

## Qualified Clinical Data Registries: How Wound Care Practitioners Can Make the Most Out of the Merit-Based Incentive Payment System

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**Significance:** Wound care practitioners have no professional society to promote participation in a Qualified Clinical Data Registry (QCDR), which is essential to thrive under the Merit-Based Incentive Payment System (MIPS), and until recently have lacked relevant quality measures to report. Practitioners can now participate in the nonprofit U.S. Wound Registry (USWR) QCDR for MIPS credit, which can receive data from any certified electronic health record (EHR) and, in so doing, generate data useful for comparative effectiveness research.

**Recent Advances:** For 2018, the Centers for Medicare and Medicaid Services (CMS) has approved 12 wound care and hyperbaric medicine–relevant quality measures and several clinical practice Improvement Activities, which can be reported for MIPS credit through the USWR. Several QCDR measures have met the CMS 3-year reporting criteria to establish national benchmark rates, likely enabling practitioners to achieve higher quality scores than possible with standard MIPS measures. The structured registry data generated have been harnessed to evaluate adherence to evidence-based clinical practice guidelines, understand real-world patient healing rates, and demonstrate the comparative effectiveness of wound therapies.

**Critical Issues:** Wound care practitioners can participate in a QCDR for MIPS credit, which enables them to optimize their MIPS score, particularly if they transmit data directly from their EHR. Utilizing structured data for comparative effectiveness research may help ensure patient access to advanced therapeutics.

**Future Directions:** By 2019, to overcome technological barriers to participation, USWR quality measures will be available as “apps” for EHRs that support the interface required to achieve the next stage of EHR certification as part of the open Application Programming Initiative.

**Keywords:** Qualified Clinical Data Registries, electronic health records, quality measures, quality reporting, comparative effectiveness research

### SCOPE AND SIGNIFICANCE

TO SUCCESSFULLY PARTICIPATE in the Merit-Based Incentive Payment System (MIPS), practitioners need an electronic health record (EHR) that supports relevant quality measures and transmits data directly to a

Qualified Clinical Data Registry (QCDR). Unfortunately, wound care practitioners have no specialty society to promote quality reporting and QCDR participation, nor have they had relevant quality measures to report, the availability of which have



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bolstered funding for comparative effectiveness research in other specialties. Consequently, there is a dearth of evidence to support the value of advanced therapeutics in clinical practice. We review the potential benefits of QCDR participation to optimize MIPS performance and discuss how QCDR data can be leveraged for real-world comparative effectiveness research.

## TRANSLATIONAL RELEVANCE

The development of specialty-specific quality measures was a major impetus for the creation of QCDRs, so it was assumed that specialty societies would initiate most QCDRs. Since wound care was not a recognized specialty, in 2013, the Centers for Medicare and Medicaid Services (CMS) agreed that the Alliance of Wound Care Stakeholders, composed of wound care-related clinical associations, would act in lieu of a specialty society. The Alliance partnered with the U.S. Wound Registry (USWR), a 501(c)(3) nonprofit organization and one of the first data registries recognized by the CMS in 2008, to develop wound care and hyperbaric medicine-relevant quality measures, 12 of which have been approved by CMS for 2018 (Table 1), as well as relevant clinical practice improvement activities (IAs).

**Table 1.** The U.S. Wound Registry wound care and hyperbaric medicine-relevant quality measures

Quality Measure Name	Definition
CDR 1	Adequate offloading of DFU at each visit
CDR 2	DFU healing or closure
CDR 5	Adequate compression of VLU at each treatment visit, appropriate to arterial supply
CDR 6	VLU healing or closure
CDR 8	Appropriate use of HBOT for patients with DFUs
CDR 9	Appropriate use of cellular or tissue-based products for DFU or VLU
USWR 13	Patient vital sign assessment and blood glucose check before HBOT treatment
USWR 16	Major Amputation in Wagner Grade 3, 4, or 5 DFUs Treated with or without HBOT
USWR 20	Nutritional screening and intervention plan in patients with chronic wounds and ulcers
USWR 22	Patient reported nutritional assessment and intervention plan in patients with wounds and ulcers
USWR 23	Arterial assessment of patients with lower extremity wounds or ulcers for determination of healing potential
USWR 24	Patient reported experience of care: wound outcome

Developed in collaboration with the Alliance of Wound Care Stakeholders, the American Podiatric Medical Association, and the Undersea and Hyperbaric Medical Society and approved by the Centers for Medicare and Medicaid Services for reporting to the Merit-Based Incentive Payment System in 2018.<sup>1</sup>

DFU, diabetic foot ulcer; HBOT, hyperbaric oxygen therapy; USWR, U.S. Wound Registry; VLU, venous leg ulcer.

## CLINICAL RELEVANCE

Participation in a wound care-relevant QCDR can bridge the gap faced by wound care practitioners in the transition to value-based payment. The structured data transmitted by the practitioner's EHR can be leveraged to identify variations in adherence to evidence-based treatment guidelines and to generate real-world outcome data. The availability of risk-stratified outcomes enables the comparative effectiveness research needed to optimize the use of advanced therapies and may enable payors to better allocate resources for patients with chronic wounds.

