. Powe, M. D., M. P. H., M.B.A.
                                                        Claudia A. Steiner, M. D., M.P.H.
                                                        1830 E. Monument St., 8th floor
                                                               Baltimore, MD 21205
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12						
HEALTH MAINTENANCE ORGANIZATIONS						
SECTION III: INSURER AND RESPONDENT CHARACTERISTICS						
The following section contains a selection of questions covering characteristics of your company and yourself. Please read and answer these questions only in reference to your health insurance business.						

# 36 Coverage of Laser Technology By Health Insurers

Q-1 What is the approximate number of current enrollees and/or claims processed by your company?
Enrollees Claims
(1)0-19,999       200         (-2)20,000-49,999       — (2)20,000-49,999         (-3)50,000-99,999       — (3)50,000-99,999         (-4)100,000-249,999       — (5)250,000-99,999         (-5)250,000       — (5)250,000,000         (-6)250,000       — (6)250,000         (-7)Data not available
Q-2 Approximately what percent of your enrollees are: (Estimate percentages, o-loo)
<u>Percent</u>
Children ( <18 years)
Young Adults (18-40 years) — 205
Middle-aged Adults(41-64 years)
Older Adults (>65 <u>years)</u>
100
<sup>(1)</sup> Data Not Available
Q-3 Which HMO plan(s) does your company represent? (Estimate percentages in terms of enrollees, 0-100)
Type of HMO Percent
Staff model* 219
Group model** 210
IPA model***
Network model**** 22
Q-4 Do you offer any of the following non-traditional products? (Estimate percentages in terms of enrollees 0-100)
Percent
Onen Ended Bredust#
Open Ended Product#
Preferred Provider Product##
Traditional indentity Froduction = = = = = = = = = = = = = = = = = = =
*An organized prepaid health care system that delivers health services through a salaried physician group that is employed by the Hi ** An organized prepaid health care system that contracts with one independent group practice to provide health services.  *** An organized prepaid health care system that contracts with two or more independent group practices to provide health service  *** An organized prepaid health care system that contracts directly with physicians in independent practice, with one or management of physicians in independent practice, and/or with one or more multi-speciality group practices to provide health service  # A product where individuals are enrolled in the HMO, but may self-refer to providers outside the network, typically with deduction or extensive cost sharing required.
## A product whereby a third-party payer contracts with a group of medical care providers to furnish services at lower than usual in return for prompt payment and a certain volume of pet i rots.  ### A product where benefits are paid in a product where the paid in a paid in a product where the paid in a
### A product where benefits are paid in a predetermined amount in the event of a covered loss.

14					UMO2	
_ ~ ~	n payment method is used for t nate percentages. 0-100)	ne <i>primary care</i>	and specialty (	care pnysicians ii	n your HMO?	
	Primary Care Physicians			Specialty Care Physicians		į
	Perce	<u>ent</u>			<u>Pe</u>	rcent
	Salary —	230-230		Salary	_	246-241
	Capitated payment — -	230-241		Capitated p	payment — — —	248-250
	Payment-for-service — -	242-244		Payme	nt-for-s <u>e</u>	rvice 261-263
Q-6 For v	which plans and/or products off	ered do you dec	ide on medical	policy coverage	decisions?	
	<ul> <li>Staff model</li> </ul>					254
	Group model					255 256
	— IPA model					257
	<ul><li>Network Model</li><li>PPO product</li></ul>					258
	Open-ended product					259 260
	<ul> <li>Traditional indemnity pr</li> </ul>	oduct				200
Q-7 Are i	medical coverage decisions mad	e similarly acros	s the types of i	nsurance for whic	h you decide or	n medical policy?
	(¹)Yes	•	<i>,</i>		,	261
	<sup>(2)</sup> N o					
If no	<b>):</b>					
	For which types of insurance	e do your respo	nses in Section	I and II apply?		
	<ul><li>Staff model</li></ul>					262
	<ul><li>Group model</li></ul>					263 264
	— IPA model					265
	<ul><li>Network Model</li><li>PPO product</li></ul>					266
	<ul> <li>Open-ended product</li> <li>Traditional indemnity p</li> </ul>	roduct				267 268
_ ~ ~	which state(s) does your compa	ny have its large	est enrollment?	(please rank the	3 states with t	he largest
(01) <b>A</b> P	•	<sup>(22)</sup> <b>M</b> E	(29) <b>N D</b>	(36) <b>O H</b>	<sup>43)</sup> TN	_ <sub>(60)</sub> WV
- (02)A L	O9)DE	— (23) <b>M</b> I	− (30)N E	- <sup>(37)</sup> O K	_ 44ITX	_ <sup>611</sup> WY
(03) A F	R <sup>- (10)</sup> F L(17)KS	— <sup>(24)</sup> M N — <sup>(25)</sup> M O	- (31)N H - (32)N J	- (38) O R - (39) P A	— (45)UT — (48)VA	
— (04) A Z	Z - (11)G A - (18)KY	- (26)M S	— (33) N M	(40)R I	- 471VT	
_ (06)C (	O - (13) A (20)MA	— <sub>(27)</sub> M T	- (34)N V	(41)S C	_ HETWA	
_ (07)C ]	T _ (14)ID _ (21)MD	(28) <b>N</b> C	Y Y	- <sup>(42)</sup> S D	_ "•WI	
Q-9 Hov	w long has your company <sup>beer</sup>	in operation?				
Q-9 1101						276
	<sup>(1)</sup> 1 year <sup>(2)</sup> 2 - 3 years					
	<sup>(3)</sup> 4 - 7 years					
	(4)8 -15 years					
	(°)16 -20 years (°)21 -50 years					
	"> 50 years					

		15				
Q-1 <b>0</b>	Is your company:					
	<sup>(1)</sup> for profit <sup>(2)</sup> not for profit	276				
Q-1 1	What are your professional/post-graduate degrees?					
	- (*)M.D.,D.O (**Ph.D. or doctorate in biological science - (**Ph.D. or doctorate in social science - (**R.N.	277-282				
	<sup>®</sup> M.P.H. <sup>®</sup> M.H.S. <sup>®</sup> M.B.A. <sup>®</sup> M. Sc.					
Q-1 <b>2</b>	If you are an M.D. or D. O., what is your medical specialty and, if applicable, sub-specialty?					
		263				
		284				
0 12	Have long have you cannot be your assent or a similar position for a causion?					
Q-13	How long have you served in your current or a similar position for a carrier?  (*) < 1 year  - (*) 1 -5 years  - (*) 6 -10 years  - (*) 1 1 -15 years  - (*) 5 - 20 years  - (*) 20 years	286				
Q-1 4	What is your job title?					
		286				
THANK YOU FOR COMPLETING THIS QUESTIONNAIRE.						
PLEASE ADD ANY ADDITIONAL COMMENTS ON THE BACK.						
	PLEASE RETURN THE QUESTIONNAIRE IN THE ACCOMPANYING PRE-ADDRESSED POSTAGE PAID ENVELOPE TO:					
	Neil R. Powe, M. D., M. P. H., M.B.A. Claudia A. Steiner, M. D., M.P.H. 1830 E. Monument St., 8th floor Baltimore, MD 21205					
	(410) 955-4128					

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