

The regulatory costs below are considered to be the maximum cost of any regulatory impact. It is likely the actual cost will be much less than the maximums quoted below.

### Option 1 - Status Quo

No Change to regulatory burden. Existing inefficiencies will remain.

### Option 2 - DRG model

#### Administrative Costs - Removal of application process

Number of new applications per year <sup>1</sup>	Average number of hours for medical device companies to complete application <sup>2</sup>	Hourly rate (default rate has been used) <sup>3</sup>	Total <sup>4</sup>
1496	1	\$ 73.05	\$ 109,246.28

1. This uses information captured from the Prostheses List Management System (PLMS) for both new and amendment applications. Only includes two years' worth of data as previous benefit reductions applied required dummy applications to be made for each item subject to benefit reductions, skewing the figures for other years.
2. Estimate based on the complexity of the form. Supporting information should already be collected as a result of seeking to TGA approval.
3. Default hourly rate used
4. This figure represents potential (maximum) savings associated with the removal of the application process.

#### Delay costs - removal of waiting for listing (automatic listing after TGA approval)

Yearly Prostheses List spend <sup>5</sup>	7 month Prostheses List spend <sup>6</sup>	per item delay cost (lost revenue) <sup>7</sup>	Total delay cost per year (lost revenue) <sup>8</sup>
\$ 2,090,564,414.29	\$ 1,219,495,908.33	\$ 410.13	\$ 347,791.93

5. 3 year average prostheses expenditure based on APRA data.
6. Timeframe between applying to list a product and it getting listed (assuming it is recommended for listing) can be up to seven months, assuming the applications are received within one week of the application closing date (as per usual processes). Therefore the delay in potential lost revenue could be as much as 7 months worth of revenue
7. Calculates the per item delay cost based on the 7 month PL spend and the average number of prostheses used
8. Total potential savings from the removal of the 'delay cost' when the application process no longer exists and a product is eligible for reimbursement once TGA approved.

#### Increased costs associated with changed data processing arrangements

Number of Total Prostheses Used <sup>9</sup>	Estimated Effort for Changed Data Processing Arrangements (hours) <sup>10</sup>	Hourly rate (default rate has been used) <sup>11</sup>	Total Increase in Data Collection/Reporting Activities for Hospitals
2,973,423	19822.82	\$ 73.05	\$ 1,448,057.00

9. Number of total prostheses to reflect the number of data entries that will need to be made by private hospitals when reporting their data
10. Assumes a rate of 30 seconds data entry required for each prosthesis used, with a .2 per cent reduction as some hospitals already provide this information voluntarily

#### Other Assumptions

11. No review or compliance functions will be introduced.
12. Assumes negligible changes to Private Health Insurers, Clinicians, Consumers
13. Does not include any consideration of the regulatory burden of hospitals negotiating device costs with insurers. As an average price model, the DRG model allows both low and high cost devices to be used. Any negotiation hospitals choose to do will be in their benefit.

**Total Regulatory Cost Option 2** \$ **991,018.79**

### Option 3 - Redefine the Prostheses List

#### Administrative Costs - Streamlined listing process

Number of new applications per year <sup>1</sup>	Average number of hours taken to complete application <sup>2</sup>	Hourly rate (default rate has been used) <sup>3</sup>	Total
1496	0.5	\$ 73.05	\$ 54,623.14

1. This uses information captured from the Prostheses List Management System (PLMS) for both new and amendment applications. Only includes two years' worth of data as previous benefit reductions applied required dummy applications to be made for each item subject to benefit reductions, skewing the figures for other years.
2. This assumes the new IT system, assessment pathways, grouping structures etc will simplify the application process by 50%.
3. Default hourly rate used

#### Compliance & Review Costs

##### Assumptions

1. Assumes any input from device companies, insurers, hospitals etc would require a similar level of details for a new application, though with additional time to collect more contemporary data or evidence if needed.
2. Assumes the complexity of the review or compliance activity would be a sliding scale, with a broader generic review/compliance activity requiring less detailed input from a greater number of people, and a specific, single-item review/compliance activity requiring significant input from one supplier.

