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ALSO IN THIS ISSUE

Reporting on Quality Measures in Specialty Practices

Allison Inserro

Urologists, oncologists, or other specialty physicians should not be judged solely by the same quality measures used by internists when it comes to reporting quality data to CMS, most would agree.

With the advent of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), physicians are incentivized in a different way to provide high-value care to their patients. Reporting on the quality measures required by CMS in order to receive the highest payment possible under the Merit-Based Incentive Payment System (MIPS) Quality Payment System (QPP) requires monitoring of 4 performance categories: quality, improvement activities, advancing care Information, and cost.

How to submit specialty data, though?

A CMS-approved Qualified Clinical Data Registry (QCDR) is an entity that collects clinical data from an individual MIPS-eligible clinician, group, and/or virtual group and submits the data to CMS on their behalf for MIPS purposes.

Unlike other types of data submission methods, a QCDR reporting option is not limited to MIPS quality measures. The QCDR can develop and submit QCDR measures for CMS review and approval. A QCDR measure is a measure that isn't in the annual list of MIPS measures for the applicable performance period, or a measure that may be in the annual list of MIPS measures but has major

SPOTLIGHT ON

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Value Assessments in the Age of Personalized Medicine May Require a Cultural Shift, Panel Says

Kelly Davio

On the closing day of the International Society for Pharmacoeconomics and Outcomes Research 23rd Annual International Meeting, in Baltimore, Maryland, stakeholders gathered to grapple with the role of value assessments in a healthcare landscape that is increasingly focused on the use of precision medicine in treating disease.

Moderating the panel was Kristen Migliaccio-Walle, director of Global

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Health Economics and Outcomes Research at Xcenda. Migliaccio-Walle opened by pointing out that, among the barriers to the increased use of personalized medicine is a lack of value recognition, both clinical and economic. Value assessment frameworks have the potential to encourage the use of personalized medicine, but that can only happen if frameworks incorporate the appropriate elements to demonstrate value.

Speaking from the perspective of the health technology assessor (HTA) was Daniel A. Ollendorf, PhD, CSO of the Institute for Clinical and Economic Review (ICER). Ollendorf began his remarks by disabusing the audience of what he said was a common perception that "…HTA bodies have a natural bias against personalized treatment… we actually feel that nothing is further than the truth."

He explained that organizations like ICER must base their assessments on evidence available to them, and "Oftentimes, a personalized approach is just emerging—or may even be a thought—at the time of FDA approval," but "We are certainly open to the idea of identifying the right population for treatment [to] make the value proposition a solid one."

Ollendorf gave the example of ICER's recent assessment of vesic-

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differences in how it's submitted by the QCDR, according to a CMS fact sheet.

These QCDR measures are different because they are not contained in the annual list of MIPS quality measures, or it is on the annual MIPS list, but is substantially different or in how it is submitted.

CMS has approved about 150 QCDRs for 2018, and one of them is IntrinsiQ Specialty Solutions, a part of AmerisourceBergen, which recently joined the list.

IntrinsiQ is one of the largest providers of electronic health records (EHRs) for urologists, said Susan Weidner, senior vice president of analytics at IntrinsiQ Specialty Solutions, in an interview with *The American Journal of Managed Care*®. And that makes it easy for their QCDR to lift and analyze data directly from the EHR and submit it to CMS on behalf of the provider, she said.

"With the shift to value-based care, specialty providers wanted new solutions, like earlier performance monitoring, centralized clinical quality of measures, and to start to expand that capability above and beyond the MIPS measures so that they represent what they do as specialty providers," she said.

Oftentimes, she said, providers may not know how they are performing until the last quarter of the year, or maybe the last 4 months. The goal of IntrinsiQ is to give providers and practices information from the time they start using it, to give them time to adjust if something is flagged as an opportunity to improve—say, an issue with a physician or with a workflow.

That helps providers "ensure that they're getting the highest level of score possible," Weidner said.

In addition to MIPS measures, IntrinsiQ provides quality measuring on 5 additional measures related to urology, such as prostate cancer and hypogonadism. During the review process with CMS to get the QCDR measure for hypogonadism approved, IntrinsiQ was able to make the case that CMS should look at not just serum testosterone, but a whole set of indicators.