## OVERVIEW

Clinical registries are the means by which the CMS hopes to partner with clinicians to reduce waste, improve compliance with Medicare coverage policy, and deliver more evidence-based care, enabling Medicare's new Quality Payment Program (QPP) to improve value through quality reporting and practice improvement.<sup>2</sup> It is no coincidence that the pace of health care payment reform gained momentum after the 2009 passage of the HITECH Act (Health Information Technology for Economic and Clinical Health).<sup>3</sup> As practitioners were incentivized to purchase and use certified EHRs in specific ways,<sup>4,5</sup> optional reporting initiatives became mandatory reporting programs, culminating in the QPP, which began on January 1, 2017.<sup>1</sup> Many practitioners are now subject to the MIPS,<sup>2,6</sup> the most complex Medicare payment program yet devised. Although it offers the potential for bonus payments, optimal performance is unlikely unless the practitioner's EHR supports relevant quality measures and can transmit data directly to a QCDR.<sup>7</sup>

Linking payment to registry participation is not new. Clinicians have willingly participated in registries when substantial reimbursement has been tied to participation (*e.g.*, trauma center recognition, stroke, prosthetic joints, venous ablation, implanted defibrillators, and so on).<sup>8,9</sup> In fact, device and drug manufacturers provide generous funding to specialties with mandatory reporting requirements (*e.g.*, cardiology and orthopedic surgery) to offset the annual costs of maintaining and operating these potentially multimillion dollar electronic systems in exchange for the utilization of registry data.<sup>9</sup> MIPS is also designed to incentivize electronic data submission to the CMS, linked as closely as possible to clinical documentation, because for the CMS to monetarily reward quality, it must have direct access to analyzable quality data.<sup>6</sup>

Unfortunately, wound care practitioners have lagged behind in the transition to value-based payment, because they have lacked the relevant quality measures available to the recognized medical and surgical specialties.<sup>8–10</sup> Recognizing that quality measurement gaps existed, the CMS empowered QCDRs to develop specialty-specific quality measures. Although the CMS has confusingly termed QCDR-developed measures as “non-MIPS measures,” practitioners get MIPS credit for reporting them.

The Council of Medical Specialty Societies (CMSS) provides a framework for specialty societies and organizations not affiliated with a recognized specialty to develop and maintain a clinical data registry.<sup>11</sup> At the most recent CMSS meeting in Chicago, the 31 specialty societies in attendance represented 49 registries and a combined operating budget of \$500 million, which is an average of \$10 million per registry (C.E.F., pers. comm., May 10, 2018). While specialty societies differ significantly in their scope of practice, their QCDRs almost universally provide:

- Quality reporting to MIPS
- Maintenance of Board Certification (MOC)
- Quality measure development
- Benchmarking of quality measure data and practice patterns to establish specialty norms
- National Quality Campaigns utilizing quality measure performance to help patients find the best care in each state or city
- Funding for research through data use agreements
- Research opportunities using registry data
- Risk models to predict patient outcomes and guide decision making
- Quality improvement initiatives guided by registry data
- Advocacy efforts in which practitioners share data with payors and policy experts to support the development of more efficient care delivery models.

All of the above functions are dependent on the existence of relevant quality measures, which the various societies develop and then report to achieve their organizational goals. It is this process that the Alliance has attempted to mirror with some success despite organizational and technological barriers. In Year 1 (2017), more than 500 wound care practitioners participated in this wound care-centric QCDR. While not intended to be a detailed discussion of the MIPS program, we will review the

potential benefits of QCDR participation for wound care practitioners, with an emphasis on the way in which it can optimize quality performance and practice improvement, as well as its use for MOC and benchmarking, with the highly valuable dividend of producing reliable data for comparative effectiveness research.

## DISCUSSION

### How QCDRs help wound care practitioners participate in MIPS

Under MIPS, every eligible provider receives a composite score from 0 to 100 based on four weighted categories: Quality, Promoting Interoperability (PI, previously Advancing Care Information), clinical practice IAs, and Cost.<sup>6</sup> QCDR participation optimizes provider performance in the first three categories. The PI category is intended to promote the use of EHRs, and practitioners can obtain PI bonus points for participating in a specialty registry like the USWR through their EHR.<sup>12</sup> Wound care practitioners can participate in the USWR QCDR by leveraging the ability of any certified EHR to transmit continuity of care documents (CCDs).<sup>8,9,13</sup> CCDs contain basic information such as demographics, diagnoses, procedures, medications, and allergies. Although this information may seem limited in value, it is powerfully important. The American Medical Association’s Relative Value Unit Committee upheld the physician payment rate for hyperbaric chamber supervision after analysis of registry data showed that the average hyperbaric patient had 10 comorbid diseases and took 12 medications.<sup>13</sup> This is but one example of how real-world QCDR data can be used to support reimbursement.