**Category review - 1 every 4 years<sup>3</sup>**

Maximum number of items per category <sup>4</sup>	Number of hours to collate information required	Hourly rate (default rate has been used) <sup>5</sup>	Total per review	Total per year <sup>6</sup>
829	2	\$ 73.05	\$121,161.85	\$30,290.46

3. Assumes a large scale review or compliance activity could only occur once every four years.

4. Calculated on the total number of Part A applications / the current 13 categories.

5. Default hourly rate used

6. Yearly cost assuming such a review takes place once every four years.

**Comparative clinical effectiveness for a group or part of a group - 2 per year<sup>7</sup>**

Maximum number of items per group <sup>8</sup>	Number of hours to collate information required	Hourly rate (default rate has been used) <sup>9</sup>	Total	Total per year <sup>10</sup>
80	4	\$ 73.05	\$23,376.00	\$46,752.00

7. Assumes a review or compliance activity for a sub-group (or part thereof) could occur once every two years.

8. Estimate on the number of items that might be in scope, based off a review currently identified in relation to cardiac stents.

9. Default hourly rate used

10. Yearly cost assuming such a review or compliance activity could be undertaken up to twice a year

**Single product review for a single item - 1 per year<sup>11</sup>**

Number of hours to collate information required	Hourly rate (default rate has been used) <sup>12</sup>	Total per year
40	\$ 73.05	\$2,922.00

11. Assumes a single product review would be more labour intensive than other reviews, but it could be undertaken on an annual basis as needed.

<b>Total Yearly Cost Increase For Compliance and Review Activities</b>	<b>\$79,964.46</b>
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**Additional Data Reporting**

**Increased costs associated with changed data processing arrangements**

Number of Total Prostheses Used <sup>1</sup>	Estimated Effort for Changed Data Processing Arrangements (hours) <sup>2</sup>	Hourly rate (default rate has been used) <sup>3</sup>	Total Increase in Data Collection/Reporting Activities for Hospitals
2,973,423	24778.525	\$ 73.05	\$ 1,810,071.25

1. Number of total prostheses to reflect the number of data entries that will need to be made by private hospitals when reporting their data

2. Assumes a rate of 30 seconds data entry required for half of the prostheses used, noting not all hospitals will contribute to data collection and some already

3. Assumes any changes to public hospital reporting are negligible or captured in the above calculations.

<b>Total increase in regulatory costs</b>	<b>\$ 1,835,412.58</b>
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Prostheses Category	Mar-15			Jun-15			Sep-15			Dec-15			Number of prostheses
	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	
Ophthalmic	66,889	\$19,815,267	\$296	80643	\$24,462,120	\$303	75500	\$22,999,341	\$305	78,123	\$23,855,027	\$305	67,350
Ear, Nose & Throat	7,697	\$6,368,557	\$827	8412	\$7,038,755	\$837	11955	\$7,811,615	\$653	11,686	\$7,553,406	\$646	6,907
General Miscellaneous	172,607	\$49,892,811	\$289	188201	\$54,867,191	\$292	187093	\$54,935,270	\$294	192,190	\$56,714,981	\$295	172,874
Neurosurgical	6,242	\$13,151,258	\$2,107	7366	\$16,188,351	\$2,198	7417	\$16,332,046	\$2,202	7,209	\$16,728,663	\$2,321	6,307
Urogenital	8,615	\$6,738,333	\$782	9800	\$7,930,694	\$809	9419	\$8,470,061	\$899	9,736	\$8,486,214	\$872	8,958
Specialist Orthopaedic	111,753	\$45,758,310	\$409	124440	\$51,502,279	\$414	122683	\$51,967,286	\$424	121,265	\$51,187,900	\$422	110,571
Plastic and Reconstructive	18,045	\$3,544,034	\$196	18077	\$3,780,237	\$209	18052	\$3,988,531	\$221	20,538	\$4,282,310	\$209	18,165
Cardiac	13,644	\$85,712,067	\$6,282	14861	\$97,255,866	\$6,544	14052	\$90,381,200	\$6,432	14,231	\$93,370,432	\$6,561	13,568
Cardiothoracic	1,473	\$4,863,027	\$3,301	1601	\$5,132,554	\$3,206	1502	\$4,806,013	\$3,200	1,561	\$5,005,143	\$3,206	1,423
Vascular	17,435	\$12,520,215	\$718	20079	\$15,165,007	\$755	20206	\$13,868,762	\$686	18,868	\$13,940,265	\$739	16,284
Hip	24,944	\$50,546,779	\$2,026	26972	\$54,221,445	\$2,010	26781	\$54,167,621	\$2,023	28,600	\$58,328,324	\$2,039	25,101
Knee	26,654	\$56,532,808	\$2,121	30834	\$65,811,232	\$2,134	30181	\$63,774,291	\$2,113	33,277	\$70,580,020	\$2,121	27,889
Spinal	41,529	\$32,132,874	\$774	48085	\$37,940,736	\$789	48621	\$38,076,065	\$783	48,572	\$37,351,456	\$769	42,210
Other	52,627	\$53,197,885	\$1,011	57673	\$59,944,024	\$1,039	58828	\$61,474,065	\$1,045	65,219	\$68,236,858	\$1,046	58,815
<b>Total</b>	<b>570,154</b>	<b>\$440,774,227</b>	<b>\$773</b>	<b>637044</b>	<b>\$501,240,492</b>	<b>\$787</b>	<b>632290</b>	<b>\$493,052,168</b>	<b>\$780</b>	<b>651,075</b>	<b>\$515,620,998</b>	<b>\$792</b>	<b>576,422</b>