In addition to getting speciality-specific measures cleared, the company also wants to be aligned to what some payers would like to see measured.

"The MIPS measures that are out there were intended for things that could be implemented by any provider," she said. "The challenge is that if we're really trying to use those to measure the quality of care, it's not an accurate representation of what a specialty provider does, or the types of patients that they may be treating."

For instance, she said, not all oncologists treat all oncology patients. And whether or not an oncologist or urologist provides immunizations may not be the most appropriate measure of quality.

ADA Issues Recommendations Designed to Fix Insulin Pricing, Accessibility Crisis

Allison Inserro

The American Diabetes Association (ADA) released a set of policy recommendations designed to spotlight the increasing difficulties patients with diabetes have affording insulin or gaining access to the life-saving medication through health insurance. The recommendations follow the findings of a working group that were presented to the Special Senate Committee on Aging earlier this month.

The cost of diabetes in the United States was $327 billion in 2017, a 26% jump from 2012. That figure includes $31 billion for medication, including $15 billion for insulin.

The public policy statement creates recommendations in 4 areas, including:

- Streamlining the biosimilar process
- Increasing pricing transparency throughout the insulin supply chain
- Lowering or removing patient cost-sharing for insulin
- Increasing access to healthcare coverage

Competition and Biosimilar Insulins: Earlier this month, the FDA published a list of medications no longer under patent protection that do not have generic or biosimilar alternatives. The list includes 1 type of insulin that is off-patent but for which there are no alternative versions available. The ADA recommends the FDA continue its push to encourage additional competition in biosimilars.

Insulin Supply Chain: There is a lack of transparency at every level of the supply chain, the ADA and others have noted. ADA Chief Medical Officer William T. Cefalu, MD, told the Senate committee earlier this month that the byzantine structure of pharmacy rebates and discounts hurt patients and consumers.

To that end, the ADA wants to know exactly how money passes through the supply chain and how much each player profits: manufacturers, wholesalers, pharmacy benefit managers (PBMs), health plans, and pharmacies. Without specific pricing information, solutions to the crisis can't be created, the ADA said.

Health Plans: The ADA recommends that health plans and government programs like Medicare and Medicaid change prescription drug benefit designs so that insulins are not subject to a deductible or coinsurance. Providing

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ular monoamine transporter-2 inhibitors that treat tardive dyskinesia, an involuntary movement disorder that is caused by the long-term use of antipsychotic drugs that treat schizophrenia, bipolar disease, and other conditions. Clinical studies of these drugs were powered to assess involuntary movement, but other stakeholders raised the possibility of the drugs' having additional benefits: treating tardive dyskinesia effectively could allow for better control of underlying psychiatric disorders because patients could potentially be more adherent to their antipsychotic treatment.

Because no data were collected on this potential benefit during clinical trial, ICER worked with one drug's manufacturer to create a set of threshold analyses to try to assess whether this benefit could affect the result of the value assessment. (Eventually, even with this information, ICER determined that the drugs would need to be discounted substantially to fall within its threshold value range.)

"We are certainly open to the idea of identifying the right population for treatment [to] make that value proposition a solid one," he said. When manufacturers say there are benefits to treatments that are not

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shown in clinical trial, his response is, "Why didn't you collect information in the study? There are standardized instruments to use."

Sara Traigle van Geertruyden, JD, executive director of Partnership to Improve Care, said that ICER's experience with tardive dyskinesia therapies "underscores some of the challenges that patients are having in the value assessment world," because data that are important to patients are not always part of clinical trials, and subpopulations are not necessarily analyzed.

While value assessments are not always aligned with the outcomes that matter to patients, they do drive patients' options and choices, however.

"What it boils down to is culture," said van Geertruyden. The current culture in the United States, she said, is structured upon a fail-first approach and on limiting access to new, expensive treatments. A cultural transition should focus on building evidence to know which treatments work for which patients, and when. Such an approach would help to save on costs by preventing adverse events or nonresponse to treatment. One key to achieving this new reality is to invest in real-world evidence earlier, so that payers have more information to work from.

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diabetes medications with low or no cost-sharing has been shown to increase medication adherence and results in better long-term health outcomes, the ADA said. The ADA noted that many plans are moving toward a value-based insurance design, lowering or removing cost-sharing for high-value clinical services and medications.

