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SUBMITTED ELECTRONICALLY: http://www.regulations.gov

The Honorable Chiquita Brooks-LaSure, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
7500 Security Boulevard
Baltimore, MD 21244-1850

RE*:* [CMS-1751-P] Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

Boston Scientific Corporation appreciates the opportunity to provide comments in response to the Centers for Medicare and Medicaid Services' (CMS) Physician Fee Schedule (PFS) proposed rule for calendar year (CY) 2022.

As one of the world's largest companies dedicated to developing, manufacturing, and marketing less-invasive therapies, Boston Scientific supplies medical devices and technologies that are used by the following medical specialty areas, all of which provide Medicare beneficiary care:

- Cardiac Rhythm Management;
- Electrophysiology;
- Gastroenterology;
- Interventional Bronchoscopy;
- Interventional Cardiology;
- Interventional Radiology;
- Oncology;
- Neuromodulation;
- Urology; and
- Peripheral Interventions.

In this letter, Boston Scientific offers comments on the following elements of the proposed rule for physician payments in 2022:

I. Changes to Direct Practice Expense Inputs – Clinical Labor Pricing Update
II. Proposed work RVUs for payment of newly created CPT code 434XX (Per-Oral Endoscopic Myotomy (POEM))
III. Establishment of CPT code 33XXX describing Transcatheter placement and subsequent removal of cerebral embolic protection device(s)
IV. External Cardiovascular Device Monitoring (CPT codes 93228 and 93229)
V. Modernizing Enrollment for Emerging Technologies in Independent Diagnostic Testing Facilities (IDTFs)
VI. Proposed Valuation of Revised Bundled CPT Codes for Cardiac Ablation Services
VII. External Extended ECG Monitoring (CPT Codes (93241-93248)
VIII. Extension of Coverage & Payment: Public Health Emergency Telehealth and Movement of Neurological & Psychological Testing Codes to the List of Telehealth Services on a Category 1 Basis
IX. Separate Coding and Payment for Chronic Pain Management and Promotion of Pain Management Add-on Coding and Reimbursement
X. Closing the Health Equity Gap in CMS Clinician Quality Programs—Request for Information (RFI)

I. Changes to Direct Practice Expense Inputs - Clinical Labor Pricing Update

Boston Scientific recommends that CMS delay implementation of the clinical labor wage update and review and revise the methodology, with appropriate input from stakeholders.

CMS proposes to update the per hour wage estimates used to determine clinical labor costs, one of the components of the direct practice expense inputs, which are directly associated with the provision of a procedure. These data were last updated in 2002, and Boston Scientific conceptually agrees that CMS should update the almost 20-year-old clinical labor data. However, we are concerned about the severe and wide-ranging reductions to payment rates for office-based procedures and potential negative impact on patient access and we believe more time is needed to evaluate the methodology for these updates and to align timing with other, potentially interdependent updates to the practice expense methodology already in process. These concerns are detailed below.

A. Methodology for Updating Clinal Labor Pricing Inputs

As outlined in the proposed rule, the agency primarily used data from the 2019 Bureau of Labor Statistics (BLS) survey on wages to update clinical labor pricing. When BLS data were not available for a specific staff type, CMS used additional sources such as Salary Expert (www.salaryexpert.com).

To better understand the impact of the significant reduction to in-office procedures, Boston Scientific commissioned Braid-Forbes Health Research to conduct an analysis of the methodology CMS used to update clinical labor wages. This analysis identified several areas of concern and questions regarding use of the BLS data.

Use of BLS Occupational Employment and Wage Statistics Survey Versus National Compensation Survey

For the 2022 proposed clinical labor updates, CMS appears to have used only the BLS Occupational Employment and Wage Statistics (OEWS) survey (and Salary Expert data where BLS OEWS data were unavailable).[1] However, when CMS last updated these data in 2002, CMS also leveraged the BLS National Compensation Survey (NCS).[2] While the OEWS survey can produce estimates at metropolitan statistical areas (MSAs), the NCS can produce estimates at the national and census region level. Additionally, OEWS wage estimates represent only wages and salaries and do not include nonwage benefits, such as health insurance, retirement contributions, and bonus, whereas NCS data also includes nonwage benefits.[3]

Benefits Multiplier

For 2022, CMS proposes using the same fringe benefit multiplier as was used in 2002.[4] This might not be an accurate multiplier for 2022, given that the cost of benefits has likely changed, due to inflation among other factors. In particular, the cost of health insurance, which is a large part of fringe benefits, has gone up considerably since 2002. In fact, the 2020 Kaiser Family Foundation Employer Health Benefits survey found that the costs of employer-sponsored health insurance has increased 22% just since 2010.[5]

Use of Median Versus Mean Hourly Rates

It is unclear whether CMS used the mean or median hourly wage rate when calculating the per minute rate. In the proposed rule, CMS stated that the per minute rate:

> "*…was derived by dividing the average hourly wage rate by 60 to arrive at the per minute cost. In cases where an hourly wage rate was not available for a clinical staff type was derived by dividing the annual salary (converted to 2021 dollars using the Medicare Economic Index) by 2080 (the number of hours in a typical work year) to arrive at the per minute cost."*[6]

The Braid-Forbes Health Research analysis was able to more closely approximate CMS' numbers when using the median wage than when using the mean wage. Therefore, while CMS stated in the CY 2022 proposed rule that they used the "average hourly wage", we believe that CMS in fact

[1] Braid-Forbes Health Research, August 27, 2021 memo *Bureau of Labor Statistics (BLS) data used for inputs to clinical labor costs for the Medicare physician fee schedule 2022 proposed rule*; analysis commissioned by Boston Scientific.
[2] 66 Fed. Reg. 55257-55262 (November 1, 2001).
[3] Bureau of Labor Statistics website: https://www.bls.gov/oes/oes_emp.htm#overview and https://www.bls.gov/oes/current/oes_tec.htm and https://www.bls.gov/ncs/.
[4] 86 Fed. Reg. 39119 (July 23,2021).
[5] Kaiser Family Foundation, 2020 Employer Health Benefits Survey, Figures 1.11 and 1.12. Accessed at 2020 Employer Health Benefits Survey | KFF; Figures 1.11 and 1.12.
[6] IBID.

used the median. This is important to clarify, as the mean rate per minute in the BLS data is consistently higher than the CMS reported rate per minute.

Wage Data by Employer Type

The BLS reports wage data by employer types. For most of the relevant health care labor categories, wages are reported for hospital, physician office, and outpatient care employers, among others. Wages often vary considerably by employer type, as show below in the data for Registered nurses.

Industry	**Employment (1)**	**Percent of Industry Employment**	**Hourly Mean Wage**	**Annual Mean Wage (2)**
General Medical and Surgical Hospitals	1,729,200	30.9	$39.27	$81,860
Offices of Physicians	192,300	7.42	$34.45	$71,660
Home Health Care Services	169,630	11.35	$36.48	$75,870
Outpatient Care Centers	150,380	15.66	$42.93	$89,300
Nursing Care Facilities (Skilled Nursing Facilities)	143,250	9.34	$34.66	$72,090
Total	**2,384,760**	**75**		

Source: Occupational Employment and Wage Statistics (OEWS): https://www.bls.gov/oes/current/oes291141.htm

Based on the Braid-Forbes analysis, it appears that CMS used the national median wage across all employer types rather than the wage for physician office employers. We believe that CMS should use the physician office setting of care where possible rather than a median (or average) across all employer types.

