

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1715-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

September 6, 2019

Re: File Code CMS-1715-P; CY 2020 Revisions to Payment Policies under the Physician Payment Schedule and Other Changes to Part B Payment Policies; (August 14, 2019)

Dear Administrator Verma:

The Heart Rhythm Society (HRS) offers the following comments on the Proposed Medicare Physician Fee Schedule for calendar year (CY) 2020. HRS is the international leader in science, education and advocacy for cardiac arrhythmia professionals and patients, and the primary information resource on heart rhythm disorders. Its mission is to improve the care of patients by promoting research, education, and optimal health care policies and standards. HRS represents more than 6,700 specialists in cardiac pacing and electrophysiology, consisting of physicians, scientists and allied professionals. Electrophysiology is a distinct specialty of cardiology, with eligibility for board certification in clinical cardiac electrophysiology through the American Board of Internal Medicine, as well as certification in cardiology.

These public comments will focus on:

- Accepting the RUC's Recommendations for CPT 93297, 93298, 93299 (Remote Interrogation Device Evaluation),
- The Malpractice Risk Factor for Cardiac Electrophysiology and,
- Applying the Increased Work RVUs for Evaluation and Management Codes to Global Surgical Visits.

The Heart Rhythm Society will submit a separate comment letter focusing on the Quality Payment Program (QPP).

Remote Interrogation Device Evaluation (CPT Codes 93297, 93298, 93299, and HCPCS code GTTT1)

HRS recommends that CMS accept and implement the RUC recommendations for remote interrogation device evaluation CPT codes 93297 and 93298. We also recommend that CMS NOT implement proposed HCPCS GTTT1. We disagree with CMS' decision not to accept the direct practice expense inputs as recommended by the RUC for CPT codes 93297 (Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, including analysis of 1 or more recorded

physiologic cardiovascular data elements from all internal and external sensors, analysis, review(s) and report(s) by a physician or other qualified health care professional) and 93298 (Interrogation device evaluation(s), (remote) up to 30 days; subcutaneous cardiac rhythm monitor system, including analysis of recorded heart rhythm data, analysis, review(s) and report(s) by a physician or other qualified health care professional). HRS and the American College of Cardiology worked with the RUC to develop a thorough rationale detailing the way that this family of services is currently used. In addition, with the RUC, we determined that contractor priced CPT code 93299 will no longer be necessary when 93297 and 93298 are valued for both work and practice expense.

Establishing temporary HCPCS GTTT1 (Interrogation device evaluation(s), (remote) up to 30 days; implantable cardiovascular physiologic monitor system, implantable loop recorder system, or subcutaneous cardiac rhythm monitor system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results)) is unnecessary and will cause confusion among physician practices. In keeping with the goal of relativity, as we attempted to value 93299, it was evident that the technician staff work associated with 30-day remote monitoring services of implantable cardiovascular monitors (ICMs) and implantable loop recorders (ILRs) differ greatly, having evolved since the code initially was created. Therefore, we agreed that CPT 93299 no longer was appropriate for use with each code and assessed the practice expense inputs for each of physician work-only codes with the expectation that CMS would apply a Technical Component to each code. CPT 93297 is related to the remote monitoring of physiological measures obtained from implantable pacemakers and defibrillators related to heart failure that come at an interval of every 30 days. CPT 93298 refers to subcutaneous wireless remote monitors that provide data at more frequent intervals, requiring more clinical staff work.

CMS states "In our review of these services, we note that the RUC recommendations did not provide a detailed description of the clinical labor tasks being performed or detailed information on the typical use of the supply and equipment used when furnishing these services." Not only was this information detailed in the Practice Expense Summary of Recommendations, the RUC also provided a breakdown of the Electrodiagnostic Technologist work throughout the 30-day reporting period in the text of the RUC recommendation. Please see this below:

That data indicates that over the course of a month, a technologist interacts with patient monitoring reports 1.63 times a month to process device-generated notifications for 17 minutes, 1.74 times a month to process patient-generated notifications for 19 minutes, and once a month to generate a monthly report for 14 minutes. That is 50 minutes per month for alerts and report work. Additionally, the clinical staff engages with the patient throughout the month to perform education about the device and re-education protocols after the initial enrollment (11 minutes), troubleshoot non-connective monitoring hardware (4 minutes), and request manual transmission(s) to incorporate additional device data into reports (11 minutes). That is 26 minutes per month for patient interaction.

The table below outlines this time:

Activity	93298/93299	93297
Automated alert transmissions	17	
Technician requested transmissions	11	
Patient-initiated transmissions	19	11
Monthly report	14	14

Education/re-education	11	11
Troubleshooting	4	4
Sum	76	40

In addition to the RUC's recommendation, we developed additional detail explaining the staff's work to provide CMS with a clearer understanding of the differences in the types of work that are performed. In addition, when we were gathering data for the RUC, we included information from a manufacturer that broke down the times and duration when a technician person was logged in to the remote server, assessing data during the 30-day period.