In addition, the ADA supports HHS having the ability to negotiate prices for the Medicare Part D program—something President Donald Trump's recently announced drug pricing proposal did not include. The ADA also recommends health plans and government programs be required to limit out-of-pocket spending for medications.

Continuity of Care: The ADA recommends all health plans and government healthcare programs be prohibited from removing medications from formularies or moving medications to a higher-priced formulary tier during the plan year, except when the FDA has safety concerns. This prohibition should apply regardless of whether the pharmacy benefit is managed by a third party, like a PBM. This practice is prohibited in Medicare Part D, and some states have implemented similar restrictions for state-regulated health plans. The ADA recommends this prohibition be applied to all health plans and government healthcare programs.

Formulary Development: The ADA recommends regulators, health plans and government programs ensure that any value-based insurance design is evidence-based and that it includes consumer cost-sharing protections, such as low copays and accessible exceptions processes. The ADA recommends continued assessment of value-based models within Medicaid and Medicare, as well as provision of industry guidance regarding the role of Medicaid best price requirements in outcomes or value-based health insurance design

Improving Access to Healthcare: Citing the success of the Affordable Care Act in reducing the number of people without insurance, the ADA called for an expansion of Medicaid across all states to include individuals earning less than 138% federal poverty line.

Transparency for Consumers: The ADA recommends that all plans give information in a consumer-friendly, clear way that plainly explains the costs patients will face. For example, instead of using percentages to explain copays, plans should communicate that information using fixed dollar amounts.

The ADA also recommends that information be provided in one's native language, especially since some populations may be at a higher risk for complications from diabetes.

The Challenge of Addressing Low-Value Care Once It's Identified

Laura Joszt

Identifying low-value care can save a state hundreds of millions of dollars in just 1 year, found Beth Bortz, president and CEO of the Virginia Center for Health Innovation (VCHI). She and her fellow panelists, Lauren Vela, MBA, senior director of the Pacific Business Group on Health, and Daniel Wolfson, executive vice president and chief operating officer of the ABIM Foundation, discussed low-value care, unnecessary services, and what can be done to address overuse in healthcare during a panel at the University of Michigan Center for Value-Based Insurance Design's (V-BID) annual V-BID Summit on March 14.

VCHI was trying to let CMS know that it could lower the cost of care and in the course of trying to understand how much low-value care was happening in Virginia and what could be done about it, VCHI came across ABIM Foundation's Choosing Wisely initiative.

"We very much wanted our physician community in Virginia to be on board, and we thought the best place to start was with services that the physicians, themselves, identified and said, 'These are tests and procedures that we routinely do that we know to be unnecessary and potentially harmful,'" Bortz explained. "So that was a great starting point for us."

The point is not to look at simply if a test or procedure is done in a vacuum, because what could be a low-value service for many might be a high-value service for someone else, depending on what other factors and risks are taken into consideration.

Wolfson added that the Choosing Wisely campaign defines overuse as when the risks outweigh the benefits with the support of evidence. The campaign doesn't even define low-value care, he explained. The campaign is clinically nuanced.

"It's not an absolute," he said. "There are times when the red flags would necessitate a test that is generally recommended not to be used."

Clinical evidence is an important part of this process. With so many things that need to be paid for in healthcare, Vela said it would be a sham to pay for something that clinical evidence says does not need to be done. She said that identifying and addressing low-value care "looms as a very large opportunity." The challenge is translating a conversation around low-value care into something that is action-oriented for employers.

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Robert W. Dubois, MD, PhD, chief science officer of the National Pharmaceutical Council, added that value assessments range from simple to complex; if the FDA has approved a product with a companion diagnostic, value assessment is relatively straightforward, he said. But in other cases, including cases in which outcomes that matter most to patients have a great deal of nuance, "It's a nightmare to figure out how you develop a value assessment."

Dubois, too, felt that the United States faces a cultural challenge, saying "I think we all want more data...I don't think this is a methods issue; I think this is a social and cultural issue." He pointed to recent passage of Right to Try legislation—calling it a "uniquely American problem"—as a clue that the US culture at large is in favor of an approach to treatment access that is not evidence-based in nature.