In addition to justifying the level of work performed by a practitioner, comorbid conditions justify the cost of caring for patients. The Cost category of MIPS is Medicare’s calculation of the money spent by each provider annually.<sup>14</sup> Cost did not contribute to the MIPS composite score in 2017, but it will contribute 10% in 2018, reaching a maximum of 30%, as per current law.<sup>15</sup> The increasing importance of the Cost category represents a risk to wound care practitioners. The high cost of caring for patients with chronic wounds has been conservatively estimated at \$28.1 billion dollars per year, but it could be more than thrice that amount.<sup>16</sup> The average cost per beneficiary measure is based on claims from all beneficiaries billed in a 1-year period. This is an inverse measure in which less spending indicates better performance. Although the highest benchmark rate

for the measure was \$8,665.15 in 2016, the total per capita cost (TPCC) as calculated by Medicare for one author (C.E.F.) was \$24,306.80. Because the provider's Medicare expenditures were so much greater than other physicians in the same specialty, only 3 out of a possible 10 points were awarded. Because Cost had no contribution to the MIPS composite score in Year 1, this Cost score did not negatively impact the provider in 2017. The CMS is aware that some practitioners see much sicker patients than others. To account for this, the TPCC is stratified by the practitioner's average Hierarchical Classification Code,<sup>17</sup> which is the method Medicare uses to understand the medical complexity of patients seen by a provider. In future years, as the importance of the Cost category increases, an accurate listing of comorbid conditions will be vital to justify the expenditures associated with wound care patients. This explains why nearly every specialty society registry uses automated data transmission from EHRs for at least some part of registry participation, particularly to capture the ICD-10 diagnoses.<sup>8,9</sup>

Registries can also allow practitioners to compare themselves and their patient outcomes with their peers for quality improvement projects.<sup>8-10</sup> In 2018, practitioners working in hospital based outpatient wound care provider-based departments (PBDs) can achieve the minimum MIPS participation needed to avoid a monetary penalty (meaning, loss of some portion of Medicare Part B payment) simply by performing two medium weight IAs.<sup>18,19</sup> The USWR wound care and hyperbaric medicine IAs have been approved by the CMS.<sup>9</sup> Some of them can also be used for activities such as Part IV of the MOC in Undersea and Hyperbaric Medicine (Table 2).

Bonus points are available for participating in certain IAs when data are directly transmitted from the practitioner's EHR. Depending on how well CCDs are formatted by the EHR vendor, they can be used to participate in national benchmarking projects (e.g., average hyperbaric treatments per diagnosis, average number of debridements per

patient or per provider, and so on).<sup>9</sup> It should be emphasized that CMS is trying to drive direct-from-EHR data transmission into registries that offer national publicly available benchmarking, because transparency is a way to identify and address overuse of resources, a known problem for both wound care and hyperbaric medicine.<sup>21-24</sup>

### Quality reporting with a QCDR

As previously mentioned, in Year 2 of MIPS (2018), the CMS has approved 12 USWR non-MIPS measures for wound care and hyperbaric medicine practitioners to report (Table 1).

For most practitioners, Quality represents 50% of the 2018 MIPS score.<sup>25</sup> However, because nurse practitioners (NPs) and hospital-based physicians are exempt from reporting the PI category, the PI points accrue to Quality. Therefore, in 2018, Quality comprises 75% of the MIPS score for all NPs and practitioners whose primary site of service is the hospital based outpatient wound care PBD. For maximal MIPS participation, all practitioners must successfully pass a minimum of six quality measures, one of which must be an outcome measure. Clinicians receive two bonus points for every additional outcome measure, one bonus point for any other high-value measures, and a bonus point for each measure reported through end-to-end electronic reporting using a certified EHR,<sup>25</sup> meaning that there is no manual intervention from the point of EHR data entry to submission to the CMS. The CMS translates the performance rate of each measure into a decile ranking, which in turn determines the point value of the measure (e.g., achieving the 10th decile earns 10 points). The decile ranking is determined by the provider's quality performance score compared to the national benchmark score for that measure. In 2018, practitioners wishing to obtain bonus payments must report six quality measures as they did in 2017, but the data completeness criteria have been increased from 50% in 2017 to 60% in 2018; data must be reported on at least 60% of the patients for

**Table 2.** Examples of wound care and hyperbaric medicine improvement activities

<i>Undersea and Hyperbaric Medicine Patient Care Practice Improvement Activity</i>	<i>Equivalent Non-MIPS Quality Measure That Can Be Reported to Receive MIPS Credit for Improvement Activity</i>
Appropriate use of HBOT for patients with DFUs	CDR 8: Appropriate use of HBOT for patients with DFUs
Patient assessment before each HBOT treatment and blood glucose assessment before each HBOT treatment	USWR 13: Patient vital sign assessment and blood glucose check before HBOT treatment
Major amputations in patients with diabetic foot wounds receiving HBOT	USWR 16: Major Amputation in Wagner Grade 3, 4, or 5 DFUs Treated with HBOT
Healing rate of Wagner Grade 3, 4, and 5 DFUs following HBOT	CDR 2: DFU healing or closure <sup>a</sup>

Approved by the Centers of Medicare and Medicaid Services, which can also be used for Maintenance of Certification in Undersea and Hyperbaric Medicine.<sup>20</sup>

<sup>a</sup>Includes patients with and without HBOT.

