

05 Nov 2021 | News

Updated: iRhythm Continues To Grow Despite Reimbursement, Hospital-Staffing Challenges

CMS' Decision To Punt Remote Monitoring Payment To 2023 Disappoints iRhythm Again

by [Reed Miller](#)

Despite intense lobbying from industry and physician groups, CMS chose not to install national pricing for long-term remote cardiac monitoring in its final 2022 Medicare Physician Fee Schedule Final Rule.

[Editor's note: This article was updated on 5 November to include comments from iRhythm's management during its 4 November earnings call.]

Remote cardiac monitoring companies must continue working with local Medicare carriers to secure higher reimbursement rates for long-term remote monitoring because the US Centers for Medicare & Medicaid Services (CMS) has once again opted not to install national pricing for these services.

With support from professional cardiology societies, a consortium of device companies marketing remote monitoring technologies and services has been trying to convince CMS to include long-term remote monitoring in its calendar year 2022 Medicare Physician Fee Schedule (MPFS).

These proponents of long-term remote cardiac monitoring are seeking national payment rates for four current procedural terminology (CPT) codes related to extended external electrocardiogram (ECG or EKG) monitoring with a patch sensor system (Category I CPT Codes 93241, 93243, 93245, and 93247). (Also see "[Latest Physician Fee Schedule Proposal Could Impact Companies' Bottom Line](#)" - Medtech Insight, 16 Jul, 2021.)

Despite the pressure from industry and cardiologists, the agency did not include new payment rates for these CPTs codes in the proposed 2022 MPFS, released in July, and did not include them in [the final rule released on 2 November](#). Instead, CMS has asked the regional Medicare contractors to continue setting the rates for those four CPT codes.

CMS has agreed to continue soliciting more information on “the appropriate reimbursement” for long-term remote cardiac monitoring, but the agency concluded it does not yet have enough data to accurately set national payment rates for these services.

Also, based on its analysis of 10 invoices for these devices – ranging from \$179.80 to \$241.99 – CMS is recommending \$200.15 as the price for supplies needed for long-term remote monitoring with external ECG patches. The device companies had suggested the recommended price for those supplies should be set at \$325.98.

“We believe that in light of a potential impact to payment for other services under the [physician fee schedule], a proposal to establish national payment for these services based on this new pricing information should take into account broader stakeholder feedback,” the agency explained in the rule. “However, we encourage stakeholders to continue to provide feedback regarding invoices or other additional information ... to assist CMS in setting national prices for these CPT codes for the CY 2023 rulemaking cycle.”

***“National pricing remains the best option for all stakeholders.” –
Quentin Blackford***

The effort to secure national pricing for long-term remote cardiac monitoring has been spearheaded by iRhythm, which markets the Zio XT 14-day cardiac monitoring system.

“We firmly believe that national pricing remains the best option for all stakeholders,” iRhythm

Medicare Fee Schedules Show Cuts To Physician Services

By [Elizabeth Orr](#)

04 Nov 2021

US Medicare payments for services provided in physician offices will fall by nearly 4% in calendar 2022; elsewhere, the agency granted pass-through payments to three devices and maintained additional telehealth services.

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CEO Quentin Blackford said. (Also see "[Dexcom COO Quentin Blackford Takes CEO Job At iRhythm](#)" - Medtech Insight, 14 Sep, 2021.)

The San Francisco-based company has been trying to secure national Medicare pricing for Zio XT because it believes that the payment rate set by local Medicare carrier Novitas is too low. (Also see "[iRhythm Is 'Encouraged' By Recent Reimbursement Discussions With Novitas](#)" - Medtech Insight, 12 May, 2021.)

In early 2021, Novitas cut the payment rate for continuous long-term continuous EKG monitoring from more than \$300 – which had been the rate since 2012 – to about \$100. iRhythm depends heavily on Novitas for Medicare reimbursement because iRhythm's Zio service center is in Texas and Novitas is the Medicare Administrative Contractor (MAC) for Texas, along with the south-central states, the Indian Health Service and Veterans Affairs system nationally.

During the company's 4 November third-quarter sales and earnings call, Blackford said "iRhythm has been pursuing parallel paths to support fair and stable Medicare pricing for these Category I CPT codes. iRhythm remains engaged with the MACs regarding an alternative costing model and has continued to work with industry participants to submit additional cost data for consideration. We, along with our industry coalition, have made meaningful progress against this milestone. We are also evaluating the new information included in the final rule and its potential implications on our discussions with the MACs."