Planned Update to BLS OEWS Survey

Finally, we note that BLS is planning an update to the OEWS Survey next year that may impact the data. Specifically, the OEWS will be changing the estimation methodology starting next year. On the home page for the OEWS data[7], the agency states:

> "*With the May 2021 estimates, to be released in spring 2022, the OEWS program will use a new estimation methodology. The new model-based estimation methodology, called MB3, has advantages over the existing methodology, as described in the Monthly Labor Review article "Model-Based Estimates for the Occupational Employment Statistics program." Estimates for the years 2015-2018 were re-calculated using the new estimation methodology and are available as research estimates. Technical information is available in the Survey Methods and Reliability Statement for the MB3 Research Estimates of OEWS.*"

[7] https://www.bls.gov/oes/home.htm

While we cannot predict the impact of these modifications, it is possible they will result in important changes to the hourly wage estimates that CMS is proposing to use to update clinical labor costs in 2022.

B. Impact of the Proposal

The proposal estimates that most specialties would see an increase or reduction in payment of about one percent because of the update. However, the modest increases in office evaluation and management (E/M) services mitigate the impact of the clinical labor updates at a specialty level and masks the impact on individual procedures and physicians. The greatest impact is on individual practitioners who perform a significant number of procedures in their offices and only bill for a limited number of office visits. Our analyses indicate there are hundreds of services across multiple specialties with proposed reductions ranging from -4% to -23%, with a significant number of those reductions range from -14 to -22%.

Table I below illustrates a few examples of significant proposed reductions, including CPT code 36903 (Intro cath dialysis circuit), which is performed primarily in-office by interventional radiologists. The procedures below represent six different vascular, urologic, and rhythm management procedures commonly provided to Medicare beneficiaries, by a variety of specialists in the office.

Table I: Selected Procedures with Disproportionate Proposed Reductions

CPT Code	Short Descriptor	Proposed 2022 Reduction	2019 Medicare Claims	2019 Percent Medicare
36909	Dialysis circuit emobl	-18%	3,173	58%
36907	Balo angiop ctr dialysis seg	-20%	35,212	52%
36903	Intro cath dialysis circuit	-22%	10,132	49%
53854	Trurl dstrj prst8 tiss rf wv	-19%	7,541	86%
55874	Tprnl plmt biodegrdabl matrl	-21%	12,712	52%
64633	Destroy cerv/thor facet jnt	-13%	26,503	42%

Source: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Physician-Supplier-Procedure-Summary

The proposed clinical labor update is having an imbalanced negative impact on in-office procedures where equipment and supplies make up most direct input costs. In fact, for some services, the proposed update would create highly anomalous results, including 101 codes for which practice expense (PE) rates are less than the supply input costs. For those services, the PE amount, which is intended to reflect the direct costs (supplies, equipment, and labor) as well as indirect costs incurred to furnish a service, would not cover the cost of the supplies alone. By comparison, only nine codes were in this situation in 2021.

In Table 2, we demonstrate the anomalous effects with two urology and two venous procedure examples where the cost of the device supplies, equipment and non-physician labor substantially exceed the proposed practice expense reimbursement. Like many of the procedures with anomalous impacts, CPT code 53854, transurethral water vapor therapy for benign prostatic hyperplasia and CPT code 55874, transperineal prostatic spacing for men receiving radiation

therapy for prostate cancer are procedures, CPT Code 36465, injection of non-compounded foam sclerosant with ultrasound compression maneuvers, and CPT Code 37238, are performed more than 50% of the time in the office setting for Medicare beneficiaries.

As these examples demonstrate, if the in-office reimbursement rates are finalized as proposed, many procedures will not be financially viable in the office-based setting. The in-office setting is often a more proximate and lower cost site of service for patients as compared to the hospital outpatient department. Thus, if certain procedures cannot be performed in the office setting, it could limit access to care for many patients, particularly vulnerable populations, such as patients of color or those with lower socioeconomic status, for whom longer travel times, and/or higher costs present a particular burden. For example, a 2020 study found that non-whites had higher incidences of presenting to the ED with AUR, and the authors suggested issues of access to BPH management in outpatient settings.[8] Non-whites are significantly more likely to receive minimally invasive surgical BPH treatments in physicians' offices compared to Caucasian men.[9]

Table II: Direct Practice Expense Inputs versus Proposed Practice Expense Reimbursement for Procedure Codes 53854, 55874, 36465 and 37238

CPT Code 53854: Transurethral destruction of prostate tissue; by radiofrequency generated water vapor thermotherapy)	**Direct Practice Expense Inputs versus Proposed Practice Expense Reimbursement**	
	Device	$1,220
	Other Supplies	$181
	Total Supply Inputs	**$1,401**
	Equipment	$13
	Non-Physician Labor	$109
	Total*	**$1,523**
	CY 2022 Proposed Practice Expense Reimbursement	$1,305
CPT Code 55874: Transperineal placement of biodegradable material,	**Direct Practice Expense Inputs versus Proposed Practice Expense Reimbursement**	
	Device	$2,965

[8] Patel PM, Sweigert SE, Nelson M, Gupta G, Baker M, Weaver FM, McVary KT. Disparities in Benign Prostatic Hyperplasia Progression: Predictors of Presentation to the Emergency Department in Urinary Retention. J Urol. 2020 Aug;204(2):332-336.

[9] Boston Scientific analysis of the 5% Medicare Standard Analytic File from January 2010 to December 2018.

peri-prostatic, single or multiple injection(s), including image guidance, when performed)	Other Supplies	$128
	Total Supply Inputs	**$3,093**
	Equipment	$16
	Non-Physician Labor	$37
	Total*	**$3,146**
	CY 2022 Proposed Practice Expense Reimbursement	$2,454
CPT Code 36465: Injection(s) of sclerosant	**Direct Practice Expense Inputs versus Proposed Practice Expense Reimbursement**	
	Device	$1,054
	Other Supplies	$197
	Total Supply Inputs	**$1,252**
	Equipment	$9
	Non-Physician Labor	$71
	Total*	**$1,332**
	CY 2022 Proposed Practice Expense Reimbursement	$1,111
CPT Code 37238: Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed	**Direct Practice Expense Inputs versus Proposed Practice Expense Reimbursement**	
	Device	$3,124
	Other Supplies	$339
	Total Supply Inputs	**$3,463**
	Equipment	$322
	Non-Physician Labor	$132
	Total*	**$3,917**
	CY 2022 Proposed Practice Expense Reimbursement	$2,886

Source: CMS-1751-P CY 2022 PFS Proposed Rule Direct PE Inputs

C. Timing

There are two additional reasons Boston Scientific is recommending a delay in implementing the clinical labor cost updates: (1) the interdependency of clinical labor costs with the agency's ongoing Indirect Practice Expense Cost methodology review and (2) exacerbation of access concerns during the Public Health Emergency (PHE).