MIPS, Merit-Based Incentive Payment System.

**Table 3.** 2017 Performance rate score required to be in each decile for each quality measure

Measure Name	Measure No.	Decile 3	Decile 4	Decile 5	Decile 6	Decile 7	Decile 8	Decile 9	Decile 10
Diabetes mellitus: Diabetic foot and ankle care, peripheral neuropathy—Neurological evaluation	126	10.34–18.46	18.47–28.94	28.95–41.66	41.67–60.23	60.24–75.20	75.21–89.89	89.90–99.99	100
Diabetes mellitus: Diabetic foot and ankle care, ulcer prevention—Evaluation of footwear	127	4.26–11.10	11.11–22.80	22.81–39.99	40.00–61.69	61.70–79.56	79.57–93.74	93.75–99.99	100
Preventive care and screening: BMI screening and follow-up plan	128	39.80–45.63	45.64–50.91	50.92–56.68	56.69–64.88	64.89–75.81	75.82–87.12	87.13–97.33	≥97.34
Documentation of current medications in the medical record	130	61.27–82.11	82.12–91.71	91.72–96.86	96.87–99.30	99.31–99.99	N/A	N/A	100
Falls: Risk assessment	154	7.81–19.99	20.00–38.12	38.13–57.62	57.63–84.16	84.17–99.82	99.83–99.99	N/A	100
Falls: Plan of care	155	20.00–41.43	41.44–62.11	62.12–75.44	75.45–85.99	86.00–93.32	93.33–98.07	98.08–99.99	100
Preventive care and screening: Tobacco use: Screening and cessation intervention	226	76.67–85.53	85.54–89.87	89.88–92.85	92.86–95.14	95.15–97.21	97.22–99.10	99.11–99.99	100

Note that in 6 out of 7 measures, a perfect score is required to achieve 10 points.<sup>26</sup> BMI, body mass index; N/A, not applicable.

whom a quality measure applies; and the reporting period must span the entire 12-month calendar year (*i.e.*, there is no 90-day option for quality reporting in 2018).

Table 3 lists the measure performance rates (in percent) that were required to achieve a specific decile score for some quality measures commonly utilized by wound care practitioners in 2017. It should be understood that to realize bonus money under MIPS, practitioners need to achieve the highest possible composite MIPS score, which means achieving the highest score possible within each category. In 2017, Quality contributed 60% of the total MIPS score for most practitioners, but 75% for hospital based outpatient wound care PBD physicians. Practitioners need to reach the 10th decile in each measure to maximize the opportunity for bonus money, which in both 2017 and 2018 means reporting 6 measures for a Quality subscore of at least 60 points.<sup>25</sup> Unfortunately, national benchmark rates are so high with many standard MIPS measures that a nearly perfect score of 100% is required to reach the 10th decile, a difficult proposition for practitioners not responsible for the patient's primary care. However, achieving a score of 60 points is possible by reporting wound and hyperbaric medicine quality measures through a QCDR, when sufficient measure data have been reported to the CMS for at least 3 years, so that national benchmark rates have been established.

Table 4 depicts some benchmarked wound care and hyperbaric medicine quality measures which could be reported in 2017 for MIPS credit. Note that using QCDR measures, there were three measures for which the 10th decile could be achieved with a performance score of 75% or less, vastly increasing the odds of achieving the maximum number of

Quality points compared to standard MIPS measures. The USWR has established a benchmark rate for diabetic foot ulcer (DFU) healing at 64.3% and for venous leg ulcer (VLU) healing at 75.0% (Table 4), both of which are risk stratified by the Wound Healing Index (WHI), so that providers can report wound healing rates in relation to the predicted likelihood of healing.<sup>27</sup> This makes it possible to identify practitioners with the best outcomes in the toughest cases, a valuable metric currently not possible when employing the widely accepted—although misleading—practice of manipulating data to report ≥92% healing rates.<sup>28</sup> Importantly, the WHI risk stratification may mean that data on these QCDR wound healing measures can be publicly available on the CMS Physician Compare website.<sup>29</sup> All of the high-value quality measures available from the USWR are listed in Table 5. Advanced practitioners who wish to engage fully in

**Table 4.** Performance rate needed to earn a maximum of 10 points for some Qualified Clinical Data Registry measures

2017 USWR QCDR Measure	Measure Type	Performance Rate Needed to Earn Maximum of 10 Points (Excluding Bonus Points), %
VLU outcome measure: Healing or closure <sup>a</sup>	Outcome	≥75.00
Vascular assessment of patients with chronic leg ulcers	Process	≥79.52
DFU healing or closure	Outcome	≥64.30
Healing or closure of Wagner Grade 3, 4, or 5 DFUs treated with HBOT <sup>a</sup>	Outcome	≥66.70

Supported by the U.S. Wound Registry Qualified Clinical Data Registry in 2017 (Merit-Based Incentive Payment System Year 1).<sup>26</sup>

Note that it is not necessary to have a perfect score to achieve the 10th decile.

<sup>a</sup>Benchmark rate estimation based on 2016 data. QCDR, Qualified Clinical Data Registry.

