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CMS to Expand Episode Payment Models for Cardiac Conditions, Fractures

The Centers for Medicare & Medicaid Services (CMS) recently released the proposed rule *Advancing Care Coordination through Episode Payment Models* for three conditions—acute myocardial infarction (AMI), coronary artery bypass graft (CABG), and surgical hip/femur fracture treatment (SHFFT) excluding lower extremity joint replacement. CMS says the proposed models further its goals of improving both the efficiency and quality of care, particularly for common clinical conditions.

Participation will be required by hospitals in certain geographic markets, beginning with a five-year performance evaluation period (July 1, 2017 to Dec. 31, 2021). Each episode for these conditions will extend to within 90 days of hospital discharge. Clinical laboratory services are included in this payment bundle. These three conditions were chosen, in part, because there is known to be significant existing variation in spending for these "high-expenditure, common episodes."

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CMS Pushes Cuts in HAIs, Promotes Antibiotic Stewardship

As part of a comprehensive push to improve patient safety through a reduction in hospital-acquired infections (HAIs), the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule this summer that emphasizes adoption of current practice standards for hospitals' infection control efforts. Hospitals and critical access hospitals (CAH) wishing to participate in Medicare and Medicaid will be required to modernize their practices to reduce incidence of HAIs, cut inappropriate antibiotic use, and strengthen patient protections and quality of care, overall. CMS explained in a statement: "The proposed changes to the requirements, formally called the Conditions of Participation, would modernize and revise the requirements to reflect current standards of practice and support improvements in quality of care" by reducing HAIs, readmissions, and barriers to care while improving antibiotic usage and patient protections and responding to workforce shortages.

The proposed rule impacts an estimated 4,900 hospitals and 1,300 CAHs that are certified by Medicare and/or Medicaid and addresses mounting con-

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CMS to Expand Episode Payment Models for Cardiac Conditions, Fractures, *from page 1*

The U.S. Department of Health and Human Services previously stated its goal to promote value-based care by connecting at least 50 percent of Medicare payments to quality or value through alternative payment models by the end of 2018. This latest proposed rule follows the April launch of the Comprehensive Care for Joint Replacement (CJR) model. The CJR model similarly requires acute care hospitals in selected geographic areas to participate for all eligible lower-extremity joint replacement episodes. CMS says that approximately 800 acute care hospitals are participating.

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— Fred Bentley, VP, Avalere

Yet the models differ because CJR generally covers an elective procedure that requires less follow-up care. Additionally, CMS expects the models to have different patient populations. The episodes in the proposed rule are commonly tied to chronic conditions, which will increase the need for additional care throughout the 90-day episode period. Historically, CMS says that in the AMI model half of average spending was for the initial hospitalization and the majority of spending following discharge from the initial hospitalization was due to hospital readmissions. With the CABG model, historically about three-quarters of episode spending was for the initial hospitalization, with the remaining episode spending fairly evenly divided between professional services and hospital readmissions.

CMS says it is testing whether an episode payment model for AMI, CABG, and SHFFT care will reduce Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. It anticipates the proposed models will improve the coordination and transition of care by encouraging provider investment in the redesign of care processes across the inpatient and post-acute care spectrum.

The proposed rule includes potential financial risk and rewards for participating hospitals, phased in over time. Overall, CMS expects the episode payment models to result in savings to Medicare of $170 million over the five performance years, which will grow from $13 million in savings year 2 to $79 million in year 5.

Medicare claims payments for services per episode will be totaled to calculate an actual episode payment. The actual episode payment will be compared to an established target price. The difference between the actual and the target, if positive (savings), would be paid to the participant. If negative, after the second quarter of performance year 2 the participating hospital would need to repay CMS. In performance years 4 and 5 of the model, CMS will move from comparisons using target episode pricing based on a hospital's experience to target pricing based on regional experience.