Interdependency with Indirect Practice Expense (PE) Cost Methodology Review

Boston Scientific understands that CMS is in process of reviewing the methodology for calculating Indirect Practice Expense (PE) Costs and has engaged the RAND Corporation to conduct a comprehensive review. Per the CMS website, "CMS has not changed the data and methodology for practice expense payments under the Medicare Physician Fee Schedule for over a decade. The RAND Corporation is researching approaches to collect new data, along with potential changes to the current allocation system."[10]

Clinical labor plays a critical role in PE calculations. As a direct input, clinical labor currently is an allocator of Indirect PE for all codes. In addition, for codes with little or no physician work, clinical labor also serves as a substitute for the work RVUs in the indirect PE allocation methodology. Given that CMS is undertaking broad evaluation of indirect PE methodology, including appropriateness of indirect allocators[11], the outcome of that evaluation will likely cause PE rates to shift again.

As a result, there is a clear potential for a "whipsaw" effect, with PE rates shifting significantly from year to year. Physician PE rates have already been in flux due to the equipment and supply input updates, which were just full phased in 2021. The proposed clinical labor cost updates threaten an even more significant swing in payments for many physician services, and the Indirect PE methodology updates will undoubtedly create another round of significant – and yet unpredictable – swing in Medicare's physician payment rates for individual procedures.

Delaying the proposed update to clinical wage data until it can be considered as part of the agency's larger Indirect PE Methodology evaluation will avoid the potential for whipsawing of rates for individual services under the Medicare Physician Fee Schedule. Furthermore, it would enable CMS to take advantage of the mechanisms for stakeholder input contemplated in RAND's Indirect PE Methodology work.[12]

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[10] https://www.cms.gov/medicare/physician-fee-schedule/practice-expense-data-methods.

[11] CMS Virtual Town Hall Meeting, *Improving Data and Methods Related to Indirect Practice Expense in the Medicare Physician Fee Schedule*, June 16, 2021. Accessed on 9/1/2021 at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2017Downloads/Test.pdf.

[12] Burgette, Lane F., Catherine C. Cohen, Joachim O. Hero, Jodi L. Liu, Daniel J. Crespin, Stephanie Dellva, Roald Euller, Liisa Hiatt, Vishnupriya Kareddy, Monique Martineau, Katie Merrell, PhuongGiang Nguyen, Evan D. Peet, Nabeel Shariq Qureshi, Teague Ruder, Yaou Flora Sheng, Barbara O. Wynn, Lan Zhao, and Peter S. Hussey, *Practice Expense Methodology and Data Collection Research and Analysis: Interim Phase II Report*. Santa Monica, CA: RAND Corporation, 2020. https://www.rand.org/pubs/research_reports/RR3248.html.

Considerations During the Public Health Emergency (PHE)

While Boston Scientific believes the concerns outlined above fully support our recommendation to delay and revise the clinical labor PE data updates, the COVID-19 Public Health Emergency (PHE) further exacerbates our concerns. The PHE increases the importance of patient access to services in the physician office, where patients may have fewer safety concerns. Moreover, the PHE has further limited physicians' ability to gain additional time in the hospital for procedures that would otherwise be performed in the physician office.

BSC Recommendation

- Given the pending changes to BLS methodology, review of CMS Indirect PE methodology, discrepancies in CMS labor wage rate methodology, and the lingering effects of the COVID-19 crisis to health systems and patients, Boston Scientific recommends delaying implementation of the clinical labor wage update until the agency can revise the methodology with input from stakeholders and gain a better understanding of the impact these changes will have on patients and providers.

II. Proposed work RVUs for payment of newly created CPT code 434XX (Per-Oral Endoscopic Myotomy (POEM))

Boston Scientific recommends that CMS use the RUC recommended work RVU of 15.50 to establish payment under the 2022 Medicare Physician Fee Schedule for CPT code 434XX.

Boston Scientific supports CMS' proposal to establish national payment for CPT code 434XX (Per-Oral Endoscopic Myotomy (POEM)). This code was approved by the CPT Editorial Panel in May 2020. For CY 2022, CMS proposes a work RVU of 13.29 for the newly created CPT code 434XX based on a direct work RVU crosswalk from CPT code 36819 (Arteriovenous anastomosis, open; by upper arm basilic vein transposition). It is unclear why CMS did not accept and propose the RUC recommended work RVU of 15.50 and why CMS chose this specific code as a crosswalk. Boston Scientific is concerned that a work RVU of 13.29 does not accurately reflect the physician work and intensity required to perform a POEM procedure.

In the AMA/Specialty Society RUC Summary of Recommendations dated October 28, 2020, the RUC recommended a work RVU of 15.50 for CPT code 434XX. The RUC made this recommendation based on a review of robust survey results from 119 physicians and determined that the survey 25th percentile work RVU of 15.50 accurately reflects the physician work necessary to perform this service. A multi-specialty consensus panel reviewed the survey data for code 434XX, comparing the data and work RVUs to the current data for similar 90-day global codes that the RUC recently approved. The consensus panel agreed with the overall survey data.

The RUC compared CPT code 434XX to the top two key reference services: CPT code 43279 Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed (work RVU = 22.10 and 150 minutes intra-service time) and CPT code 43180 Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (eg, Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair,

when performed (work RVU = 9.03 and 60 minutes intra-service time). The RUC noted 43279 requires more physician time and work to perform, yet similar intensity, thus is appropriately valued more than CPT code 434XX. CPT code 43180 requires much less physician time, work and intensity, and thus is appropriately valued less than CPT code 434XX. Additionally, 74% of the survey respondents who selected key reference code 43180 indicated 434XX was more intense and complex to perform than 43180.

Furthermore, it is unclear why CMS selected CPT code 36819 as a crosswalk to approximate the work RVUs for 434XX. The American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, Society of American Gastrointestinal and Endoscopic Surgeons, and Society of Thoracic Surgeons submitted the following chart to the RUC comparing CPT code 434XX to other RUC-reviewed codes with similar time and post-operative visits supporting the survey data. The chart includes several codes (e.g., 58544, 60500, 15733, 43279, etc.) that have an intra-service time of 120 minutes equal to 43XXX. Notably, the work RVUs associated with these codes are higher than CMS' proposed work RVU of 13.29. While we believe CMS should accept the AMA RUC recommendation, there are numerous codes with a similar intra-service time and intensity with higher work RVUs that could have been selected as a more appropriate crosswalk.