Average Prostheses Cost / FY			
FY	No Prostheses	Benefits Paid	Avg Cost
15-16	2,528,109	\$ 1,995,841,428.63	\$ 789.46
16-17	2,661,557	\$ 2,090,886,035.97	\$ 785.59
17-18	2,699,064	\$ 2,091,925,257.79	\$ 775.06
18-19	3,104,255	\$ 2,081,485,131.89	\$ 670.53
19-20	3,116,950	\$ 2,098,282,853.18	\$ 673.18
<b>3 year average</b>	<b>2,973,423</b>	<b>\$ 2,090,564,414.29</b>	<b>\$ 706.26</b>

Mar-16		Jun-16			Sep-16			Dec-16			Mar-17			Jun-17			
Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses
\$20,473,988.46	\$304	83,613	\$26,141,189.34	\$313	80077	\$24,851,967	\$310	81734	\$25,905,116	316.9442	72,751	\$22,607,365	\$311	87,082	\$25,822,598.26	296.532	84284
\$5,830,949.00	\$844	8,373	\$7,032,332.00	\$840	10945	\$6,547,101	\$598	12665	\$8,048,222	635.4696	7,869	\$5,890,626	\$749	8,175	\$6,413,714.00	784.5522	10374
\$50,338,601.07	\$291	197,255	\$58,544,187.17	\$297	196121	\$57,454,346	\$293	209122	\$61,344,859	293.3448	192,173	\$58,020,984	\$302	213,640	\$65,230,633.67	305.3297	204652
\$13,581,974.94	\$2,153	8,133	\$18,925,122.21	\$2,327	8168	\$18,273,685	\$2,237	8813	\$21,418,109	2430.286	7,247	\$17,016,988	\$2,348	8,052	\$18,900,088.93	2347.254	7999
\$7,128,728.00	\$796	10,252	\$8,603,723.00	\$839	9801	\$8,174,884	\$834	10054	\$8,765,288	871.821	9,260	\$6,666,171	\$720	10,005	\$7,935,959.20	793.1993	9458
\$45,751,339.21	\$414	126,607	\$52,415,171.05	\$414	128557	\$53,328,201	\$415	129286	\$55,799,520	431.5975	118,281	\$49,275,155	\$417	132,893	\$56,131,039.02	422.3777	131828
\$3,722,283.78	\$205	18,715	\$4,080,216.25	\$218	20401	\$4,605,370	\$226	21750	\$4,948,020	227.4952	21,537	\$4,797,832	\$223	20,319	\$4,877,067.69	240.025	20345
\$88,373,790.82	\$6,513	16,717	\$99,298,076.95	\$5,940	16720	\$98,283,825	\$5,878	17441	\$101,180,893	5801.324	16,677	\$92,663,850	\$5,556	17,782	\$91,830,986.06	5164.266	17286
\$4,788,575.00	\$3,365	1,457	\$4,830,744.35	\$3,316	1474	\$4,988,962	\$3,385	1523	\$5,177,683	3399.661	1,294	\$4,542,707	\$3,511	1,526	\$5,189,269.17	3400.57	1365
\$12,480,189.25	\$766	19,334	\$14,795,669.15	\$765	19938	\$14,944,911	\$750	20727	\$15,439,273	744.887	18,686	\$14,602,790	\$781	21,204	\$16,236,031.00	765.706	19919
\$50,985,224.00	\$2,031	28,263	\$57,467,102.23	\$2,033	27512	\$55,964,049	\$2,034	30542	\$62,560,415	2048.34	27,529	\$54,708,928	\$1,987	29,140	\$54,903,891.68	1884.142	28129
\$59,138,310.67	\$2,120	32,222	\$69,062,746.00	\$2,143	30522	\$65,306,053	\$2,140	33740	\$71,473,847	2118.371	30,840	\$63,523,127	\$2,060	33,381	\$65,996,010.05	1977.053	31079
\$32,102,152.38	\$761	50,068	\$37,564,773.05	\$750	49774	\$37,916,933	\$762	48774	\$37,882,584	776.6963	47,804	\$36,497,050	\$763	51,572	\$39,958,665.00	774.8132	48280
\$62,667,236.54	\$1,065	67,313	\$71,043,867.11	\$1,055	70070	\$71,001,938	\$1,013	61264	\$65,646,309	1071.532	63,772	\$63,035,181	\$988	71,058	\$71,418,187.95	1005.069	71560
\$457,363,343.12	\$793	668,322	\$529,804,919.86	\$793	670080	\$521,642,224	\$778	687435	\$545,590,139	793.6607	635,720	\$493,848,753	\$777	705,829	\$530,844,141.68	752.086	686558