**Table 5.** Examples of “high-value” quality measures

Measure Type/Title	Comments
Risk-stratified wound outcome measures	Practitioners can earn up to 10 possible points, plus 2 bonus points each (total 12)
DFU outcome: Healing or closure (stratified by the WHI)	
VLU outcome measure: Healing or closure (stratified by the WHI)	
Appropriate use measures (HBOT and CTPs)	Worth 10 possible points plus 1 bonus point (total 11)
Appropriate use of HBOT for DFUs	
Appropriate use of CTP DFUs or VLUs	
Patient-reported measures	These are first-year measures
Patient-reported wound outcome	worth 3 points maximum
Patient-reported nutritional screen	plus 2 bonus points (total 5)

Available in the U.S. Wound Registry Qualified Clinical Data Registry in 2017.<sup>1</sup>

CTP, cellular and/or tissue-based products for skin wounds; WHI, Wound Healing Index.

MIPS are more likely to receive a bonus payment if they reach the exceptional performance threshold, which necessitates achieving the maximum base points available in each category, as well as all possible bonus points. This is best accomplished by taking advantage of QCDR non-MIPS measures.

Table 6 is a measure-by-measure breakdown of how one author (C.E.F.) was able to achieve the maximum score of 60 points for quality reporting in 2017, by reporting high-priority measures, taking advantage of bonus points, and also earning partial points for some measures. Among the six quality measures reported, the provider only achieved the 10th decile for two measures, one of which (plan of care for VLUs not achieving 30% closure at 4 weeks) had a benchmark rate of  $\geq 50\%$ , which is rather low. The provider’s performance rate was only 53%, but because she electronically reported these measures to the QCDR directly from her EHR, she earned one bonus point for end-to-end reporting for each measure. She additionally earned two bonus points for reporting two high-priority measures. She also earned 2.9 partial points, based on where

her rate fell within each decile range. For example, for the measure “controlling high blood pressure,” she scored 73.04%, which placed her in the middle of the eighth decile range (71.00–75.34%) and earned her 0.5 partial points. Partial points scored as 0.1 through 0.8 are rounded up at the 10th digit, while partial points  $>0.9$  are counted as 0.9.<sup>30</sup> Thus her final score was 63.9 points. Because the Quality category is maxed at 60 points, the provider earned 60 points for MIPS credit. This example shows how the bonus points achieved with end-to-end reporting can compensate for the difficulty of achieving a perfect performance score in standard MIPS measures and how reporting QCDR measures can enable the conscientious provider to achieve more than 10 points for some measures.

Table 7 demonstrates what would have happened if only standard MIPS measures had been reported, without direct EHR transmission (end-to-end reporting). The difference in the two total scores is 15.2, a very significant difference considering that for most wound care practitioners, the Quality score represents 75% of the total MIPS score. This point difference could determine whether the practitioner receives a bonus payment. Thus, it is possible for clinicians participating in a QCDR to optimize their MIPS score and thus their chances of bonus money, particularly in the vitally important category of Quality.

#### Using real-world QCDR data for comparative effectiveness research

The benefits of participation in a QCDR can go beyond MIPS data submission. Real-world QCDR data may also be used to determine whether clinicians are following evidence-based clinical practice guidelines or to monitor safety. In 2007, wound registry data were used to evaluate the safety of negative pressure wound therapy (NPWT) in comparison to moist wound care after the Food and

**Table 6.** Measure-by-measure breakdown of how to achieve 60 points

Quality Measure	Highest Benchmark (Decile 10)	Provider’s Score (Decile No.)	Points from Benchmark Decile	Partial Points Obtained	High-Priority Bonus Points	End-to-End Reporting Bonus Points	Total Measure Score
Documentation of current medications in the medical record	$\geq 99.76\%$	99.69% (9)	9.0	0.9	1.0	1.0	11.9
Controlling high blood pressure	$\geq 80.9\%$	73.04% (8)	8.0	0.5	N/A	1.0	9.5
Adequate offloading of DFU at each treatment visit	$\geq 95.75\%$	82.3% (8)	8.0	0.6	N/A	1.0	9.6
Vascular assessment of patients with chronic leg ulcers	$\geq 98.17\%$	93.2% (8)	8.0	0.9	1.0	1.0	10.9
Adequate compression of VLUs at each treatment visit	$\geq 84.15\%$	91.3% (10)	10.0	N/A	N/A	1.0	11.0
Plan of care for VLUs not achieving 30% closure at 4 weeks	$\geq 50\%$	50% (10)	10.0	N/A	N/A	1.0	11.0
Total points	N/A	N/A	53	2.9	2.0	6.0	63.9
Total points earned							60.0

C.E.F. was able to achieve the maximum possible score (60 points) in the Quality category, by reporting through a Qualified Clinical Data Registry in 2017. Note that the maximum number of points allowable is limited to 60.