CPT Code	Long Desc	Glob	Work RVU	Pre time	Intra Time	Post Time	Total Time	Time Source	Most Recent RUC Review	Top_Specialty	IWPUT	MPC	2019 Util
58674	Laparoscopy, surgical, ablation of uterine fibroid(s) including intraoperative ultrasound guidance and monitoring, radiofrequency	090	14.08	51	120	30	266	RUC	2016-01	OBSTETRICS/ GYNECOLOGY	0.0825		8
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g;	090	14.39	56	110	30	261	RUC	2014-04	OBSTETRICS/ GYNECOLOGY	0.0918		34
19303	Mastectomy, simple, complete	090	15.00	58	90	30	283	RUC	2016-04	GENERAL	0.1018	YES	24587
57265	Combined anteroposterior colporrhaphy, including cystourethroscopy, when performed; with enterocele repair	090	15.00	56	120	30	271	RUC	2017-01	OBSTETRICS/ GYNECOLOGY	0.0892		4370
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s)	090	15.00	56	90	30	241	RUC	2014-04	OBSTETRICS/ GYNECOLOGY	0.119		22432
434XX	**Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy**	**090**	**15.50**	**47**	**120**	**30**	**261**				**0.095**		
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	090	15.60	56	120	30	271	RUC	2014-04	OBSTETRICS/ GYNECOLOGY	0.0942		83
60500	Parathyroidectomy or exploration of parathyroid(s);	090	15.60	72	120	40	313	RUC - CMS Revised	2010-10	GENERAL SURGERY	0.086	YES	18399
15733	Muscle, myocutaneous, or fasciocutaneous flap; head and neck with named vascular pedicle (ie, buccinators, genioglossus, temporalis, masseter, sternocleidomastoid, levator scapulae)	090	15.68	58	120	30	305	RUC	2017-01	PLASTIC AND RECONSTRUCTIVE SURGERY	0.0865		5657
43279	Laparoscopy, surgical, esophagomyotomy (Heller type), with fundoplasty, when performed	090	22.10	80	150	30	404	RUC	2008-04	GENERAL SURGERY	0.097		829

Source: RUC Recommendations October 2020 | AMA (ama-assn.org)

Boston Scientific believes that a work RVU of 15.50 most accurately reflects the physician work and intensity necessary to perform this service based on the RUC recommendation and the robust survey conducted by the American Association for Thoracic Surgery, American College of Gastroenterology, American Gastroenterological Association, American Society for Gastrointestinal Endoscopy, Society of American Gastrointestinal and Endoscopic Surgeons, and Society of Thoracic Surgeons.

Boston Scientific Recommendation

- We recommend that CMS finalizes the RUC RVU recommendation of 15.50 for CPT code 434XX for CY 2022.

III. Establishment of CPT code 33XXX describing Transcatheter placement and subsequent removal of cerebral embolic protection device(s)

We support CMS' proposal to establish CPT code 33XXX describing Transcatheter placement and subsequent removal of cerebral embolic protection device(s).

We support CMS' proposal to establish CPT code 33XXX describing Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, *catheterization, imaging, and radiological supervision and interpretation, percutaneous, (list separately in addition to code for primary procedure)*. This code was approved by the CPT Editorial Panel in October 2020, as an add-on code to report transcatheter placement and subsequent removal of cerebral embolic protection device(s). Boston Scientific also supports the RUC recommendation for work RVUs and the payment associated with this new CPT add-on code 33XXX.

The SENTINEL™ Cerebral Embolic Protection System (CPS) is the only FDA approved device available in the United States, proven safe for successful delivery and retrieval. As the manufacturer of the SENTINEL™ CPS, Boston Scientific supports an established payment for the physician work associated with use of cerebral embolic protection during TAVR.

Boston Scientific Recommendation:

- We support the CPT code 33XXX describing Transcatheter placement and subsequent removal of cerebral embolic protection device(s), including arterial access, *catheterization, imaging, and radiological supervision and interpretation, percutaneous, (list separately in addition to code for primary procedure).*

IV. External Cardiovascular Device Monitoring (CPT codes 93228 and 93229)

Boston Scientific recommends that CMS accept all of the RUC recommendations for the valuation of CPT codes 93228 and 93229 for External Cardiovascular Device Monitoring

CMS proposes not to accept several RUC recommendations for the valuation of CPT codes 93228 and 93229 for External Cardiovascular Device Monitoring. Boston Scientific believes that the RUC recommendations for both codes are accurate and appropriate.

A. CPT Code 93228 *(External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional).*

For CPT code 93228, CMS proposes a work RVU of 0.43 using a direct work RVU crosswalk from CPT code 93290 rather than the RUC-recommended work RVU of 0.52. CMS states that CPT code 93290 is an appropriate crosswalk because it has the same pre-, intra-, and post-service times as the survey times for CPT code 93228 and was reviewed in October 2016.

Boston Scientific disagrees with using CPT code 93290 as a crosswalk based purely on similar work time because it disregards the intensity of work per unit of time (IWPUT) that is required to provide mobile cardiovascular telemetry services. According to the National Coverage Determination (NCD) for Electrographic Services (20.15), CPT code 93228 is a 24-hour attended service requiring that "technicians should have immediate, 24-hour access to a physician to review transmitted data and make clinical decisions regarding the patient." Article A57476, Billing and Coding: Electrocardiographic (EKG or ECG) Monitoring (Holter or Real-Time Monitoring) also states that CPT code 93228 "includes review and interpretation of each 24-hour cardiac surveillance as well as 24-hour availability and response to monitoring events within a course of treatment that includes up to 30 consecutive days of cardiac monitoring" and "a physician must be available 24 hours a day for immediate consultation to review the transmission in case of significant symptoms or ECG abnormalities." In addition to being immediately notified of critical and serious events, Article A57476 also states that for CPT code 93229, "medical chart documentation including daily report" and "summary report at the end of the monitoring episode" must be created for physician review and interpretation.

As shown in Table III below, Boston Scientific believes that recently the AMA RUC reviewed (February 2020) work RVUs of 0.50 for CPT code 93244 and 0.55 for CPT code 93248 should be used as lower/upper limit crosswalk boundaries for assessing the relative value of work (RVW) for CPT code 93228. CPT codes 93244 and 93248, which are for the review and interpretation of extended ECG monitoring data, are more clinically like CPT code 93228 than CPT code 93290, which is for cardiovascular physiologic monitoring data. Furthermore, CPT code 93244 shares the same median intra-service time of 10 minutes as CPT code 93228 but with fewer total minutes - 20 compared to 23 - which makes for an appropriate lower limit on the codes that should be used as a crosswalk. CPT code 93248 has greater median intra-service time of 12 minutes, which makes for an appropriate upper limit for the crosswalk codes.

Boston Scientific recommends that CMS implement the RUC-recommended work RVUs of 0.52 for CPT code 93228 using CPT codes 93244 and 93248 as lower/upper limit crosswalk boundaries.

Table III: Physician Work Time and Relative Value Units for Ambulatory ECG Codes

CPT Code	Median Intra-Service Time (mins)	CY 2022 Proposed Work RVUs	BSC Recommended CY 2022 Final Work RVUs
93244	10	0.50	0.50
93228	10	0.43	0.52
93248	12	0.55	0.55

Source: RUC Recommendations October 2020 | AMA (ama-assn.org), CMS-1751-P CY 2022 PFS Proposed Rule Physician Work Time and Addendum B Relative Value Units

For CPT code 93228, CMS also proposes using the standard 2 minutes for "Provide education/obtain consent" (CA011) rather than the RUC-recommended 10 minutes. CMS states that the minutes should not be based on a direct crosswalk to CPT code 93229. CMS contends that while patient education and consent are provided when both CPT codes 93229 and 93228 are performed, the provider of 93229 will provide more in-depth education than the provider of CPT code 93228.[13]

Boston Scientific believes that the duplication of clinical labor to "Provide education/obtain consent" (CA011) is a key factor to producing high quality and clinically actionable data when providing mobile cardiovascular telemetry services as described by CPT code 93228. We agree that the content of the education differs between what is provided in CPT codes 93228 and 93229. For CPT code 93228, the clinical staff in the physician office first obtains patient consent, details the mobile cardiovascular telemetry service itself, ensures that patients understand how the data being generated will be used in the diagnosis of their condition, educates the patient on the process for obtaining equipment, and informs the patient that further instructions are to be expected from the IDTF. Later when the patient receives the equipment, the IDTF, as part of CPT code 93229, provides an overview of the mobile cardiovascular telemetry service but focuses more so on educating the patient on the correct use of the equipment including preparing the skin, attaching the monitor to the patch, placing the monitor on the chest, turning on the monitor, recording symptomatic events, and troubleshooting.