According to recent calculations by the consulting firm Avalere Health, the number of hospitals expected to be winners and losers under the proposed program are fairly evenly distributed. Some institutions whose spending greatly exceeds the average spending for their region could face significant penalties. However, Avalere projects the large majority of hospitals required to participate in the cardiac bundled payment model—85 percent—will likely not experience gains or losses larger than $500,000 per year.

"Given the array of new cardiac bundles, there is no magic bullet to achieving savings. Instead, participating hospitals will need to pull multiple levers to drive down costs," said Fred Bentley, vice president at Avalere, in a statement. "They will be working more closely than ever with their physicians to streamline care and pro-

mote adherence to clinical guidelines. And they will accelerate the development of high-performance post-acute networks to cut readmissions and achieve efficiencies for their medically-managed heart attack episodes."

There are opportunities for both laboratories and post-acute providers to partner with hospitals to improve post-discharge care and transitional care processes. Efforts will need to focus on increasing post-hospitalization follow-up and medical management and better coordination across the care spectrum.

Takeaway: The proposed episode payment models for cardiac conditions and some fractures are part of a broader national shift toward value-based payment. Laboratories can expect bundled payments to become the norm and should position themselves as a partner to drive efficient, coordinated care.

Are Commercial Payers Using Proposed CMS Gapfill Rates to Ratchet Down Reimbursement?

During the summer, the Centers for Medicare & Medicaid Services (CMS) published proposed interim gapfill prices for 15 molecular tests. The agency said it would likely publish final prices later this year for placement on the Clinical Laboratory Fee Schedule.

The proposed prices cut payments to some tests as much as 85 percent from the current rates set by regional Medicare administrative contractors, or MACs, and several tests by more than 70 percent. The proposed rates have been much aligned by the laboratory community as a result, with significant pushback from the sector. Sector advocates such as the Coalition for 21st Century Medicine said at the time the proposed rates were published that they were "inconsistent" with the intent of the Protecting Access to Medicare Act, or PAMA. That law intends to reset some Medicare rates lower to commercial levels, but capped at annual reductions of no more than 10 percent.

But are commercial payers using the proposed rates of reimbursement to push down their own payments? It depends on whom you speak with. Two sources close to the situation have told *Laboratory Industry Report* that some commercial payers are indeed using the proposed rates as leverage to make their own cuts, particularly among Medicare Advantage enrollees. Both asked that their identity be kept anonymous.

According to one of the sources, a lab executive, some payers cited a table of proposed rates published in the July 21 issue of *Laboratory Industry Report* that "appeared to be final mentioned and therefore 'justifies' their low pay rate for Medicare Advantage beneficiaries."

Another source, who advises laboratories, confirmed that the labs had been under pressure.

The sources indicated that the three plans that have been advocated for lower rates are UnitedHealth, Humana and WellCare. All three carriers have sizable Medicare Advantage populations.

Laboratory sector observers say that commercial payers have been ratcheting down payments for tests in recent years, using their large patient populations as leverage.

In some instances, cuts for some tests have been significantly below Medicare rates. UnitedHealth and Humana did not respond to requests seeking comment. WellCare denied it was pressuring labs to accept reduced payments.

"As a provider of government-sponsored managed care services, including Medicare Advantage and Medicaid plans, WellCare adheres to the determined CMS Fee Schedule for the appropriate plan year and pays the standard rate for all codes as outlined in our contracts with laboratory providers," said a statement provided by company spokesperson Crystal Warwell Walker.

Meanwhile, at least one lab executive contended they have not been pressured to reduce their commercial reimbursement in line with the proposed Medicare cuts.

"That is not our experience," said Veracyte Chief Executive Officer Bonnie Anderson. The California-based Veracyte is facing a potential 30 percent cut in reimbursement—nearly $1,000—for its Afirma thyroid cancer test. "We negotiate rates for our tests with commercial payers, which are supported with the value we deliver in patient benefit and surgical cost reductions."