"While we are disappointed that national pricing was not included in the 2022 Physician Fee Schedule, we are appreciative that CMS continues to engage with industry and other stakeholders to further their understanding of the cost components of AI-based solutions such as iRhythm Zio Service," he said. "National pricing remains the best option for all stakeholders given the category is now operating under permanent CPT Category I codes. We believe the final rule was a positive development towards national pricing, but also recognized there remains work to be done. We will continue to engage with CMS rulemaking process next year for calendar year 2023 pricing."

"This final rule includes positive signs for iRhythm." – Marie Thibault

In a 3 November note, BTIG analyst Marie Thibault wrote, "This final rule includes positive signs for iRhythm, including that \$200 is significantly higher than the current contractor pricing, that

the industry's efforts and invoice submissions had an impact on the agency's decision-making, and that there seems to be a fairly high likelihood of a national pricing decision for [calendar year] 2023.”

Thibault added that CMS’ solicitation of more input on national pricing “is a new twist, and one we didn't expect – reimbursement always bring new surprises!”

The \$200 price recommended in the MPFS final rule is not as high as iRhythm suggested, but it “should be enough to enable a viable business model for the Medicare segment and, importantly, limit major rate cuts by commercial payers in the future,” Thibault wrote.

Growth Despite Challenges

On 4 November, the iRhythm reported third-quarter revenue of \$85.4m, representing an 18.7% increase compared to third quarter 2020. The net loss for the third quarter was \$23.7m, or a loss of \$0.81 per share, compared with net loss of \$4.7m, or \$0.17 per share, in the third quarter of 2020. Cash and short-term investments totaled \$256.8m as of the end of the quarter, \$1.1m increase over the end of the second quarter.

The company's operating expenses for the third quarter of 2021 were \$79.4m, compared to \$58.5m for the same period in 2020. The increase was primarily due to increases in compensation and legal spending.

"Volume growth for Zio XT remains very strong, and importantly we have shown the ability to grow revenue in spite of the Medicare pricing headwinds we have faced this year," Blackford said.

He explained that the recent surge in COVID-19 cases driven by the Delta variant has not had much impact on the company so far, but the staffing-shortages facing many hospitals this fall is making it more difficult for the company to serve customers. (Also see "[Hospital Staffing Shortages Could Impede Recovery Of Procedure Volumes](#)" - Medtech Insight, 8 Oct, 2021.)

"We have seen a significant increase in staffing issues with our customers, which is having a negative impact on patient volumes and presenting patient scheduling challenges," he said. "This is leading to capacity constraints at accounts and in the system, and in some cases, limiting our ability to open new accounts or expand within existing accounts. How and when these issues get resolved is difficult to predict, but we believe the impact on our business will persist throughout the end of the year before potentially normalizing."

The company has also been made "tremendous progress" to improve its "turnaround times," so it can provide diagnostic results to patients faster.

"We have the systems, the people, and the processes in place to meet demand," he said. "It is

clear that in some situations, the extended turnaround times created additional challenges for our customers on top of the staffing challenges they were facing. Beginning in June and continuing through the third quarter, we were intentional about slowing the addition of new accounts as we prioritize serving our existing customers while we manage through our extended turnaround times."

Because of the staffing issues and the company's decision to focus more on improving turnaround times and less on signing-up new customers, the company expects to "more measured growth in registration volumes" in the fourth quarter.

Blackford reported that iRhythm and Verily have submitted a 510(k) to the US Food and Drug Administration for a new diagnostic system co-developed by both companies. The system combines iRhythm's artificial intelligence system for diagnosing arrhythmias with Verily's health data analytics technology. The companies expect to start a limited market launch for the product by the end of 2022. (Also see "[Verily And iRhythm Agree To Collaborate On Atrial Fibrillation](#)" - Medtech Insight, 9 Sep, 2019.)

He also noted that the [three-year data](#) from the [mSToPS](#) study, which showed the value of active screening for atrial fibrillation with iRhythm's Zio XT in high-risk individuals, was recently published in *PLOS One*. The data were originally presented about a year ago at the American Heart Association conference. (Also see "[Reimbursement For Long-Term Cardiac Monitoring Remains Uncertain, iRhythm Reports](#)" - Medtech Insight, 1 Mar, 2021.)

"We are only approximately 20% penetrated in our core market today and have the opportunity to continue to capture more share, grow the overall market, and expand our addressable market," he said. "Our competitive differentiation remains very strong. With the continued focus on clinical evidence generation and educating our customers on our value proposition ... we can continue to take share in the market for many years. Our data platform and deep learning capability position to be one the leading edge of world-class research and innovation with respect to predictive analytics and outcomes, allowing us the potential to meaningfully transform the health care landscape into the future while reducing the cost of care."