Given these education and consent requirements, Boston Scientific disagrees with using the standard 2 minutes for CA011 for CPT code 93228 and believes that 10 minutes is the minimum necessary for clinical staff in the physician office to properly educate patients on their role and responsibilities in the procurement of clinically meaningful ECG rhythm data. Patient compliance is a significant challenge and this education must be repeatedly emphasized by both the physician office and IDTF. Therefore, Boston Scientific recommends that for CPT code 93228 CMS implement the RUC-recommended 10 minutes for "Provide education/obtain consent" (CA011).

B. CPT Code 93229 *((External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; review and interpretation with report by a physician or other qualified health care professional)*

Quality Assurance Overread Time

For CPT code 93229, CMS proposes using 0 minutes for quality assurance "overread" done by a second, senior technician rather than the RUC-recommended 24 minutes. CMS states that this is a new clinical activity (CA021) and questions the typicality of using a second senior technician when performing CPT code 93229. CMS requests additional information about the IDTF's current quality assurance measures and parameters within the ECG recording programing that should act

[13] CMS-1751-P. *Federal Register*. 23 July 2021;86(139): page 39169.

as some degree of quality assurance that would obviate the need for a second, senior technician to perform an overread.[14]

Boston Scientific disagrees with the proposed 0 minutes and recommends that CMS implement the RUC-recommended 24 minutes for quality assurance "overread" done by a second, senior technician (CA021). Quality assurance "overread" done by a second, senior technician is a critical process component in the delivery of clinically meaningful ECG rhythm data for physician review and interpretation. As part of standard operating procedure, ECG rhythm data are triaged on first pass according to severity with rhythm events categorized as critical, serious, or stable. Events identified as critical (e.g. ventricular tachycardia, third degree heart block, syncope, symptoms of suspected stroke) or serious (e.g. atrial fibrillation, bradycardia, supraventricular tachycardia, pause) trigger immediate notification of a medical doctor. A second, senior technician overreads 100% of these critical/serious events to confirm findings and that the events meet the criteria for physician notification prior to building the notification report and initiating a call to the physician. Furthermore, as part of the end of service report process, senior technicians routinely review event interpretations summarized in the end of service report for accuracy and completeness prior to delivery for physician review and interpretation. The entire quality assurance standard operation procedure also includes the oversight by a physician medical director whose time is not accounted for in in CPT code 93229, which is assigned 0 Work RVUs. Nor are these physician medical director expenses that are typically captured by the indirect portion of practice expense.[15]

Cost of Equipment Item EQ340 (Patient Worn Telemetry System)

CMS states that acquisition costs for equipment item EQ340 *Patient Worn Telemetry System* were unattainable due to the proprietary nature of this equipment and is seeking additional cost information from IDTFs to help update the equipment item for CY 2022.[16] Boston Scientific understands CMS' desire to validate supply/equipment acquisition costs with traditional commercial invoices as we often sell products directly to hospitals and physician offices. As part of that traditional business model, invoices are easily generated. However, the IDTF model for providing the services described by CPT code 93229 does not generate traditional third-party commercial invoices. As a result, invoices cannot easily be provided for this equipment.

Boston Scientific appreciates that CMS is seeking additional information about the acquisition costs of equipment item EQ340 from nontraditional manufacturers such as IDTFs and is willing to consider alternative costing methodologies for validating acquisition costs for nontraditional manufacturers. We have a foundational understanding of the cost categories that should be captured as part of the equipment costing methodology for EQ340, including the following:

[14] CMS-1751-P. *Federal Register*. 23 July 2021;86(139): page 39169.
[15] Burgette, Lane F., Catherine C. Cohen, Joachim O. Hero, Jodi L. Liu, Daniel J. Crespin, Stephanie Dellva, Roald Euller, Liisa Hiatt, Vishnupriya Kareddy, Monique Martineau, Katie Merrell, PhuongGiang Nguyen, Evan D. Peet, Nabeel Shariq Qureshi, Teague Ruder, Yaou Flora Sheng, Barbara O. Wynn, Lan Zhao, and Peter S. Hussey, Practice Expense Methodology and Data Collection Research and Analysis: Interim Phase II Report. Santa Monica, CA: RAND Corporation, 2020. https://www.rand.org/pubs/research_reports/RR3248.html.
[16] IBID.

- Direct labor and costs of goods sold,
- Sustaining research and development specific to mobile cardiovascular telemetry devices,
- Software platform and algorithm development specific to mobile cardiovascular telemetry services,
- Customer account maintenance, and
- Ongoing patient care and customer service.

However, as CMS acknowledges, due to the proprietary nature of IDTFs, which serve as both equipment manufacturer and diagnostic provider, third-party commercial equipment invoices are not available to document these costs, nor do they represent the typical case for mobile cardiovascular telemetry services used by the majority of physicians and provided through IDTFs.

As a result, Boston Scientific recommends that for CY 2022, CMS implement on an interim basis the fully transitioned Market Research Pricing Update recommended equipment price of $23,494.00 for equipment item EQ340. We look forward to working with CMS in the coming months to determine an appropriate costing methodology to help update the cost for equipment item EQ340 in time for the 2023 rulemaking cycle.

Useful Life of Equipment Item EQ340 (Patient Worn Telemetry System)

In the proposed rule, CMS raises questions regarding the current useful life of equipment item EQ340. CMS states that the currently assigned useful life of 3 years is incongruent with other equipment items that have more than 500 minutes of equipment time. CMS is seeking additional information regarding the useful lifetime of EQ340.[17]

Boston Scientific agrees that patient worn telemetry devices have experienced significant technological changes since the useful life was last updated in 2008. It is these advancements that make it difficult to compare equipment time and useful life for these devices to other procedures.

Battery life is the most significant driver of useful life of this equipment. Technological advances have provided patient and physician benefits but have created additional pressures on batter life. For example, when critical and serious arrhythmia events are detected, augmented intelligence algorithms automatically trigger the device to initiate processes for immediate data transmissions to the IDTF. These data transmissions initially occur from the device to the patient phone via Bluetooth, which consumes significant battery power. Battery life is a multivariate function of storage times/conditions, use environment, frequency/type of data transmissions, and charge cycles. The 3.7 V lithium ion battery used in these devices typically lasts between 2 and 3 years. The BodyGuardian® Mini device is waterproof and can safely be submerged in water as deep as 3 feet, which allows for continuous wear when showering, bathing, or swimming. While this unique feature improves patient satisfaction and increases the continuity of data capture, the battery cannot be replaced without completely disassembling the device, ending its useful life. Thus, battery longevity is a primary driver in the useful life of equipment item EQ340 being on average less than 3 years.

[17] IBID.