"In the absence of data, what is the right approach? Until you get the answer to that question, I don't think you can ask our value assessors to do more than what society is doing."

The fact that the Choosing Wisely campaign and the actions of VCHI were never supposed to just be to reduce costs is also an important message to get out. Wolfson explained that the purpose of Choosing Wisely was to enhance safety, quality, and affordability—some of the recommendations actually increase costs. He provided the example of tube feeding versus manual feeding in nursing homes. While tube feeding is less costly, it kills people over time; but manually feeding a patient costs more money, so it was less popular.

"We wanted to take a baby step," Wolfson said. "And a baby step was just looking at low-hanging fruit. Cost effectiveness is a more difficult, nuanced thing to be able to look at. We wanted to be able to get people in the game first and then think about cost effectiveness."

In Virginia, Bortz's organization looked at 42 measures out of approximately 500 and the claims data on 5 million Virginians and found that more than $700 million a year was spent on unnecessary care, as defined by the Choosing Wisely program and those services that received a D grade from the United States Preventive Services Task Force.

VCHI took this report out into the field to show to employers and providers. Bortz made the mistake of leading with the top 5 services by cost and "got schooled pretty quickly." Physicians didn't want to hear the word "waste" in these discussions and they wanted to see a low-value index, which should what services are they doing wrong all the time. Employers didn't want their employees to feel like "this was all about a money grab." They wanted to see the top 5 list by harm.

From the employer perspective, Vela explained that there may be need to take actions once these services are identified. Employers need to know how to measure the low-value care being provided in their population, or they won't know if the endeavor is worthwhile to undertake. But ultimately, employers and health plans have to encourage physicians to stop ordering the services and tests that are identified as low value.

"What can the employer do to impact, at the end of the day, so the physicians have the information, the authority, and the incentive to do the right thing?" Vela asked.

The panel also discussed the top 5 low-value care services identified by the Task Force on Low-Value Care:

- Avoid unneeded diagnostic testing and imaging for low-risk patients before low-risk surgery
- Avoid vitamin D screening tests
- Avoid prostate-specific antigen screening in men 75 and older
- Avoid imaging for acute low-back pain for the first 6 weeks after onset, unless clinical warning signs ("red flags") are present
- Avoid use of more expensive branded drugs when generics with identical active ingredients are available

Employers seem to believe that as the industry moves toward alternative payment models, some of these top 5 services will be taken care of.

"At the end of the day, it's really, really tough to stop physicians from doing all these things…but, at the end of the day, if we have accountable providers who understand their accountability and can measure their accountability, then, in fact, this would be the great stuff for them to get rid of," Vela said. "It's the low-value care they want to get rid of."

Bortz had been part of the task force that came up with the top 5, and since Virginia had so much data and access to an All-Payer Claims Database, the state's data was used as a reference point to help provide a sense of scale. When choosing the 5, the task force knew it didn't want to pick something right out of the gate that would prove controversial and possibly turn some people off the idea immediately. However, they wanted to ensure they picked at least 1 or 2 that were meaningful and could have a financial impact.

ABIM Foundation had created its own "dirty dozen" list that included 3 of the top 5 from the task force. Wolfson views these lists as a signal to the community that employers and

purchasers are thinking about the issue and "are not going to tolerate low-value care."

"We have well-intentioned people doing things routinely because that's how it's been done," Wolfson said. "You've got to get their attention."

However, since the Choosing Wisely campaign took off in 2012, there has been only some movement in the use of identified unnecessary tests and procedures. Wolfson explains that nothing happens without and intervention, and even then it takes time.

"We talked about underuse for 30 years," he said, and admitted that he was part of that conversation. Shifting in the other direction to prevent overuse will take time, he said. "I'm very humbled about what it's going to take to stop people from doing things they've been doing for a long period of time."

How Public Payers Are Adopting VBID Principles Despite Constraints

Christina Mattina

During a session on expanding the role of value-based insurance design (VBID) in public payers at the University of Michigan V-BID Center's annual V-BID Summit on March 14, panelists representing 3 different payers shared how they have seen value-based principles take hold in their plans and their predictions for the future.

Moderator Cliff Goodman, PhD, senior vice president at The Lewin Group, asked the panelists to introduce themselves and describe the type of payer they represent.