Anderson added that "our contracted rates are not tied to CMS rates and we have not had our commercial contracts challenged during this CMS process. We are confident CMS will finalize rates that are consistent with reimbursement rates in place now for Afirma." Veracyte recently won a local coverage determination from the Noridian MAC for its Percepta lung cancer test.

Other labs contacted for this article did not respond to a request seeking comment.

Takeaway: Commercial payers are potentially using the gapfill rates proposed by CMS as a template for cutting their own reimbursement for testing among their Medicare Advantage population, although it is unclear how widespread the practice currently is.

Despite Passing More Laws, States Flunking Health Price Transparency

Despite the fact that the majority of state legislatures have passed some laws relating to pricing transparency for health care services, only seven states are receiving passing grades for both the statute's design and implementation, according to the report, *Report Card on State Price Transparency Laws*. Price transparency is necessary to combat significant pricing variation for health care services and the increasing financial burden individuals face, according to the study authors, the Health Care Incentives Improvement Institute (HCI3; Newtown, Conn.) and Catalyst for Payment Reform (Berkeley, Calif.).

Many recent studies highlight regional variation in health care costs, including for laboratory tests. This variation is receiving more attention as of late as patients become responsible for a larger percent of their own bills as a result of high deductible health insurance plans. New data from the Kaiser Family Foundation shows that in 2016 the average deductible for the most commonly purchased plan sold in health insurance marketplaces is $3,065.

"The lack of information on the price of care hurts the pocket books of Americans every day," writes François de Brantes, HCI3 executive director and lead author of the report.

Analysts from the Source on Healthcare Price and Competition at the University of California, Hastings College of the Law and the University of California, San Francisco assessed each state's enacted and proposed legislation on health care price transparency. Each state is given a letter grade with an explanation of the shortcomings that are holding back transparency. The authors say the scoring methodology rewards states that both have an all-payer claims databases (APCDs) and that publish that data on a well designed, searchable website.

The researchers found that all but seven states (Alaska, Alabama, Hawaii, Idaho, Mississippi, Oklahoma, and Wyoming) have passed some price transparency legislation. However, the quality of transparency varies due to differences in design and implementation of state laws.

"We recognized a trend in proposed legislation focusing on directing providers or insurers to disclose prices to patients prior to a procedure or service," the authors write. "Such mandates are a step toward meeting consumers' needs, but they are not a substitute for a robust state price transparency resource."

2016 Price Transparency Grades

According to the Report Card on State Price Transparency Laws,

- Three states earned As - Colorado, Maine, and New Hampshire.
- Oregon received the only B.
- Vermont and Virginia earned Cs.
- Arkansas received the only D.
- 43 states received Fs.

Colorado and Maine jumped in this iteration of the grading from Bs in 2015 to As, as a result of the quality of their websites. Oregon became a leading state for the first time this year, earning a B, as a result of a new law and website. The authors say not all Fs are "equal" and expect several of the states to rapidly emerge as leaders in transparency. For example, both Louisiana and Washington enacted new APCD legislation, but have not yet launched websites to share the collected price data.

Takeaway: Laboratories should be prepared for more states to enact legislation mandating price transparency and full consumer disclosure.

New Policies Could Enhance Minorities' Benefit from Precision Medicine

Racial and ethnic groups currently are less likely to benefit from advances in genetics, according to a study published Aug. 8 in Health Affairs. The authors say a multi-pronged strategy involving expanding genetic research, improving genetic literacy, and enhancing access to genetic technologies among minority populations is needed to ensure that adoption of precision medicine does not further widen existing health disparities.

While certain variants may cluster in certain racial or ethnic groups, health disparities are largely the result of non-genetic factors that shape health, including socioeconomic conditions. However, minority groups may lack access to genetic testing and treatments based on these findings due to lower rates of genetic testing and a lack of generalizability of genetic findings to members of minority groups.

"Even if disparities in access to genetic counseling and testing could be overcome, understudied minority communities might still be less likely than whites to benefit from current and emerging genetic technologies," writes a group of authors supported by grants from the National Institutes of Health's Centers for Population Health and Health Disparities.