These technological enhancements that benefit the physician and patient have also significantly increased the data throughput from these devices, increasing the work required by electrodiagnostic technologists, but not increasing useful life of the equipment. Although other technological changes have been developed to help electrodiagnostic technologists handle the increase in data throughput, significant technologist time is still required. For instance, augmented intelligence algorithms now assist technicians with their initial review and analysis of recorded ECG data and/or triggered event data. However, even with augmented intelligence algorithms, the RUC-recommended 281 mins for monitoring performed by an electrodiagnostic technologist is an accurate estimate given the volume of data. The time required would be even longer in the absence of augmented intelligence advances.

Boston Scientific believes that the above-mentioned attributes of the mobile cardiovascular telemetry service are unique to CPT code 93229 and equipment item EQ340, and thus comparisons of useful life for EQ340 based solely on total minutes of equipment time is flawed.

Boston Scientific urges CMS to keep the currently assigned 3 years of useful life for equipment item EQ340 Patient Worn Telemetry System.

Boston Scientific Recommendation:

- Boston Scientific recommends that CMS accept all of the RUC recommendations for the valuation of CPT codes 93228 and 93229 for External Cardiovascular Device Monitoring.

V. Modernizing Enrollment for Emerging Technologies in Independent Diagnostic Testing Facilities (IDTFs)

Boston Scientific supports the proposed modifications to 42 CFR § 410.33 to exempt those IDTFs that do not require direct or in-person beneficiary interaction, treatment, or testing from certain Medicare enrollment requirements.

CMS proposes modifications to 42 CFR § 410.33 which covers traditional IDTF suppliers that engage in direct or in-person beneficiary interaction, treatment, and/or testing to address concerns of IDTF providers that utilize diagnostic tests via computer modeling and analytics, or other forms of testing not involving direct beneficiary interaction. These entities often cannot meet certain IDTF requirements and cannot enroll in Medicare strictly because of the test's indirect nature. In this rule CMS proposes exempting IDTFs that provide services that do not require direct or in-person beneficiary interaction from specific IDTF requirements. We support CMS' proposal to modify its regulations concerning IDTFs to provide greater flexibility for diagnostic testing providers who do not have in-person beneficiary interaction. CMS also proposes to exempt such IDTFs from other regulatory requirements outside the construct of an in-person patient interaction and recognizes that these do not make sense for innovative technologies such as digital health or AI systems. We support these changes and appreciate CMS' attention to this issue.

Boston Scientific Recommendation:

- Finalize proposed modifications to 42 CFR § 410.33 to exempt those IDTFs that do not require direct or in-person beneficiary interaction, treatment, or testing from certain Medicare enrollment requirements.

VI. Proposed Valuation of Revised Bundled CPT Codes for Cardiac Ablation Services

Boston Scientific recommends that CMS use the revised AMA RUC survey data to publish interim final values or use an alternate crosswalk or budget neutral valuation approach to appropriately value the revised bundled CPT codes for cardiac ablation services.

In consideration of confounding AMA RUC survey results, CMS is proposing to maintain the valuation of CPT codes 93653-93657, 93613, 93621 and 93662, using the current physician times and current work RVUs, until the AMA RUC proposes a more definitive and accurate valuation based on a re-fielded survey. While Boston Scientific understands that the AMA RUC has since resurveyed the revised codes, 93653-93657. The new survey data were presented at the RUC's spring meeting, which took place slightly past the CMS deadline to be considered in this updated recommendation for the CY2022 NPRM. However, we believe it is reasonable for CMS to use the April 2021 RUC recommendations to set interim final values in the CY 2022 Final Rule, thus permitting full stakeholder review and comment on the Final Rule.

If the revised survey data cannot be used, we recommend that CMS account for *all* elements in the new bundled CPT codes that were previously billed separately, instead of CMS' proposal to cross walk the values from only one of the components of the revised CPT codes. Boston Scientific is concerned that CMS may have overlooked all three elements of the bundled cardiac ablation procedures by maintaining the current work RVUs of 14.75 for 93563 and 19.77 for 93656 as interim for CY 2022. The proposed rule does not take into account the work RVUs of the newly bundled services, 3D mapping (5.23) and left atrial pacing (2.10) which were previously billed separately as 93613 and 93621, respectively, for 93653 and 3D mapping (5.23) and ICE (2.80) which were previously billed separately as 93613 and 93662, respectively, for 93656. Consequently, the proposed interim RVUs create a substantial payment reduction for physicians that provide these services, effectively resulting in these bundled services going unpaid for CY 2022.

As an alternative to using the revised RUC survey data, we therefore recommend that CMS crosswalk these revised CPT codes for CY 2022 based on the current RVUs for all of the separate codes previously used to report those services. We alternatively suggest that for interim CY 2022 CMS seek to establish a payment rate that is budget neutral regarding the *total* RVUs for all of the previously separately coded components of the three procedures as a temporary solution. Specific recommendations are detailed below.

Option 1: Crosswalk the new CPT codes for CY 2022 based on current cardiac ablation services CPT RVUs. As add-on codes in CY 2021 CPT codes 93613, 93621, and 93662 do not include pre or post service work RVUs ensuring that CMS would not duplicate RVUs when employing a crosswalk.

CPT Code	2021 Work RVUs	2022 Crosswalk Work RVUs for 93653		CPT Code	2021 Work RVUs	2022 Crosswalk Work RVUs for 93656
93653	14.75	22.08		93656	19.77	27.80
93613	5.23			93613	5.23	
93621	2.10			93662	2.80	

Option 2: We recommend the following budget neutral interim CY 2022 RVUs to stabilize physician payment while full consideration of the April 2021 RUC recommendations can be presented for stakeholder review and comment in future rulemaking.

CPT 93653

We recommend using a budget neutral total work RVU approach by summing the frequency adjusted work RVUs as an interim for CY 2022. For CY 2022, we recommend as an interim **20.74** work RVUs for **CPT 93653**.

CPT Code	Bundled Utilization	Source Work RVU	Total Source Work RVUs	Frequency Adjustment Factor	Freq Adj Work RVU	Total Freq Adj Work RVUs
93653	31,821	14.75	469,360	1.000	14.75	469,360
93613	27,172	5.23	142,110	0.854	4.47	142,110
93621	23,134	2.10	48,581	0.727	1.53	48,581
Total		**22.08**	**660,051**		**20.74**	**660,051**

CPT 93654, 93655, and 93657

For CY 2022, we recommend as an interim **19.75** work RVUs for **CPT 93654**, **7.50** work RVUs for **CPT 93655, and 7.50** work RVUs for **CPT 93657.**

CPT 93656

We recommend using a budget neutral total work RVU approach by summing the frequency adjusted work RVUs as an interim for CY 2022. For CY 2022, we recommend as an interim **27.14** work RVUs for **CPT 93656**.

CPT Code	Bundled Utilization	Source Work RVU	Total Source Work RVUs	Frequency Adjustment Factor	Freq Adj Work RVU	Total Freq Adj Work RVUs
93656	53,327	19.77	1,054,275	1.000	19.75	1,054,275
93613	49,327	5.23	257,980	.925	4.84	257,980
93662	48,227	2.80	135,176	.905	2.53	135,176
Total		**27.80**	**1,447,431**		**27.14**	**1,447,431**

Boston Scientific Recommendation:

- Boston Scientific recommends that CMS use the revised AMA RUC survey data to publish interim final values or use an alternate crosswalk or budget neutral valuation approach to appropriately value the revised bundled CPT codes for cardiac ablation services.