**Table 7.** Measure-by-measure breakdown of the Quality score without using end-to-end electronic reporting

Quality Measure	Highest Benchmark (Decile 10)	Provider's Score (Decile No.), %	Points from Benchmark Decile	Partial Points Obtained	High-Priority Bonus Points	End-to-End Reporting Bonus Points	Total Measure Score
Controlling high blood pressure	100	73.04	8	0.5	N/A	N/A	8.5
Screening for alcohol use	100	53.72	4	0.4	N/A	N/A	4.4
Use of high risk medications		1.23	7	0.9	1		8.9
Documentation of current medications in the medical record	100	99.69	9	0.9	1	N/A	10.9
Hemoglobin A1c poor control	0	100	0	0	N/A	N/A	3
Pain assessment and follow-up	100	93.85	8	0.1	1	N/A	9.1
Total points earned	N/A	N/A	36	2.8	3.0	N/A	44.8

Breakdown of Quality score C.E.F. would have achieved if she had reported only Merit-Based Incentive Payment System measures through a standard qualified registry rather than a Qualified Clinical Data Registry, without using end-to-end electronic reporting.

Drug Administration delayed clearance of a new NPWT device until they were satisfied it did not represent a significant safety risk in the outpatient setting.<sup>8,31</sup> The USWR initiated the “Do the Right Thing”<sup>TM</sup> quality initiative when analysis of 2008 data suggested that practitioners were doing a poor job implementing clinical practice guidelines for VLU compression and DFU offloading.<sup>8</sup> The USWR developed quality measures for DFU offloading, VLU compression, and peripheral arterial screening which were approved by the CMS through the QCDR. Nearly a decade later, in 2017, benchmark rates set by the CMS confirm that there has been a dramatic improvement in adherence to these basic interventions (Table 4).

The most exciting untapped resources are the registry data reported as part of the DFU and VLU healing measures, which are risk stratified by the WHI. In a previous review, we showed the dramatic difference between real-world patients and subjects enrolled in cellular and/or tissue-based products for skin wounds (CTPs) trials performed in a consortium of clinics.<sup>10</sup> Real-world patients were older, sicker, and had much more severe wounds than those included in randomized controlled trials at the same clinics. Because of strict exclusion criteria, only 4.3% of VLU patients could be included in the VLU trials performed by the consortium, and only 3.8% of DFU patients could be included in DFU trials. The VLUs of real-world patients were five times the size of those included in clinical studies, whereas the real-world DFUs were three times the size of those allowed to participate in the DFU clinical trials. Although the DFU clinical trials enrolled Wagner Grade 1 and 2 ulcers only, among patients in the consortium suffering from DFUs, 43.6% had an ulcer that was worse than a Wagner Grade 2, excluding them from consideration for the trial.<sup>10</sup> In other words, real-world patients are dramatically different than subjects enrolled in wound healing trials,

with the result being that little is known about the real-world effectiveness of CTPs.<sup>8–10,28</sup> Unfortunately, the absence of effectiveness data among such patients is commonly cited by payors as a reason to deny coverage for advanced therapeutics in this population. QCDR data enable real-world analytics, particularly since it is possible to use quality measure performance to control for variations in adherence to evidence-based guidelines. The USWR has data that could enable the comparison of DFU healing and amputation rates between patients with and without NPWT, CTPs, and hyperbaric oxygen therapy (HBOT), for example.

## SUMMARY

Wound care and hyperbaric medicine practitioners have no mandatory registry reporting requirements for payment. Perhaps more importantly, unlike virtually every medical or surgical specialty society, wound care and hyperbaric medicine have no professional society leadership or national organizational structure to drive quality reporting or QCDR participation, depriving these fields of the data needed to support advocacy efforts, defend the medical necessity of delivered services, and garner adequate research funding.<sup>8–10</sup> This is of particular concern in the area of HBOT. Practitioners can demonstrate their compliance with Medicare coverage policy, adherence to clinical practice guidelines, and the clinical effectiveness of HBOT by participating in the wound QCDR, and they may need to do so. The Department of Justice (DOJ) recently settled allegations made under the False Claims Act that the nation's largest wound care management company knowingly caused practitioners to bill Medicare for medically unnecessary HBOT treatments. The DOJ settlement mandates that practitioners participate in Corporate Integrity Agreements, which require them to demonstrate

compliance with Medicare coverage policy.<sup>23</sup> The CMS has recently listed HBOT as a proposed topic for Recovery Audit Contractors. The risk of these audits might be reduced by public reporting of national benchmarking data, which would enable practitioners to demonstrate whether they are within industry norms of practice.<sup>24</sup> CTP charges are similarly at risk. For example, among Medicare Administrative Contractors that provide detailed Local Coverage Determinations on the use of CTPs, coverage is restricted to DFUs and VLU's that generally resemble those enrolled in prospective clinical trials (e.g., superficial wounds that do not expose bone or tendon, among patients without arterial disease, autoimmune disease, inflammatory state, uncontrolled diabetes, or cancer, but who have granulated wounds without infection, and so on).<sup>8-10</sup> Unfortunately, as demonstrated previously, patients enrolled in clinical trials bear little resemblance to real-world patients. With 15% of Medicare beneficiaries suffering from a chronic wound,<sup>16</sup> the existence of the WHI to create matched cohorts for analysis, and the availability of ample structured data, it is unfortunate that the lack of funding for comparative effectiveness research negatively affects the availability of therapeutic options for these complex but common wounds.