The group proposes multiple policy changes that can improve access to testing and meaningful results for minorities. These include:

- **Minority-focused genetics research** - It could improve representation of minority groups in genetic databases and better understanding of the full range of genetic diversity associated with disease risk.
- **Community-based participatory research** - These approaches could aid minority recruitment efforts and improve the dissemination of genetic information.

"The 'normal' genetic sequence of the BRCA1 and BRCA2 genes was determined based on information about women of European or Ashkenazi descent," writes senior author José Ordovás, Ph.D., from Tufts University (Boston). "The small samples of tumors from minority women available for study, insufficient details about patient and tumor characteristics in the data, and limited follow-up information on minority women continue to limit translation of genetic knowledge into clinical benefits for all individuals. … This situation perpetuates disparities in personalized health care based on genetic information."

Takeaway: Study calls for measures to ensure precision medicine benefits minorities.

House Committee Asks CDC to Address Laboratory Response Network Capabilities

The U.S. House of Representatives Energy and Commerce Committee recently requested that the Centers for Disease Control and Prevention (CDC) provide information to the Committee about the capabilities of the CDC's Laboratory Response Network (LRN). The LRN launched in 1999 to improve our public health laboratory system and its capability to respond to bioterrorism and other public health emergencies. The network includes more than 150 federal, state, local, military and international labs.

House Committee members emphasized the network's responsibility for ensuring the U.S. has the technology and resources to "test suspicious materials" and promptly detect and respond to potential incidents of bioterrorism or other public health emergencies. Specifically, the committee wants to know how many labs in the U.S. can participate in such activities and the extent of their capabilities. The committee also asked about the number and type of assays that have been developed to facilitate response to such public health emergencies and the network's ability to detect "emerging infectious diseases" such as Zika and Ebola—as well as the process for qualifying those assays for use in the LRN. Questions also addressed the Public Health Actionable Assay Program, the number of assays developed through the program and the roles of federal agencies in the program.

CMS Pushes Cuts in HAIs, Promotes Antibiotic Stewardship, *Continued from bottom of p.1*

HAIs Present Sizeable Problem Says CDC

The U.S. Centers for Disease Control and Prevention (CDC) estimates there are about 722,000 HAIs in U.S. acute care hospitals annually and HAIs contribute to 75,000 patient deaths during their hospitalizations. HAIs not only can be life threatening, but they are also costly. A 2013 *JAMA Internal Medicine* study showed that overall, $9.8 billion is spent each year treating HAIs, which add an average cost of $896 for each catheter-associated urinary tract infection to $45,814 for each central line–associated bloodstream infections.

CDC data shows HAIs are declining, but they remain a pervasive problem given that on any given day, approximately one in 25 U.S. patients contracts at least one infection during their hospital care. Stubbornly high HAI rates demonstrate the need for improved infection control in U.S. hospitals.

cerns over high rates of preventable HAIs and fears over mounting numbers of multi-drug resistant organisms. Specifically, hospitals and CAHs would be required to:

- Implement hospital-wide infection prevention and control for the surveillance, prevention, and control of HAIs and other infectious diseases
- Employ hospital-wide antibiotic stewardship programs to improve the appropriate use of antibiotics
- "Designate leaders of the infection prevention and control program and the antibiotic stewardship program respectively, who are qualified through education, training, experience, or certification."

"We would promote better alignment of a hospital's infection control and antibiotic stewardship efforts with nationally recognized guidelines and heighten the role and accountability of a hospital's governing body in program implementation and oversight," CMS writes in the June 16 *Federal Register*. "We believe that these changes, together, would promote a more patient-centered culture of safety focused on infection prevention and control as well as appropriate antibiotic use, while allowing hospitals the flexibility to align their programs with the guidelines best suited to them."