93297

Many implantable pacemakers and defibrillators now have the additional capability of providing physiologic monitoring to anticipate early warning signs of decompensated heart failure. It is helpful to explain a few aspects of how these devices communicate.

- Devices fall into 1 of 2 categories, those that will trigger an automatic notification when a physiologic parameter is abnormal and those that simply send a report once a month.
- If a device generates an alert it will be communicated to the manufacturer's servers.
- Office practice staff log on to each of the vendors' remote monitoring server to see if any of their patients with an implantable physiological monitor have generated alerts.
- If an alert is received the technician will then prepare a report for the physician to review.
- If a remote monitor ceases communication for any reason during the 30-day window, the technician will contact the patient to troubleshoot and restore communication.
- Patients and family often call the technician with questions about the physiologic monitor, transceiver, and communication of their data. The transceivers unfortunately do not provide feedback to the patient regarding success or failure of a transmission. Therefore, education has become a significant component of the technician's role.
- At the beginning of each 30-day cycle, the physiologic monitor will send a complete report of activity over the previous 30 days. The practice technician will prepare a monthly report for the physician to review. It is at this point that the encounter charge is typically generated.

93298

In order to explain the work involved in remote monitoring for implantable loop recorders (ILR) (also known as subcutaneous cardiac rhythm monitors) it is helpful to explain a few aspects about how these devices communicate:

- When the monitoring process begins, the initial transmission includes the programmed parameters of the ILR, battery status and any recorded arrhythmias.
- Each night over the following 30 days the remote transceiver (located on the patient's bedside table) wirelessly communicates with the ILR. If the ILR has detected any abnormal rhythm or any malfunction with the device, it will send an alert back to the manufacturer's servers (automated alert transmission).
- Patients may also trigger the ILR to initiate a recording, which will later be communicated as an alert to the manufacturer when the transceiver communicates with the ILR in the middle of the night (patient-initiated transmission).
- Each morning, office practice staff log on to each of the vendors' remote monitoring server to see if any of their patients with an ILR have recorded any alerts.

- If one of their patients has had an alert the technician, then calls the patient and will ask the patient to place the transceiver's wand over the ILR so that the heart rhythm recordings can be downloaded by the practice (technician requested transmission).
- The technician will then prepare a report for the physician to review.
- If a remote monitor ceases communication for any reason during the 30-day window, the technician will contact the patient to troubleshoot and restore communication.
- Patients and family often call the technician with questions about the ILR, transceiver, and communication of their data. The transceivers unfortunately do not provide feedback to the patient regarding success or failure of a transmission. Therefore, education has become a significant component of the technician's role.
- At the beginning of each 30-day cycle, the ILR will send a complete report of activity over the
 previous 30 days. The practice technician will prepare a monthly report for the physician to
 review. It is at this point that the encounter charge is typically generated.

CMS stated that they are "...seeking additional comment on the appropriateness of CPT 93296 (Interrogation device evaluation(s) (remote), up to 90 days; single, dual, or multiple lead pacemaker system, leadless pacemaker system, or implantable defibrillator system, remote data acquisition(s), receipt of transmissions and technician review, technical support and distribution of results) as the reference code." CPT 93296 is appropriate as a reference code in the practice expense spreadsheet. The current recommendation uses CPT 93296 because it is a similar service addressing remote interrogation of an electrophysiology device. As we discussed during our discussions with the RUC and was addressed in the RUC's recommendations, the inputs for CPT 93297 and 93298 are based on new data and are not cross walked to the inputs of CPT 93296.

Finally, CMS requested clarification on the number of patients that are monitored concurrently. Implantable loop recorders generate more alerts than pacemakers or defibrillators because they are implanted in the subcutaneous tissue. Unlike pacemakers and defibrillators which have transvenous leads implanted in the heart, ILRs obtain subcutaneous recordings via electrodes at either end of the device. This wide antenna is susceptible to detecting pectoral muscle stimulation, motion artifact, and other interference. This leads to frequent alerts that require careful review. It can often be challenging to determine if an event is due to an arrhythmia. For this reason, it is imperative that each event be reviewed by a physician. A typical arrhythmia center that provides remote monitoring services for its patients will monitor a panel of patients with pacemakers, defibrillators, and ILRs. The number of patients with ILRs being concurrently monitored varies but could range from 50 to 75.

We urge CMS to accept the RUC's recommendation for CPT codes 93297 and 93298, accept the deletion of 93299, and cancel its plan to implement HCPCS code GTTT1.