VII. External Extended ECG Monitoring (CPT Codes (93241-93248)

Boston Scientific supports setting an initial fair and stable national rate for Extended ECG Monitoring.

In this year's proposed rule, CMS reviews its decision to use contractor pricing for CY 2021 for certain External Extended ECG Monitoring Codes to allow additional time to receive more pricing information. The agency also notes that since the final CY 2021 PFS rule, stakeholders have continued to engage directly with CMS and the MACs on payment for this service and states that it is once again seeking public comment and information to support CMS' future rulemaking to establish a uniform national payment that appropriately reflects the PE that are used to furnish these services.

Boston Scientific believes it is in the best interest of Medicare beneficiaries to establish a national rate that will ensure patient access to Extended ECG Monitoring. As referenced in the proposed rule, CMS acknowledges that the current contractor rates do not adequately cover the costs for providing the Extended ECG Monitoring Services. CMS has data that represents the typical case for Extended External ECG Monitoring used by the majority of physicians and provided through Independent Diagnostic Testing Facilities to treat Medicare beneficiaries enabling the agency to determine a fair and stable rate for CY 2022. We encourage CMS to set an initial fair and stable national rate for the External Extended ECG Monitoring CPT codes for CY 2022 and look forward to continued engagement with the agency in its efforts to serve Medicare beneficiaries.

VIII. Extension of Coverage & Payment: Public Health Emergency Telehealth and Movement of Neurological & Psychological Testing Codes to the List of Telehealth Services on a Category 1 Basis

Boston Scientific supports CMS' proposal to extend coverage and payment of Category 3 Telehealth Services until at least the end of CY 2023, but also recommends that CMS make Neurological & Psychological Testing codes 96130-96139 permanent (Category 1) telemedicine codes.

A. Extension of Coverage and Payment of Category 3 Telehealth Services

Given uncertainties and impact associated with the COVID-19 public health emergency, enabling care through telehealth mediums will help to minimize patient risk of exposure to the virus and potential variants. Therefore, we support CMS' proposal to extend coverage and payment of Category 3 Telehealth Services until at least the end of CY 2023.

B. Movement of CPT codes 96130 – 96133 and CPT codes 96136 – 96139 to the List of Telehealth Services on a Category 1 basis

On October 2, 2020, Boston Scientific submitted comments to CMS on the CY 2021 Medicare Physician Fee Schedule proposed rule (CMS-1734-P) requesting that CPT nine Neurological and Psychological testing codes be added to the List of Telehealth Services on a Category 1 basis. For CY 2022, CMS again states that these codes do not meet the criteria for permanent addition to the

Medicare telehealth services list because CMS believes these services require close observation by the furnishing practitioner to monitor how a patient responds and progresses through the testing.

These codes describe the administration, scoring and evaluation of psychological and neuropsychological testing as follows:

- 96130 – Psychological testing evaluation (first hour);
- 96131 – Psychological testing evaluation (each additional hour);
- 96132 – Neuropsychological testing evaluation (first hour);
- 96133 – Neuropsychological testing evaluation (each additional hour);
- 96136 – Psychological or neuropsychological test administration & scoring by a professional (first 30 minutes);
- 96137 – Psychological or neuropsychological test administration & scoring by a professional (each additional 30 minutes);
- 96138 – Psychological or neuropsychological test administration & scoring by a technician (first 30 minutes); and
- 96139 – Psychological or neuropsychological test administration & scoring by a technician (each additional 30 minutes).

While we appreciate that telehealth coverage will be extended for these codes though at least the end of CY 2023, Boston Scientific believes that permanent extension of access through telehealth mediums is appropriate and will best serve Medicare beneficiaries. These services describe physician or other qualified health care provider administration and scoring of psychological or neuropsychological testing. These services are administered through a series of tests in thinking, reasoning, judgment, and memory to evaluate the patient's neurocognitive abilities by qualified physicians and other health care professionals. The testing may be administered in written, oral, computer, or combined formats to measure personality, emotions, intellectual functioning, and psychopathology. These procedures can be appropriately administered through telehealth modalities, without in-person observation/monitoring.

These services are appropriately provided for a range of patients and can be a requirement for coverage of treatments. For example, psychological evaluation is a requirement for Medicare coverage of spinal cord stimulation, indicated for chronic pain.[18] These patients frequently have limited mobility, may be taking opiates, or suffering loss of function. Certain populations, such as those living in rural/remote locations, may have limited access to in-person psychological evaluations, and that access may be exacerbated by the PHE. Continuing to enable access through telehealth will help ensure continued access for Medicare beneficiaries with chronic pain, who are indicated for interventions proven to reduce or eliminate the need for narcotics.

Therefore, we reiterate our recommendation to add these nine Neurological & Psychological Testing Codes to the list of permanent telehealth services, as they meet all Category 1 requirements and are like services already on the Telehealth Services List based on Category 1.

[18] CMS National Coverage Decision, Electrical Nerve Stimulators (160.7).

Boston Scientific Recommendation:

- Boston Scientific supports CMS' proposal to extend coverage and payment of Category 3 Telehealth Services until at least the end of CY 2023, but also recommends that CMS make nine Neurological & Psychological Testing codes (96130-96139) permanent (Category 1) telemedicine codes.

IX. Separate Coding and Payment for Chronic Pain Management and Promotion of Pain Management Add-on Coding and Reimbursement

We applaud CMS for its proposed decision and support of add-on coding and reimbursement enabling person-centered pain care. As noted by the agency, unique complexities in the evaluation, counseling and management of pain are significant, and differentiated from evaluation and management services. Areas include consideration of medical management, tapering or eliminating opioid use, drug-to-drug interactions, lifestyle, mental health, and activities of daily living. We acknowledge the agency's thoughtful recognition that certain ethnic or socioeconomic groups reported a higher incidence of high impact pain, presenting opportunities to expand access to underserved populations or those historically disadvantaged. Use of telehealth, data analytics, revised coding and policy reforms will serve to address the significant financial and social impact pain has upon those insured through CMS programs.

Through creation of dedicated coding and adequate payment for the clinician, Boston Scientific believes the agency will encourage greater focus and remediation of deficits created by these conditions. Coding which requires a personalized care plan, care coordination, education and use of validated measures will prove valuable. Operationalizing the agency's vision, we invite CMS to consider interdependencies including coverage policies, Part C administration and leverage of data analytics tools upon which future quality metrics might be dependent. Ideally, coding would be independent and separately payable from existing evaluation and management services. As noted by CMS, the complexity of patient engagement for chronic pain is significant and may not be related to or appropriately described and included as part of the values for existing codes.

X. Closing the Health Equity Gap in CMS Clinician Quality Programs – Request for Information (RFI)

Boston Scientific appreciates the opportunity to provide comments in response to CMS' Request for Information (RFI) entitled "Closing the Health Equity Gap in CMS Clinician Quality Programs." For more than 15 years, Boston Scientific has worked to eliminate health care inequities in underserved communities through our industry-leading program Close the Gap. Our Close the Gap initiative focuses on partnering with healthcare providers by:

- Identifying the prevalence of disease in communities and disparities in treatment rates,
- Collaborating for improved outcomes through local health equity initiatives, and
- Enrolling more diverse patients in clinical studies.