Sep-17		Dec-17			Mar-18			Jun-18			Sep-18			Dec-18		
Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item
\$24,854,683	\$295	87630	\$26,231,978	\$299	77826	\$22,578,244	\$290	92,824	\$26,582,393	\$286	90752	\$26,711,479.74	\$294	92,692	\$27,103,393.83	\$292
\$6,211,308	\$599	11048	\$7,014,865	\$635	7673	\$5,427,630	\$707	8,453	\$10,367,545	\$1,226	10341	\$9,237,604.00	\$893	10,728	\$7,292,675.00	\$680
\$61,662,877	\$301	220790	\$71,132,420	\$322	208274	\$61,474,720	\$295	245,776	\$67,932,900	\$276	245288	\$64,783,752.81	\$264	259,065	\$70,540,330.40	\$272
\$19,748,503	\$2,469	8532	\$21,357,978	\$2,503	7675	\$18,030,600	\$2,349	9,140	\$22,684,597	\$2,482	8560	\$21,387,773.96	\$2,499	8,607	\$20,406,658.62	\$2,371
\$8,057,987	\$852	9611	\$8,083,667	\$841	9783	\$7,749,201	\$792	10,240	\$8,480,287	\$828	9383	\$7,488,538.80	\$798	9,889	\$8,041,814.10	\$813
\$54,566,718	\$414	130220	\$56,759,611	\$436	123035	\$51,916,693	\$422	140,065	\$57,047,564	\$407	141045	\$57,278,638.49	\$406	139,099	\$58,118,499.42	\$418
\$5,133,194	\$252	23582	\$6,353,692	\$269	23079	\$5,851,068	\$254	22,771	\$6,155,731	\$270	21464	\$5,922,871.18	\$276	25,785	\$7,915,310.67	\$307
\$88,934,761	\$5,145	18406	\$95,181,209	\$5,171	17285	\$81,924,605	\$4,740	19,155	\$84,875,136	\$4,431	19776	\$83,667,616.07	\$4,231	20,319	\$84,541,691.70	\$4,161
\$4,501,734	\$3,298	1446	\$5,061,202	\$3,500	1463	\$4,985,112	\$3,407	1,494	\$4,784,543	\$3,203	1616	\$5,326,160.42	\$3,296	1,738	\$5,750,683.11	\$3,309
\$15,305,605	\$768	20869	\$16,061,753	\$770	19344	\$14,023,705	\$725	21,636	\$15,551,287	\$719	20579	\$15,080,296.65	\$733	21,246	\$15,206,667.44	\$716
\$52,660,387	\$1,872	30552	\$57,485,579	\$1,882	27754	\$50,686,708	\$1,826	30,106	\$54,051,100	\$1,795	28810	\$51,082,261.80	\$1,773	30,792	\$53,811,180.02	\$1,748
\$61,241,644	\$1,971	34998	\$68,221,712	\$1,949	30435	\$58,269,680	\$1,915	35,193	\$65,687,848	\$1,867	30890	\$56,965,521.86	\$1,844	35,676	\$65,057,993.50	\$1,824
\$36,079,534	\$747	53385	\$40,691,729	\$762	48647	\$37,111,496	\$763	55,721	\$40,535,940	\$727	51790	\$36,649,649.32	\$708	56,094	\$39,325,419.93	\$701
\$70,345,173	\$983	79563	\$78,677,578	\$989	66484	\$65,656,575	\$988	79,373	\$76,387,673	\$962	76500	\$64,772,039.02	\$847	81,565	\$71,095,343.91	\$872
\$509,304,107	\$742	730632	\$558,314,973	\$764.15	668757	\$485,686,037	\$726	771,947	\$541,124,544	\$701	756794	\$506,354,204.12	\$669	793,295	\$534,207,661.65	\$673