Captain Edward Simmer, MC, USN, chief clinical officer for the TRICARE program, explained that he oversees the clinical care provided to 9.5 million military service members, retirees, and dependents covered by the Military Health System. TRICARE is unique in that service members are not charged for medications or care, and cost sharing for retirees or dependents is capped at $3500 per year. The generous benefit requirements and cost-sharing restrictions imposed by Congress have forced program officials to be creative in how they incentivize beneficiaries to change their healthcare utilization habits, Simmer explained.

Claire Levitt, MS, deputy commissioner for the New York City Mayor's Office of Labor Relations, could empathize with that challenge, as the 1.2 million city employees, dependents, and retirees in the city's health benefits program are represented by unions that consistently ensure that their health plans have no deductibles or premiums.

Finally, Adam Finkelstein, JD, MPH, counsel with Manatt Health, explained that his prior experience as a health insurance specialist at CMS' Center for Medicare & Medicaid Innovation had given him insight on how VBID principles are being tested in Medicare Advantage (MA) plans. He called it "remarkable" that CMS was willing to take the leap into VBID by letting MA plans offer reduced cost sharing for some high-value services in certain chronic diseases.

Asked to explain their plans' specific strategies to implement VBID, the panelists presented the program changes and outcomes they had seen so far. Levitt explained that the city had agreed with the unions to attempt to save $3.4 billion in healthcare costs over 4 years by strategically adding costs in specific areas and "changing plan design in concert with foundational VBID principles."

For instance, the plan increased co-payments for emergency department (ED) and specialist visits and covered all preventive care services, thus shifting utilization toward the primary care setting. It also offered wellness initiatives and health management programs at work sites, which she said have resulted in positive engagement and retention outcomes.

Simmer outlined some of the ways that TRICARE attempts to steer beneficiaries to the right care instead of charging different amounts for different services, which current law

likely would not allow. One tactic was to require a referral for ED visits, but not urgent care visits, to encourage patients to choose urgent care over the costlier ED. Lists of participating maternity care providers now feature a "golden stork" next to high-performing providers as ranked by Leapfrog scores. Members receiving preventive care, such as mammograms, get a pass that rewards them with the privilege of going to the head of the line at the pharmacy.

"In a way, we're kind of building up a set of tools and leverage that aren't necessarily financial," Goodman paraphrased, "and we've also learned that they don't have to apply to all services."

According to Finkelstein, CMS hasn't collected many data since the limited test model was rolled out in 10 MA parent organizations in 2017, but no news may be good news: the agency has not heard any public complaints from participants. Although not many plans have rushed to apply yet, Congress has mandated that the model be conducted in all 50 states by 2020.

"Both Congress and the administration have given plans a lot of new flexibility … so there's a bigger palette for plans to paint with in terms of benefits," Finkelstein explained.

In response to an audience question about communicating the "carrots and sticks" of VBID, the panelists described strategies that differed based on which group or entity needs to buy into the changes. Simmer explained that TRICARE has convinced Congress to adopt VBID principles in the program by partnering with the constituents and advocacy groups that policy makers tend to listen to.

Levitt recounted her experiences negotiating with the municipal labor committee by tying wage increases to the unions' willingness to participate in the health cost savings experiment. Union leadership had to be on board with the idea and then sell it to the employees, she said. The plan is on track to save more than $3.4 billion by the end of the 4-year period in July, so the unions will receive any extra savings above that benchmark.

Next, Goodman asked the panelists to share their practical expectations about the viability of VBID expanding to all 50 states. Finkelstein anticipated that we will see plans "start to get braver" about adopting VBID; specifically, the private sector may respond well to being able to choose a standardized VBID plan "off the shelf."

Levitt agreed that the movement focusing on VBID and population health will have to grow nationally in order for plans to push back against rising costs while still benefiting the patient population. She also noted that these efforts in the city's health plan moved more slowly than she had hoped, but they have still accomplished a number of positive changes.

Simmer said that the next area of focus for TRICARE will be to involve the beneficiaries by asking what value means to them. He also talked about the need for greater flexibility, which can be difficult in TRICARE, which has a 5000-page manual governing how the program provides healthcare.

"How do we work that 5000-book to allow that flexibility so that each patient and provider can find the right solution for them?" he asked.

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