In the second half of last year, through the collaboration with providers to address treatment gaps, we found that more than *28,000 patients* who identified as women and people of color were

underserved compared to the treatment rates of patients who identified as white males for the same disease.

We commend CMS' efforts to close the health equity gap in its clinician quality programs through the stratification of quality measures by race and ethnicity. Racial and ethnic inequities as well as their resulting health disparities have persisted over many decades despite national efforts to eliminate them.[19] However, scientific research on the value and methods to eliminate health disparities is evolving rapidly, as shown by the January 2019 supplement issue of the *American Journal of Public Health*.[20] As national healthcare priorities continue to focus on quality and move towards precision medicine, inequities in healthcare access and service delivery only hinder these efforts. These inequities result in significant annual costs: $35 billion in excess health care expenditures, $10 billion in illness-related lost productivity, and nearly $200 billion in premature deaths.[21] It is in the interests of all stakeholders, including federal and state governments, health industry organizations, consumers, health systems and individual healthcare providers to target disparities and implement effective interventions to eliminate them. Fortunately, effective interventions have been developed and we know that disparities are not inevitable, as demonstrated by the elimination of racial and ethnic disparities in some child vaccination rates.[22]

We believe that data collection, reporting, and analysis are critical themes in the RFI that CMS can address under its authority. Data collection, specifically detailed demographic data collection on race and ethnicity, as well as disparity variables such as preferred language, tribal identity, disability status, sexual orientation, gender identity, socioeconomic status, social, psychological and behavioral health factors, are the foundation for identifying and addressing health disparities.[23] It is therefore critical that the CMS Quality Payment Programs leverage this opportunity to collect meaningful patient data, especially with regard to the aforementioned disparity variables. Although robust demographic data collection is often cited as a critical component for reducing health disparities,[24,25,26] opportunities to maximize data collection through policy have been

[19] U.S. Department of Health and Human Services, Report of the Secretary's Task Force on Black and Minority Health, vol. 1. Washington: U.S. Government Printing Office, August 1985.
[20] Nancy Breen, PhD, Rina Das, PhD, Tilda Farhat, PhD, MPH, Nancy Jones, PhD, and Richard Palmer, DrPH, JD. New Perspectives to Advance Minority Health And Health Disparities Research. American Journal of Public Health. January 2019 Vol 109 No S1.
[21] Ayanian, JZ. The Costs of Racial Disparities in Health Care. Harvard Business Review. October 1, 2015. Available at https://hbr.org/2015/10/the-costs-of-racial-disparities-in-health-care.
[22] Hutchins SS, Jiles R, Bernier R. Elimination of measles and of disparities in measles childhood vaccine coverage among racial and ethnic minority populations in the United States. J Infect Dis. 2004 May 1;189 Suppl 1:S146-52. PubMed PMID: 15106103.
[23] Institute of Medicine. Race, Ethnicity, and Language Data: Standardization for Health Care Quality Improvement. Washington, DC: National Academy Press; 2009.
[24] Agency for Healthcare Research and Quality. 2012 National Health Care Disparities Report. 2013;Pub No. 13-0003. Available at http://www.ahrq.gov/research/findings/nhqrdr/nhdr12/2012nhdr.pdf.
[25] Joint Center for Political and Economic Studies. Patient Protection and Affordable Care Act of 2010: Advancing Health Equity for Racially and Ethnically Diverse Populations. 2010. Available at http://csmh.umaryland.edu/Toolbar/Toolbardocs/reformdiversepopulations.pdf.
[26] Health Research & Educational Trust. (2013, August). Reducing health care disparities: Collection and use of race, ethnicity and language data. Chicago: Health Research & Educational Trust. Retrieved from www.hpoe.org

missed.[27,28] We believe robust demographic and disparity data collection through the CMS Quality Payment Programs is critical to laying the foundation for advanced use of demographic data to target existing health disparities for elimination. Certified EHR Technology (CEHRT), used in many hospitals and clinics, facilitates stratification across most of these disparity variables and thus it does not create additional burden to report such data through the CMS Quality Payment Programs.[29]

We agree with CMS that self-reported race and ethnicity data are the gold standard, and we urge CMS to prioritize assessing the barriers to determine the resources needed to facilitate this standard over an imputation algorithm. Effective collection of self-reported demographic data on race and ethnicity are foundational in addressing health disparities. This activity is critical to disparity identification and targeted health interventions and is not being effectively performed to the extent it is needed to support health disparity analysis. For example, Craddock Lee et al. demonstrated that high quality race and ethnicity data is attainable, however in some health care settings, especially where data collection is not prioritized, quality is poor with many "unknown" or blank fields.[30] There is a need to incentivize high-quality data collection on race and ethnicity at the hospital level. Performance on this activity could be demonstrated by the percentage of complete records. Additionally, consideration should be given to a standardized demographic data collection protocol to assess whether the information collected is self-reported or filled in by staff. A standardized protocol would facilitate more robust data collection and provide additional opportunities for standardization and data improvement.

BSC Recommendations:

- Prioritize assessing the resources needed to facilitate the gold standard of self-reported race and ethnicity data over an imputation algorithm.
- Standardize demographic data collection protocol by introducing provider incentives for more robust data collection.
- Update the collection of demographic data with a minimum set of data elements that include race, ethnicity, preferred language, tribal identity, disability status, sexual orientation, gender identity, socioeconomic status, social, psychological, and behavioral health factors.
- Include for data collection additional disparity variables such as preferred language, tribal identity, disability status, sexual orientation, gender identity, socioeconomic status, social, psychological, and behavioral health status.

[27] Douglas MD, Dawes DE, Holden KB, Mack D. Missed Policy Opportunities to Advance Health Equity by Recording Demographic Data in Electronic Health Records. Am J Public Health. 2015 Jul;105 Suppl 3:S380-8. doi: 10.2105/AJPH.2014.302384. Epub 2015 Apr 23. PubMed PMID: 25905840; PMCID: PMC4455508.

[28] Department of Health and Human Services. (2011). Implementation Guidance on Data Collection Standards for Race, Ethnicity, Sex, Primary Language, and Disability Status. Available at http://aspe.hhs.gov/datacncl/standards/aca/4302/index.pdf

[29] 2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications. 80 Fed Reg 62602 (Oct. 16, 2015) (codified at 45 CFR Part 170).

[30] Lee SJ, Grobe JE, Tiro JA. Assessing race and ethnicity data quality across cancer registries and EMRs in two hospitals. J Am Med Inform Assoc. 2016 May;23(3):627-34. doi: 10.1093/jamia/ocv156. Epub 2015 Dec 11. PubMed PMID: 26661718.

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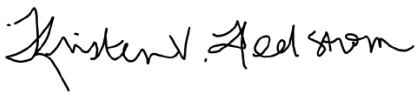
Thank you for the opportunity to comment on the 2022 proposed PFS rule. Please contact me at (202) 713-0701 or Kristen.Hedstrom@bsci.com or Chris Timmerman, Director of Government Affairs and Health Policy, at (202) 637-8022 or Christopher.Timmerman@bsci.com if you have any questions.

Sincerely,



Kristen Hedstrom
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