Malpractice Calculations for Cardiac Electrophysiology

We recommend that CMS map Risk Factors for cardiac electrophysiology (21) to the risk factor for cardiology (surgery) and cardiology (no surgery) (06). Currently cardiac electrophysiology has surgical and non-surgical risk factors. We do not understand the rationale that CMS applied to determine that the risk factor should be set at 1.89 and ask CMS to detail how it arrived at that recommended risk factor. As a small specialty of less than 4,000 physicians in the United States, gathering premium data may be challenging; however, it is unclear how interventional cardiology, a similarly small specialty, was assigned a risk factor of 5.92 while electrophysiology somehow was calculated to have a risk factor of only 1.89.

There is a high likelihood that many of the services considered under the cardiology (surgery) RF are primarily electrophysiology services, thus our recommendation that the RF for cardiac electrophysiology be mapped to cardiology (surgery). In addition, many electrophysiology services are included in CMS' list of Invasive Cardiology Services Outside of the Surgical HCPCS Code Range Considered Surgery. In addition, many of the services on that list have 000 or ZZZ global periods with all codes having greater than 5.00 work RVUs, going as high as 19.54 RVUs. Discounting the risk factor for electrophysiologic services not only grossly undervalues the nature of the services, it also results in overall inappropriate payment decreases of an average 7% for these procedures.

Samples of the procedures noted above are:

CPT Code	Descriptor	Global Period	Work RVU
93613	Electrophysiology mapping, 3d add-on	ZZZ	5.23
93620	Electrophysiology evaluation	000	11.32
93653	Electrophysiologic study and ablation, supraventricular tachycardia	000	14.75
93655	Ablate arrhythmia, add-on	ZZZ	7.50
93656	Treatment atrial fib with pulmonary vein isolation	000	19.77

Cardiac electrophysiology services are highly invasive, involving implanting leads and generators for pacemaker and cardiac defibrillators; and conducting catheter ablations via femoral vein or arterial access to treat arrythmias in the heart. Electrophysiology studies to determine the prevalence of arrythmias also is an invasive procedure that requires sending electrical impulses to the heart to attempt to induce arrythmias under certain conditions. It is unacceptable to apply a risk factor of "ALL" that is equal to the non-surgical risk factor cardiology.

In addition, we are concerned about the crosswalk methodology on which CMS relies for several non-physician specialties and the impact it has on the overall distribution of malpractice RVUs. For several non-physician specialties for which CMS did not obtain enough premium data, CMS continues to crosswalk these non-physician specialties to the lowest premium rate for a *physician* specialty (allergy/immunology). This is inappropriate and CMS does not provide adequate rationale for assigning a physician premium rate to non-physicians. While we continue to encourage CMS to obtain more comprehensive premium data for accurate valuation of malpractice RVUs, in the meantime, HRS agrees with the AMA RUC that the non-physician specialties for which CMS does not have adequate premium data should be cross-walked to a non-physician rate, in particular Optometry. CMS should not crosswalk non-physician specialties to a physician premium rate.

<u>Valuation of Evaluation and Management Services for 10 and 90-Day Global Services</u>

We urge CMS to apply the work values for the upcoming Evaluation and Management codes, to the post-procedural visits within the global services package as recommended by the AMA RUC.

With the understanding that the Evaluation and Management code changes will not go into effect until January 1, 2021, CMS should carry the upcoming new work values for E/M coding to the global services visit in order to maintain relativity across the fee schedule. CMS directly undermines the entire system of relativity on which the RBRVS is based by not making commensurate increases in values where the value is derivative of the office and outpatient E/M codes. While we share CMS' objective of promoting the accuracy of all code values in the Medicare Physician Fee Schedule, if CMS implements this policy as proposed it will make it increasingly difficult to appropriately value services with 10- and 90-day global periods. By citing CMS concern about whether global codes have accurately packaged the correct number of E/M visits in the global period as a reason to not commensurately update the global code values, CMS has erroneously and arbitrarily conflated the issues of value accuracy and relativity. In addition, CPT codes are not specialty specific and statute forbids CMS for paying physicians differently for providing the same service on the basis of specialty type. Failing to apply the updated RVUs for a follow-up visit packed into a global period that is considered a level 3 E/M code should not be considered to involve less work than a stand-alone level 3 E/M visit. CMS' proposal skews the entire fee schedule, inappropriately re-allocating work values based on a non-relative approach. If CMS believes that codes are inappropriately valued, it should work the RUC to review the specific codes for accuracy. Instead, CMS is attempting to implement a flawed policy that would undermine core tenets of the RBRVS. CMS should reconsider its proposal and finalize the RUC recommendation related to updating the values of global codes which included packaged office and outpatient E/Ms.

We look forward to working with you on these and other topics as you develop the final rule for FY2020. For questions, please contact Kimberley Moore, HRS' Director of Reimbursement and Regulatory Affairs at KMoore@hrsonline.org.

Sincerely,

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President