The last barrier preventing access to wound care quality measures may finally be overcome as EHR vendors achieve the next stage of EHR certification ("2015 Certification").<sup>32</sup> This standard requires that EHR vendors support interfaces that utilize FHIR<sup>®</sup> (Fast Healthcare Interoperability Resources)<sup>33</sup> as part of the "open Application Programming Initiative (API)." This means that by 2019, EHRs should be able to support quality measures as "apps." The USWR non-MIPS measures will soon be available as "apps" for certain EHRs that support FHIR.

The American taxpayer and U.S. health care providers have invested billions of dollars in health information technology, hoping to use it to drive improvements in quality of care and enable the transition to value-based payment. Wound care practitioners participating in a wound QCDR can make this shift and, in the process, leverage the structured data transmitted by their EHR to address questions of compliance with Medicare policy and perform comparative effectiveness research.

### TAKE-HOME MESSAGES

- Practitioners wanting to thrive under MIPS need an EHR that supports relevant quality measures and transmits data directly to a QCDR.
- The USWR is the only QCDR that has a suite of wound care-relevant quality measures, including outcome measures using the WHI, and IAs that can be reported MIPS credit.
- A dividend to QCDR participation is a repository of structured registry data, which can be used to demonstrate compliance with Medicare policy and adherence to clinical practice guidelines and for performing comparative effectiveness research.
- Recognized medical specialties successfully use QCDR data to obtain research funding and support advocacy efforts. If wound care practitioners unify around their shared MIPS reporting requirements through QCDR data submission, they might not only raise clinical standards for wound care but also increase the availability of wound care therapies in clinical practice.