CMS also proposes introduction of the term surveillance, which they define as including infection detection, data collection, and analysis, monitoring. Surveillance includes both testing as well as methods of "automated surveillance" based on the use of medical informatics and computer science technologies. Hospitals would be required to document these surveillance activities.

Active surveillance—the systematic collection of samples from either all or high-risk asymptomatic patients—is thought to be an effective tool in hospitals' arsenal to combat HAIs. A landmark study published in the *Journal of the American Medical Association* in June 2015 showed that a "bundle" of pre-surgical interventions can significantly reduce the incidence of surgical site infections due to Staphylococcus aureus. Central to this strategy was early nasal screening of patients undergoing total hip or knee replacements and cardiac operations. Yet, active surveillance is not as widely adopted as some in infection control would hope, in part because of mixed results of studies assessing the strategy's clinical and cost effectiveness. For more information of the design of infection control programs, including the role of active surveillance testing, please see the September issue of *Diagnostic Testing & Emerging Technologies*.

For U.S. fiscal year 2017 the Centers for Medicare and Medicaid Services is adopting new safety measures for the outcome domain in its Hospital Value-Based Purchasing Program, which intends to tie Medicare payments to the quality of inpatient care. It affects payment for inpatient stays at 3,000 hospitals across the country. There will be penalties for hospitals with too high rates of hospital-onset methicillin-resistant Staphylococcus aureus bacteremia and Clostridium difficile infection. Additionally, the safety domain will carry increased weight (20 percent) in determining payments.

Takeaway: CMS proposes requirements for hospitals promoting reduction of costly hospital acquired infections and better antibiotic stewardship.

Source: "Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care; Proposed Rule," Centers for Medicare & Medicaid Services, Federal Register, June 16, 2016 pp. 39448-39480.

CAP Formulating New Treatment Guidelines for HPV-Related Head and Neck Cancers

The College of American Pathologists (CAP) is moving toward firm treatment guidelines regarding the diagnosis of the human papilloma virus (HPV) in head and neck cancers.

Commonly known as HPV, the virus has caused a doubling of HPV-positive forms of squamous cell carcinomas in recent years. Even as the actual overall number of head and neck cancers have dropped since 1980, incidents of HPV-positive oropharyngeal cancer—generally the middle throat area including the tongue, the tonsils, the soft palate—have risen. At least 25 percent of all head and neck cancers are now associated with a positive HPV result. About 70 percent of oropharyngeal carcinomas are associated with HPV.

"These patients may be candidates for less aggressive or tailored therapies, so accurate HPV assessment in head and neck cancers is becoming critical."

— William C. Faquin, M.D.

There are more than 15,000 diagnoses of such cancers in the U.S. every year, according to data from the Centers for Disease Control and Prevention, with men about four times more likely to be diagnosed than women.

Tobacco usage is the primary risk factor for non-HPV head and neck cancers, but clinicians say the factors for oropharyngeal carcinoma are different. That has potentially led to some doctors skipping diagnostic tests and missing potential diagnoses. Moreover, HPV-related head and neck cancers are in many instances not as aggressive as non-HPV forms of the disease—five-year survival rates are typically between 80 and 90 percent—requiring treatment pathways different from other head and neck cancers.

"These patients may be candidates for less aggressive or tailored therapies, so accurate HPV assessment in head and neck cancers is becoming critical," said William C. Faquin, M.D., a pathologist at Massachusetts General Hospital in Boston and co-chairman of the committee CAP convened to promulgate the guidelines. "It is also important to know when testing is not indicated."

The committee is comprised of surgeons, radiation oncologists, medical oncologists and pathologists. Draft guidelines were initially released over the summer for public comments, although CAP spokesperson Kerry Lydon said they are no longer available.

"At this point, the expert panel reviews all comments; they refresh the literature search; and from there they begin to draft final guidelines, which (will) then go through additional review/revision," Lydon said. The final guidelines are expected to be released by the third quarter of 2017, she added.

Takeaway: The College of American Pathologists is developing new guidelines for diagnosing HPV-associated head and neck cancers.

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