Mar-19			Jun-19			Sep-19			Dec-19			Mar-20			Jun-20		
Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item	Number of prostheses	Prostheses Benefits paid \$	Ave \$/item
82,537	\$23,696,855.12	\$287	93,995	\$27,284,075.14	\$290	95,085	\$27,668,533.16	\$291	93,666	\$27,313,333.96	\$292	82,920	\$22,719,425.54	\$274	60,496	\$16,207,566.26	\$268
7,593	\$7,316,565.26	\$964	7,986	\$8,892,275.17	\$1,113	10,528	\$8,285,100.15	\$787	10,889	\$8,477,972.12	\$779	7,843	\$8,444,219.20	\$1,077	4,212	\$4,913,141.79	\$1,166
245,629	\$64,840,169.56	\$264	298,573	\$79,120,340.12	\$265	286,253	\$74,806,423.99	\$261	294,555	\$76,190,581.89	\$259	268,676	\$69,979,899.22	\$260	222,170	\$58,967,319.63	\$265
7,992	\$18,074,286.16	\$2,262	9,516	\$21,946,802.24	\$2,306	9,129	\$21,174,614.46	\$2,319	9,338	\$22,302,467.79	\$2,388	8,148	\$17,872,985.72	\$2,194	7,145	\$14,353,084.69	\$2,009
9,508	\$6,889,287.46	\$725	10,575	\$8,381,197.46	\$793	9,837	\$8,256,081.02	\$839	10,397	\$8,706,695.31	\$837	10,411	\$7,835,157.87	\$753	8,472	\$5,267,944.39	\$622
134,171	\$56,119,913.02	\$418	154,163	\$64,605,688.29	\$419	154,125	\$66,295,635.45	\$430	154,228	\$68,729,296.08	\$446	142,547	\$60,463,842.70	\$424	122,995	\$49,955,010.20	\$406
24,049	\$6,857,563.50	\$285	22,933	\$6,901,801.07	\$301	23,994	\$7,182,845.50	\$299	26,812	\$8,740,692.64	\$326	25,335	\$8,765,949.50	\$346	17,404	\$5,439,070.20	\$313
20,356	\$83,662,428.16	\$4,110	23,693	\$95,007,086.05	\$4,010	23,546	\$94,554,410.78	\$4,016	23,868	\$95,898,086.00	\$4,018	22,837	\$89,798,076.56	\$3,932	22,855	\$88,141,921.19	\$3,857
1,457	\$4,729,379.47	\$3,246	1,672	\$5,980,213.70	\$3,577	1,687	\$5,656,785.93	\$3,353	1,804	\$5,888,982.97	\$3,264	1,805	\$5,480,492.31	\$3,036	1,695	\$5,946,453.01	\$3,508
20,152	\$14,379,642.97	\$714	22,423	\$15,532,941.15	\$693	23,623	\$16,674,930.13	\$706	22,837	\$16,800,918.35	\$736	21,545	\$14,836,028.58	\$689	20,954	\$14,145,241.93	\$675
28,642	\$50,213,390.46	\$1,753	32,830	\$56,110,019.34	\$1,709	30,623	\$52,872,496.16	\$1,727	32,848	\$57,229,761.42	\$1,742	29,981	\$50,410,289.10	\$1,681	25,510	\$41,784,971.48	\$1,638
33,253	\$61,117,857.38	\$1,838	36,865	\$66,543,151.98	\$1,805	34,721	\$62,782,095.91	\$1,808	38,879	\$69,950,102.51	\$1,799	34,132	\$60,504,543.66	\$1,773	25,944	\$45,453,975.93	\$1,752
52,133	\$38,123,737.02	\$731	52,987	\$41,020,741.77	\$774	54,922	\$41,395,780.44	\$754	59,847	\$44,691,658.69	\$747	53,057	\$39,462,557.35	\$744	49,352	\$36,301,637.56	\$736
67,139	\$60,166,247.27	\$896	51,344	\$47,409,609.83	\$923	67,763	\$60,691,804.08	\$896	80,814	\$73,648,839.34	\$911	70,379	\$64,416,431.14	\$915	61,512	\$57,548,690.24	\$936
734,611	\$496,187,322.81	\$675	819,555	\$544,735,943.31	\$665	825,836	\$548,297,537.16	\$664	860,782	\$584,569,389.07	\$679	779,616	\$520,989,898.45	\$668	650,716	\$444,426,028.50	\$683



**Application volumes as per PLMS**

<b>7 APPLICATION TYPES</b>	<b>2020</b>	<b>2019</b>	<b>Average</b>
Create	940	590	
Amended	698	763	
<b>TOTAL</b>	<b>1,638</b>	<b>1,353</b>	<b>1,496</b>