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## REFERENCES

1. U.S. Wound Registry. MIPS Program Quality Measures. [www.uswoundregistry.com/QualityMeasures](http://www.uswoundregistry.com/QualityMeasures) (last accessed July 17, 2018).
2. The Centers for Medicare and Medicaid Services. Quality Payment Program overview. <https://qpp.cms.gov/about/qpp-overview> (last accessed July 17, 2018).
3. Stark P. Congressional intent for the HITECH Act. *Am J Manage Care* 2010;16(12 Suppl HIT):SP24–SP28.
4. Menemeyer ST, Menachemi N, Rahrkar S, Ford EW. Impact of the HITECH act on physicians' adoption of electronic health records. *J Am Med Inform Assoc* 2016;23:375–379.
5. Fife CE, Walker D, Thomson B. Electronic health records, registries, and quality measures: What? Why? How? *Adv Wound Care (New Rochelle)* 2013;2:598–604.
6. The Centers for Medicare and Medicaid Services. MIPS overview. <https://qpp.cms.gov/mips/overview> (last accessed July 17, 2018).
7. Centers for Medicare and Medicaid Services. Quality measure requirements. <https://qpp.cms.gov/mips/quality-measures> (last accessed July 17, 2018).
8. Fife CE, Eckert KA. Harnessing electronic healthcare data for wound care research: standards for reporting observation registry data obtained directly from electronic health records. *Wound Repair Regen* 2017;25:192–209.
9. Fife CE, Eckert KA. The Hyperbaric Oxygen Therapy Registry: driving quality and demonstrating compliance. *Undersea Hyperb Med* 2018;45:1–8.
10. Serena TE, Fife CE, Eckert KA, Yaakov RA, Carter MJ. A new approach to clinical research: integrating clinical care, quality reporting, and research using a wound care network-based learning healthcare system. *Wound Repair Regen* 2017;25:354–365.
11. Council of Medical Specialty Societies (CMSS). CMSS Primer for the Development and Maturation of Specialty Society Clinical Data Registries. For Specialty Societies and Organizations Developing and Advancing Clinical Data Registries. First Edition January 2016. [https://cmss.org/wp-content/uploads/2016/02/CMSS\\_Registry\\_Primer\\_1.2.pdf](https://cmss.org/wp-content/uploads/2016/02/CMSS_Registry_Primer_1.2.pdf) (last accessed July 25, 2018).
12. The Centers for Medicare and Medicaid Services. 2018 MIPS promoting interoperability performance category fact sheet. <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Promoting-Interoperability-Fact-Sheet.pdf> (last accessed July 17, 2018).
13. Fife CE, Gelly H, Walker D, Eckert KA. Rapid analysis of hyperbaric oxygen therapy registry data for reimbursement purposes: technical communication. *Undersea Hyperb Med* 2016;43:633–639.
14. The Centers for Medicare and Medicaid Services. 2018 Merit-Based Incentive Payment System (MIPS) cost performance category fact sheet. <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/2018-Cost-Performance-Category-Fact-Sheet.pdf> (last accessed July 18, 2018).
15. The Centers for Medicare and Medicaid Services. Medicare Program; CY 2018 Updates to the Quality Payment Program. 42 CFR Part 414. CMS-5522-P. <https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-13010.pdf> (last accessed July 18, 2018).
16. Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, Nussgart M, et al. An economic evaluation of the impact, cost, and Medicare policy implications of chronic nonhealing wounds. *Value Health* 2018;21:27–32.
17. Scan Health Plan. Risk score calculator. [www.hccuniversity.com/risk-score-calculator](http://www.hccuniversity.com/risk-score-calculator) (last accessed July 18, 2018).
18. U.S. Podiatry Registry. Clinical Practice Improvement Activities (CPIA). 2017. <http://uspodiatryregistry.com/CPIA> (last accessed July 18, 2018).
19. The Centers for Medicare and Medicaid Services. The Merit-Based Incentive Payment System: MIPS scoring overview. <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/MACRA-MIPS-and-APMs/MIPS-Scoring-Methodology-slide-deck.pdf> (last accessed July 18, 2018).
20. Undersea and Hyperbaric Medical Society. Undersea and Hyperbaric Medicine ABPM Maintenance of Certification Part IV Patient Care Practice Improvement (PCPI Activity). [https://www.uhms.org/images/MOC/UHMS\\_MOC\\_Part\\_4\\_Packet\\_2017.docx](https://www.uhms.org/images/MOC/UHMS_MOC_Part_4_Packet_2017.docx) (last accessed July 18, 2017).
21. Le PJ. Lessons to learn from federal convictions of HBOT fraud. *Today's Wound Clinic* 2015;9:27–31.
22. U.S. Department of Health and Human Services. Office of Inspector General. Hyperbaric oxygen therapy. Its use and its appropriateness. October 2000; OEI 06-99-00090. <http://oig.hhs.gov/oei/reports/oei-06-99-00090.pdf> (last accessed July 25, 2018).
23. The United States Department of Justice. Healogs Agrees to Pay Up to \$22.51 Million to Settle False Claims Act Liability for Improper Billing of Hyperbaric Oxygen Therapy. June 20, 2018. <https://www.justice.gov/opa/pr/healogs-agrees-pay-2251-million-settle-false-claims-act-liability-improper-billing> (last accessed July 19, 2018).
24. Fife CE. Why audits are happening in wound care & how to (maybe) avoid them. *Today's Wound Clinic* 2015;9:11–14.
25. The Centers for Medicare and Medicaid Services. Quality measures requirements. <https://qpp.cms.gov/mips/quality-measures> (last accessed July 18, 2018).
26. The Centers for Medicare and Medicaid Services. Explore measures. <https://qpp.cms.gov/mips/explore-measures/quality-measures?py=2018#measures> (last accessed July 18, 2018).
27. Horn SD, Fife CE, Smout RJ, Barrett RS, Thomson B. Development of a wound healing index for patients with chronic wounds. *Wound Repair Regen* 2013;21:823–832.
28. Fife CE, Eckert KA, Carter MJ. Publicly reported wound healing rates: the fantasy and the reality. *Adv Wound Care (New Rochelle)* 2018;7:77–94.
29. Centers for Medicare and Medicaid Services. Physician compare. <https://www.medicare.gov/physiciancompare> (last accessed July 31, 2018).
30. The Centers for Medicare and Medicaid Services. Merit-Based Incentive Payment System (MIPS) Scoring Guide for the 2017 Performance Period. <https://www.cms.gov/Medicare/Quality-Payment-Program/Resource-Library/MIPS-Scoring-101-Guide.pdf> (last accessed July 31, 2018).
31. Fife CE, Walker D, Thomson B, Otto G. The safety of negative pressure wound therapy using vacuum-assisted closure in diabetic foot ulcers treated in the outpatient setting. *Int Wound J* 2008;5(Suppl 2):17–22.
32. The Centers for Medicare and Medicaid Services. Stage 3 Program Requirements for Providers Attending to their State's Medicaid EHR Incentive Program. [https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage3Medicaid\\_Require.html](https://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Stage3Medicaid_Require.html) (last accessed July 18, 2018).
33. HL7.org. 2.11 FHIR overview. <https://www.hl7.org/fhir/overview.html> (last accessed July 18, 2018).

**Abbreviations and Acronyms**

API	=	Application Programming Initiative
BMI	=	body mass index
CCD	=	continuity of care document
CMS	=	Centers for Medicare and Medicaid Services
CTP	=	cellular and tissue-based product for skin wound
CMSS	=	Council of Medical Specialty Societies
DOJ	=	Department of Justice
DFU	=	diabetic foot ulcer
EHR	=	electronic health record
FHIR <sup>®</sup>	=	Fast Healthcare Interoperability Resources
HBOT	=	hyperbaric oxygen therapy
HITECH	=	Health Information Technology for Economic and Clinical Health
IA	=	Improvement Activity
ICD-10	=	International Statistical Classification of Diseases and Related Health Problems
MIPS	=	Merit-Based Incentive Payment System
MOC	=	Maintenance of Board Certification
NP	=	nurse practitioner
NPWT	=	negative pressure wound therapy
PBD	=	provider-based department
PI	=	Promoting Interoperability
QCDR	=	Qualified Clinical Data Registry
QPP	=	Quality Payment Program
USWR	=	U.S. Wound Registry
TPCC	=	total per capita cost
VLU	=	venous leg ulcer
WHI	=	Wound Healing Index